ViiV Healthcare Meet the Management
Getting Ahead of HIV Together
28 September 2023
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All forward-looking CAGR and sales guidance, outlooks, ambitions and expectations should be read together with the guidance, assumptions and cautionary statements in GSK’s Q2 2023 earnings release and GSK’s 2022 Annual Report.
100% focused on HIV – innovation leaders for 35 years

Reshaping the HIV treatment and prevention market

Leaders and disruptors in innovation – the future is long-acting

Q&A

David Redfern
President, Corporate Development, GSK
Chairman, ViiV Healthcare

Deborah Waterhouse
CEO, ViiV Healthcare
President, Global Health GSK

Kimberly Smith, MD, MPH
Head of R&D, ViiV Healthcare
Leaders in HIV focused on ending the global epidemic

Our mission is to leave no person living with HIV behind.

- **2009**: GSK and Pfizer<sup>1</sup> created a joint venture dedicated to HIV
- **2012**: Shionogi<sup>2</sup> became partner and shareholder
- **2013**: First dolutegravir launch
- **2016**: Acquired BMS<sup>3</sup> HIV pipeline and discovery assets
- **2019**: Launched Dovato
- **2020**: Launched Rukobia, first attachment inhibitor
- **2021**: Launched Cabenuva, first long-acting injectable. Strengthened pipeline with Halozyme and Shionogi collaborations
- **2022**: Launched Apretude, first long-acting injectable for PrEP

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Reshaping the HIV treatment and prevention market

Deborah Waterhouse
CEO, ViiV Healthcare and President Global Health, GSK
Recap of our 2021 commitments

- Pioneering innovation for treatment and prevention
- Mid-single digit sales CAGR 2021-26
- Dovato and cabotegravir drive growth via competitive execution
- Cabotegravir long-acting (LA) portfolio replaces dolutegravir (DTG) as foundational medicine
- Innovative LA pipeline 2026-31 powers potential revenue renewal beyond dolutegravir
What’s new today

1. 2021-2026 sales CAGR upgraded to 6% - 8%*

2. Dosing intervals for long-acting regimens increased to every-four-months in prevention and treatment

3. Roadmap to extend dosing interval to every-six-months by end of decade

4. IP for Dovato and Juluca is anticipated to extend through the end of the decade

*Forecasted CAGR is based on a constant exchange rate and includes an estimated ~£200m annual impact from 2025 of the US Inflation Reduction Act which has up to a one percentage point impact on the CAGR
Strong commercial execution driving growth
Strong execution drives 2021-2026 CAGR upgrade from mid-single digits to 6% - 8%*

$\text{2021-26 growth drivers}$

$\text{Dovato}$

$\text{Cabenuva}$

$\text{Apretude}$

$\approx \text{£7bn sales in 2026}$

$\text{2026-31 LA pipeline growth drivers}$

Ultra-long-acting (ULA) for PrEP

ULA for treatment

Self-administered LA for treatment

LA portfolio on track to deliver $\approx \text{£2bn in sales in 2026, representing one-third of overall HIV sales}$. 

*Forecasted CAGR is based on a constant exchange rate and includes an estimated ~£200m annual impact from 2025 of the US Inflation Reduction Act which has up to a one percentage point impact on the CAGR. Anticipated 2026 sales are based on 2023 exchange rates.
Fastest growing company in HIV in both sales and market share

**Dovato**

Leading oral 2-drug regimen

“I want a treatment that will keep me undetectable with fewer medicines”

**CABENUVA**

First and only long-acting complete regimen for treatment

“I worry that someone will see my meds and realise that I have HIV”

“Every time I take my meds it’s a reminder that I have HIV”

**Apretude**

First and only long-acting prevention medicine

“Taking PrEP makes me feel more relaxed in the moment and gives me control so I don’t have to worry”

- Fastest growing company in HIV driven by strong innovation and execution
  - *Dovato* sales on track to deliver £2bn in 2024
  - LA portfolio sales on track to more than double in 2023 and exceed £2bn in 2026
- Included in guidelines worldwide for treatment and prevention
- >90% patients in treatment and prevention prefer LA medicines versus oral therapy¹
- 84% US healthcare professionals believe LA will be a key part of HIV care²

¹Forecasts include estimated impact of the US Inflation Reduction Act from 2025
²Source: SOLAR study (treatment), HPTN 083 study (US – PrEP)
³Source: Demand study, March 2023, n=98 HCPs
Growth of long-acting portfolio and extended period of exclusivity reduces impact of DTG LOE

- ~40% of ViiV revenue estimated to be in long-acting by 2027
- DTG composition of matter protection until April 2028 in US and July 2029 in EU
- Dovato and Juluca protected by additional formulation and other patents until ~2030 in the US
- LA portfolio protected by patents until 2031, with potential for future protection significantly beyond 2031 for new LA medicines, formulations and regimens

2027 sales breakdown

2027 DBR* breakdown

Loss of exclusivity timing

<table>
<thead>
<tr>
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Anticipated US Dovato
Anticipated US Juluca

Financial outlook includes estimated impact of the US Inflation Reduction Act
*DBR – Dolutegravir-based regimens
1Includes Rukobia
Reshaping the HIV market to long-acting
Key trends shaping HIV treatment and prevention

Continued HIV transmission
1.5m new cases of HIV per year

LA, oral and injectable, dominate pipelines based on strong patient demand
ViiV Healthcare, Gilead and Merck

Low PrEP utilisation
Only 25% of eligible US patients currently taking PrEP

Stigma and inequity persist
With key populations and marginalised groups disproportionately affected

Community engagement high
Strong focus on access and equity

Payer pressure increases through LOE
Patient preference for LA vs reimbursement pressures

1. UNAIDS Global HIV Statistics factsheet for 2021; 2. JP Morgan conference Jan 2023; 3. CDC surveillance Data
ViiV Healthcare’s leadership in LA drives market dynamism in treatment and prevention

- LA injectables expected to represent ~30% of the treatment value by 2031, ~80% of PrEP value by 2031
- HIV treatment market stable at ~£20bn, PrEP market is expected to more than double in size to £4-5bn
- ViiV Healthcare leadership in LA injectables

Sources: CDC population estimates (treatment/PrEP), internal share and pricing estimates, informed by external market insights
An industry-leading pipeline driven by patient insights

Kimberly Smith, MD, MPH
Head of R&D, ViiV Healthcare
Industry-leading pipeline delivering the next wave of innovation

Search for remission and cure

Long-acting prevention
Apretude (cabotegravir)

Attachment inhibitor for multi-drug resistant patients
Rukobia (fostemsavir)

Oral two-drug regimens
Juluca (dolutegravir/rilpivirine)
Dovato (dolutegravir/lamivudine)

Long-acting two-drug regimens
Cabenuva / Vocabria + Rekambys² (cabotegravir + rilpivirine)

Dolutegravir-based regimens
Tivicay (dolutegravir)
Triumeq (dolutegravir/abacavir/lamivudine)

Paediatrics
Tivicay PD, Triumeq PD, cabotegravir¹

Target product profiles
1. Ultra-long-acting (ULA) PrEP
2. ULA treatment
3. Self-administered treatment

Pipeline assets¹,³
• Reformulated cabotegravir
• ULA integrase inhibitor VH310A
• Third generation ULA integrase inhibitor VH184
• CD4 binding site broadly neutralising antibody (bNAb) VH109
• Bi-specific bNAb VH079
• Capsid inhibitors VH280, VH499
• Maturation inhibitor VH937

¹ Potential new medicines not currently approved for prescription
² The marketing authorisation holder for Rekambys (rilpivirine) is Janssen Pharmaceutical Companies of Johnson & Johnson.
³ Clinical discovery programme
Insight driven, long-acting patient profiles across treatment and prevention

**ULA prevention**

- Is aware of own risk for HIV and wants to protect himself
- Struggled with daily PrEP and experienced gastro-intestinal side-effects
- Wants PrEP that integrates seamlessly into his life

- “It’s definitely going to save me time. I won’t need to pick up prescriptions or remember to take it every day”
  
  Harvey 33, Florida

**ULA treatment**

- Drained from taking daily meds
- Nervous about others discovering her HIV status
- Trusting relationship with HCP
- Wants to take meds as infrequently as possible

- “If I can go for several months without burden, without thinking about it, I’d take it”
  
  Patricia 55, Germany

**Self-administered LA treatment**

- Open about HIV status
- Good relationship with HCP and adherent to daily anti-retroviral treatment (ART)
- Wants control over where and when to take his meds
- Prefers fewer clinic appointments

- “I like the convenience. You’re not tied down, can inject once and forget about it”
  
  Eric 41, New York
INSTIs are the foundation of ART regimens in HIV treatment guidelines around the world\(^1\)\(^2\)

Gold standard status because of potency, long-term tolerability and high barrier to resistance

~23 out of 28 million people on HIV treatment are on a DTG-based regimen\(^*\)

Cabotegravir is the first and only approved long-acting INSTI

Our past, present and future portfolios are built on integrase inhibitors

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\(^*\)Source: IQVIA MIDAS in top 9 markets, share of Core Agent + Complete Regimen Days of Therapy (DoT) market

Integrase Inhibitors includes any individual/combination therapy of Dolutegravir, Raltegravir, Cabotegravir, Elvitegravir, Bictegravir

\(^\text{**}\) Source: GSK ESG performance Report, US IQVIA, EU IQVIA and internal tracking
“I think what people are saying is, when is it going to be every three months...when is it going to be every six months? And that’s pretty exciting because they’re really enjoying the long-acting therapy.”

Dr. Gary Blick, Co-founder HIV Advocates
Switching to cabotegravir and rilpivirine LA every-two-months was associated with improved treatment satisfaction, preferred by 90% of participants, while also providing emotional well-being benefits including relief from the fear of disclosure and anxiety surrounding adherence.

SOLAR study
International AIDS Society 2023

Long-acting was preferred by 99% vs prior daily oral therapy at month 6, mainly for "convenience, adherence concerns and pill fatigue." Most participants found every two months dosing and injection visit duration very (86%) or extremely (92%) acceptable.

CARLOS study
International AIDS Society 2023

Cabotegravir and rilpivirine LA injections may be a feasible option for people who struggle to stay engaged with traditional HIV care and have been unable to maintain viral suppression on oral antiretroviral therapy.

Ward 86 clinic study
CROI 2023

Study revealed that among participants who chose cabotegravir, 77% cited preferring injections as the reason, whereas 11% desired a convenient or discrete PrEP method, and 8% valued cabotegravir effectiveness.

Mina Hosseinipour, University of North Carolina Chapel Hill
International AIDS Society 2023

Study conclusion: A total of 314 initiation and maintenance LA injectable cabotegravir PrEP injections and care were successfully delivered by non-medically licensed, trained health workers to 139 PrEP users with high client satisfaction, greater reach of at-risk populations than oral PrEP services.

Dr. Rupa Patel, Washington University St. Louis
International AIDS Society 2023

Nearly all HPTN 083 participants (95.9%) from the US chose cabotegravir LA over oral emtricitabine/tenofovir/disoproxil fumarate (FTC/TDF) upon transition to the open-label extension phase of the study.

Pre-Exposure Prophylaxis Product Choice in United States participants in HPTN 083
CROI 2023
Doubling the dosing interval of cabotegravir to every-four-months in treatment and PrEP

**New formulation of cabotegravir**

- Double the concentration of the current cabotegravir (CAB) formulation
- >2x half-life when dosed intramuscularly or subcutaneously, enabling every-four-month (Q4M) dosing with the potential for up to every-six-months (Q6M)
- CAB 400 data to be presented at CROI 2024

**In PrEP, for launch in 2026:**
- CAB 400

**In treatment, two potential partners for launch in 2027:**
- Option one: CAB 400 + rilpivirine (RPV)
- Option two: CAB 400 + VH109 (bNAb N6LS)
Option one: evolving Cabenuva with CAB 400 + RPV

- Improved patient experience with fewer clinic visits
- RPV half-life of ~200 days\(^1\)
- Builds on HCP and patient confidence and familiarity
- Potential to improve the patient and clinic experience
- Working with Janssen to evaluate alternative doses and formulations

Option two: CAB 400 + VH109 (N6LS) advances to phase IIb clinical trial

VH109 is a novel bNAb with broad and potent neutralisation activity *in vitro*\(^1\)

- Neutralises up to 98% of viral strains\(^1\)

VH109 + rHuPH20 delivers therapeutic exposures with subcutaneous dosing every four months and high tolerability

Single dose in humans demonstrated viral load reductions up to -2.8 log/ml\(^{1-3}\)

Phase IIb EMBRACE study* is open to enrolment

- VH109 +/- rHuPH20 + cabotegravir
- Subcutaneous dosing enabled by Halozyme partnership

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\(^{1}\) Leone et al. HIV Drug Therapy Glasgow 2022; Virtual and Glasgow, Scotland. Slides O34; 2. Wu et al. CROI 2023; Virtual and Seattle, WA. Poster 499; 3. Leone et al. CROI 2023; Virtual and Seattle, WA. Poster 520

4. Wu et al. Abstract 499 Conference on Retroviruses and Opportunistic Infections Feb 2023

*GSK*
Novel methods of action offer multiple options for development of new LA regimens

1. **Binding and fusion**
   - **Class:** bnAb
   - **VH109** (N6LS)
   - **Phase:** IIb
   - **VH079** (Bi-specific)
   - **Phase:** Pre-clinical

2. **Nuclear entry and uncoating**
   - **Class:** Capsid Inhibitor
   - **VH280/VH499**
   - **Phase:** II

3. **Integration**
   - **Class:** INSTI
   - **VH184**
   - **Phase:** I

4. **Assembly and budding**
   - **Class:** Capsid Inhibitor
   - **VH280/VH499**
   - **Phase:** II

5. **Maturation**
   - **Class:** Maturation Inhibitor
   - **VH937**
   - **Phase:** I
Multiple pathways to deliver long-acting treatment and prevention

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<td>NRTTI (rilpivirine)</td>
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# Clear roadmap of innovation delivery

**INSTI-based LA regimens anchor pipeline**

## TPPs

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<td>File and launch</td>
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*All time estimates between file and launch are subject to Regulatory Agency timelines.*
LA is the key to ending the HIV epidemic

ViiV Healthcare continues to lead the way
Reshaping the HIV treatment and prevention market

Deborah Waterhouse
CEO, ViiV Healthcare and President Global Health, GSK
Our updated commitments

• Pioneering innovation for treatment and prevention
• 6% to 8% sales CAGR 2021-26
• Dovato and cabotegravir drive growth via competitive execution
• Cabotegravir LA portfolio replaces dolutegravir as foundational medicine
• LA performance and pipeline offers the potential to significantly replace revenue from dolutegravir LOE

*Forecasted CAGR is based on a constant exchange rate and includes an estimated ~£200m annual impact from 2025 of the US Inflation Reduction Act which has up to a one percentage point impact on the CAGR