INTRODUCTION
Iain Mackay

1. New GSK: new ambitions for patients and shareholders

Good morning and good afternoon. I am Iain Mackay, CFO of GSK and it’s my pleasure to welcome you to our investor update. We have a packed agenda which I will detail in just a minute. However, before I do that I would like to mention a couple of house-keeping details:

• First, you should have received our press release and you can view the presentation on GSK’s website. For those not able to view the webcast, the slides that accompany today’s event are located on the investor section of the GSK website.
• Second, during the question and answer session we would ask that you limit your questions to two, so that everyone has a chance to participate.

2. Cautionary statement regarding forward-looking statements

Before we begin, please refer to slide 2 of our presentation for our cautionary statements. Our basis of preparation can be found in an appendix.

3. Agenda

With that, please advance to slide 3 and let me take you briefly through our agenda.

Our speakers today are Emma Walmsley, Luke Miels, Dr Hal Barron, Deborah Waterhouse, Dr Kimberly Smith, myself and Roger Connor, who is joining us via video as he has been tracked and traced by the NHS and is on his last day of self-isolation.

• Emma will open the event outlining the strategic transformation, outlook and ambitions for New GSK.
• Luke and Hal will then present an overview of the progress we have made in Commercial and R&D and how this will support delivery of growth over the next decade.
• We will then head into a series of deep dive sessions on Vaccines with Roger and Hal, our HIV therapy area with Deborah and Kim, and other key high-potential Specialty pipeline assets with Luke and Hal.
• I will then set out details on our financial outlooks, capital allocation and dividend policy, as well as details on separation before we close and move to Q&A.

Our presentation will last for two and a half hours and there will be a refreshment break approximately halfway through.

With that, I hand over to Emma.

STRATEGIC TRANSFORMATION, OUTLOOK AND AMBITIONS
Emma Walmsley

4. Strategic Transformation, outlook and ambitions

Thank you and a very warm welcome from me to our investor update.

During the course of today, we will set out clearly why post separation of our consumer business, New GSK will be a growth company able to create significant value for patients and shareholders from 2022 and for the next decade.

5. New GSK: new ambitions for patients and shareholders

Firstly, you will hear about competitive performance. Over the next five years, with 2021 as a base year, we expect to deliver highly attractive growth with sales and adjusted operating profit of more than 5% and more than 10% respectively on a compound basis. These are new commitments and a clear step-change in performance from GSK – and we are confident we can deliver.
This growth will be accompanied by a new progressive dividend policy. And we expect New GSK’s annual dividend to start at 45p per share in 2023. Iain will walk through more details of expected dividends, including for next year, later on.

By 2031, we aim to achieve sales of more than £33 billion. This ambition is driven by our current late-stage pipeline and is before any significant sales contribution from our early-stage pipeline or any contribution from future business development. Our late-stage pipeline has the potential to deliver over £20 billion in non-risk adjusted peak year sales, supporting our confidence in these revenue expectations.

Very importantly, this sees New GSK growing through the decade, despite the anticipated loss of exclusivity for dolutegravir.

New GSK will prioritise innovation in Vaccines and Specialty Medicines, maximising opportunities that are increasingly evident across prevention and treatment of disease. We will support investments in innovation through the attractive profitability and cash flow of our General Medicines business, which we expect to continue to optimise.

New GSK will benefit from a strengthened balance sheet after the separation of Consumer Healthcare, also enabling us to pursue a growth-oriented capital allocation policy. And we will deliver this performance whilst meeting the high standards expected of us - retaining leading-edge ESG performance and driving a culture of ambition, accountability and responsibility.

This is the New GSK. One that is ambitious for patients and for shareholders. A new company with a strong focus on delivering improved performance, shareholder value and positively impacting the health of more than 2.5 billion people over the next 10 years.

6. Team to deliver

Now, alongside the right strategy and level of ambition, of course what matters is having the right people to deliver. And I am delighted with the transformed strength and depth of the leadership all across GSK - you’re going to hear from several of these exceptional leaders today. My team is talented, accountable, energised and empowered to deliver our growth ambitions together.

7. Delivering major strategic transformation and cultural change

Before we get into why we are confident about the future growth of GSK - and why we think we will create significant shareholder value over the coming decade - I want to spend a few minutes focusing on what has been achieved over the last 4 years and how this creates a completely different platform for growth.

Since 2017 we have undertaken an enormous amount of work to fix longstanding issues across the company which have been a direct cause of historic underperformance and negative impact to total shareholder returns. Our focus has been to improve R&D productivity, commercial execution, group structure and capital allocation, and very importantly drive a new culture with new leadership for more accountability, ambition and delivery.

We have done this by prioritising Innovation, Performance and Trust – across the entire company – driving a significant and sustained multi-year programme of strategic transformation and investment.

8. Significant scale of change and delivery 2017-20

The scale of the changes made in the last 4 years is unprecedented. And we have made enormous progress - on multiple fronts – to improve performance, strengthen capabilities and prepare GSK for a new future.

Our sales and cash flow performance has improved - despite the loss of multi-billion-pound Advair to generics. And we have maintained operating profit levels whilst making much needed increases in R&D investment. This investment - up 30% over the period - and Hal’s leadership, have substantially strengthened our R&D performance and productivity. Since 2017, we have delivered 11 major product approvals – a top quartile performance - and doubled the number of assets in Phase 3 and registration to 22. We now have a pipeline of 20 vaccines and 42 medicines – many of which are potential best or first in class.
New GSK: new ambitions for patients and shareholders
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Commercial execution has been transformed by Luke and Deborah. New & Specialty product sales have reached £10 billion growing double digits, and Vaccine revenues have increased 35%, since 2017, under Roger’s leadership.

We have made significant changes to our portfolio and network. Driving changes to our business mix, reducing our footprint, streamlining our supply chain, achieving annual savings in excess of projections and divesting non-core brands. And work on all these continues as we look for further ways to optimise and deliver value to shareholders.

We have created an outstanding, new world-leading Consumer Healthcare business of scale following two successful global mergers and integrations, with a radically transformed portfolio and with profit nearly doubled to sector leading levels over the period.

And we have maintained our acknowledged leadership in ESG – delivering new commitments and progress in all areas of E S and G. Powering it all, has been a new culture for more accountability and more ambition, underpinned by the integrity and humanity that GSK is known for. This change has started at the top where we have transformed our leadership; 85% of top 125 leaders are new in role since 2017, including 30% recruited externally. And it has been driven across the entire company, with new people, new incentives and new governance.

9. Ready to separate and unlock shareholder value

And so, we are now ready to deliver the most significant corporate change seen for GSK in more than 20 years. To separate and create a New GSK and New Consumer Healthcare – each with their own appropriately skilled independent Boards. Both these businesses will have scale impact on human health and the opportunity to deliver compelling performance and attractive returns for shareholders.

10. New world leader in Consumer Healthcare

With the separation, we will create a new world-leader in Consumer Healthcare. A £130 billion market with very favourable dynamics for consistent future growth. Expertly built and integrated by Brian McNamara and his team, this business will serve 100 markets with a portfolio generating annual sales of more than £10 billion.

It will be driven by brands and innovation, with leading-edge science and human understanding to deliver better everyday health. And with 9 global power brands holding category leadership positions; a major sales presence in the US and China; and 11 other brands each generating more than £100 million in sales, the business is well placed to address consumer needs and achieve future revenue ambitions.

It will also have industry-leading operating margins - offering tremendous prospects for profit growth, cash generation and sustainable returns for shareholders. A comprehensive update on its prospects is planned for investors in the first half of 2022.

11. Separation on track for mid-2022

The separation will take place in the middle of next year.

The Board has reviewed multiple separation options, always with a lens of unlocking the potential of both businesses, strengthening New GSK’s balance sheet, and, of course, maximising shareholder value. So on this basis, the separation will take the form of a demerger of at least 80% of GSK’s holding in the business to shareholders.

New GSK will retain up to 20% as a short-term financial investment which will be monetised in a timely manner to further strengthen the balance sheet.

The demerger is intended to be tax efficient for shareholders, as compared to alternative separation options – which has been an important consideration - and will be subject to shareholder approval. Iain will provide more details on this and new GSK’s balance sheet later on.
12. New GSK

Turning now to New GSK. With new ambition comes new purpose. For New GSK this is to unite science, talent and technology to get ahead of disease together – all with the clear ambition of delivering human health impact; stronger and more sustainable shareholder returns; and as a new GSK where outstanding people thrive.

Getting ahead means preventing disease as well as treating it. It means innovating together, fusing ideas, capabilities, and know-how inside and outside of GSK. Our R&D focus is to deliver new vaccines and medicines, using the science of the immune system, human genetics and advanced technologies, together with a deep commitment to operating responsibly for all our stakeholders.

And we remain committed to getting ahead of issues that matter for the sustainability of our company be it pricing and access, the environment, or stronger diversity and inclusion. How we do all this is through our people and our culture. A culture that is ambitious for patients, accountable for impact and committed to doing the right thing so we deliver what matters better and faster. To have clear ownership for goals and the support needed to succeed. And always with integrity and care.

13. New commitments to growth

Our ambitions are reflected in the new commitments to growth we are making today. Both these goals represent significant step-changes in delivery. In the next five years we expect to deliver more than 5% sales and more than 10% adjusted operating profit growth on a compounded basis. By 2031 we aim to deliver more than £33bn in sales.

With strong and effective commercial execution, we are confident we can deliver compelling growth. We have clear metrics in place and incentives at company and individual levels, to drive performance in-year and over these time frames.

Existing incentive measures include delivery of innovation sales, pipeline progress, operational performance and relative total shareholder returns – so performance targets and reward are strongly aligned to shareholder interests and shareholder value creation and will be for new GSK.

14. From historical underperformance to ambitious top quartile growth

I am very aware that GSK shares have underperformed for a long period. The transformation achieved over the last 4 years creates a completely different platform for growth and significant shareholder value – one that will move GSK from historical underperformance to a new, ambitious top quartile growth outlook and delivery.

15. Investing to drive step-change in growth and business mix

To drive our step change in growth, we will continue to prioritise investment to Vaccines and Specialty Medicines, which we expect to grow to around three-quarters of our revenue base by 2026.

Over the next five years, in CAGR terms, we expect sales to grow at high single-digits for Vaccines; and double-digits for Specialty Medicines. Our newly defined General Medicines business will contain all our primary care brands. We will optimise this business for profitability and cash flow.

And, as we have done in the last 4 years, we will continue to look for opportunities to streamline the portfolio and maximise its value for shareholders. With the plans we have in place we expect General Medicine sales to be broadly stable over the next 5 years – which is a significant change from the recent dynamic.

16. Maximising opportunities in prevention and treatment

A key reason for prioritising investment to Vaccines and Specialty Medicines is to realise the increasing opportunities now being seen across prevention and treatment. Our understanding of the relevance of the science of the immune system continues to grow and modalities are converging. We have the approach, the tools, the portfolio and the capabilities to deliver growth and value here.
17. Focusing in key therapeutic areas

Investment and resource allocation to Vaccines and Specialty Medicines are focused across four core therapy areas: Infectious Diseases, HIV, Oncology, and Immunology including Respiratory. In each of these areas there are major unmet patient needs and significant opportunities for growth. Agility is also important - and we will pursue great opportunities in organic research and in Business Development consistent with the science of the immune system and human genetic validation. This we describe as ‘Opportunity Driven’. Each of these therapy areas contain marketed key growth drivers and promising late-stage pipeline candidates.

18. Vaccines and Specialty high potential late-stage assets add to current growth drivers

Together they will deliver strong growth over the next decade. The next 5 years will see us building on the momentum we have delivered to date, and we expect growth to be increasingly supplemented by contributions from late-stage pipeline assets. The potential of these late-stage assets is significant. On a non-risk adjusted basis, they have the potential to deliver peak year sales of more than £20bn.

19. Portfolio and pipeline to secure growth over next 10 years

The major contributions to our top-line ambitions are summarised here.

Of course, alongside expected positive contributions from key assets, are generic expirations. From 2021 to 2026, New GSK’s loss of exclusivity exposure is negligible and compares very favourably to peers.

As can be seen here, our next major anticipated loss of exclusivity comes with patent expiration of dolutegravir in 2028 in the US and 2029 in Europe. Deborah will explain the transition we expect to see in our HIV portfolio to long-acting medicines. This significantly reduces our exposure to genericization and supports profitable revenue renewal in our HIV portfolio. Importantly, at a company level, we expect the loss of dolutegravir to be more than offset by the expected sales contribution from the late-stage pipeline.

From 2026 to 2031 growth will be driven by executing on these late-stage assets - through which we aim to achieve, at a minimum, £33 billion in sales. And I repeat, we do not include any significant contribution from the early-stage pipeline or any contribution from future business development, which we of course will continue to pursue. I should also be clear that these outlooks do not include any revenues or profits from COVID-19 solutions.

20. Meaningful margin expansion from 2022

We will leverage top-line growth to drive meaningful margin expansion. We expect to drive our adjusted operating profit margin from the mid-20s level currently to over 30% by 2026, so that we deliver double-digit compounded profit growth over the period.

We now expect to achieve £1.0bn of annual savings from our Future Ready programme by 2023, a £200m uplift from our previous estimate – and we’re therefore revising our combined total for programmes to £1.5bn of savings. Approximately one-third of total savings are being reinvested to drive growth in the business, with the remainder expected to drop through to the bottom line. These programmes are expected to complete in 2022 and no further major restructuring programmes are planned.

Our focus on driving out cost will continue. This will include more R&D productivity initiatives, further streamlining our manufacturing network, embedding new ways of working with pandemic learnings, and disciplined prioritisation of projects with the highest returns. And, of course another important driver of margin expansion will be the change we drive in sales mix towards higher margin Vaccines and Specialty Medicines.

21. Improved capital position supports growth investment

Turning now to capital allocation priorities. Our first priority will still be to invest in our pipeline including with business development activity with a focus on bolt-on acquisitions and in-licensing deals. We will strengthen our balance sheet with the separation and with the strong operating cash flow we expect in the coming years.
By 2026 we expect cash generated from operations to exceed £10 billion. This will allow us to focus capital deployment on supporting growth. We will support successful product launches, continue to improve the sustainability of our operations, including reducing our carbon footprint.

And of course, we intend to deliver attractive and growing returns to shareholders through our progressive dividend policy.

22. ESG performance to deliver health impact and shareholder returns

For New GSK, ESG will continue to be an integral part of our strategy and our investment case. And it will be a key driver in our goal to deliver health impact and shareholder returns as well as being core to the motivation of our people. We will pursue a focused approach to ESG, driven by our strengths, informing our strategy and addressing the key challenges of our industry over the long-term. We will prioritise our resources around the 6 areas you see here - which we see as material for our business and sit across E. S. and G.

Accountabilities for each of these six focus areas sit with respective members of my leadership team. And, for New GSK, we expect to strengthen the alignment of remuneration to delivery of ESG performance and increase the visibility of this for investors in our reporting. We will also continue to report against a set of public trust commitments. We believe our approach to ESG will support delivery of sustainable performance and long-term growth; build trust with all our stakeholders; reduce risk to our operations; and enable delivery of very positive social impact.

23. New GSK to positively impact the health of >2.5 bn people over 10 years

In line with New GSK’s purpose a defining measure of success will be health impact at scale. Our plan shows that New GSK can positively impact the health of more than 2.5 billion people over the next 10 years. With the company making meaningful contributions in all parts of the world. Protecting people and helping them fight disease.

24. New GSK: new ambitions for patients and shareholders

So, New GSK has new ambitions. For patients. And for shareholders. The team you will hear more from today have been leading our extraordinary programme of change and we are now ready to take New GSK forward into a new decade of growth and impact together.

Let's start by hearing from Luke and Hal on how we deliver.

DELIVERING GROWTH: 2021- 26 AND BEYOND
Luke Miels

25. Delivering growth: 2021 – 2026 and beyond

Thank you, Emma. The aim of this part of the presentation today, is to give you confidence that the commercial organisation can deliver a CAGR above 5% from 2021 to 2026.

26. Delivering growth: 2021-26 and beyond

Over the next few slides I will outline:
- The changes we have made to people, products and processes since 2017
- Provide you depth at the operating level on our execution in specialty and vaccines
- Then give you colour to the way we will optimise our general medicines business
- And finally demonstrate how we have established a highly effective partnership between commercial and R&D that will set us up to deliver our ambition of more than 33 billion pounds in sales by 2031

Throughout I will provide the numerical evidence of our progress.
27. Portfolio and pipeline to secure growth over next 10 years

Right. This slide outlines the path for us to get there, at a product level. Our sales growth ambitions to 2026 and beyond are underpinned by strong execution against key in-market assets ... and our ability to deliver and unlock the value of our pipeline. You will hear from Roger and Deborah about our growth drivers in Vaccines and HIV. And then Hal and I will cover our other Specialty opportunities, including a review of the late-stage pipeline assets.

28. Comprehensive new commercial approach to drive growth

So, this is the framework we have used since 2017 to improve our ability to compete in the market. You can see there are three main phases to this, and it remains a work in progress. Phase 1 was essentially about getting the right people in the right jobs, fixing how we operate and then sorting out the cost base.

In Phase 2 the focus is on finding ways to maximise the growth in existing products and markets. And Phase 3 is about working very closely with Hal and his team in R&D to maximise the value of the pipeline.

29. Transformed commercial capabilities and organization

On this slide I’ve shared some examples of what phase 1 means and what has been executed. The first order of business was to appoint the right leaders across the markets and in key global roles. We have appointed new General Managers in 64 countries which drive over 90% of our sales today. For these important roles, we have a specific phenotype. Each of these new leaders have then driven change deeper into their respective organisations.

The next priority was to rebuild the commercial team who interact directly with R&D to select and develop the pipeline assets. These people, if they provide the right commercial input at this point can create enormous, multi-year value. And we want the best and the brightest in these roles. From 2017 a 2-3 year rotation in this team was made mandatory prior to appointment as a first-time general manager. Their time in role at headquarters is capped so they don’t become permanent residents. And success here results not only in influencing working with R&D but a fast track to larger commercial roles. So, this ensures we get the best people. The overall dynamic that our people operate in, with our peers in R&D, is strong because Hal and I like working together.

We also strengthened our marketing and medical capability in Specialty Medicines by hiring over 900 people with the right expertise to compete.

In parallel, we took a very critical look at our footprint and reduced our direct presence from 140 markets to 70, whilst further concentrating our investment in the top 10 markets which drive the bulk of our growth. Another key driver to right sizing the organization was to reduce our back-office costs which we did by significantly reducing non-customer facing commercial infrastructure and reallocating the savings to high growth markets and specialty products.

In bringing our policies to par with industry best practice this has further allowed us to improve our competitiveness whilst maintaining trust. Combined, these changes have enabled us to establish an organization that is pointing the right way, knows how to launch in speciality and can thrive with complex products.

30. Improved sales force effectiveness across key markets

Then, in Phase 2, our focus moved to product strategy and the translation of this on the ground. Starting with a back to the basics approach, the changes we made at the leadership level coupled with strong marketing-medical and sales force collaboration have resulted in measurable improvement of our sales force effectiveness and productivity across key markets.

As you would expect, we track and assess this progress via third party audits across our markets. The audits of actual Rep and doctor face to face interactions seek to determine if a call is effective by stratifying it in a manner which correlates with changes in prescribing behaviour.
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Taking Nucala as a representative example you can see in this data set that we have delivered material improvements in Good Selling Outcomes where a change in the customer’s behaviour is agreed. This the outcome with the highest correlation with a positive change in prescriptions. And this positive trend is also demonstrated across our other key brands. For example in the US Trelegy went from 22% Good Selling Outcomes in 2018 to 30% in 2020. We placed these audits on hold when COVID hit face to face interactions in field. Now that Reps are going back into the field in the US, we will restart these audits. We have just ran our first wave, in this case with Benlysta, and the new data showed we moved from 16% in 2018 to 25%, which is above the industry top quartile.

31. Deployed digital and predictive analytics to further enhance outcomes

STEM data is a measure of quality and we remain disciplined and focussed on continuing to become more competitive in our face to face interactions. However … the number of face to face sales and medical interactions collapsed from early 2020. But this disruption presented us with an opportunity to accelerate several initiatives in digital and predictive analytics.

Rapid execution of these initiatives combined with an immediate shift to virtual activities by our customer facing teams have enabled us to maintain leading share of voice where we compete, as shown in the third-party tracking data on the left-hand side of the slide.

In the middle panel, you can see the impact on new prescriptions when a data-driven customer experience strategy is adopted on top of traditional field force activity. For example when we applied this to Trelegy field promotion in the US, we saw a 47% increase in prescriptions.

On the right, in lupus, we deployed a machine learning algorithm, which processed in total over 4 terabytes of data, including claims and diagnosis codes. From this we concentrated on 3 distinct areas where there was a gap to treatment and have directed our medical efforts to address these.

Agility is very important here. We encourage a decentralised approach to innovation in our operations but when we see something decentralised that works, we adopt a centralising mindset and drive execution across markets.

All these elements give us confidence that we can make the scientific case for our products, across multiple therapy areas.

32. Focus on execution has increased speed to market following regulatory approval

One more key measure to gauge effective execution is how quickly a business can mobilize following regulatory approval. This is a good indicator as by its nature it is a complex undertaking, involving a spectrum of cross functional activities, ranging from packaging and supply at one end - all the way through to pricing, reimbursement and training.

Competitive pace here requires a team on the ground to have clarity of purpose, alignment, - and thoroughness, driven by a commitment to getting the product to patients in the best possible timeframe. In 2013, it took the team in the US 5 months for Breo. In 2020, it took our new team 5 hours for Blenrep.

33. Consistent delivery of competitive launches

Pulling these elements together… has resulted in better commercial outcomes across therapy areas and in diverse scenarios. For example in the case of launching products - you can see here that Trelegy had the best launch of an inhaled respiratory product in 10 years and continues to lead in total prescriptions and New Patient starts in a highly competitive disease area.

We have also demonstrated that we can launch well into new therapy areas for GSK as shown here with Blenrep, which despite a complex REMS programme and a challenging environment had sales surpassing key competitors in late-line multiple myeloma within the first quarter. And with Shingrix we demonstrated the ability to fully utilise a compelling product profile to disrupt and then rapidly expand what was a relatively modest, stable established market.
34. Translating label expansion into higher market share

As I said earlier, we have also been able to deliver better commercial outcomes in diverse scenarios. The performance of Zejula following the Tesaro deal is a fair demonstration of this in my mind. On acquiring Zejula we inherited an existing oncology commercial infrastructure and a product with an established profile in the eyes of many doctors. We saw an opportunity to reposition the product and improve execution on the ground in one of the most competitive areas in oncology.

On this basis we overhauled the entire commercial and medical approach. This placed us in a good position following the read out of the PRIMA 1L Ovarian cancer study. And Zejula is on now track to be the most prescribed PARPi in 1L ovarian cancer with leading new patient share in both the US and EU.

35. Driving growth of mid-life cycle products

We have also worked hard during this second phase of change to create more opportunities for growth in parts of the portfolio which are at the mid-point of their life cycle.

For Bexsero, we re-doubled our efforts to educate physicians and parents about the devastating impact of Men B and the strong protection they can expect from our vaccine, supported by newly available real-world evidence. We also invested more in the US with a new campaign and this led to an increase in market share, moving from 64% in 2017 up to 73% now. While COVID impacted performance in 2020, the strong fundamentals and large cohorts of children and adolescents who would benefit from Men B protection point to recovery and growth.

On the right-hand side is Benlysta, which prior to 2018 had relatively limited investment... We changed our strategy in the markets and re positioned the product resulting in a 24% CAGR in the last 3 years. The recent launch in Lupus Nephritis further increases our growth potential and is more proof that specialty medicines with good life cycle management can deliver many years of strong growth beyond their initial launch.

36. Key growth drivers: 2021-26

The examples over the last few slides demonstrate that we are now more effective as an organisation at translating the science behind our products into appealing patient and commercial outcomes. Looking forward we are very clear in our areas of focus, as you heard from Emma. We expect New GSK growth to be driven by vaccines and specialty medicines underpinned by a highly profitable and resilient general medicines business. We are confident that this combination of existing and new assets can deliver greater than 5% sales CAGR between 2021 and 2026. Over the next few slides and again later with Hal I will seek to add some colour to this projection.

37. Relaunch of Shingrix post COVID-19 vaccine roll out

Firstly with Shingrix, we expect it to be the number one driver for growth of our Vaccines portfolio over the next five years. As you would expect our focus right now is to relaunch the product following the roll out of the Covid vaccine programmes which necessarily disrupted normal vaccination schedules. We’re taking steps to ensure we reach patients by activating a range of activities and we are generating data both on the impact of COVID on shingles and on safe co-administration with COVID vaccines, which should read out in Q4 this year.

Market research conducted in April indicates that almost 60% of individuals intending to get both a COVID and Shingles vaccine, plan to do so within 3 months of their COVID shot. We are also seeing encouraging signs of a recovery in prescriptions, which are now up to nearly 69,000 in the most recent weekly NBRx data, approximately double the numbers we saw in mid-March and April when the COVID Vx campaign took off. The recent ACIP recommendation on adult vaccinations gives us further confidence that the market will rebound.

And looking beyond the pandemic – we have a multi-pronged strategy which will allow us to fully capitalize on the huge potential of Shingrix. This includes addressing the large population of unvaccinated individuals in the US, driving growth in China and launching in new geographic markets, on top of life cycle innovation.
38. Vaccines and Specialty Medicines priorities in key markets: US

Geographically as expected, the US is central to this overall growth ambition as it accounts for more than 40% of New GSK sales and it will remain our most important market as we concentrate the bulk of our effort on Vaccines and Specialty Medicines.

From 2021 to 2026, a large component of our growth will come from our in-line products, including Shingrix and Zejula, as well as the evolving HIV portfolio which Deborah will cover later. We are also preparing the organisation to compete in the next wave of launches, notably for our new vaccine to prevent RSV – which from a revenue perspective has a similar potential to Shingrix in the US and globally.

39. Vaccines and Specialty Medicines priorities for key markets: China

For China, execution will be key to achieve our growth ambition, particularly with vaccines. We are pleased with the opportunity we have for Cervarix. The government has an Expanded Program on Immunization that focuses on 12 vaccine preventable diseases through routine immunization. In 2020, Cervarix was awarded the first tender for school-aged girls and - in Q1 of this year we grew Cervarix 117%.

Shingrix has already launched in the private pay market in more than 50 cities and there is plenty of room to grow. Shingles is estimated to affect more than 1.5 million people aged over 50 in China every year and it continues to be recognized by the government as a priority disease.

We were very pleased to see both Trelegy and Benlysta successfully achieve reimbursement coverage within the National Drug Reimbursement List for 2021. To put this into perspective, about 100m people suffer from COPD in China and currently only around 8m are on maintenance medication. We are now making good progress in gaining market share in the single inhaler market. And with more than a million SLE patients, China is expected to be Benlysta’s second largest market by 2025.

40. General Medicines portfolio resilient and highly profitable

If I turn now to our General Medicines portfolio, this comprises all our primary care assets including Trelegy and Anoro. This business currently accounts for around 40% of New GSK sales but we expect it to drop to around a quarter by 2026 due to the growth in Vaccines and Specialty Medicines.

With the majority of the LOE impact behind us by the end of 2021, we expect General Medicines to provide a broadly stable and highly profitable base from which we can continue to fund investments in our priority therapy areas. Overall, whilst several mature products will remain in decline, we see selected, localised growth opportunities in the portfolio, through a combination of targeted effort behind key brands and an optimized multi-channel approach to promotion.

Trelegy is already a global growth driver and we are competitively resourced to win, by gaining share and growing the single inhaler triple market in both Asthma and COPD. We expect significant growth in Emerging Markets, as well, where we are focusing our investment behind key brands like Seretide and Augmentin. We are working to make our infrastructure and capabilities more productive to drive General Medicines.

Strategically these improvements should serve the business well when the time comes to launch new products in the region.

Finally, to optimise the profitability and cash flow of General Medicines, we are actively managing the portfolio by focusing on a smaller number of brands, improving COGS and managing an efficient supply chain. We’ve already reduced from more than 400 brands globally to around 200 since 2017 through divestment or partnering. This focus on portfolio simplification, margins and streamlining will continue.

41. Late-stage pipeline potential for >£20bn in NRA sales

So, when we look beyond 2026, we have multiple opportunities to sustain growth, despite the loss of exclusivity of dolutegravir in 2028/9.

As you will hear from Hal, the majority of our late-stage assets have the potential to be first or best in class. Combined with our growing commercial execution capabilities we see the potential of the pipeline in these
Therapy Area’s to deliver peak year sales in aggregate of more than 20 billion pounds on a non-risk adjusted basis.

Now, with the nature of our industry it would be unrealistic to expect every reagent in our pipeline to succeed, but the potential for growth is substantial – even before we add in contributions from the early stage pipeline and future business development opportunities.

Several pipeline products here have the potential to achieve more than 1 billion pounds, some like RSV and HBV ASO have non risk adjusted potential peak sales of more than 2 billion pounds. They are almost all specialty or vaccines in nature, requiring smaller infrastructure than primary care.

42. Portfolio and pipeline to secure growth over next 10 years

To conclude we have made a large amount of changes in the commercial organisation over the last three years with the objective of improving our capacity to compete and make the scientific case for our products. We have also sought to partner very closely with R&D to identify and develop Vaccine and Speciality assets in the pipeline that are compelling for doctors, payers and patients.

In doing this effectively we have a stronger case to secure future growth. The aim of this presentation today was to provide you with details on the actions taken and most importantly the in-market evidence of the results of this progress.

I will now hand over to Hal who will talk about the significant progress we’ve made in R&D.

R&D
Hal Barron

43. R&D

Thanks Luke. I am going to spend the next 15 minutes sharing an update on the progress we have made in R&D over the past few years and how the approach we set out in 2018 is delivering today for both patients and shareholders. I will also highlight some of the key late-stage assets in our pipeline that we think have the potential to be transformational vaccines and medicines in the future. I’ll then mention a few of our most exciting early-stage assets and how these, coupled with further business development, will continue to contribute to our future growth.

44. R&D approach focused on the science of the immune system, human genetics and advanced technologies

- As you will see, our R&D approach has resulted in a significantly stronger pipeline and improved productivity.
- Our approach is based on five key pillars.
- First, we decided to focus on the science of the immune system given its increasingly recognised importance in the pathophysiology of many diseases, beyond the classic autoimmune diseases.
- Second, by harnessing human genetics, functional genomics and advanced technologies such as AI/ML we can now identify numerous novel targets with a higher probability of success. I will highlight an example of this when I discuss Blenrep in combination with Gamma Secretase Inhibitor for patients with multiple myeloma later.
- Third, we are strategically leveraging business development to augment our organic pipeline. Our recently announced deal with iTEOS and this weeks’ announcement by Deborah and the Viiv team on Halozyme highlight this.
- Fourth, we are working hard to improve our approach to developing our innovative vaccines and medicines following approval through more robust life cycle innovation.
- Lastly, culture and talent are critical to our success and we are making excellent progress towards improving senior leadership talent in R&D, reflected by the fact that 80% of Vice Presidents and above are either new-to-role or new to GSK in the past three years.
- In addition, this approach is delivering operational benefits across vaccines and pharma with the recent creation of a single development organization which allows us to optimize the design and execution of clinical trials as well as now having a single capital allocation process to ensure we’re investing in the programmes with the greatest benefit to patients and the most attractive returns.
There are also important scientific synergies across pharma and vaccines given the increasing convergence of prevention and treatment in the same diseases, and sometimes in the same patients. COVID-19 is a clear example of this with the development of both vaccines and therapeutics. We are also pursuing this approach in hepatitis B with our antisense oligonucleotide and our hepatitis B vaccine. Influenza is another good example and there are many other opportunities we are exploring.

Our deep expertise in the science of the immune system and our focus on advanced technologies will continue to enhance our unique ability to deliver transformational medicines and vaccines for patients.

45. Improved pipeline and productivity

These five pillars have had a significant impact on R&D with 11 major new medicines and vaccines approved since 2017, which is a top quartile performance. We also achieved a more than 90% success rate for pivotal studies and doubled the number of assets in phase 3 compared with 2017.

We’ve seen around a 20% reduction in overall cycle times across clinical development and a 50% increase in the average number of lifecycle projects per asset.

Importantly, this significant progress in R&D will contribute to our revenue growth, with pipeline approvals since 2017, along with the anticipated approvals in the next four years, accounting for more than 100% of our forecasted growth from 2021 to 2026.

With continued pipeline delivery and investments in business development, we are well positioned to support the longer term growth ambitions highlighted by Emma.

46. We have delivered 11 major approvals for new medicines or vaccines in the past four years

I am very proud of this slide. It shows the 11 new medicines and vaccines R&D has obtained approval for in the last four years. The approval of Jemperli in April was our fifth in the last 12 months and in addition to that we also received Emergency Use Authorization for sotrovimab. We have also had numerous approvals for our marketed medicines, which Luke highlighted earlier, including Benlysta for patients with lupus nephritis and Nucala for patients with hyper eosinophilic syndrome and patients with eosinophilic granulomatosis with polyangiitis.

47. External benchmarks position GSK in the top quartile for R&D output from 2017-2020

This is another very important slide which highlights our R&D performance compared with our peers over the last four years based on data from Evaluate Pharma. As you can see GSK is in the top quartile on key performance metrics from 2017 to 2020 including the number of launches achieved during this period, the number of launches per billion dollars of R&D spend and the median peak year sales per launch.

Compared to our peer group, we have delivered 40% more launches, nearly 50% more launches per billion dollars invested in R&D, and almost double the peak year sales forecast per launch. All of these improvements were driven by focusing on key assets, taking smart risks and improving productivity as I will highlight on the next slide.

48. Significant improvement in R&D productivity

Simplifying governance has allowed us to significantly improve R&D productivity. It has enabled us to make better decisions faster and has contributed to an improved probability of success with a more than 90% success rate from our pivotal studies since 2018. This is an improvement on the preceding three-year period and as a reminder, the industry average success rate for pivotal studies is around 70%.

In addition, we have reduced our average cycle time by almost 20% which is good progress versus our previous performance and although we still need to do a little more in order to be top quartile on cycle times we are moving in the right direction. This progress combined with our focus on life cycle innovation has enabled a significant transition in our pipeline and we now have double the number of assets in Phase 3 studies compared to 2017.
49. Improvements in cycle times have been driven by focus, operational excellence and smart risk taking

Improvements in cycle times have been driven by focus, operational excellence and smart risk taking and this slide highlights a number of these examples. The first is Blenrep, our anti-BCMA targeting agent for patients with multiple myeloma which was approved just over two years after the start of its first pivotal study.

The second is our RSV for older adults vaccine where we implemented an accelerated development plan and have initiated a Phase three study in order to be first-in-class.

Third is our two COVID therapeutics. Our partnership with Vir was signed in April 2020 for a late-stage research project and we received EUA from the FDA 13 months later.

Similarly, for otilimab we initiated a proof of concept study weeks after the start of the pandemic and delivered encouraging proof of concept data within 8 months.

50. We have built an innovative pipeline: 62 potential vaccines and medicines

This slide shows our R&D pipeline and our 62 potential vaccines and medicines in development.

Over 70% of the pipeline now focuses on modulating the immune system with an industry-leading Infectious Diseases portfolio making up more than 50% of all assets and a growing Oncology therapy area accounting for approximately 25% of the pipeline.

As you can see there are a number of assets here that form part of our response to COVID-19, including four vaccine programmes, three of which leverage our proven adjuvant technology and two of these will have pivotal data in the second half of 2021. We also have an mRNA COVID vaccine through our collaboration with CureVac on their second-generation technology, which I will cover in more detail later.

And, we have two therapeutic programmes, sotrovimab which recently received EUA, as I mentioned, and otilimab, where we will have additional data before year end.

51. A robust late-stage pipeline with FiC or BiC potential and more than £20bn in NRA sales potential

- We are very excited about our robust late-stage pipeline with many assets having the potential to be first and or best in class as well as most of them offering significant strategic lifecycle opportunities.
- Deborah, Kim, Roger, Luke and I will spend much of the presentation today covering these assets in more detail.
- These programmes all have significant potential, on a non-risk adjusted basis, and as you will see on the next slide drive a substantial proportion of our expected growth over the next five years.

52. Recent approvals and late-stage pipeline will drive >100% of sales growth 2021-26

Specifically the vaccines and medicines approved between 2017 and 2021 are expected to account for over 60% of the 2021 to 2026 sales CAGR. The anticipated approvals of some of the late stage programs I highlighted on the previous slide are expected to drive over 40% of the sales CAGR over this period.

53. Innovative early programmes plus continued business development offer potential for sustained growth beyond 2026

In addition, as well as having an exciting late stage pipeline, we also now have a robust early-stage portfolio with a number of innovative programs that we believe have the potential to transform the lives of many patients and contribute to our growth ambition, beyond that mentioned by Emma.

In addition to this organic innovation, we will continue to strengthen our pipeline through business development where we will remain focused on programs that are genetically validated and or complement our commitment to the science of the immune system. We will begin to provide more details on these assets in due course.
54. Internal R&D innovation complemented by BD

To that point, it is important to note the progress we have made on our commitment to leveraging business development to strengthen our pipeline. In the last 3 years we have doubled the number of deals signed with a long-term strategic intent underpinning these agreements and their synergistic impact on R&D.

Our deals are already delivering significant value through the creation of a synthetic lethality pipeline and research unit, the acceleration and expansion of our immuno-oncology portfolio, the building of a state-of-the-art human genetics, functional genomics and AI/ML capability and the access to key platform technologies such as mRNA, antibody drug conjugates, antisense oligonucleotides and T cell therapies.

Together these deals have added new programs to the pipeline and helped to create a portfolio of exciting early-stage assets. Going forward, we will continue to augment our pipeline and capabilities through business development.

55. R&D is delivering a sustainable pipeline of innovative medicines and vaccines to achieve our 10-year ambition

In conclusion, our numerous approvals, significant business development, continued progress on key assets and commitment to improving R&D productivity has resulted in a significantly stronger pipeline. The momentum we are generating across R&D is helping to build a sustainable pipeline of innovative vaccines and medicines that will deliver for patients and for shareholders.

I am very pleased with what the R&D organization has achieved over the past few years and while there remains more to do I am confident in our R&D approach and that it will continue to accelerate our progress and benefit many patients in the future. With that, I will now invite Roger to join me to share our plans in vaccines.

VACCINES: STRENGTHENING LEADERSHIP
Roger Connor

56. Vaccines: Strengthening leadership

My name is Roger Connor and it is my privilege to lead GSK Vaccines. Today Hal and I will tell you all about this extraordinary business and show how we intend to strengthen our leadership and remain at the forefront of vaccines for years to come.

57: Strengthening leadership in Vaccines

There has never been a time where the importance of vaccines has been more visible to the world. As an integral part of New GSK, we intend to be the world’s leading vaccines company over the coming decade and to deliver a high single digit sales CAGR in the next 5 years.

We have scale; we are present in 160 markets with 25 marketed vaccines, supplying more than half a billion doses a year. We have world-class scientific capability, significant manufacturing expertise and know-how and a commercialisation capability that we believe is second to none.

There are three key takeaways we would like you to remember from this session:
First – we have the industry’s leading pipeline with multiple potentially first and best in class assets and 16 assets in mid-late-stage development. We are planning 5 new launches by 2026, the most important of which is our vaccine for RSV in older adults. This is on track to be first- and best-in class, entering an estimated 5-billion-pound market.
Second – our pipeline is underpinned by an unrivalled portfolio of technology platforms, including mRNA, that will ensure we continue to deliver highly innovative vaccines.
Third – we will drive significant growth in the key categories where we compete. The biggest contributor will be Shingrix, our vaccine to prevent shingles, which we expect to double revenues over the next five years. We also aim to double revenues in the next ten years in our market-leading meningitis franchise. And we are
today announcing a new strategy to strengthen our position in flu – the category in our current portfolio which mRNA technology has real potential to disrupt – by taking a lead in this disruption and advancing a portfolio of mRNA vaccine and antibody candidates, with an ambition to double our flu revenues in the next ten years. As a final point, you should note that our sales outlook in Vaccines - and for New GSK as a whole - does not include revenue potential from our COVID-19 solutions.

58: Industry leading portfolio: high efficacy & protection

Before I hand over to Hal – I wanted to show you the incredible portfolio of products we have in GSK vaccines. We have the broadest portfolio in the industry and as I mentioned, supplying 25 vaccines across 160 countries.

Most importantly the efficacy profile of our vaccines is excellent, 90% of our portfolio by sales has an efficacy level of above 90% - this is an incredibly high bar protecting our portfolio from potential disruption from new technologies.

One key question I am frequently asked is ‘Is mRNA technology a risk for GSK and will it disrupt your portfolio?’ I am very confident the answer is no. mRNA is a massively exciting technology and in fact we see it as a major opportunity for the future and this is why we are investing in it significantly. Hal will say more on this later. The risk to the current GSK portfolio from mRNA however is small, two reasons for this, first mRNA technology will not work against all pathogens (eg Meningitis or DTP) and also because of the very high efficacy bar I mention before.

Now, in disease areas such as Flu, where the efficacy is sub-standard there is a real opportunity for technology disruption – and GSK plans to be part of that - more on that later.

Hal – over to you

59. Industry-leading pipeline: Largest number of mid/late-stage assets in areas of significant unmet medical need

Hal Barron

Thanks Roger, it’s great to see the progress you’ve made leading the vaccines group and I’m really looking forward to partnering more closely with you on our pipeline in the future. When you get out of quarantine!

To be able to optimally prevent or treat infectious diseases, we need better vaccines and better medicines and increasingly for them to be used together. As I mentioned earlier, we are well positioned in this important area given our R&D strategy of focusing on the science of the immune system.

Our vaccines pipeline is the foundation of our world class infectious diseases portfolio and several of our programmes have the potential to be transformational. Starting with RSV. In people over 65, there is a substantial risk of developing RSV pneumonia with around 180,000 hospitalisations and unfortunately 14,000 deaths each year in the US alone. Our older adults’ vaccine is in phase 3 and has the potential to be first and best in class. We also have a phase 3 programme ongoing for our maternal vaccine to prevent infection in newborns for up to six months. Roger will cover both of these in more detail shortly.

We are also working to make the first pentavalent meningitis vaccine available. Meningococcus is a gram-negative bacterium which can cause invasive meningococcal disease. This is another area of significant unmet medical need with an estimated 1.2 million people a year being infected with a mortality rate of around 10%.

Anti-microbial resistance or AMR is a significant public health problem of increasing concern which contributes to approximately 700,000 deaths globally each year. We have 2 vaccines in the clinic targeting key resistant pathogens as well as three candidates in late-stage research. In addition, in our Specialty Medicines pipeline we are developing gepotidacin, our novel topoisomerase inhibitor for uncomplicated UTI and gonorrhea. We also have a phase 1 asset, called FimH, which has a novel mechanism of action targeting uropathogenic E coli that is not dependent on bacterial killing and therefore not prone to developing resistance.
60. Extensive technology platform portfolio across R&D: Unlocking the synergy between Vaccines and Specialty Medicines

We believe the key to a successful vaccines portfolio is access to a wide range of platform technologies allowing the best vaccine to be designed for each pathogen, be it a virus or bacteria. I want to highlight the importance of several of these technologies.

Starting with adjuvants. Adjuvants are an area of strength for GSK, particularly AS01, the adjuvant used in Shingrix. We are applying AS01 across a number of our pipeline assets and adjuvants will continue to deliver a significant competitive advantage for GSK as they induce a more robust immune response allowing for increased efficacy.

As Roger mentioned, with the successful vaccines for COVID, mRNA is clearly now an established modality for vaccine development. GSK is making good progress on this important technology, and I will cover this in more detail in a moment.

For prevention of bacterial disease, glycoconjugation technology is one of the most effective technologies and our proprietary platform is ideal for developing vaccines for example against meningococcus. Viral vector technology is also useful to induce cellular immunity which is required in certain settings such as with our hepatitis B vaccine.

Finally, our expertise with monoclonal antibodies, our deep capabilities in human genetics and functional genomics as well as our focus on the science of the immune system will enable us to benefit from the scientific synergies that are increasingly evident across prevention and treatment.

61. mRNA: an important technology in our pipeline

I want to take a few minutes to cover in more detail our approach to mRNA including the collaboration with CureVac on their second-generation technology, which Roger and the team signed last summer and expanded earlier this year.

The key to next generation mRNA vaccines is having multi-valent potential while managing reactogenicity. We are focused on two approaches to achieving this. The first is to optimize the 5 prime and 3 prime regions to enable more efficient translation, which is the focus of our CureVac collaboration. The second is to use modified bases.

As you can see on the left-hand side of this slide, the 5 prime 3 prime optimization results in a 10-fold higher immune response compared with an unoptimized approach. Of course, we need to confirm this in the clinic, but it is clearly very encouraging. It is also worth highlighting that these vaccines have the potential to be stable at 2 to 8 degrees Celsius.

We expect two mRNA vaccines from our CureVac collaboration to enter the clinic in the next 12 months. The first is a multi-valent COVID booster. The second will be for influenza. We know that efficacy for a flu vaccine is driven by the number of different strains you can immunize against and with lower doses of mRNA we believe we can develop a multi-valent, best-in-class vaccine candidate.

The GSK vaccines group has been moving quickly to ramp up our capabilities at our research center in Rockville, Maryland and globally. We now have more than 200 GSK scientists focused on mRNA and are making large-scale capital investments in a global mRNA manufacturing network. With the investments we are making in this area, we are well positioned to play a leading role with mRNA in 2022.

62. Pipeline with multiple potential first- and/or best-in-class assets

So, in summary on this slide you can see our industry-leading vaccines pipeline, the majority of which we expect to be either first or best in class. We have the potential to launch 5 new vaccines by 2026 and will
continue to progress our early-stage pipeline with five proof of concept read outs anticipated by the end of 2023 and five first time in human clinical starts planned this year.

I will now turn it over to Roger, who will go into more detail on how this will contribute to our future growth.

63. Key growth drivers: opportunities & investment priorities
Roger Connor

Thanks Hal. This slide shows the key assets that we expect to drive our high single digit CAGR growth ambition to 2026. The most significant is Shingrix, supported by our meningitis franchise, primarily Bexsero. In the latter part of the timeframe, our pipeline kicks in when we launch our RSV older adults vaccine, our meningitis ABCWY vaccine and we start to see the fruits of our new flu strategy. I will come back to all of these.

64. Shingrix: Aim to doubling revenues in the next five years, protecting more than 100m adults

Starting with our crown jewel, Shingrix, which delivered nearly £2bn in turnover in 2020. Shingles is a painful condition that will affect 1 in 3 of us in our lifetime. Shingrix delivers outstanding overall efficacy of up to 97% with similar efficacy out to 4 years and we have data awaiting publication which shows the duration of protection extends to double this- up to 8 years. This incredible profile sets the bar so high we feel good about any potential attempts by competitors to enter this market in the coming years.

Prior to the pandemic, our performance had been constrained by supply; demand was unprecedented – but thanks to acceleration of our capacity expansion, we are now unconstrained and in a position to supply all the countries where we want to launch and where the value of the vaccine can be maintained.

What’s really important to note is that, despite the success we’ve had to date, we’re just getting started with Shingrix.

In the US, there are still about 100 million adults age 50+ remaining unvaccinated. Beyond the US, we have major opportunities for geographic expansion. We expect to be in 35 markets within the next 3 years, including 16 by the end of this year.

As Luke mentioned, there is a substantial growth opportunity in China where we launched in 2020 and are initially focused on the private market in major cities. And, longer term, we have significant lifecycle management opportunities - with plans to expand the indication to adults with auto-immune disease and to reformulate into a fully liquid presentation which will put us even further out of reach for any potential rivals in development.

Taken together we are highly confident that Shingrix has the potential to double sales in the next five years, compared with a 2020 base, protecting more than 100 million adults along the way.

65. Meningococcal franchise: Aim to double revenues in next decade, building on world leading MenB vaccine

Another important contributor to growth will be our meningitis franchise where we have the industry’s leading portfolio of vaccines. We currently hold more than 50% share of the £2 billion market. Looking ahead, we expect to build on our leadership position, with the ambition to double revenues in the next decade through market expansion and new improved combination products.

In the near term, we expect to drive growth from our flagship MenB product Bexsero. In the US, in particular, we see a market expansion opportunity given that MenB is the most common serogroup affecting healthy infants, children and adolescents and that penetration is currently below 25%.

Our medium to long term plans centre on new combinations. Both our MenB and MenACWY vaccines are competitive vaccines – the next step is to combine them into one shot. We have two MenABCWY combination vaccines in the clinic.

Our first is in Phase 3 and will report pivotal data in 2H 2022. If successful, this would be a first in class asset with potential launch in 2024.
We are also in the clinic with a second generation ABCWY vaccine that we believe will deliver further differentiation by providing the broadest strain coverage for infants and adolescents. As the only vaccine to potentially address every major meningococcal strain worldwide, we believe this has the potential to further build our leadership.

66. RSV Older Adults: potential first- and best-in-class £multi-billion opportunity: Leveraging our proven adjuvant technology

Next, I want to talk about the late stage asset in our vaccines pipeline that I am most excited about. RSV is a very common respiratory virus and one of the highest-value remaining unmet need in infectious diseases.

In older adults, the hospitalization burden associated with RSV infection is higher than that of influenza. This is really important – the burden of disease created by influenza is seen by Governments as a very high priority to address with improved vaccines – the burden of disease of RSV is comparable, with an even higher risk of severe outcomes in hospitalised patients.

With 1 billion people age 60+ in the world and 70 million in the US alone exposed to RSV every year, there is a significant addressable population making the scale of this opportunity very large. We estimate the market size for RSV older adults alone at £5bn annually.

We have the most advanced RSV older adults vaccine candidate in development. As Hal mentioned, what is important is that this vaccine incorporates our proven adjuvant AS01, the same platform used in Shingrix, a highly efficacious vaccine in a similarly aged older adult population.

Last year we reported Phase 2 data that showed neutralising antibodies are boosted 10-fold compared to baseline and that the vaccine induces a strong T cell response - similar to that seen in young adults. In older adults, this is of fundamental importance in fighting viral infections.

The FDA has granted fast-track designation for this programme and, assuming we are successful in Phase 3, we have the opportunity to launch a first and best-in-class asset in 2024. It won’t end with launch in older adults as we are planning lifecycle innovation to expand use to younger adult populations with underlying conditions that may put them at high risk of RSV - as well as assessing combinations with other adult vaccines.

This vaccine is a major commercial opportunity with multi-billion pound, Shingrix-like annual potential and we intend to maximise it fully.

67. RSV Maternal: Potential to provide broad protection to infants from first breath of life

The burden of RSV is also significant in infants. We believe the best way to protect them, that is likely to be most acceptable to new parents, is through maternal vaccination. This will create immunity from the first breath, without the need for injection of the baby in the first days of life. The opportunity here is the annual birth cohort, which is four million each in the US and the EU alone – and 140m globally.

Polyclonal induced immunity by our maternal vaccine offers broader protection than a monoclonal approach, addressing the risk of escape viral mutants. It also has the potential benefit of protecting the mother which is good for her and potentially reduces the risk of transmission from mother to baby. This vaccine is in Phase 3 and - with fast track from the FDA - could launch as early as 2024, assuming positive pivotal data.

This is a crowded competitive space so the opportunity for further innovation is important. We are developing an RSV and pertussis combination vaccine which is expected to move to first time in human study in 2022. This will be the first combination vaccine designed specifically for pregnant women to protect newborns from two important diseases; being able to give a single injection against 2 pathogens the baby most needs protection from, will deliver a competitive advantage.
68. Influenza: Innovating to deliver greater protection, new ambition to double revenues in next decade

I am going to finish with flu where today we are announcing a new strategy, based on the renewed opportunity in this space. The disease burden remains significant with up to 650,000 deaths from flu-related disease each year. Governments around the world are increasing vaccination levels – and we believe this will be maintained post-COVID. Consequently, despite sub-optimal current vaccines, the market is expected to grow by more than a third by 2026. Our strategy will be delivered in a stepwise approach, leveraging new technologies to supersede our current egg-based approach.

First, we have a clinical collaboration with Medicago to develop a flu vaccine using their innovative plant-based technology, combined with our pandemic adjuvant. This combination has shown very strong immunogenicity in COVID, amongst the best across all vaccines, including mRNA. This vaccine will be targeted at the 65 plus population and we believe will be an improvement on the egg-based approach. Our collaboration is currently at the clinical stage with phase 3 data readout expected in 2H 2023. We are in discussions regarding details of a commercialisation agreement.

Secondly, within the next 12 months, as Hal noted, we are starting a first time in human study using the CureVac second generation mRNA platform to pursue a multi-antigen seasonal flu vaccine with expected better efficacy than the current standard of care. In addition, we plan to develop a universal flu vaccine using the same technology.

And finally, through our partnership with Vir, we have exclusive rights to collaborate on VIR-2482, a monoclonal antibody designed as a universal prophylactic for influenza A, with the potential to overcome the limitations of current flu vaccines leading to meaningfully higher levels of protection due to its broad strain coverage.

Flu is the one part of our current portfolio that is at risk from emerging mRNA technology and our new strategy aims to ensure that we are net beneficiaries from this disruption to this marketplace. As a consequence, we have a new ambition to double our flu sales in the next decade and this would be upside to New GSK’s 2031 sales ambition.

69. Strengthening leadership in vaccines

In summary, we are extremely confident that Vaccines will deliver a high single digit sales CAGR in the next five years. Furthermore, we have all the necessary ingredients, underpinned by a powerful pipeline and long-term competitive capabilities, to sustain attractive growth and leadership over the next decade.

I want to leave you with one important fact - which is why I get out of bed every day to lead this fantastic business – around 40% of infants in the world receive a vaccine made by GSK every year – the public health impact we make is immense and it is something all of us at GSK are very proud of.

Thank you. I’ll now hand you over to Deborah Waterhouse and Dr. Kimberly Smith who lead the ViiV Business.

RESHAPING HIV TREATMENT AND PREVENTION

70. Reshaping HIV treatment and prevention
Deborah Waterhouse

Good afternoon. My name is Deborah Waterhouse and I am the CEO of ViiV Healthcare. I am delighted to be joined by our Head of R&D, Dr. Kimberly Smith.

71. Reshaping the HIV treatment and prevention landscape

In this section we are going to walk you through our strategy for the HIV business, our growth ambitions, the transition of our portfolio from oral based regimens to long-acting injectables, and of course our pipeline. Our strategy is to remain innovation leaders in HIV; achieve a mid-single digit CAGR to 2026 and digest the loss of exclusivity of dolutegravir through the changing mix of our portfolio and the success of our pipeline.
In 2019 we changed the approach to HIV treatment with the launch of our two drug regimen Dovato with efficacy non-inferior to a Dolutegravir-based three-drug regimen. And we are now bringing to market the first long-acting injectables for the treatment and shortly for the prevention of HIV.

We believe Dovato, Cabenuva and Cabotegravir for PrEP will each deliver significant benefits for people living with HIV and will make a multibillion pound sales contribution. As we move into the second half of the decade, we anticipate we will see a significant acceleration in the uptake of our long-acting regimens with Cabotegravir replacing Dolutegravir as the foundational medicine in our portfolio.

And we are excited by our early-stage development pipeline, which we believe offers potential for revenue renewal from 2026 onwards.

72. Delivering on significant unmet needs in HIV: Key challenges remain in £23bn treatment and prevention market

HIV remains a global health challenge with significant unmet needs and a global market of around 23 billion pounds in value. The WHO and UNAIDS estimate that 38 million people are currently living with HIV, with 1.7 million new infections per year. The burden remains greatest in sub-Saharan Africa and it is a sobering fact that around six thousand adolescent girls and young women are infected every week.

In the US, there are around 38,000 new infections per year and the epidemic continues to disproportionately impact people of colour and predominantly men who have sex with men. And in Europe, we have a similar picture with around 22,000 new infections per year. Despite treatment advances, this epidemic remains pressing and relevant. And the market opportunity remains compelling for those who deliver new and meaningful innovation.

73. HIV delivering mid-single digit % CAGR 2021-26 with pipeline optionality beyond

Our HIV business is positioned for growth and we expect to deliver mid single digit CAGR from 2021 to 2026. Through the first half of the decade the launch of new medicines, represented in orange, aims to accelerate the growth outlook for ViiV, underpinned by the continued trajectory of the oral 2 Drug Regimens, notably Dovato.

During this period, we anticipate transitioning to the long-acting portfolio with Cabotegravir creating two new market segments in treatment and in prevention. As we end 2026, we estimate that Cabotegravir-based regimens will equate to around 35% of the portfolio. Post 2026, we are excited about our early-stage pipeline of new and innovative long-acting medicines which will have the potential to power revenue renewal.

Kim will cover this later.

74. Dovato: Best in class two-drug regimen

Dolutegravir-based regimens are now taken by more than 17 million people living with HIV – that represents one in two on treatment today. Dolutegravir is an integrase inhibitor, which since launch has become a proven gold standard in treatment with 8 superiority studies vs competitors, setting an incredibly high bar in terms of barrier to resistance and tolerability. We believe that innovative regimens, whether oral or long-acting, need to contain an integrase inhibitor.

In 2019 we launched Dovato, which is a best in class two drug regimen with Dolutegravir at the core. Dovato is a pivotal medicine for our business. It has consistently demonstrated efficacy non-inferior to a Dolutegravir-based three-drug regimen and delivers significant benefits to people living with HIV. A person living with HIV will be on treatment for the remainder of their life. Why should patients be exposed to 3 drugs when 2 is all they need?

Despite the ongoing challenges posed by the Covid pandemic, Dovato has continued to perform strongly as the graph on the left of this slide demonstrates.
As a result of our excellent commercial execution and strong investment behind Dovato, we are now driving strong growth in both the US and Europe and particularly in the switch market. We expect Dovato to deliver more than 1 billion pounds of revenue in 2022 with further potential beyond that. We see the opportunity for Dovato as being balanced globally, with around 50% of the potential sales in the US and the remainder split between Europe and the rest of the world. Dovato is patent protected until 2028 in the US and 2029 in Europe.

75. LA pipeline with opportunity for revenue renewal post DTG LoE: Portfolio transition through decade with LA regimens ~ £2bn by 2026

I am now going to walk you through the shape of the HIV business through the decade and our ambition to retain our leadership position as innovators in HIV. In this section we will outline the expected transition from oral therapy to long-acting regimens and why despite the loss of exclusivity of Dolutegravir at end of the decade, we remain confident in the outlook for our HIV business.

Between 2021–2026 our HIV business is expected to grow mid single digit CAGR driven by Dovato, Cabenuva and Cab PrEP. By 2026 we estimate LA regimens will be generating around 2 billion pounds of our sales and then post 2026, we are working to launch a self administered long-acting treatment, and ultra long acting regimens for treatment and for prevention.

By 2031, we estimate 90% of our business will be in long-acting regimens, delivering significant value to patients and enabling our HIV business to deliver attractive growth. I will now hand to Dr. Kimberly Smith to take you through the transition to long-acting regimens and our pipeline.

76. Shifting the paradigm towards long-acting treatment: Cabenuva: world’s 1st and only long-acting regimen for HIV treatment

Dr. Kimberly Smith

Thanks Deborah. Long-acting regimens are the future of HIV and the driver of growth through the next 10 years. We are and expect to continue to be the leaders in this space. Through the next few slides I will articulate the comprehensive patient insights and scientific rationale that underpin our confidence. On the left of this slide, you can see that patients are telling us why they want long acting medicines. In our pivotal trials, 9/10 preferred the long-acting regimen over daily orals.

And the reasons behind this are clear. There are significant challenges with daily therapy – fear of HIV status disclosure, stress and anxiety about staying adherent; and the daily reminder of living with HIV which is highly stigmatized.

Simply put, long-acting gives people freedom from the burden of daily oral therapy. In January of this year we were thrilled to receive FDA approval for Cabenuva the world’s first long-acting injectable treatment for HIV. It is also approved in Europe under the brand name Vocabria/Rekambys with dosing every 2 months. We anticipate approval of 2 monthly dosing in the US by the end of the year and launch in early 2022.

This is the first and only approved long-acting regimen. It reduces dosing days from 365 to 6. It is powered by an integrase inhibitor, it has non-inferior efficacy and comparable safety to a daily oral 3 drug regimens. Excitement from prescribers and patients since launch has been palpable and we are investing confidently in execution to support the launch.

We have created a separate US sales force and we are creating a robust digital and online presence to reach every appropriate provider and person living with HIV who could benefit. We are also generating strong phase 3b/4 data, including a head to head study vs Biktarvy, to ambitiously evolve the label further.

We believe the significant interest in long-acting from prescribers and patients will lead the long acting market segment to grow at a fast pace, reaching 4-5 billion pounds by 2030. With at least 5 years head start on the competition; robust and compelling data and positive launches currently underway - we are confident about the potential of Cabenuva to transform the HIV treatment paradigm.
77. Major opportunities in pre-exposure prophylaxis (PrEP): Cabotegravir for PrEP: offers potential to transform the shape of the epidemic

Let’s switch now to a strategic priority for our HIV business - the prevention space; commonly known as PrEP. There are currently circa 200,000 people on PrEP in the US, which is a fraction of the population that could benefit. The US market is strong and viable – approximately £1.5bn in value today. We expect this to more than double over the next decade to reach £4-5bn.

The US market is going to grow further because there is significant motivation from prescribers and health systems to increase PREP use among individuals vulnerable to HIV; and the US government continues to focus on the goal to end the HIV epidemic by 2030 with an ambitious target to reduce new infections by 75% by 2025.

CAB is a new long acting injectable for the prevention of HIV and offers the potential to transform the shape of the epidemic. It is the first long acting injectable for PrEP and it is dosed every two months.

US patient demand for a long-acting injectable for PrEP is high. Stigma around PrEP use and the perceived hassle of daily dosing are currently the top drivers for discontinuation of PrEP.

Prescribers express concern around their lack of ability to observe adherence with current PrEP options. Cabotegravir addresses these concerns. And the data behind cabotegravir is outstanding as you can see on the right of this slide, data from the HPTN 084 study, which compared cabotegravir long acting to oral daily Truvada for prevention of HIV acquisition in women. In the graph you see the rising solid purple line that represents increasing new HIV cases on the TRUVADA arm while the red dotted line across the bottom of the graph shows the much lower number of cases on the CAB arm.

HPTN 083 which studied men who have sex with men, had similar results. These pivotal studies demonstrated superior efficacy in men and women - 3x-9x better than oral Truvada - both studies were stopped early by the independent data monitoring board and all participants were offered the opportunity to switch to cabotegravir. This is unprecedented in HIV prevention.

Last month we began a rolling submission with the FDA for cabotegravir for PrEP which we expect to be completed next month; anticipate approval late this year or early next with launch in early 2022.

If approved, we believe cabotegravir will represent a new and persuasive option in the PrEP market – dosed every two months – with efficacy that is superior to the current standard of care.

78. Integrase inhibitor-based LA pipeline drives future growth: Potential options for self administration and ultra long acting

Now let’s move to our pipeline – the engine which will drive future growth. We are confident in our pipeline of innovative medicines that all offer the potential to partner with cabotegravir to form complete HIV regimens.

Importantly, integrase inhibitors, the proven gold standard of HIV medicine, are at the core of our portfolio. Cab 200 is our current formulation. Cab 400 is a new formulation that provides more dosing options for future regimens. There are two clear objectives: to provide the world’s first self administered long-acting regimen. And to provide an ultra-long acting regimen with dosing intervals of at least 3 months.

Each of the assets on this slide has the potential to partner with cabotegravir and each offers new mechanisms of action which attack the virus in unique and powerful ways.

With multiple shots on goal, we are confident that as we have over the last decade, we can deliver continued innovation over the next ten years and beyond, and ensure no person living with HIV is left behind.

79. Strategic collaboration with Halozyme: Expands portfolio of long-acting agents

This week we had an exciting announcement about an exclusive licensing agreement with a life-sciences company, Halozyme. Halozyme’s recombinant human hyaluronidase, or PH20, is a unique product allowing increased volumes of medicines to be delivered subcutaneously.
It offers the ability to reduce volume limitations for subcutaneous dosing, potentially increasing dosing intervals. This expands opportunities for ultra long-acting regimens combining Cabotegravir with the ViiV pipeline products, for treatment and PrEP. The exclusive collaboration covers targets for integrase inhibitors, capsid inhibitors, NRTTIs and GP 120 CD4-binding site broadly neutralizing antibodies orbNAbs.

80. Maintaining HIV leadership beyond Dolutegravir: Integrase inhibitor-based LA regimens deliver new levels of convenience

We are the leaders in long-acting therapy today and we have a robust plan to continue to be the leaders in this space. So let’s lay out our ambition for our future pipeline.

Dolutegravir has been the anchor for our regimens over the last 10 years. Cabotegravir will be the anchor for the next stage, and is the future of long-acting regimens. We see this future in three stages.

In stage 1, you have the world’s first and only approved long-acting regimen -- Cabotegravir for treatment and hopefully soon, long-acting cabotegravir for prevention, administered in the clinic offering privacy, reduced stigma and reduced anxiety.

In stage 2, our ambition is to deliver the first self-administered long-acting regimen for treatment, continuing to offer the option of long-acting to more patients with fewer clinic visits; and with Halozyme we have the potential to increase the dosing interval of cabotegravir for prevention from two months to every 3-to-6 months.

In stage 3, we have a pipeline of agents with new mechanisms of action to combine with cabotegravir, which we believe we will have the potential to create ultra long-acting (3 month+) regimens.

We now have the world’s only long-acting injectable for treatment which has been approved. And we are continuing to build on that first-ever, transformative option, which will allow us to continue to lead the industry towards a future of long-acting treatment and prevention, to improve the quality of life for people living with HIV.

Now back to Deborah.

Deborah Waterhouse

81: Reshaping the HIV treatment and prevention landscape

In summary our ambition is to reshape the HIV treatment and prevention landscape, maintaining innovation leadership in the long-acting space.

We expect to deliver mid single digit sales growth over the next 5 years. Our exciting long-acting pipeline provides the opportunity for revenue renewal post the Dolutegravir loss of exclusivity. It offers PLHIV freedom from daily oral medication and governments the ability to transform the shape of prevention efforts.

With that we invite you to enjoy a 10 minute break before Luke and Hal start the second session on Other Specialty assets. Thank you.

MAXIMISING HIGH POTENTIAL SPECIALTY MEDICINES

Luke Miels

82. Maximising high-potential Specialty Medicines

Welcome back and I hope you are all suitably refreshed and ready for the second session.

So you have heard about the exciting growth drivers in Vaccines and HIV, let’s now move to our other Specialty Medicines.
83. Maximising high-potential specialty medicines

As outlined by Emma, we expect Specialty Medicines to deliver a double-digit compound annual growth rate to 2026. In this session, we will go into some depth on the products driving this forecast across our Infectious diseases, oncology and immunology/respiratory therapy areas, as well as an important reagent in our opportunity-driven area.

84. Delivering high potential specialty medicines and strong commercial execution

Hal and I are going to highlight 10 specific high-potential assets, which you can see marked on this slide with an orange box around them.

The large and small molecules we will be highlighting are almost all first or best in class, and each has the potential to deliver compelling benefit to patients as well as significant commercial opportunity for shareholders.

85. Late-stage pipeline potential for >£20bn in NRA sales

To re anchor you in terms of the scale of the opportunity with these projects, this is a slide that was shown earlier today.

The numbers in the middle outline how our late-stage pipeline could deliver greater than £20bn in sales, on a non-risk adjusted basis, with a summary statement including the primary advantage supporting the peak sales estimates on the right hand of the table.

86. Specialty medicines: deliver double digit % CAGR 2021-26, strong growth over next 10 years

Assembling these and our existing inline products in this bridge slide you can see that the trajectory leads to a 2031 sales ambition of more than £33bn. Please note this does not assume a significant contribution from the early pipeline, such as some of the oncology assets Hal will be describing or the novel long-acting HIV combos that Deborah discussed. Also it does not include any contribution from future business development, although this will be an important element of our strategy.

So, with that brief introduction, let’s move and discuss the assets. I am going to start with two innovative infectious disease projects, namely gepotidacin and our HBV therapeutic, ‘836.

87. Gepotidacin: Potential first-in-class oral antibiotic: targeting antibiotic resistance

Gepotidacin is the first in a new class of antibiotics, with the potential to play a major role in combating antibiotic resistance in patients with uncomplicated urinary tract infections or with gonorrhoea. This is an attractive commercial opportunity, particularly in urinary tract infections.

Uncomplicated UTIs are one of the most common bacterial infections that women experience, with over 15 million cases per year in the US alone. However, resistance is increasing, and driving the need for new second line reagents. 38% of patients will have some form of resistant infection and 1/3 of all patients will fail their initial treatment, requiring a second line agent.

At the same time as the need for them is increasing, the second line options are dwindling due to resistance and safety concerns. Fluroquinolones are the most commonly used second line agent. IDSA guidelines say they should not be used empirically where resistance exceeds 10%, yet we know resistance in the US is already double that at 20%. The FDA has also issued a black box warning for fluroquinolones and guidance not to prescribe them for uncomplicated UTIs if alternate treatment options are available due to the risk of serious adverse events. Despite these issues this class still has a 25% share due to a lack of alternatives.

This is the opportunity for Gepo. Its novel mode of action gives it efficacy against resistant pathogens, making it the ideal potential treatment to replace fluroquinolones as the preferred 2nd line treatment option for women with uUTIs where resistance is a concern. Gepo only needs to displace one quarter of current fluroquinolones use to become a blockbuster and we look forward to Phase 3 results in 2022.
88. HBV ASO (‘836): potential FiC ‘functional cure’ for Chronic HBV

Moving to ‘836, we are excited by the potential to deliver a first in class functional cure for Chronic Hepatitis B where there is a substantial unmet need. The high prevalence of Hep B, coupled with low diagnosis rates and sub-optimal treatments, means this disease continues to have a devastating impact on patients, with an estimated 900 thousand people dying annually from complications of liver disease due to Hep B.

Around a third of patients are in China, where you heard me talk earlier about the ongoing transformation and upscaling of our business there to one based on Vaccines and Specialty Medicines.

‘836 is a unique asset, designed to bind to the Hep B RNA, resulting in its degradation thereby halting generation of Hep B surface antigen, ideally restoring the immune system’s natural ability to eliminate infected liver cells and control the infection for the long term. This was clearly demonstrated in our Ph2a programme, in which ‘836 resulted in a significant reduction in Hep B surface antigen across all treatment groups after only 4 weeks of treatment. We anticipate data from our robust ongoing Ph2b programme, assessing ‘836 vs standard of care in 2022. If successful this could be a paradigm changing medicine.

With that, now let me now hand over to Hal.

89. Oncology strategy focused on the science of the immune system and human genetics

Dr Hal Barron

Thanks Luke and I just want to add my excitement about both gepotidacin and our HBV antisense oligonucleotide which have the potential to be transformational for patients.

Moving to Oncology where our portfolio has grown and advanced significantly since 2018 and benefited from our focus on the science of the immune system and human genetics as well on business development. We have evolved from having no approved medicines and 8 assets in clinical development, the most advanced being all in Phase 1, to today where we have 3 approved medicines, all of which have considerable life cycle innovation opportunity, 13 assets in development, as well as numerous exciting pre-clinical targets beyond that.

The portfolio advancement we have delivered has been driven by internal research efforts as well as through business development resulting in exciting immuno-oncology, cell therapy and synthetic lethality portfolios. Let me turn now to the asset in our pipeline which has seen the most significant acceleration since 2018.

90. Blenrep: first-in-class BCMA treatment for patients with multiple myeloma

Blenrep, our first-in-class BCMA targeted therapeutic, was our first new oncology medicine to launch and was approved based on the deep and durable responses seen in patients with advanced multiple myeloma in the DREAMM-2 study. As I mentioned earlier this is an example of rapid development with the approval of Blenrep coming just over two years after the initiation of this study.

Multiple myeloma is the second most common haematological malignancy with a global incidence of more than 175,000 patients per year and sadly it is almost always still a death sentence. Fortunately for patients there are a number of therapeutic options available or in development with the most prominent being those that target BCMA.

Blenrep has a number of advantages beyond being first to market. As an ADC it is an off-the-shelf product which can be administered in a community setting and is immediately available to patients via a simple, 30 minute infusion every three weeks.

Our extensive, ongoing clinical trial programme is designed to extend the use of Blenrep to earlier lines of treatment based on the compelling efficacy we’ve seen to date including with the Algonquin data shown on this slide where a 95% response rate was achieved with the 2.5mg/kg dose. The majority of patients do not develop symptomatic ocular events and only around 3% of patients actually discontinue treatment due to these events.
However, we are investigating ways to better manage these ocular events and as you can see on the slide, in the Algonquin study reducing the dose by just 25% led to a significant reduction in grade 3/4 keratopathy. We are optimistic that further dose optimisation work will reduce these events and enable more patients to get this important medicine.

In addition we have a number of ongoing combination studies including one with a gamma secretase inhibitor to further lower the dose which I will cover in more detail now.

91. The power of functional genomics: combining Blenrep with a gamma secretase inhibitor (GSI)

I have mentioned this combination previously and remain very excited about the potential for this proof-of-concept study.

This is a terrific example of how incredibly powerful functional genomics can be in identifying potential targets. The study on the left of this slide by Kampmann et al., uses a CRISPR knock out screen to identify targets which increase BCMA cell surface expression. Basically, these types of studies evaluate the impact of knocking out a gene and seeing if it increases expression, the dots on the right, or decreases expression, dots on the left.

This can be done on a whole genome scale routinely now through our collaborations with the LGR and the Broad. Amazingly, the top hit in this screen were the 4 sub-units of gamma secretase. This implies that of all the genes explored, inhibiting GSI is the most likely to provide synergistic activity.

We complement these studies with biology where we now understand the mechanism by which GSI prevents the shedding of the receptor and, as you can see on the far-right, there is a marked improvement in the cytotoxicity assay when combined with Blenrep.

Thus, we believe this will allow us to maintain the impressive efficacy at a lower dose of Blenrep which should reduce the incidence of ocular events. Of course, we need to see if this will translate in patients and we have a sub study within DREAMM-5 exploring this combination ongoing and we expect to have preliminary data by the end of this year.

92. Jemperli*: enabling next generation Immuno-Oncology with our innovative pipeline

Next I would like to highlight our most recently approved oncology medicine, Jemperli. While there are a number PD1’s approved and in development, Jemperli provides GSK with several unique opportunities.

Firstly, we are very proud to have received approval for Jemperli as a second line monotherapy treatment for women with dMMR endometrial cancer given the significant unmet medical need. The second opportunity is in areas where PD1s have not yet been licensed including in the first line treatment of women with endometrial cancer where we will see data from the RUBY study in combination with chemotherapy in the second half of this year. We are also exploring combinations with Jemperli in ovarian cancer and multiple myeloma. Lastly, the most significant opportunity is the potential for combinations with our novel immuno-oncology portfolio, though it is worth remembering that IO is a high risk area as reflected by recent readouts on ICOS and TGF beta.

We continue to believe some novel combinations will be successful and given the profound potential impact on patients we think this represents a very smart risk.

One of the most exciting opportunities in this space is through modulating the CD226 axis, and the next slide describes this in more detail.

93. Unique pipeline targeting CD226 axis: TIGIT^, CD96, PVRIG with potential for synergistic anti-tumour effect

Based on robust preclinical data, human genetics and recent randomised clinical trial data, modulating the CD226 axis looks to have very promising potential.
Let me take a minute to explain why this is: TIGIT, CD96 and PVRIG are all expressed on different T and NK cell subsets and each function as immune checkpoints, by binding to CD155 and CD112 and thus preventing activation of CD226 axis. Antibodies to TIGIT, CD96 and PVRIG disrupt this binding to CD155 and CD112, allowing the immune system to recognize and kill the cancer cell.

The preclinical data on the right-hand side of this slide shows that by combining antibodies against PD-1, CD96 and TIGIT synergistic benefit is achieved, compared to either doublet alone.

I hope you can see we are in a very unique position now to fully unlock this axis having acquired a PD-1 through our acquisition of Tesaro, advanced anti-CD96 with 23andMe, in-licensed anti-PVRIG from Surface Oncology and most recently obtained an antibody for TIGIT from iTeos Therapeutics.

If this translates in the clinic we will be leaders in a new era of immuno-oncology delivering transformational medicines to patients and value to shareholders.

94. World leading functional genomics platform will enable our synthetic lethality pipeline

Moving to another exciting area of oncology.

I highlighted the GSI example to demonstrate the immense power of functional genomics. Our confidence in Zejula and the PRIMA study was another example of these unique insights. Based on functional genomics we were confident that Zejula would benefit more women than just those with the BRCA mutation. Given the results of the PRIMA study I now believe we have the best in class PARP inhibitor, and Luke will speak to this in more detail in a moment.

Through building world class human genetics, functional genomics and AI/ML capabilities we have expanded our synthetic lethality pipeline beyond Zejula now with the Ideaya collaboration. This has added a number of exciting targets to our portfolio including the MAT2A inhibitor which entered the clinic earlier this year.

The finding that MAT2A inhibition is synthetically lethal in tumours with MTAP deletion is very exciting, and as you can see on the slide MTAP deletion is common in a number of solid tumours.

We have two other promising pre-clinical targets with Ideaya, the Pol Theta and the Werner Helicase, and the emerging data from our progress in functional genomics is identifying a number of targets. I am confident this will enable us to have a world class synthetic lethality pipeline.

I will now hand over to Luke to cover Zejula in more detail.

95. Zejula: best-in-class and only PARP inhibitor approved for all 1L ovarian cancer patients

Luke Miels

We covered the recent performance of Zejula earlier. This slide outlines the longer-term potential.

The current pandemic unfortunately has seen a delay in the diagnosis and subsequent treatment of new cancers. However we expect this to recover towards the end of 2021.

When we look at maintenance therapy in the first line setting, it remains under-utilised with around 60% of women who could potentially be receiving maintenance therapy, still on a ‘Watch and Wait’ strategy, despite the data.

To address this gap we continue to invest in education of both physicians and patients – and I’m very pleased to report, patient awareness of their options for maintenance therapy is increasing, up from 29% in 2020 to 45% in early 2021.

We see opportunity to further drive market growth as PARP inhibitors remain underutilised in 1LM OC, particularly in BRCAwt and HRp patients, for which Zejula is the only PARP inhibitor indicated for 1L monotherapy maintenance.
96. Zejula: maximizing patient benefit through multiple development opportunities

We also believe ZEJULA has potential to improve outcomes beyond ovarian cancer. In terms of the life cycle work with Zejula, we have four pivotal studies currently ongoing in lung, breast, endo and ovarian in addition to a large number of investigator-initiated experiments.

Pleasingly in November, we dosed our first patient in the exciting Phase 3 pivotal ZEAL-1L study. With our unique pharmacokinetic property of penetrating the blood-brain barrier there is the potential to impact disease with brain mets and CNS involvement, which could result in a best-in-class label in Non Small Cell Lung Cancer (NSCLC).

And finally, we’ve recently started opening centres for our Phase 3 registrational trial for Zejula in breast cancer called ZEST. The design includes two cohorts, BRCAm and BRCAwt and like Ovarian, we expect that there will be biomarker populations beyond BRCAm that will benefit from Zejula.

This study employs circulating tumour DNA to identify a tumour recurrence after adjuvant treatment before it progresses to radiologically detected metastatic disease. This is the first time ctDNA has been employed in a pivotal breast cancer study, identifying those patients that are most likely to progress. This is really important as physicians may be reluctant to initiate treatment in these women at this stage of disease. However, confirmed presence of tumour DNA would be expected to shift this balance substantially in favour of niraparib therapy.

97. GSK ‘294 (depemokimab): potential best-in-class long-acting IL-5 antagonist with ambition to transform SEA treatment

If we move now to immunology and respiratory, our long acting IL-5, ‘294 or depemokimab is our opportunity to expand our leadership in severe eosinophilic asthma, given the continuing high unmet need and economic burden.

Interleukin-5 (IL-5) antagonists and other biologics are effective drugs but currently, only 27% of eligible patients receive a biologic and of those 50% remain uncontrolled despite being on therapy. This low adherence and treatment reluctance with injectables factors strongly in these numbers.

Building upon the efficacy and safety of mepolizumab, ‘294 has been engineered for high affinity and longer lasting suppression of IL-5, enabling continuous control. Our development programme has been designed to optimise eosinophil levels, whilst offering patients more control and quality of life with a single injection delivered every 6 months. A robust real-world evidence programme is also in place to cement the importance of patient preference and is linked to clinically meaningful outcomes. The attractive profile of 294 and a development plan informed by deep experience with the IL-5 mechanism could see 294 not only become the biologic of choice in severe eosinophilic asthma (SEA) but could also expand large molecule usage in these patients.

Back to you Hal.

98. Otilimab (anti-GM-CSF): novel MoA to address unmet need in rheumatoid arthritis (RA)

Dr Hal Barron

Thanks Luke and I just want to add my excitement about the development of depemokimab which we progressed in to phase 3 earlier this year, straight from phase 1, based on robust PK/PD data.

Another important asset within our immunology therapy area is otilimab which I mentioned earlier when I discussed our solutions for COVID. Otilimab is also in a Phase 3 development programme for rheumatoid arthritis (RA).
Around one percent of the world’s adult population suffer from RA and despite many treatment options being available, around 40% of patients treated with a biologic still report daily pain. What we hear from clinicians is that patients need better treatment options to control their symptoms, especially pain.

Otilimab is a novel monoclonal antibody targeting GM-CSF and Phase 2 data suggests that it may have a differentiated profile, in terms of pain and disease control independent of inflammation control. Our Phase 3 trial programme called CONTRAST is on track to readout by the end of 2022 and will provide us with data versus JAK and IL-6 inhibitors.

99. Daprodustat (HIF-PHI): potential to be best-in-class for anaemia of chronic kidney disease

The final asset I will cover today is daprodustat. Daprodustat has the potential to be a very transformative new medicine for patients with anaemia associated with chronic kidney disease to improve upon the current standard of care by effectively, consistently and safely managing hemoglobin with the convenience of oral delivery.

We have a fully recruited, robust Phase 3 clinical development programme which employs active standard of care comparators in both the dialysis and non-dialysis populations. It also utilises a single haemoglobin target worldwide and we believe the studies will provide adequate power to describe the cardiovascular safety profile without the requirement for meta-analyses. We look forward to sharing the data from the ASCEND programme soon. If positive, these data could have a significant impact on patients and represent significant value for GSK.

So in conclusion, I want to take a moment to highlight the strength of the pipeline we have covered today. I hope these assets, along with the approvals we have already delivered since 2017, our emerging early science and our commitment to further business development gives you confidence in our ability to deliver on our future growth ambition.

With that I will hand it back to Luke.

100. Portfolio and pipeline to secure growth over next 10 years

Luke Miels

Thanks Hal, so this concludes our overview of the products with the greatest near, and long term potential across Vaccines and Specialty Medicines. I hope you found it useful.

We have an attractive and balanced portfolio focussed on our key therapy areas whilst allowing ourselves the flexibility to be opportunistic where the science takes us.

Key in the near term will be the strong execution and delivery of our development and commercial organisations. This underpins our growth expectation of more than 5% CAGR between now and 2026. Equally we are clear that we can unlock the value of our current late-stage pipeline to deliver our ambition of more than £33bn in sales in 2031, on top of which we would of course expect to add in growing contributions from our early pipeline and from future business development.

Thank you and with this I turn over to Iain.

SUSTAINABLE GROWTH, COMPETITIVE RETURNS

Iain Mackay

101. Sustainable growth, competitive returns

Thank you, Luke and Hal.
As you have heard today, we are confident in delivery of sustainable growth and competitive shareholder returns.

**102. Sustainable growth and competitive shareholders returns**

What we mean by this, is captured on this slide.

We expect to deliver a sales CAGR of more than 5% between 2021 and 2026, secured through pipeline productivity and commercial excellence. We expect to deliver an adjusted operating margin of over 30% by 2026, driven by a significant shift in sales mix towards Vaccines and Specialty medicines and continued cost discipline across New GSK.

With sales growth and continued cost discipline, we expect to deliver adjusted operating profit CAGR of more than 10% over the next five years. To be clear these outlooks do not include any revenues or profits from COVID-19 solutions.

From 2022 New GSK’s cash generated from operations is expected to be further improved by operating leverage, cost productivity and working capital improvements.

In addition to strong operating cashflow performance, on separation of the Consumer Healthcare business we will strengthen New GSK’s balance sheet, giving us the financial flexibility needed for a growth-focused capital allocation strategy. We expect to have leverage of less than 2 times net debt to adjusted EBITDA at the point of separation.

Regarding capital allocation, our disciplined approach is focused on strengthening the pipeline, ensuring long-term sustainability of all aspects of our operations and delivering sustainable shareholder returns. A progressive dividend policy is a central element of our capital allocation discipline and I’ll cover this in detail shortly.

As a leadership team we are confident in our ability to deliver this growth. And for the next 10 minutes or so, I will to provide the detail that informs our confidence.

**103. Competitive sales outlook: Pipeline productivity and commercial excellence**

This slide sets out our ambition for sales growth over the coming decade and the key drivers of that growth. Through pipeline productivity and commercial excellence, as set out earlier by my colleagues, we expect to deliver top quartile sales growth over the next five years and aim to grow revenues to more than £33bn by 2031, more than offsetting the anticipated impact of loss of exclusivity of dolutegravir.

From 2021 to 26 we expect to deliver more than 5% sales CAGR, driven by both recently launched products and anticipated approvals from our late stage pipeline.

We expect sales of products behind major pipeline approvals between 2017 and 2021, to deliver over 60% of sales growth over the next five years. Each of the Marketed Assets noted here will play a significant part in delivering this growth.

We expect anticipated approvals of transformative best in class assets, like cabotegravir for PrEP and RSV for older adults, continued development of Zejula and Blenrep as well as other assets from our late stage pipeline to deliver the remaining 40% in top-line growth to 2026.

Looking further ahead to 2031, we have set an ambition of delivering more than £33bn in sales. This is driven by effective commercialisation of in-market assets and anticipated progress in our late-stage pipeline, which you have heard about from Hal, Luke, Roger, Deborah and Kim, and is before any significant sales contribution from earlier stage pipeline or any contribution from future business development opportunities.

As a consequence we are very confident in our ability to execute on our 2031 sales ambition.
Reflecting on our late-stage pipeline, we see a combined peak year sales potential of over £20bn on a non-risk adjusted basis. Not only is this well above non-risk adjusted consensus forecasts but it provides the opportunity to take us substantially beyond our risk adjusted ambition of more than £33bn in sales in 2031. Our top-line ambition for the coming decade is robust. The very significant transformation realised in R&D productivity and commercial execution across our portfolio underpins our confidence in delivering these expected outcomes.

104. Adjusted Operating Margin expansion to at least 30% by 2026: More than 10% Adjusted Operating Profit CAGR 2021-26

We expect to expand our operating margin to at least 30% by 2026, with more than 10% adjusted operating profit CAGR over the next five years.

The key drivers of this growth are:

- Higher sales of Vaccines and Specialty medicines delivering improving margins through operating leverage and mix
- Completion of major restructuring programmes and disciplined cost control. There are no further major restructuring programs planned
- Increased R&D productivity will allow us to continue to secure pipeline approvals, while slowing the significantly increased rate of R&D investment seen in the last few years
- And ongoing productivity initiatives across supply chain, commercial operations and global functions, reflecting our ambition of achieving and maintaining upper quartile peer benchmark comparators further contributes to improving operating margins.

At the same time, to win in the market, we must invest. We will invest the right resources behind our pipeline, new launches and commercial capabilities to ensure we sustain our potential for growth. We will do this while maintaining a sharp focus on enhancing return on investment, to constantly manage the impact on margin and operating profit.

Finally on this page, you’ll note that we expect cessation of Gardasil royalties in 2023.

105. Mix shift delivers improving margins

An important driver of margin improvement over the next five years is a marked shift in portfolio product mix. The growth of Vaccines and Specialty sales relative to a broadly stable revenue and margin outlook for our General Medicines portfolio contributes to operating margin improvement up to 2026.

In addition to this very significant mix shift to Vaccines and Specialty we will continue to actively manage the General Medicines portfolio for operating profit and cash generation.

As Luke mentioned earlier we have already delivered significant streamlining and simplification of the GM product range. This work has been achieved through a combination of reducing the complexity of the product range and divestment of certain brands where the economics are attractive.

This work will continue.

Close collaboration between our commercial and supply chain teams will continue to deliver network simplification and improvements in Cost of Goods Sold (COGS). With our commercial team we will continue to sharpen our focus on growth markets and tailored-go-to market strategies. And across our businesses we will maintain a disciplined approach to cost management.

You will find an Appendix detailing how we intend to report each of our three product areas as well as the overall reporting framework for New GSK.

106. Disciplined cost management: Major restructuring complete in 2022, ongoing productivity initiatives
New GSK: new ambitions for patients and shareholders
Investor update, 23 June 2021

Over the last three years we’ve made great progress in delivering improved cost productivity. We will build on this progress and maintain a focus on further sharpening our resource allocation and cost discipline. We will continue to see delivery of the results of major restructuring carried out over recent years, with these programmes completing in 2022. In total, for these projects implemented between 2018 and 2022 we expect to deliver annual savings of £1.5bn by 2023.

And, as noted earlier no major restructuring programs are planned.

From our Future Ready program, announced in early 2020, we expect to deliver an additional £200m savings for a new total of £1bn, with no additional implementation cost.

Of the total expected annual savings of £1.5 billion, we expect to reinvest approximately one third into the growth drivers of our business.

Our focus on disciplined cost management is evident across all parts of the business. Examples of savings included in the £1.5bn total are:

- In R&D, synergies are being unlocked through the implementation of our One Development organisation, which encompasses both Vaccines and Specialty medicines development, and supported by R&D productivity improvements as Hal shared earlier. This contributes to savings of around £300m.
- In our manufacturing network following site and brand rationalisation, plus efficiencies derived from the application of automation and AI across our global network, we will deliver savings of around £400m.
- And in our re-shaped global support functions we expect to deliver top quartile efficiency and cost competitiveness, allowing New GSK to be leaner and more productive.

This focus is a major contributor to the very significant savings in SG&A cost categories, but it goes well beyond reshaping the capabilities of our Global Support Functions. We continue to assess all categories of SG&A spend with a particularly sharp focus on non-customer facing activities.

We’ve made very significant progress and we know that new ways of working in the post-COVID environment, as well as agile resource allocation, which prioritises return on investment, will support delivery of more savings in the future.

You can see the progress we’ve already made. This is work we now do well. Our progress in every area gives us confidence that we can deliver the changes needed to make new GSK highly competitive and more financially efficient.

107. Cash and working capital

Turning to cash generation and conversion.

The expected revenue growth and margin expansion I’ve noted, combined with effective working capital management and the completion of restructuring programmes, will strengthen cash generation and conversion. We expect cash generated from operations for New GSK to exceed £10 billion by 2026 - a significant step-up from 2020 levels.

Our teams are delivering top quartile performance in working capital management for Days Sales Outstanding (DSO), Days Payables Outstanding (DPO) and Returns and Rebates (RAR) management.

There is both significant focus on and significant opportunity to deliver improved inventory management. This is a long cycle opportunity, but our teams have actions in place to deliver significant improvement in Days Inventory Outstanding over the next five years.

Through the investment cycle, and supported by recapitalisation upon separation of Consumer Healthcare, we expect to continue to strengthen our balance sheet.

From a credit ratings perspective, we are targeting short-term ratings of A-1/P-1 and commensurate long-term ratings.
Our Corporate Treasury team continues to deliver improvements in our cash management processes and is very effective in deploying efficient, low cost funding strategies in support of our capital allocation priorities.

108. Robust capital allocation framework: Priorities aligned on growth drivers, improving productivity, enhancing RoI

Our capital allocation priorities remain unchanged:
- further strengthening our R&D pipeline, including through focused, bolt on acquisitions and in-licensing arrangements,
- ensuring successful new product launches;
- and 3. delivering growing and sustainable shareholder returns.

Our capital allocation framework is clear and simple.

Firstly, we invest in the pipeline and R&D capabilities, to continue to innovate, improve productivity and deliver future growth. This includes business development which will continue play an important role in strengthening our pipeline, where we will prioritise bolt-on acquisitions and strategic collaborations to strengthen the pipeline. To ensure we make the best use of our resources, we have set clear criteria for evaluating opportunities. These include:
- Alignment to our R&D strategy, focused on our core therapeutic areas
- Sizeable market opportunities with significant unmet need, and first-in-class or best-in-class potential
- Balance between non-organic and organic investments; and
- NPV and IRR thresholds set to deliver improving returns

Secondly, we invest behind product launches and customer and patient facing activities delivering commercial excellence.

Thirdly, we intend to invest between £1 and £1.5 billion annually in capital projects focusing on efficiency and effectiveness of all aspects of our business and long-term sustainability of New GSK.

And last, but by no means least, shareholder dividends.

109. Dividend

Moving onto our dividend policy for New GSK.

As Emma mentioned earlier, we will implement a progressive dividend policy, guided by a 40 to 60 percent pay-out ratio through the investment cycle. This is a key part of our capital allocation framework. We believe that setting dividend policy in this way, ensures we deliver competitive, growing and sustainable shareholder returns, while supporting the investment needed to deliver growth.

On this slide we set out our expectations for dividends over the next two years.

There is no change in the expected dividend for full year 2021 of 80p per share. For 2022, for the first half of the year, we expect to declare a 27p dividend for the current GSK group. GSK is on track to separate into the two new companies early in the second half of 2022. We expect the aggregate dividend, across the two new businesses, to be a 28p per share for the second half. On a full year 2022 basis this is equivalent to a pro-forma Group dividend of 55p per share, representing a 31% cut from the 80p/share dividend expected for 2021. This expected pro-forma, aggregate 55p per share dividend for full year 2022 is comprised of 44p representing New GSK’s policy, and an expected 11p from the Consumer Healthcare business.

Dividend policy for the new Consumer Healthcare company will be set by its Board of Directors.

In 2023, the first full year of standalone operations for new GSK, we expect to declare a full year dividend of 45p per share.
New GSK: new ambitions for patients and shareholders
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110: Separation of Consumer mid 2022

On this slide I set out more detail on the Consumer Healthcare separation.

We remain very much on track to separate in mid-2022. Over the last two years Brian McNamara and the Consumer team have done an incredible job integrating two large and complex businesses. Commercial integration activities are all but complete and manufacturing activities well underway. The team expect to deliver the targeted integration synergies of £500mn annual savings and are on track to deliver operating margins in the mid to high 20s. Brian and his team are establishing a unique and highly attractive, growth orientated Consumer Healthcare business.

The GSK board has reviewed multiple alternative approaches to separation of Consumer Healthcare, always with a lens focused on unlocking potential in both new businesses, strengthening GSK’s balance sheet and maximising shareholder value.

We intend to demerge at least 80% of GSK’s holding in the joint venture in to a new company with a premium London Stock Exchange listing. We believe this approach creates an attractive growth opportunity for our investors, and is intended to be structured in a manner that is tax efficient for UK and US shareholders, as compared to alternative separation options. Importantly, a significant majority of our long-term investors have expressed a preference for this approach to separation.

We intend to retain up to 20% in Consumer Healthcare as a short-term financial investment, and expect to monetise this holding in a timely manner to fund our capital allocation priorities and help fund certain pension benefit obligations.

Before separation we will build the capital structure of new Consumer Healthcare and expect to lever the company up to 4 times Adjusted EBITDA.

Shareholders of the Consumer JV will receive a pre-split dividend and we expect GSK’s share to be worth up to £8bn. This represents a significant recapitalisation of GSK’s balance sheet and is in addition to proceeds realised from monetisation of the retained shares.

We expect New GSK’s leverage will be less than two times net debt to adjusted EBITDA at separation, with the reduction primarily driven by the pre-split dividend. Along with the strong cash generated from operations mentioned earlier, this will support our growth-focused capital allocation framework.

111. Financial outlooks confirm expectations for strong sales, profit growth and returns

Bringing together these financial factors, the outlook for New GSK is compelling.

We see strong sales, profit growth and shareholder returns over the coming decade. From 2021 to 2026, we expect sales CAGR of more than 5%, which combined with disciplined cost management is expected to deliver more than 10% adjusted operating profit CAGR and at least 30% operating profit margin by 2026.

The resulting strong cash generated from operations will support our growth-focused capital allocation framework and a progressive dividend policy.

We have set a 2031 sales ambition of more than £33 billion and have confidence, for all the reasons you have heard today, in our ability to deliver this ambition.

With that I’ll hand back to Emma.
New GSK: new ambitions for patients and shareholders
Investor update, 23 June 2021

CLOSE

112. Platform to deliver step-change in performance and create shareholder value

Emma Walmsley

Thank you, Iain. The last four years have seen transformative change across GSK. Across multiple dimensions. Addressing long-term historic issues.

We now have in place a clear platform to deliver a step change in performance and create value for shareholders.

Value delivered by New GSK – a business revitalised around new Vaccines and Specialty Medicines. And value delivered through separation, to unlock the potential of a new world-leader in consumer health.

113. New GSK: new ambitions for patients and shareholders

New GSK will deliver a step change in performance.

Over the next 5 years and beyond we have the portfolio and pipeline to deliver meaningful new growth. We are confident we can deliver the targets we have set. More than 5% sales growth. More than 10% adjusted OP growth. And more than £33bn sales by 2031.

This is a holistic performance model – sales, profit, cash flow, capital allocation and dividends – founded on a rigorous assessment of our plans and expected delivery.

With our innovation we can prevent and treat disease. Our purpose will be to unite science, talent, technology to do this. Operating in a responsible and sustainable way.

We are committed to delivering global scale human health impact, together with improved performance, returns and value for shareholders.

From a company where outstanding people thrive.

We have the ambition, the momentum - and the team - to get ahead of disease together. Thank you.

After a very short break we’ll now move to Q&A – over to Iain on how to ask your questions

Iain Mackay

There are two ways of asking a question.

If you’re watching on our platform you can submit a question by using the Q&A function. If you are listening to this on the conference call, the operator will give you instructions shortly.

We’ll be back in a couple of minutes.

POST Q&A

Emma Walmsley

Thank you all for joining us. As I hope you’ve heard today, we have big ambitions for patients and shareholders and we are confident in our ability to deliver as a New GSK.