

39th annual JP Morgan Virtual Healthcare Conference – Hal Barron

Good morning. Thank you, James. Thank you all for joining us here today. Let me first refer you to our cautionary statement on slide 2 of my presentation.

Building 2 world leading companies

Two years ago we laid out the pathway to the creation of 2 new companies: a biopharma company with a strong presence in Specialty medicine and Vaccines, focused on the science of the immune system and genetics and a world-leading Consumer Health company.

We have taken great steps towards realizing this vision and - as a consequence - we are moving more confidently than ever toward the creation of these two companies that will deliver significant new options for sustainable growth and attractive returns for shareholders.

Significant progress on our priorities in 2020

On slide 4 you can see some of the significant progress we made in 2020 towards our strategic objectives, despite the challenges of the pandemic.

From an R&D perspective, we continued to strengthen and advance our pipeline. We received nine major approvals, including the approval of four new molecular entities. We delivered positive data on multiple high-value programs leading to the initiation of nine pivotal studies. Our focus on genetics has resulted in more than 70% of the targets in research now being genetically validated. And, importantly, Business Development continued to augment the pipeline, with more than 20 business development deals signed.

In terms of performance, our fundamentals continued to improve, despite short term disruption most notably on vaccines. In particular, we achieved strong commercial execution in Specialty products, and we made substantial progress on our Consumer integration and company separation programmes.

Lastly, we continued to build trust in the company, exemplified by our efforts to advance a unique portfolio of COVID solutions and our adoption of industry-leading environmental targets.

Against this backdrop of significant progress, I want to focus the remainder of my comments today on our continued efforts to drive innovation and build a sustainable, high value pipeline that will provide significant benefit to patients.

Building a sustainable pipeline of transformational vaccines and medicines

Turning to slide 5, in July of 2018 I introduced our new R&D approach focused on Science, Technology and Culture. Today I will not have time to talk about the significant progress we have made on improving our Culture and I will only briefly be able to touch on some of the advances we have made related to our focus on Technology such as with Functional Genomics. Instead, I will spend the majority of my time focusing on the Science, particularly our late stage pipeline assets.

Across our pipeline we have seen the benefit of our commitment to immunology and human genetics. In Oncology our focus on immunology has resulted in numerous novel Immuno-Oncology medicines and several innovative Cell Therapies. Our focus on human genetics and functional genomics has led to the formation of a Synthetic Lethality Research Unit and through business development a growing portfolio of programmes and several important collaborations.

In Infectious Diseases, this has led to a significant number of opportunities across both Vaccines and Pharmaceuticals including solutions for the COVID-19 pandemic.

We are also now seeing real value coming from our commitment to life cycle innovation – due, in part, to closer collaboration between the commercial and R&D organisations. A particularly good example of this is the number of new launches with Nucala, our IL-5 inhibitor, and most recently with the advancement of our long acting IL-5 programme which we are planning to move into pivotal studies this year.

I will spend today speaking about each of these areas and highlight assets which we believe have the potential to be transformational vaccines and medicines in our fight to treat and prevent disease.

Strong R&D pipeline

Moving to slide 6, this slide highlights the 60 vaccines and medicines in our pipeline which are focused predominantly on Infectious Disease, Oncology, and immune mediated diseases.

25 of these assets are in Phase 1, 14 in Phase 2 and 21 in potentially pivotal studies, with the vast majority of these assets likely being first- or best-in-class.

High value late-stage pipeline; >10 potential blockbuster launches by 2026

As you can see on slide 7, based on our current projections, by 2026 we will likely gain approval for numerous new vaccines and medicines as well as new indications for existing assets.

In addition, and importantly, we believe we have more than 10 vaccines and medicines in the late-stage portfolio that could change medical practice and have sales potential in excess of one billion dollars – and several, such as our RSV vaccine in older adults, could have multibillion dollar potential.

Given time constraints, I cannot discuss all of these programmes today, but we will be holding an R&D event in June where you will hear a lot more about our exciting portfolio of transformational vaccines and medicines.

Innovative oncology portfolio

Turning to slide 8, we have made significant progress in Oncology and this slide highlights our current development portfolio with 15 assets broken down by the research area they came from.

We decided in 2018 to focus on human genetics, functional genomics and advanced technologies such as machine learning in order to become leaders in the field of Synthetic Lethality. This led us to acquire Tesaro, bringing Zejula – the potentially best-in-class PARP inhibitor, based on the PRIMA study – into our portfolio.

Subsequently we established a research unit based in Boston focused on Synthetic Lethality and announced a collaboration with IDEAYA to bring additional synthetic lethal targets into our portfolio.

And very recently we established our collaboration with one of the world's leading functional genomic centers, the Broad, which allows us to leverage this great institution's focus on genetics and drug discovery.

Another commitment we made in 2018 was that our primary focus would be on immunology. As we have noted, and is widely appreciated, one of the more promising areas to develop medicines in immunology today is within oncology. We have made significant progress in this area and now have nine promising I-O agents and three cell therapies in our portfolio, giving us a very exciting immunology focused oncology portfolio and one that will enable numerous combination studies, several of which I will highlight today.

BLENREP: first-in-class BCMA targeted therapeutic for multiple myeloma

Moving to slide 9, Blenrep, the first approved BCMA targeted therapeutic, is our most advanced immune-modulating asset. In addition to blocking BCMA and delivering a potent drug toxin, it has enhanced ADCC activity, and induces an immunogenic cell death both of which we believe are important for its impressive efficacy.

Treatment with Blenrep resulted in a 32% overall response rate in heavily pre-treated multiple myeloma patients leading to a 12-0 positive FDA ODAC vote, US and European approvals, and encouraging uptake since launch.

As many of you are aware, keratopathy is a side effect that some patients experience when receiving Blenrep. We take patient safety very seriously and are focused on helping physicians and patients understand and manage the corneal events as well as finding ways of reducing the risk including through alternative doses, schedules and potentially combination therapies.

One of the approaches I am particularly excited about is the novel combination of Blenrep with SpringWorks' gamma secretase inhibitor which inhibits the cleavage of BCMA from the cell membrane. This could result in higher expression of BCMA on plasma cells which could enable a lower dose to be used and still preserve the impressive efficacy seen. We should have some preliminary data on this combination – from the ongoing DREAMM-5 study – by the end of the year.

There is significant potential for Blenrep in earlier lines of therapy and this was highlighted at ASH last month when the Canadian Myeloma Research Group reported compelling data from the Phase 1/2 ALGONQUIN study in the second line setting.

The key message from this study was that deep responses are being seen with Blenrep when given in combination with PomDex. Across the two different dose regimens, the combined overall response rate was 88% and there was a 100% response rate in patients who were refractory to an IMiD, PI, and daratumumab. In terms of safety, the overall incidence of corneal events was reduced with the lower dose regimen, supporting our belief that the GSI combination study could be very valuable to patients if we can reduce the dose while preserving efficacy.

These encouraging results also reinforce our confidence in our two pivotal second-line studies, DREAMM 7 & 8, which we expect to report in the 2022 to 2023 timeframe.

Finally, these data and data that will be generated in the next 12 months in DREAMM-9, the ongoing dose exploration study in newly diagnosed patients, will help us understand what the optimal dose and

schedule of Blenrep is in the front-line setting, enabling us to unlock the full potential of this transformational medicine.

Feladilimab, ICOS receptor agonist: several near-term catalysts anticipated

On slide 10, I highlight another potential medicine in our I-O portfolio. Our unique, first-in-class, ICOS agonist antibody called feladilimab.

ICOS is an agonist receptor on T cells that stimulates T cell expansion. Feladilimab is an IgG 4 antibody designed to stimulate and grow cytotoxic T-cells without depleting them as seen with other antibodies.

We are developing our antibody in combination with pembrolizumab for patients with first line relapsed/metastatic head and neck squamous cell cancer in two phase 2/3 studies, INDUCE-3 and INDUCE-4.

INDUCE-3 is enrolling ahead of schedule, despite COVID, and we expect to have data from the first interim analysis in the first half of this year which may support progression to the pivotal phase.

ENTRÉE lung is our randomized phase 2 study looking at overall survival in NSCLC patients which should read out in the first half of the year and we intend to share new data from INDUCE-1 in various different tumour types by year end.

So, as you can see, there are a number of upcoming data readouts which will clarify the potential of this potentially transformational medicine.

Innovative approach to the CD226 axis (anti-CD96, anti-PVRIG)

On slide 11, I want to highlight one other area in Immuno Oncology that, while early, is very exciting to us, that is modulating the CD226 axis.

CD226 is a costimulatory receptor on T cells and NK cells that we believe plays an important role in cancer immune surveillance. We have in the clinic, the first agonist CD96 antibody, being developed with 23andMe, and through a recent business development deal with Surface Oncology a potential best in class anti-PVRIG which should enter the clinic in 2022.

The potential to combine these two medicines or frankly to combine them with a PD-1 inhibitor or even with a TIGIT antibody – where the preclinical data shows synergy – is very exciting and is another approach we are pursuing to become a leader in Immuno-Oncology.

World leader in Infectious Diseases

On slide 12, I want to switch from Oncology to Infectious Disease, where we have a world class pipeline of 32 vaccines and medicines and a marketed portfolio of 21 vaccines and medicines which had revenues in excess of \$17 billion in 2019.

In light of COVID and the advancements made, it is also important to highlight that we also have some exciting early-stage vaccines that leverage our extensive portfolio of platform technologies including mRNA, both non-replicating and what we call self-amplifying, as well as viral vector and adjuvants, with several of these expected to move into the clinic over the next 18 months.

Of the 32 vaccines and medicines in development that have the potential to transform patients' lives I would like to highlight 5.

First, our antisense compound GSK'836 which may provide the first functional cure for people with chronic hepatitis B.

Second gepotidacin, which could be an important new treatment option to combat antimicrobial resistance and potentially the first new antibiotic in 20 years to treat patients with uncomplicated urinary tract infections and urogenital gonorrhoea.

I will now spend a few minutes on the other three assets I want to highlight.

RSV older adults: major opportunity with high unmet need

Turning to slide 13, one of the highlights of 2020 was the exciting Phase 2 data we shared on our RSV vaccine for older adults and mothers at the ID Week in October.

Both vaccines are based on a recombinant subunit pre-fusion RSV antigen which is believed to trigger the required immune response. For older adults we combine this with our proven AS01 adjuvant to enhance the immune response.

This Phase 2 data showed our vaccine induced a near 10-fold increase of protective antibodies. Importantly, T cells were boosted to a similar range to that observed in the younger adults given non-adjuvanted vaccine. And importantly, the vaccine was well tolerated.

Clearly, this is highly encouraging data and we will move into Phase 3 this quarter. We anticipate receiving initial results in the second half of 2022.

Vaccinating the elderly against RSV represents a major unmet medical need, with RSV infection resulting in over 170,000 hospitalisations and 14,000 deaths a year in people over 65 in the US alone. Not only could this vaccine have profound clinical benefit but from a commercial perspective, when you take into account that this population often receives vaccines against flu and pneumococcus, you can see this represents a very sizable opportunity.

Cabenuva and CAB PrEP: meeting important patient needs in HIV treatment and prevention

Staying with infectious diseases and moving to HIV on slide 14. We are progressing two very important indications for our long-acting injectable cabotegravir.

Cabenuva, which combines our integrase inhibitor cabotegravir with rilpivirine, is the first and only once-monthly treatment regimen to show non-inferior efficacy and comparable safety to a daily oral three-drug regimen.

Why is this important? For many people infected with HIV, the stigma and daily reminder of their HIV status is a serious issue and one which can affect treatment compliance. Our market research suggests that up to two-thirds of people with HIV express strong interest in a long-acting therapy and in our pivotal studies nearly all patients showed a preference for Cabenuva.

European approval was granted last month and we expect FDA approval this quarter.

We also reported very compelling data last year for long acting cabotegravir in the prophylaxis setting. Compared with oral daily therapy, long acting cabotegravir reduced the incidence of HIV by two-thirds in men and transgender women and by nearly 90% in women.

While the clinical implications of these data are profound, there is also substantial commercial value here. Specifically, there are over 200,000 US patients on PrEP and it has been estimated by the CDC that as many as 1.2 million people could benefit from prophylactic treatment.

We expect US submission in the middle of this year and we believe both Cabenuva and CAB PrEP will provide significant benefit to patient, as well as have blockbuster potential which will help our HIV business deliver attractive revenue growth in the coming years.

VIR-7831: potential best-in-class COVID-19 antibody

Turning to slide 15, we have also been active in the search for solutions to the COVID global pandemic. We have an ongoing study for our anti-GM-CSF antibody otilimab as a treatment for patients with severe pulmonary COVID-related disease which we expect data from soon.

We also have collaborations underway with Medicago, Clover and Sanofi in which our proven vaccine adjuvant is being used to support the development of vaccines for COVID. We expect pivotal data from each of our vaccine collaborations by the end of this year.

I want to focus today on Vir-7831 which we, along with our partners at Vir, believe has the potential to be the best-in-class antibody for COVID. This is due to 3 unique characteristics

First, this is a very potent neutralising antibody and by binding to a unique and highly conserved epitope it is expected to confer a high barrier to resistance. This might become extremely important given some of the recent reports of mutant strains, as I'm sure you're all aware.

Second, this antibody was designed to have increased effector potency potentially allowing for greater efficacy and this is in part why the NIH chose it for the ACTIV-3 in-hospital study.

And finally and importantly, Vir-7831 has been engineered to extend half-life with the so called "LS mutation", which should enable us to observe efficacy at a lower dose – which could enable IM dosing.

Currently, Vir-7831 is in two Phase 3 studies. COMET-ICE in out-patients at high risk of hospitalisation and ACTIV-3 for the treatment of hospitalised patients. The latter is a setting where other monoclonal antibodies have failed, however, as noted we believe Vir-7831's impact on effector function may confer unique activity.

I know George Scangos, the CEO of Vir will be sharing more on this programme during his presentation which I strongly encourage you to attend.

Extending IL-5 leadership through Nucala LCI and next generation long-acting antibody

Turning to slide 16, as I mentioned earlier, the R&D organization is working very effectively with the commercial organization to ensure we have robust life cycle innovation plans. Benlysta's recent approval for lupus nephritis is a great example of this, as is the expansion of Zejula into non-small cell lung cancer with the start of the ZEAL-1L pivotal study at the end of last year.

The third example, that I would like to spend some time on is our IL-5 programme. Nucala, which we have developed for numerous indications, is the first biologic now approved for severe eosinophilic asthma, eosinophilic granulomatosis with polyangiitis and hyper eosinophilic syndrome. Nucala is also under regulatory review for treating patients with nasal polyps and in a phase 3 development for patients with COPD.

In addition, we have developed a long-acting IL-5, GSK'294, which has been engineered for high affinity and long-lasting suppression of IL-5, allowing it to be dosed as a convenient subcutaneous injection once every six months. We are moving this medicine into pivotal studies this quarter based on positive in-house data and with its validated mechanism of action we believe it has a high probability of success and significant commercial value. We expect results from our Phase 3 program around 2024.

As an aside, this asset will have progressed from first in human study start to Phase 3 in just three and a half years, a great example of the cultural shift we are driving at GSK and the focus within the organization on delivering at pace.

BD has been key to augmenting our pipeline and providing access to differentiating technologies

Turning to slide 17, Business Development has been critical to augmenting our pipeline, and we have accelerated the pace of activity here and will continue to do so. I have mentioned a number of these deals and collaborations – including the Broad, IDEAYA, Tesaro, 23andMe, Surface Oncology, Vir – during my presentation already.

I quickly want to highlight a recent collaboration with Steve Jackson and Adrestia addressing a new area of science called Synthetic Viability, complementing our focus on Synthetic Lethality.

All of the deals on this slide should deliver significant value to GSK, either by adding strategically targeted assets to our pipeline or providing access to world-leading technologies and outstanding scientists. And business development has and will continue to have a significant role in optimising our portfolio.

Multiple important catalysts in 2021

We had a lot of important news flow in 2020, with multiple approvals, positive data read outs and pivotal study starts. We expect to build on these with a number of notable events in 2021 as shown on slide 18.

Building a sustainable pipeline of transformational vaccines and medicines

So, in summary on slide 19, let me say I am extremely pleased with the progress we have made over the last few years. I am confident that the approach we are taking will deliver transformational vaccines and medicines for patients.

That said, we will continue working to build an even stronger, more productive and more innovative R&D pipeline, leveraging the strong foundation we have in immunology, human genetics and the advanced technologies we have established.

I highlighted today a small number of the many assets in our pipeline that could be both transformational for patients and have significant commercial opportunity.

Successful development of these assets underpins our confidence in the accelerated performance we expect to see as we move through 2021 and beyond.

I look forward to providing a more detailed R&D update in June.

And with that I will hand back to James to open up for Q&A.