SPECIALTY: RESHAPING HIV TREATMENT AND PREVENTION

Deborah Waterhouse and Dr. Kimberly Smith
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.

Forward-looking statements are subject to assumptions, inherent risks and uncertainties, many of which relate to factors that are beyond the Group’s control or precise estimate. The Group cautions investors that a number of important factors, including those in this document, could cause actual results to differ materially from those expressed or implied in any forward-looking statement. Such factors include, but are not limited to, those discussed under Item 3.D ‘Risk Factors’ in the Group’s Annual Report on Form 20-F for 2020 and any impacts of the COVID-19 pandemic.

Any forward-looking statements made by or on behalf of the Group speak only as of the date they are made and are based upon the knowledge and information available to the Directors on the date of this presentation.

A number of Adjusted measures are used to report the performance of our business, which are non-IFRS measures. Adjusted results, CER and other non-IFRS measures may be considered in addition to, but not as a substitute for or superior to, information presented in accordance with IFRS. These measures are defined and reconciliations to the nearest IFRS measure are available in our first quarter 2021 earnings release and Annual Report on Form 20-F for FY 2020 and in the “Reporting definition” slide at the end of this presentation. GSK provides guidance and outlooks on an Adjusted results basis only, for the reasons set out in the “Reporting definition” slide at the end of this presentation.
Reshaping the HIV treatment and prevention landscape

Mid single digit % sales CAGR 2021-26

Pioneering innovation for treatment and prevention

Dovato and cabotegravir drive growth

Cabotegravir LA portfolio replaces dolutegravir as foundational medicine

Innovative LA pipeline powers revenue renewal beyond dolutegravir

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.

LA long acting
Delivering on significant unmet needs in HIV
Key challenges remain in £23bn treatment and prevention market

38m people living with HIV (PLHIV) worldwide
1.7m infections per annum, mostly in Africa
6,000 young women infected every week
38,000 new infections per annum in US
Only 50% of PLHIV in USA virally suppressed
22,000 new infections per annum across EU

Source: Epidemiology data from WHO and UNAIDS statistics
HIV delivering mid-single digit % sales CAGR 2021-26 with pipeline optionality beyond

Illustrative

- Mature products
- Growth drivers

Post 2026 LA pipeline potential for revenue renewal

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.
Dovato: Best-in-class two-drug regimen

Switch share growing strongly in US and EU

>£1bn by 2022 and further potential beyond

- Integrase inhibitors gold standard with proven high bar to resistance and tolerability
- Only 2DR to deliver durable efficacy and high barrier to resistance in naïve and switch
- One in two people on treatment globally on DTG regimens with 8 superiority studies
- Patent protection to April 2028 US/July 2029 EU*

*Dovato is protected by composition of matter patent protections until 2028 in US / 2029 in EU, and assuming paediatric exclusivity granted.

DTG dolutegravir.

Source: IQVIA (R4W) and ActOne (R3M)
LA pipeline with opportunity for revenue renewal post DTG LoE
Portfolio transition through decade with LA regimens ~ £2bn by 2026

2021-26 growth drivers
- Dovato
- Cabenuva
- Cab PrEP

2026 Portfolio Mix
- Oral portfolio
- LA portfolio launching by 2022

Post 2026 LA pipeline growth drivers
- Self Admin for Treatment
- Ultra LA for Treatment
- Ultra LA for PrEP

DTG dolutegravir; LoE loss of exclusivity
Shifting the paradigm towards long-acting treatment
Cabenuva: world’s 1st and only long-acting regimen for HIV treatment

LA preferred by 9/10 patients vs orals\(^1\)

**Fear of disclosure**
- Reported taking pills everyday means a greater chance of revealing their HIV status to others\(^2\)

**Anxiety with staying adherent**
- Said that needing to take treatment every day causes stress or anxiety\(^2\)

**Daily reminder of HIV**
- Reported that taking pills for HIV every day is a daily reminder of HIV in their life\(^2\)

LA injectable treatment market £4-5bn by 2030

- Integrase inhibitor at core provides unique resistance and tolerability profile versus competition
- Treatment dosing days reduced from 365 to 6
- Five-year head start over competition
- Patent protection extends through 2031* 

\(^1\) In ATLAS and FLAIR studies
\(^2\) ViiV Healthcare. 2020. Positive Perspectives Wave 2 Study
* Cabotegravir is protected by composition of matter patent protections through 2031 in US and EU and assuming patent term extensions granted
Major opportunities in pre-exposure prophylaxis (PrEP)
Cabotegravir for PrEP: offers potential to transform the shape of the epidemic

**LA injectable PrEP market**
£4-5bn by 2030

- US political will to end epidemic by 2030
- First LA injectable PrEP administered every two months
- Cabotegravir superior in men and women vs. daily oral Truvada
- Cab for PrEP filed with US FDA in H1 with expected launch in early 2022

**Cabotegravir LA superior to daily oral standard of care**

![Graph showing cumulative incidence over weeks since enrollment, with Cabotegravir having a lower incidence rate compared to Truvada.](image)
Integrase inhibitor-based LA pipeline drives future growth
Potential options for self administration and ultra long acting

**Cabotegravir**

**Capsid Inhibitor**
- Inhibits formation of HIV capsid which is critical for viral replication

**Maturation Inhibitor**
- Blocks protein processing late in the viral replication cycle

**Broadly Neutralising Antibodies (N6LS)**
- Blocks HIV replication by attaching to CD4 binding site

**Nucleoside Reverse Transcriptase Translocation Inhibitor (NRTTI)**
- Blocks key enzyme HIV needs to make copies of itself

Delivering continued innovation leaving no person living with HIV behind
Strategic collaboration with Halozyme
Expands portfolio of long-acting agents

Unique partnership aimed at significantly improving patient experience in HIV treatment and PrEP

Focused on developing ultra long-acting regimens (3 months plus)

Exclusive license in HIV treatment for integrase inhibitors, capsid inhibitors, NRTTI and bNAb

Potential in PrEP to increase Cabotegravir dosing interval from every two months to up to six months
Maintaining HIV leadership beyond Dolutegravir
Integrase inhibitor-based LA regimens deliver new levels of convenience

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<thead>
<tr>
<th>2021-2024</th>
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<th>2028+</th>
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<tr>
<td><strong>Cabenuva (CAB + RPV) for treatment</strong>&lt;br&gt;— 1st LA regimen launched in US and EU with more planned</td>
<td><strong>1st self-administered LA regimen for treatment</strong>&lt;br&gt;— CAB + MI-937&lt;br&gt;— CAB + N6LS</td>
<td><strong>Ultra long-acting ≥Q3M for treatment</strong>&lt;br&gt;— CAB + Capsid&lt;br&gt;— CAB + N6LS&lt;br&gt;— CAB + NRTTI</td>
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<td><strong>Cabotegravir for prevention (PrEP)</strong>&lt;br&gt;— US approval expected Q1 2022</td>
<td><strong>Cabotegravir for prevention (PrEP)</strong>&lt;br&gt;— Ultra long-acting CAB for PrEP</td>
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Reshaping the HIV treatment and prevention landscape

- Mid single digit % sales CAGR 2021-26
- Pioneering innovation for treatment and prevention
- Dovato and cabotegravir drive growth
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LA long-acting
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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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
Contact

GSK Investor Relations Team
+44 (0)20 8047 5000 or at
GSK.Investor-Relations@gsk.com