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# VACCINES: STRENGTHENING LEADERSHIP

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Roger Connor  
and  
Dr. Hal Barron

# Cautionary statement regarding forward-looking statements



All outlooks, targets, ambitions and expectations regarding future performance and the dividend should be read together with the section “Basis of preparation, assumptions and cautionary statement” on pages 5-7 of our stock exchange announcement relating to an update to investors dated 23 June 2021 and the “Basis of preparation, assumptions and cautionary statement” and “Reporting definitions” slides at the end of this presentation.

This document contains statements that are, or may be deemed to be, “forward-looking statements”. Forward-looking statements give the Group’s current expectations or forecasts of future events. An investor can identify these statements by the fact that they do not relate strictly to historical or current facts. They use words such as ‘aim’, ‘ambition’, ‘anticipate’, ‘estimate’, ‘expect’, ‘intend’, ‘will’, ‘project’, ‘plan’, ‘believe’, ‘target’ and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. In particular, these include statements relating to future actions, prospective products or product approvals, future performance or results of current and anticipated products, sales efforts, expenses, the outcome of contingencies such as legal proceedings, dividend payments and financial results. Other than in accordance with its legal or regulatory obligations (including under the Market Abuse Regulation, the UK Listing Rules and the Disclosure and Transparency Rules of the Financial Conduct Authority), the Group undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise. The reader should, however, consult any additional disclosures that the Group may make in any documents which it publishes and/or files with the SEC. All readers, wherever located, should take note of these disclosures. Accordingly, no assurance can be given that any particular expectation will be met and investors are cautioned not to place undue reliance on the forward-looking statements.

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## Strengthening leadership in vaccines

**High single digit % sales CAGR 2021-26**

**Global reach and commercial execution**

**World class manufacturing capability and scale**

**Industry-leading pipeline, FiC / BiC potential, 16 Phase 2/3 assets**

**Unrivalled portfolio and breadth of technology platforms**

**Advancing COVID solutions**

**5 planned new launches by 2026, including £multi-billion RSV opportunity**

**Doubling Shingrix revenues in 5 years**

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Shingrix, meningitis and flu revenues from 2020 base

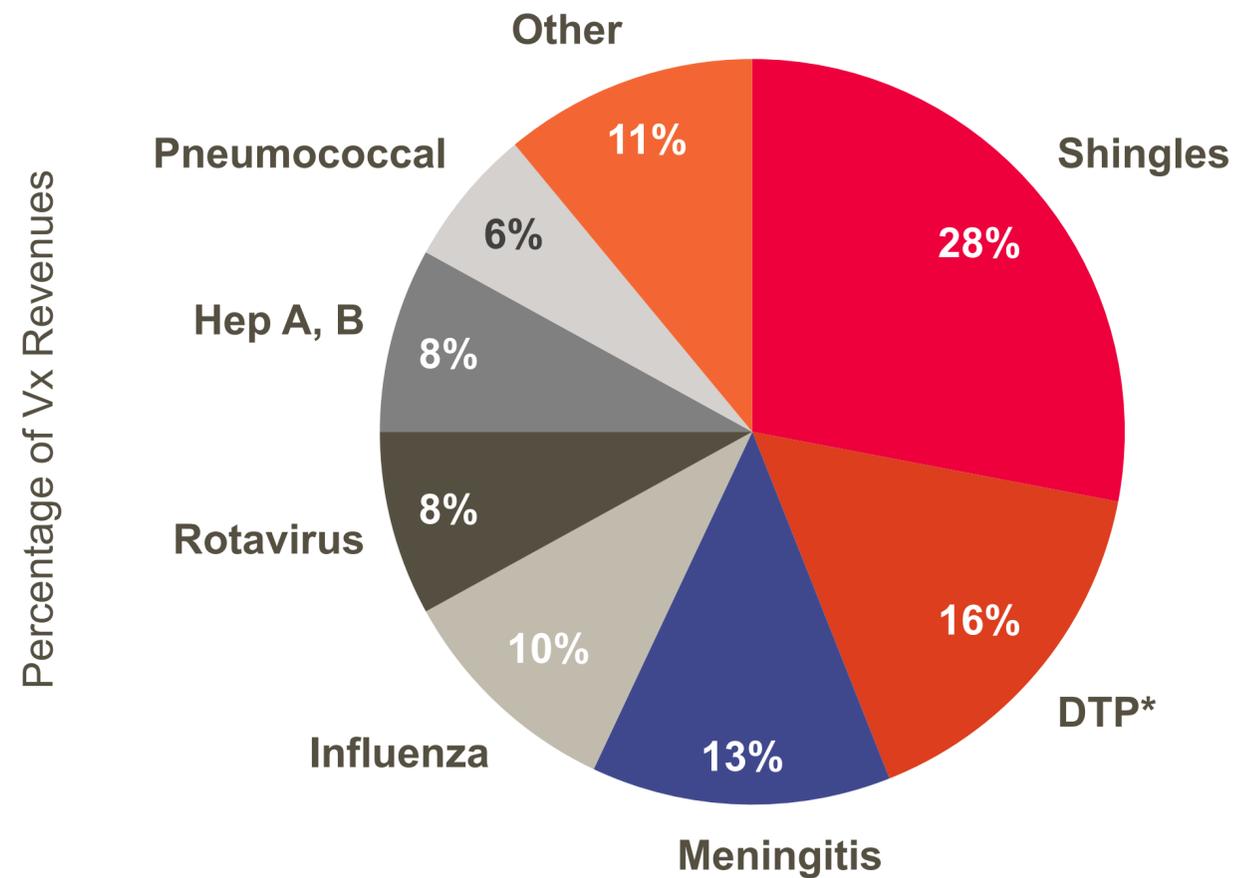
FiC First-in-Class; BiC Best-in-Class

# Industry leading portfolio

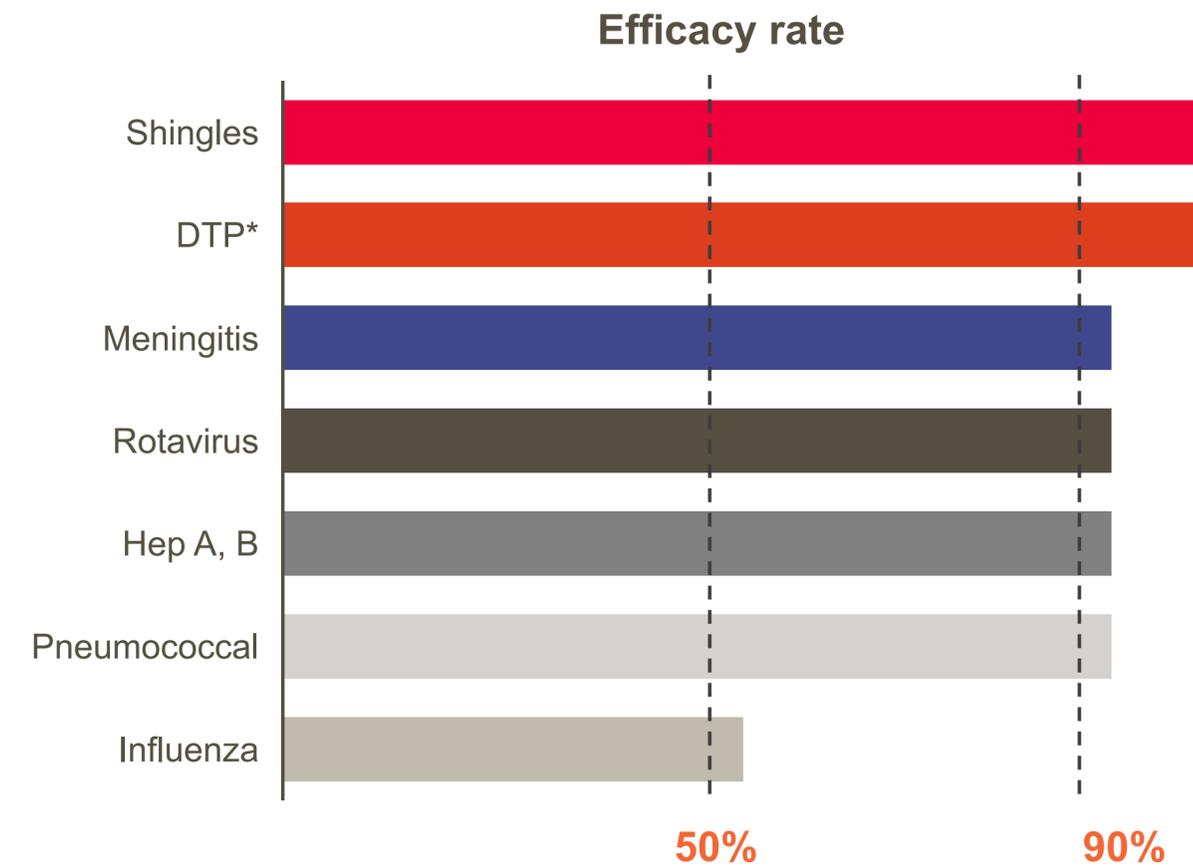
## High efficacy and protection



### Extensive and highly diversified portfolio



### 90% of portfolio offers >90% protection

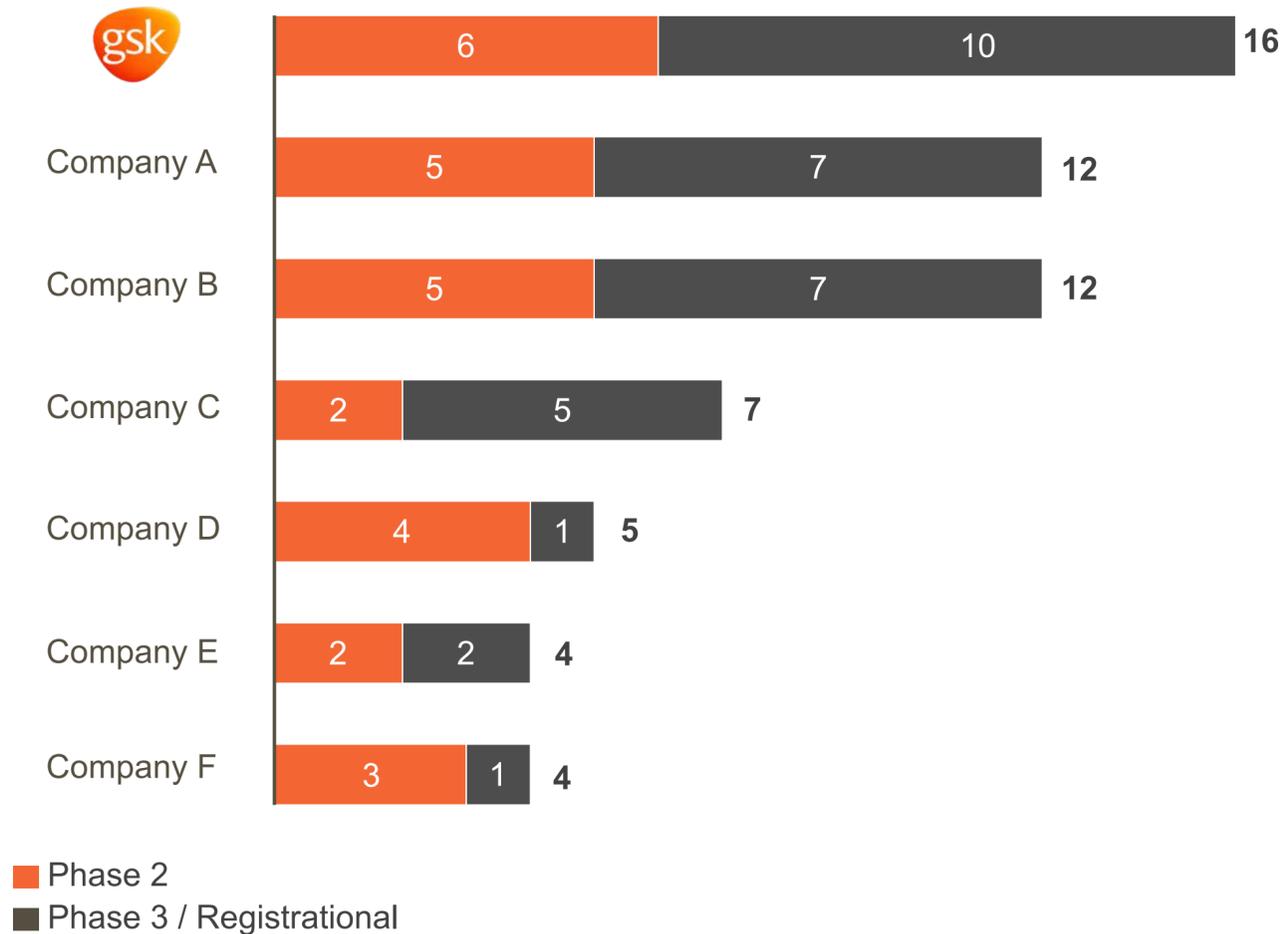


Vaccines revenues 2020

\*DTP family vaccines (Diphtheria, Tetanus, Pertussis, Hib, Polio and Hepatitis B)

# Industry leading pipeline

Largest number of mid/late-stage assets in areas of significant unmet medical need



## RSV

177k hospitalisations, 14k deaths per year in 65+ adults annually in the US<sup>1</sup>

## Meningitis

1.2m cases of IMD annually with ~10% mortality rate

## Antimicrobial Resistance

700k deaths annually & est. 8x increase within 30 years<sup>2</sup>

## COVID-19

~2bn cases and close to 3m deaths globally to date

Note: Includes Phase 2 and Phase 3 trials for non-cancer vaccines

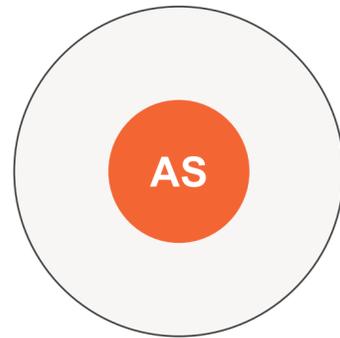
Sources: Company websites and Clinicaltrials.gov (March 2021); Registration as reported on company websites (March 2021)

1. Centers for Disease Control and Prevention (CDC), 2018. RSV in older adults and adults with chronic medical conditions. <https://www.cdc.gov/rsv/high-risk/older-adults.html> (accessed July 2019); 2. Interagency Coordination Group on Antimicrobial Resistance, 'No time to wait: securing the future from drug-resistant infections', April 2019. Available at <https://www.who.int/antimicrobial-resistance/interagency-coordination-group/final-report/en/>.

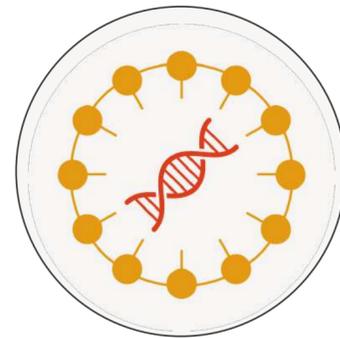
IMD Invasive Meningococcal Disease

# Extensive technology platform portfolio across R&D

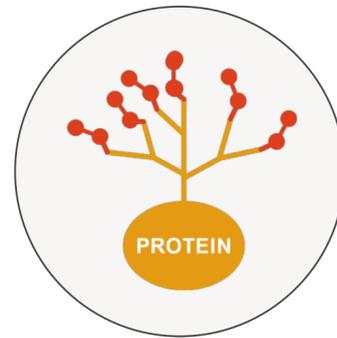
Unlocking the synergy between vaccines and specialty medicines



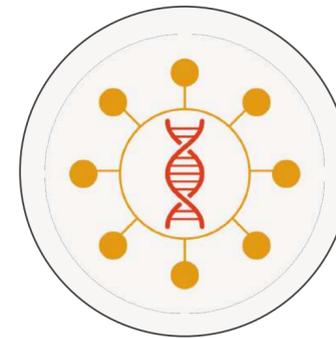
Protein +/-  
adjuvant



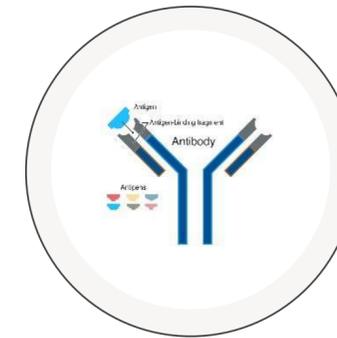
mRNA



Glycoconjugate



Viral  
vector



Monoclonal  
antibodies



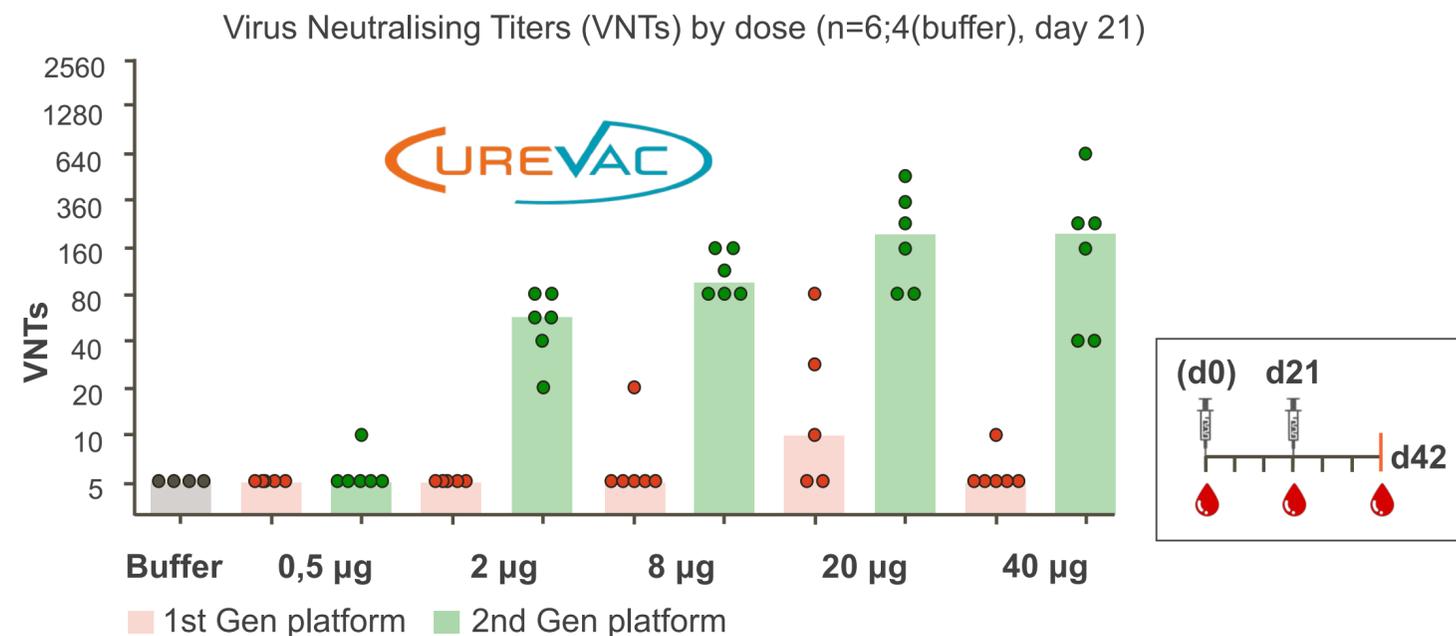
Human genetics  
& functional  
genomics

Underpinned by our focus on the science of the immune system

# mRNA: an important technology in our pipeline

## Our differentiated mRNA approach to enable multivalent and combination vaccines

### 5' and 3' optimisation (CureVac)



- 10x higher immune response allowing for lower doses\*
- Refrigerator-stable (2-8°C)

### Further optimisation using modified bases

## Investing at pace and building capabilities

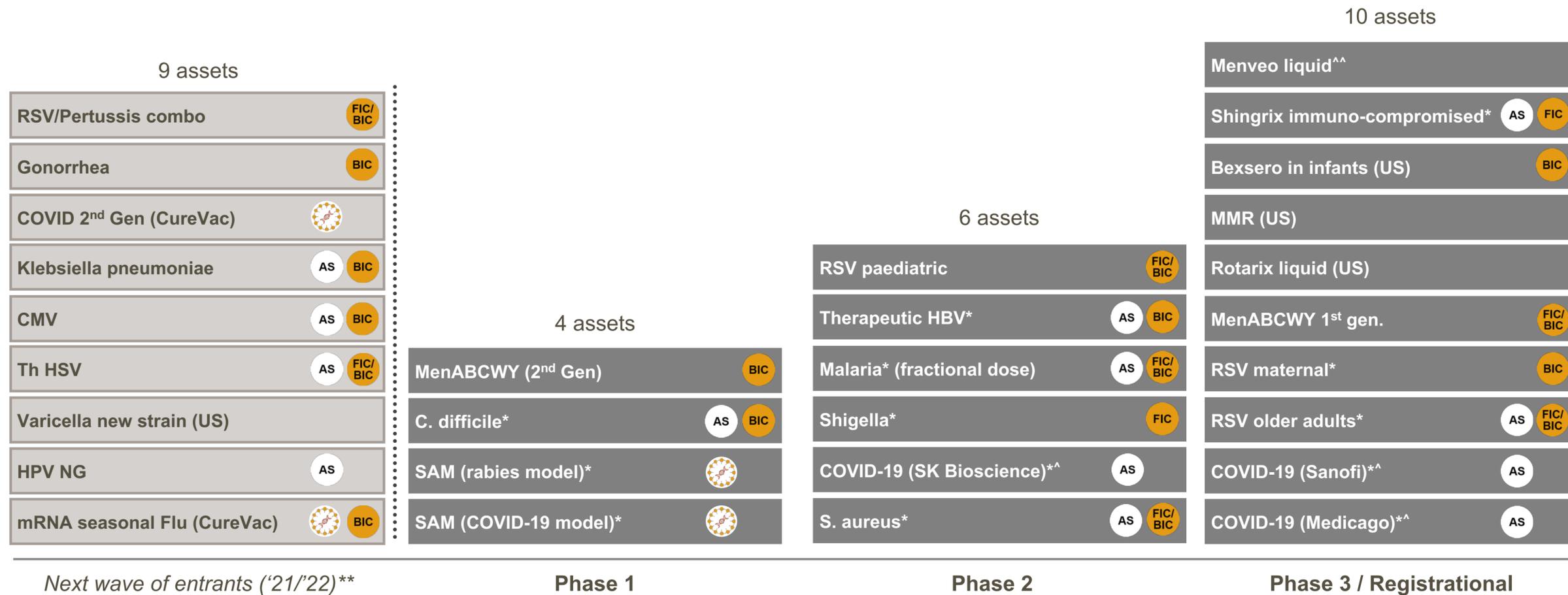
- mRNA research centre in Rockville (USA)
- >200 GSK mRNA scientists globally
- 6 clinical candidates in the next 4 years
- 2 assets in clinic within 12 months
  - COVID-19 booster; multi-valent, addressing emerging variants
  - Improved seasonal influenza with multi-antigen construct
  - Combination (COVID/Flu) under evaluation

\*preclinical data in animal models

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



## Total number of candidates



## Potential for:



● FIC First-in-class 
 ● BIC Best-in-class 
 AS Adjuvant system 
 ● mRNA

\*In-license or other alliance relationship with third party

\*\*New wave of entrants exclude Global Health targets;

^GSK is contributing pandemic adjuvant to COVID-19 vaccines collaborations; ^^Ph2 registrational trial  
 Pipeline information updated June 2021

5 new launches by 2026: RSV OA, RSV maternal, Men ABCWY 1st gen, COVID-19 NG, MMR US

5 PoC by 2023: Men ABCWY-7B 2nd gen, mRNA improved flu, RSV ped, Th HBV, Staph aureus

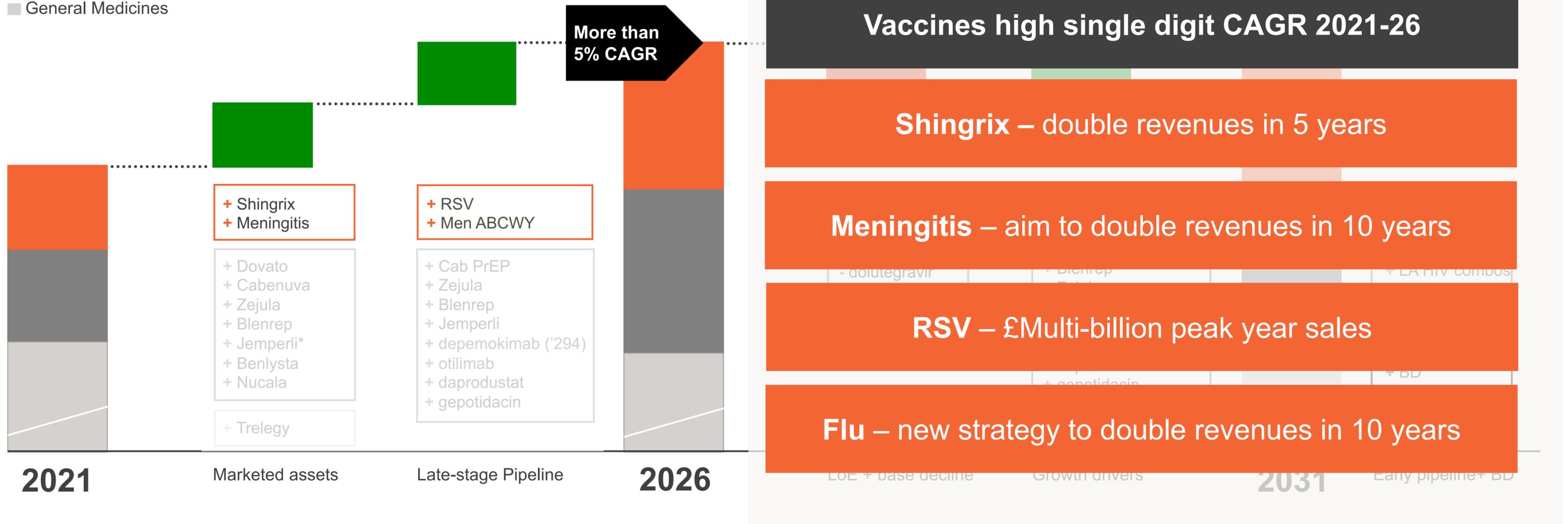
5 FTIH starts in 2021: COVID-19 NG, Men ABCWY-7B 2nd gen, Klebsiella pneumonia, CMV, Varicella NS

# Key growth drivers: opportunities and investment priorities



## Illustrative

- Vaccines
- Specialty Medicines
- General Medicines



Note: Bars are not at scale. All outlook and ambition statements are given on a constant currency basis and use 2021 forecast exchange rates as a base, assuming a continuation of Q1 2021 closing rates. See basis of preparation and assumptions in Appendix. CAGR is for the 5 years to 2026, using 2021 as the base year. Pipeline sales are risk-adjusted and include anticipated sales of new products and Life Cycle Innovation (LCI) launched from 2021 onwards. Note: COVID therapeutic and vaccine solutions are excluded from the above. Assets highlighted reflect major contributions to growth in period shown.

\*Tesaro asset

# Shingrix

Aim to double revenues in the next five years, protecting more than 100m adults



## Major opportunity in US, China and beyond

— **Expanding** target populations: 50+ & 18+ (immunocompromised)

~**1.9bn** 50+ people worldwide +

~ **90m** new people each year<sup>1</sup>



**US opportunity** ~100m 50+ people remain unvaccinated with Shingrix<sup>2</sup>



**Untapped China opportunity**

## Gold standard for shingles prevention

— **Unprecedented high efficacy** >90% with proven 4-year duration of protection<sup>3</sup>

— **Unconstrained supply** to support growth ambition

— **Geographic expansion:** 35 markets within next 3 years

— Active **life cycle management**

– Label expansion: e.g., auto-immune disease

– Fully liquid formulation



1. United Nations, Department of Economic and Social Affairs, Population Division (2019). World Population Prospects 2019, custom data acquired via website 2. 121m 50+ people in US in 2021 based on ACIP recos. 24m vaccinated with Shingrix between 2017 and 2020 which leaves 97m yet to get vaccinated. 3. >80%, proven 8-year duration of protection [https://academic.oup.com/ofid/article/7/Supplement\\_1/S4/6057510](https://academic.oup.com/ofid/article/7/Supplement_1/S4/6057510)

Shingrix, ambition uses 2020 base.

# Meningococcal franchise

Aim to double revenues in next decade, building on world-leading MenB vaccine



## High growth opportunity through market expansion

- **1.2m** cases of Invasive Meningococcal Disease (IMD) worldwide annually
  - Severe & devastating; ~10% mortality rate
  - Only ~**17-25%** receive MenB vaccine<sup>1</sup>

## Potential best-in-class portfolio & pipeline

- **Market leader** >50% share in a ~£2bn market with proven benefit backed by **real world evidence**<sup>2</sup>
- Sustaining leadership & expanding market with **Men ABCWY**. In Phase 3 - **2024\* launch**
- **World's broadest coverage** for all ages with improved convenience, **2nd Gen ABCWY** in Phase 1-2



1. Teens between 13-17y in US; source: National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years — United States, 2019 | MMWR (cdc.gov)

2. N Engl J Med 2020; 382:309-31; \* Subject to regulatory approval  
Meningitis ambition uses 2020 base.

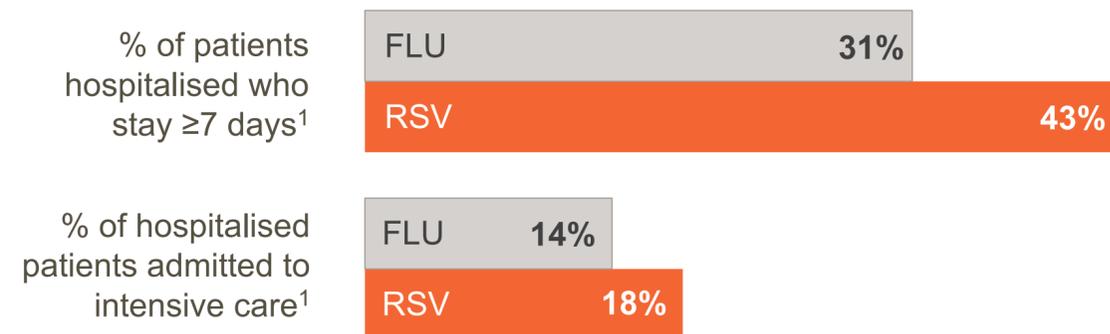
# RSV Older Adults: potential first- and best-in class £multi-billion opportunity

## Leveraging our proven adjuvant technology



### One of the highest value, unmet need remaining in infectious diseases

Higher risk of severe outcomes than Influenza<sup>1</sup>



RSV OA: **£5bn** market opportunity\*\*

**>1bn 60+ people** globally exposed to RSV annually

### Most advanced RSV OA vaccine candidate in Phase 3 with best-in class potential

- **Pre-fusion F antigen** combined with **proven AS01 adjuvant** in older adults
- **Positive Phase 2** data:
  - Adjuvanted approach boosts **neutralising antibodies ~10x** with **T-cell restoration** similar in range to young adults
- **FDA fast-track** designation; launch in 2024\*
- **Planning** for **expanded adult indications & combinations** with other adult vaccines

1. Higher risk of severe outcomes than influenza in hospitalised patients - Ackerson et al. Clin Infect Dis. 2019;69(2):197 2. United Nations, Department of Economic and Social Affairs, Population Division (2019). World Population Prospects 2019, custom data acquired via website.

\*subject to regulatory approval; \*\*GSK estimate for total RSV OA market

# RSV Maternal

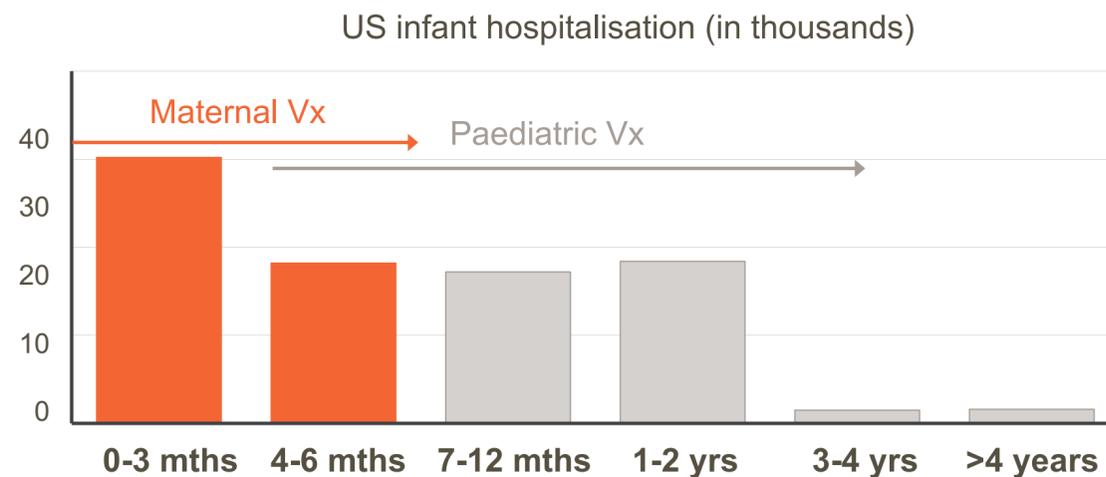
Potential to provide broad protection to infants from first breath of life



## One of the largest unmet need in pediatrics



## More hospitalisations in first 2 years of life



## Polyclonal protection with potential game-changing RSV pertussis combo to follow

- **Differentiated** approach with polyclonal passive immunity designed to offer **broad protection** across strains
- **Positive Phase 2** data through maternal antibody transfer to baby, launch **2024\***
- Potential protection of the mother & reduced transmission risk from mother to child
- Developing next generation **RSV and pertussis combination**; FTIH 2022

Source: Adapted from Paramore LC et al. Economic impact of respiratory syncytial virus-related illness in the US: an analysis of national databases. Pharmacoeconomics. 2004.

\*subject to regulatory approval

# Influenza

Innovating to deliver greater protection, new ambition to double revenues in next decade



## Significant burden of disease remains<sup>1</sup>

**~1bn**  
illnesses  
annually

**~3-5m**  
severe  
illnesses  
annually

UP TO  
**650,000**  
deaths

**£4.4bn<sup>2</sup>**  
market size in  
2020

UP TO  
**£6.1bn<sup>2</sup>**  
market size by 2026

## Sub-optimal existing solutions

## Innovative technologies for superior efficacy

1. Innovative plant-based protein adjuvanted vaccine for 65+ segment\*, **Phase 3 data 2H 2023**

2. Next generation mRNA vaccine\*\* ; **Phase 3 data 2H 2025**

— **Multi-antigen construct**

— Ambition of superiority vs standard of care

— Potential for combinations with COVID & other respiratory IDs

3. Transformational universal flu vaccine & add-on mAb<sup>^</sup> providing higher efficacy

1. 2018-2019 flu season data from the Centers for Disease Control and Prevention; Zhou et al. Clinical Infectious Diseases. 2012;54:1427–1436. 2. EvaluatePharma March'21.

\*GSK & Medicago collaboration agreement includes clinical supply of AS03 for development of an adjuvanted flu vaccine targeting the 65-plus age group; this vaccine is currently in phase I/II; phase III read out in 2H2023. The companies are in discussion regarding details of a commercialisation agreement; \*\*in collaboration with CureVac; ^in collaboration with Vir.

IDs infectious diseases

Flu ambition uses 2020 base.

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Shingrix, meningitis and flu revenues from 2020 base

FiC First-in-Class; BiC Best-in-Class



# Appendix

## Basis of preparation, assumptions and cautionary statement



### **Assumptions relating to the 2021-2026 sales and adjusted operating profit growth outlooks, 2026 cash generated from operations outlook, 2031 sales ambition and 2021-2023 dividend expectations**

In outlining the growth outlooks for the period 2021-2026, the 2026 cash generated from operations outlook, the 2031 sales ambition and the 2021-2023 dividend expectations (the “Relevant Statements”), GSK has made certain assumptions about the healthcare sector (including regarding possible governmental, legislative and regulatory reform), the different markets and competitive landscape in which it operates and the delivery of revenues and financial benefits from its current portfolio, its development pipeline of drugs and vaccines, its restructuring programmes and its plans for the separation of Consumer Healthcare, details of which are set out in this document.

GSK expects and assumes the next several years to be challenging for the healthcare industry with continued uncertainty related to the impact of the COVID-19 pandemic on adult vaccinations and continued pressure on pricing of pharmaceuticals. GSK assumes no premature loss of exclusivity for key products over the period. GSK also expects volume demand for its products to increase, particularly for Shingrix in the US, as healthcare systems are expected to return to normal following disruption from governments’ prioritisation of COVID-19 vaccination programmes and ongoing measures to contain the pandemic, and for Shingrix in China.

The assumptions underlying the Relevant Statements include: successful delivery of the ongoing and planned integration and restructuring plans and the planned demerger of Consumer Healthcare; the delivery of revenues and financial benefits from its current and development pipeline portfolio of drugs and vaccines (which have been assessed for this purpose on a risk-adjusted basis, as described further below); regulatory approvals of the pipeline portfolio of drugs and vaccines that underlie these expectations (which have also been assessed for this purpose on a risk-adjusted basis, as described further below); no material interruptions to supply of the Group’s products; no material mergers, acquisitions or disposals or other material business development transactions; no material litigation or investigation costs for the Company (save for those that are already recognised or for which provisions have been made); no share repurchases by the Company; and no change in the shareholdings in ViiV Healthcare.

The Relevant Statements also factor in all divestments and product exits announced to date as well as material costs for investment in new product launches and R&D. Pipeline risk-adjusted sales are based on the latest internal estimate of the probability of technical and regulatory success for each asset in development.

Notwithstanding the Relevant Statements, there is still uncertainty as to whether our assumptions, targets, outlooks expectations and ambitions will be achieved, including based on the other assumptions outlined above.

The statement that GSK estimates that certain assets in late-stage development have the potential to deliver peak year sales of more than £20 billion on a non-risk adjusted basis is an aggregation, across the relevant portfolio of assets, of the maximum sales that GSK considers might be achieved from each such asset (including from lifecycle innovation) in the year that that asset attains its highest sales level, in all cases before taking into account any risks that could impair GSK’s ability to reach that level of sales for that asset, including risks relating to technical and regulatory success, trial outcomes, launch dates and execution, exclusivity periods and the impact of changes in the market and healthcare landscape for that asset. The aggregation is of the peak year sales of each individual asset within the portfolio and not for one particular year. Accordingly, the statement of estimated non-risk adjusted potential peak year sales of the relevant assets in late-stage development does not comprise, is wholly different in nature to, and is subject to very significantly higher levels of uncertainty than the Relevant Statements. As such, while GSK does not expect to achieve the aggregate amount of those estimated non-risk adjusted peak year sales, a risk-adjusted assessment of sales of relevant assets during the relevant periods is (as stated above) taken into account, where relevant, within the Relevant Statements.

All outlook and ambition statements are given on a constant currency basis and use 2021 forecast exchange rates as a base, assuming a continuation of Q1 2021 closing rates (£1/\$1.38, £1/€1.17, £1/Yen 152). 2021-2026 outlook refers to the 5 years to 2026 with 2021 as the base year.

# Basis of preparation, assumptions and cautionary statement



## Assumptions and cautionary statement regarding forward looking statements

The Group's management believes that the assumptions outlined above are reasonable, and that the targets, outlooks, ambitions and expectations described in this document are achievable based on those assumptions. However, given the forward-looking nature of these assumptions, targets and expectations, they are subject to greater uncertainty, including potential material impacts if the above assumptions are not realised, and other material impacts related to foreign exchange fluctuations, macro-economic activity, the impact of outbreaks, epidemics or pandemics, such as the continued COVID-19 pandemic and ongoing challenges and uncertainties posed by the COVID-19 pandemic for businesses and governments around the world, changes in legislation, regulation, government actions or intellectual property protection, product development and approvals, actions by our competitors, and other risks inherent to the industries in which we operate.

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## Reporting definitions

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GSK provides earnings guidance to the investor community on the basis of Adjusted results. This is in line with peer companies and expectations of the investor community, supporting easier comparison of the Group's performance with its peers. GSK is not able to give guidance and outlooks for Total results, including Total Operating Profit and Total Operating Margin as it cannot reliably forecast certain material elements of the Total results, particularly the future fair value movements on contingent consideration and put options that can and have given rise to significant adjustments driven by external factors such as currency and other movements in capital markets. Therefore a reconciliation of the guidance for Adjusted results to equivalent guidance for Total results is not available without unreasonable effort.

Compound Annual Growth Rate (CAGR) is defined as the compound annual growth rate and shows the annualised average rate of revenue or profit growth between two given years, at constant currency, assuming growth takes place at an exponentially compounded rate.

Adjusted EBITDA is defined as Adjusted Earnings before interest and tax, depreciation and amortisation.

# New GSK financial reporting considerations



## IFRS income statement

### Operating segments

**Commercial**  
*Revenue and Adjusted OP*

**R&D**  
*Adjusted OP*

**Corporate / other /  
adjusting items**  
*OP*

### Product Area Revenues

**Vaccines**

**Specialty Medicines**

**General Medicines**

*Revenue and Revenue by key product*



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## Contact

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