

# 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.

# Agenda

100% focused  
on HIV – innovation  
leaders for 35 years



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

Reshaping the HIV  
treatment  
and prevention  
market



Deborah Waterhouse  
CEO, ViiV Healthcare  
President, Global Health GSK

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



Kimberly Smith, MD, MPH  
Head of R&D, ViiV Healthcare

Q&A

# Leaders in HIV focused on ending the global epidemic



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



Leaders and disruptors in innovation



Focused and agile, backed by scale of GSK



Built on novel collaborations and powerful partnerships



Strong commitment to communities

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<sup>4</sup> and Shionogi collaborations

2022

Launched *Apretude*, first long-acting injectable for PrEP

# Reshaping the HIV treatment and prevention market

**Deborah Waterhouse**

CEO, ViiV Healthcare and President Global Health, GSK



**Jayson**



## 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

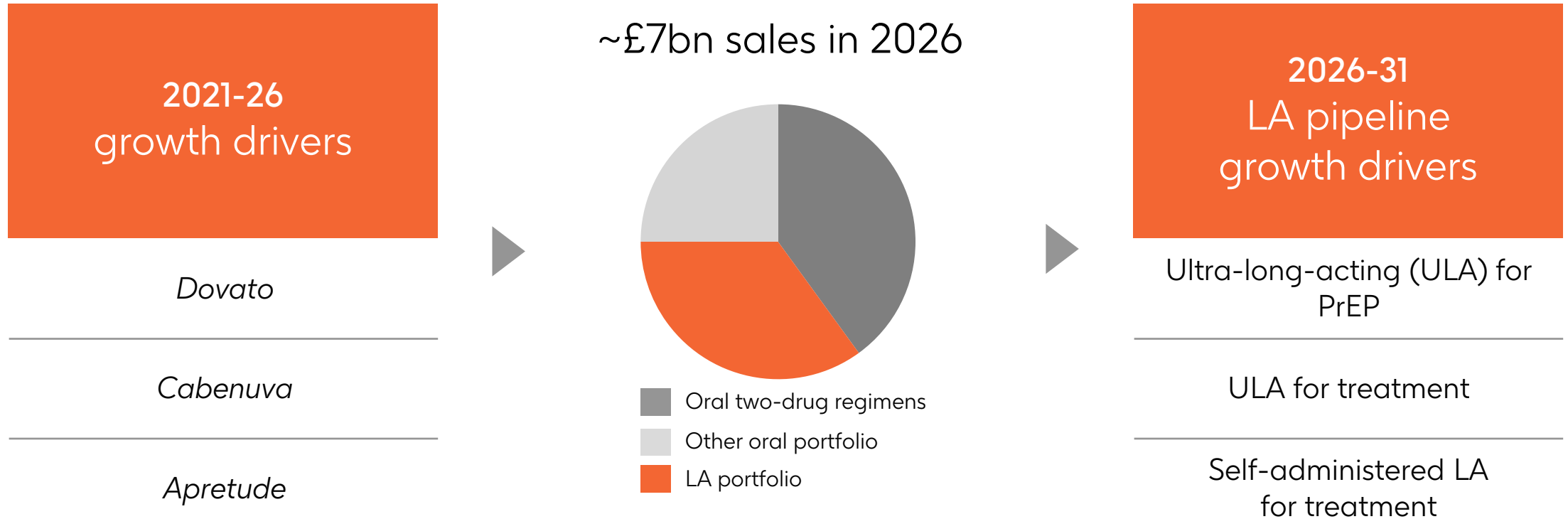
\*Forecasted CAGR is based on a constant exchange rate and includes an estimated ~£200m annual impact from 2025 of the US Inflation Reduction Act which has up to a one percentage point impact on the CAGR





Strong commercial execution driving growth

# Strong execution drives 2021-2026 CAGR upgrade from mid-single digits to 6% - 8%\*



LA portfolio on track to deliver >£2bn in sales in 2026, representing one-third of overall HIV sales

# Fastest growing company in HIV in both sales and market share



Leading oral 2-drug regimen

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



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”



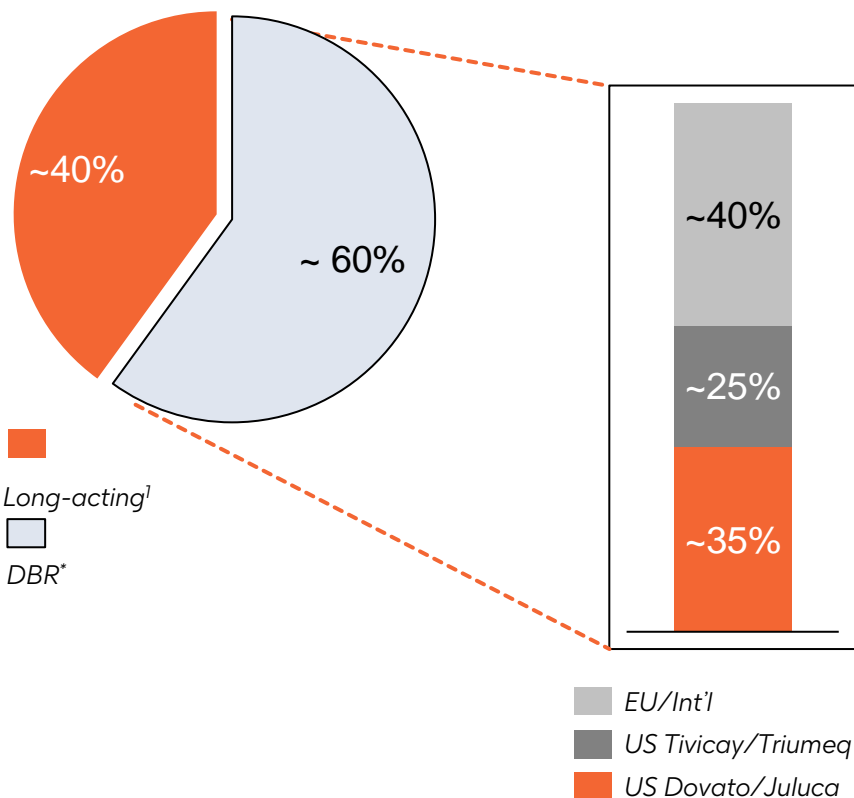
First and only long-acting prevention medicine

“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 therapy<sup>1</sup>
- 84% US healthcare professionals believe LA will be a key part of HIV care<sup>2</sup>

# Growth of long-acting portfolio and extended period of exclusivity reduces impact of DTG LOE

2027 sales breakdown      2027 DBR\* breakdown



Loss of exclusivity timing



- ~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

Reshaping the HIV market to long-acting

# Key trends shaping HIV treatment and prevention

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## Continued HIV transmission

1.5m new cases of HIV per year<sup>1</sup>

LA, oral and injectable, dominate pipelines based on strong patient demand

ViiV Healthcare, Gilead and Merck<sup>2</sup>

## Low PrEP utilisation

Only 25% of eligible US patients currently taking PrEP<sup>3</sup>

## 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

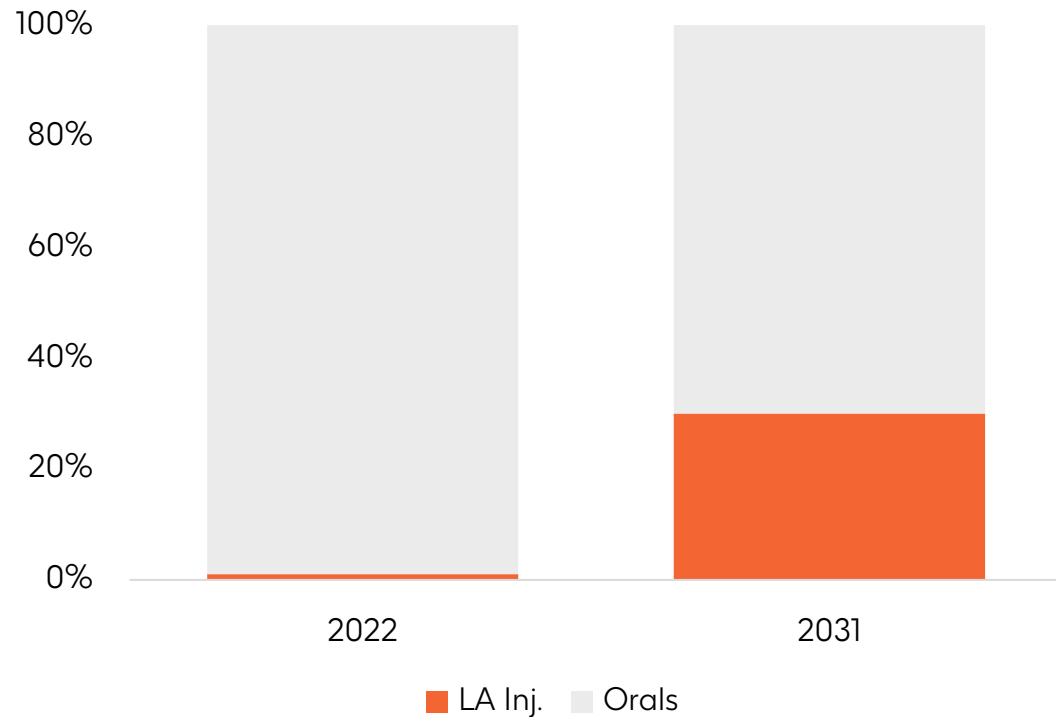
Patient preference for LA vs reimbursement pressures

1. UNAIDS Global HIV Statistics factsheet for 2021; 2. JP Morgan conference Jan 2023; 3. CDC surveillance Data

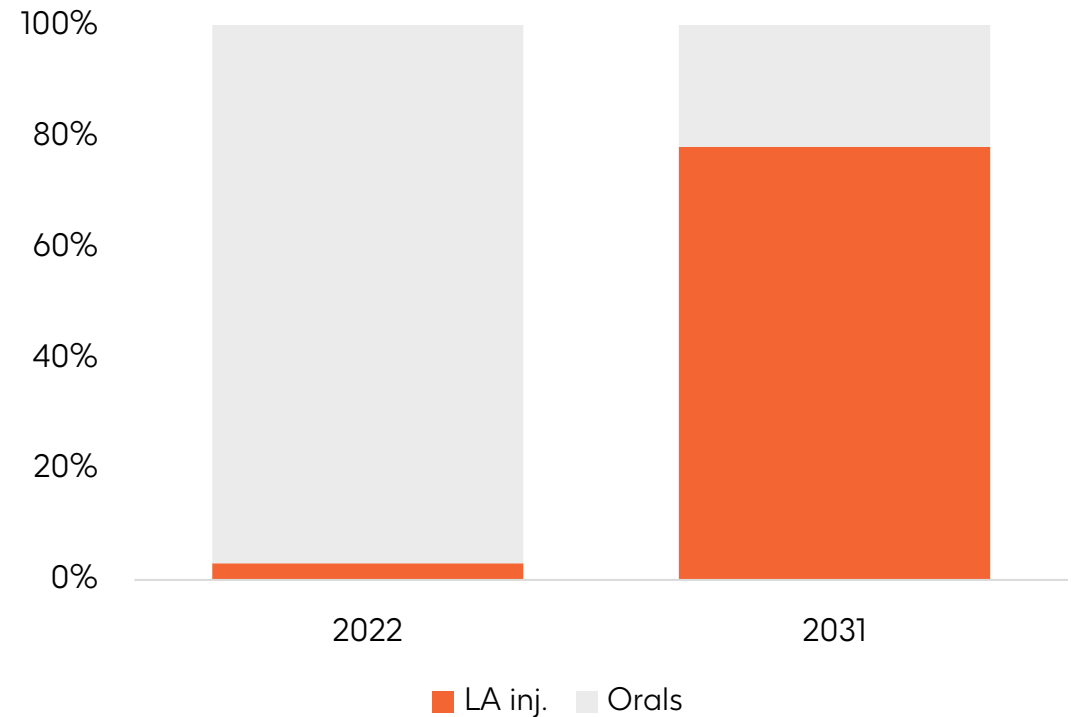


# ViiV Healthcare's leadership in LA drives market dynamism in treatment and prevention

## Global HIV treatment market value



## Global PrEP market value



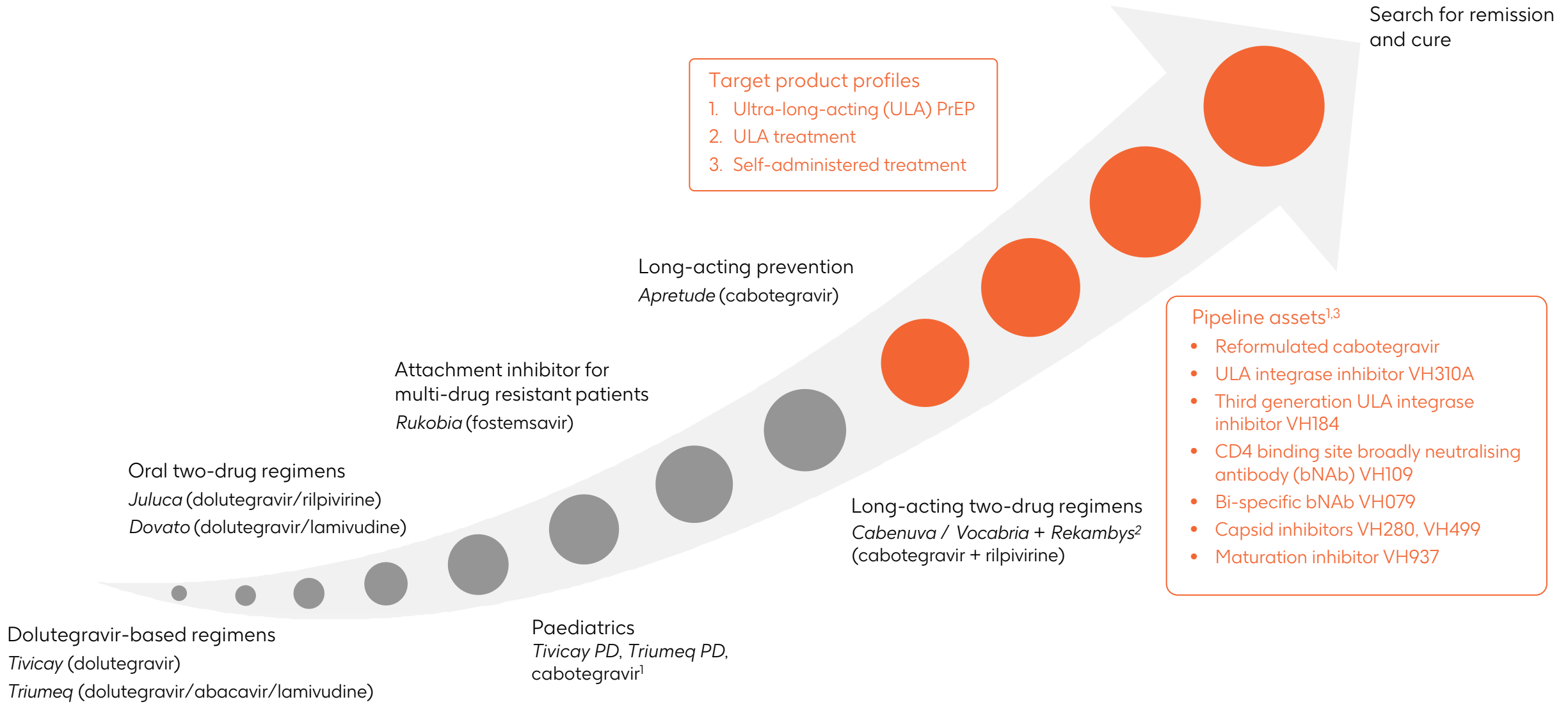
- LA injectables expected to represent ~30% of the treatment value by 2031, ~80% of PrEP value by 2031
- HIV treatment market stable at ~£20bn, PrEP market is expected to more than double in size to £4-5bn
- ViiV Healthcare leadership in LA injectables

# 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



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

"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



- 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

## ULA treatment

"If I can go for several months without burden, without thinking about it, I'd take it"

Patricia 55, Germany

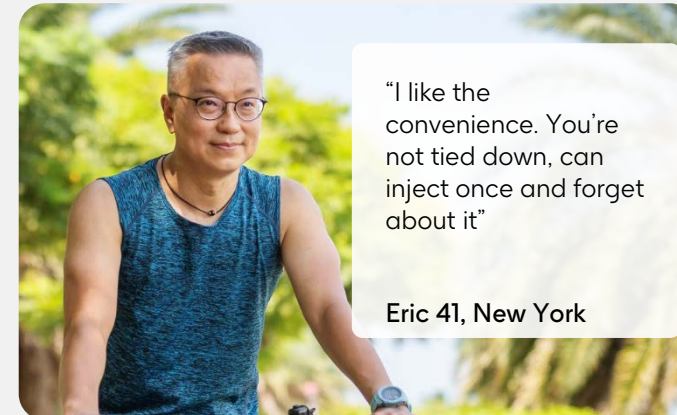


- Drained from taking daily meds
- Nervous about others discovering her HIV status
- Trusting relationship with HCP
- Wants to take meds as infrequently as possible

## Self-administered LA treatment

"I like the convenience. You're not tied down, can inject once and forget about it"

Eric 41, New York



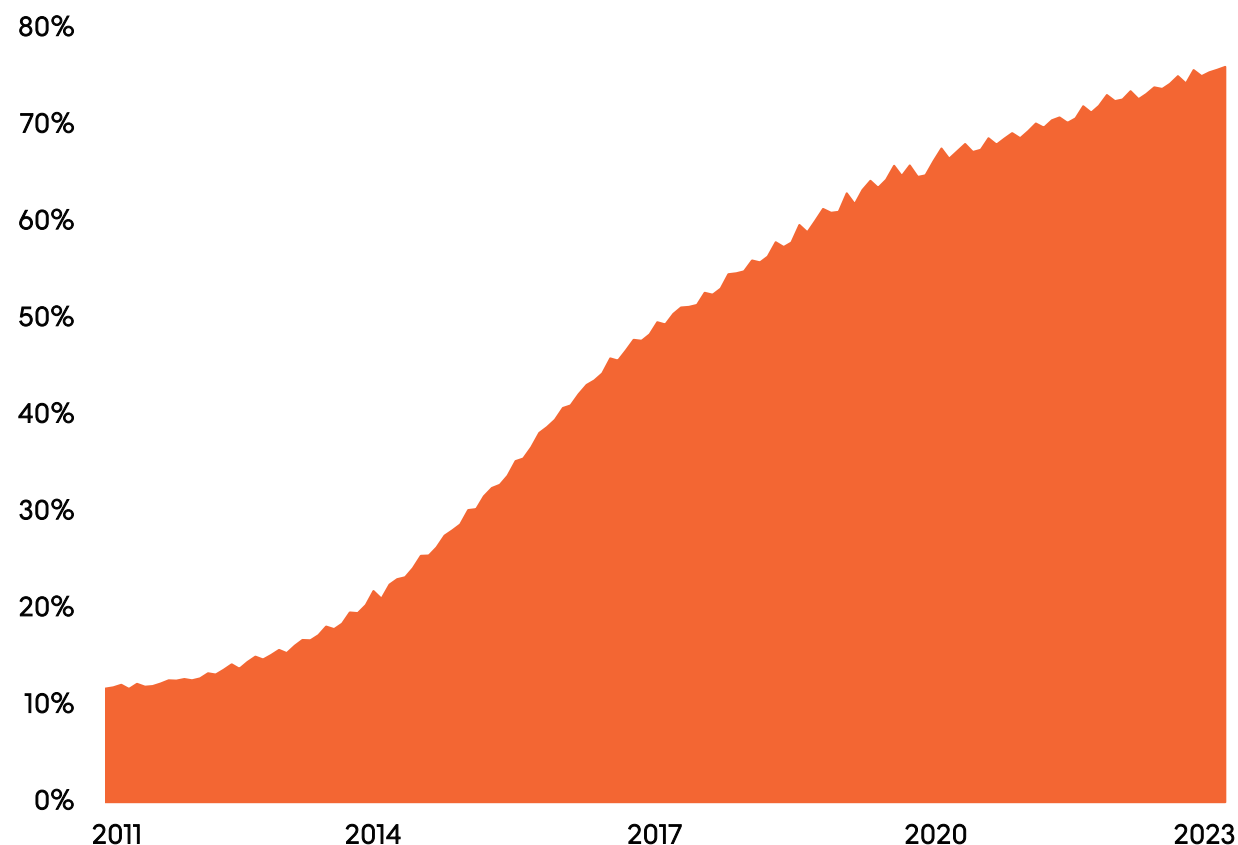
- Open about HIV status
- Good relationship with HCP and adherent to daily anti-retroviral treatment (ART)
- Wants control over where and when to take his meds
- Prefers fewer clinic appointments

# Integrase inhibitors (INSTI) at the core of HIV treatment and prevention

ViiV Healthcare continues to lead in INSTI innovation

- INSTIs are the foundation of ART regimens in HIV treatment guidelines around the world<sup>1,2</sup>
- 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<sup>\*\*</sup>
- Cabotegravir is the first and only approved long-acting INSTI
- Our past, present and future portfolios are built on integrase inhibitors

76% share for integrase inhibitors across top 9 markets\*



1. [https://www.eacsociety.org/media/final2021eacsguidelinesv11.0\\_oct2021.pdf](https://www.eacsociety.org/media/final2021eacsguidelinesv11.0_oct2021.pdf)  
2. <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>  
3. [https://www.unaids.org/sites/default/files/media\\_asset/UNAIDS\\_FactSheet\\_en.pdf](https://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf)

## Cabotegravir LA is transformative

“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



# Cabotegravir LA: robust data drives momentum and success

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**

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**

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**

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**

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**

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

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Improved **patient**  
experience with **fewer**  
**clinic visits**

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Builds on HCP and  
patient **confidence**  
and **familiarity**

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RPV half-life of **~200**  
**days**<sup>1</sup>

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Potential to **improve**  
the patient and  
clinic **experience**

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Working with Janssen to  
evaluate **alternative**  
**doses and formulations**

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

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VH109 is a **novel bNAb** with **broad and potent** neutralisation activity *in vitro*<sup>1</sup>

- Neutralises up to 98% of viral strains<sup>1</sup>

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

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Single dose in humans demonstrated **viral load reductions** up to **-2.8 log/ml<sup>1-3</sup>**

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**Phase IIb EMBRACE study\*** is open to enrolment

- VH109 +/-rHuPH20+cabotegravir
- Subcutaneous dosing enabled by **Halozyne partnership**

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

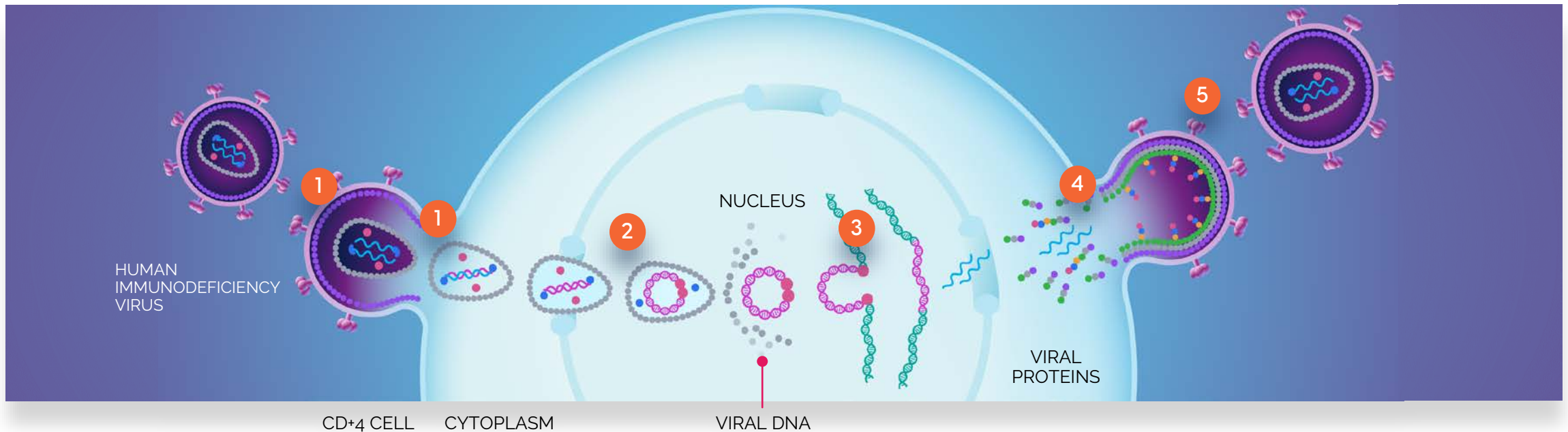
\*NCT05996471



# Next generation LA regimens with INSTIs at the core

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

1	2	3	4	5		
<b>Binding and fusion</b>	<b>Nuclear entry and uncoating</b>	<b>Integration</b>	<b>Assembly and budding</b>	<b>Maturation</b>		
<u>Class: bnAb</u> VH109 (N6LS) Phase: IIb VH079 (Bi-specific) Phase: Pre-clinical	<u>Class: Capsid Inhibitor</u> VH280/VH499 Phase: II	<u>Class: INSTI</u> Cabotegravir – CAB 400 Phase: I	<u>Class: INSTI</u> VH310A Phase: Pre-clinical	<u>Class: INSTI</u> 3 <sup>rd</sup> generation INSTI VH184 Phase: I	<u>Class: Capsid Inhibitor</u> VH280/VH499 Phase: II	<u>Class: Maturation Inhibitor</u> VH937 Phase: I



# Multiple pathways to deliver long-acting treatment and prevention

Asset	Self-administered	ULA Q4M	ULA Q6M
CAB 400 (INSTI)	●	●	●
VH184 (INSTI)	●		●
VH310 (INSTI)			●
VH109 (bNAb N6LS)	●	●	●
VH937 (maturation inhibitor)	●		
VH280/VH499 (capsid inhibitor)	●		●
NRTTI (rilpivirine)		●	

# Clear roadmap of innovation delivery

INSTI-based LA regimens anchor pipeline

TPPs

Key milestones

	2023	2024	2025	2026	2027	2028 - 2030
ULA PrEP	CAB 400 dose selection	Q4M registrational study start (H1)		Q4M file and launch	Q6M registrational study start	Q6M file and launch
ULA Treatment		Q4M regimen selection (H2)	Q4M registrational study start (H2)		Q4M file and launch	Q6M file and launch
				Q6M regimen selection/registrational study start		
LA Self-Administration Treatment		Regimen selection (H2)	Device set-up (H2)	Registrational study start		File and launch

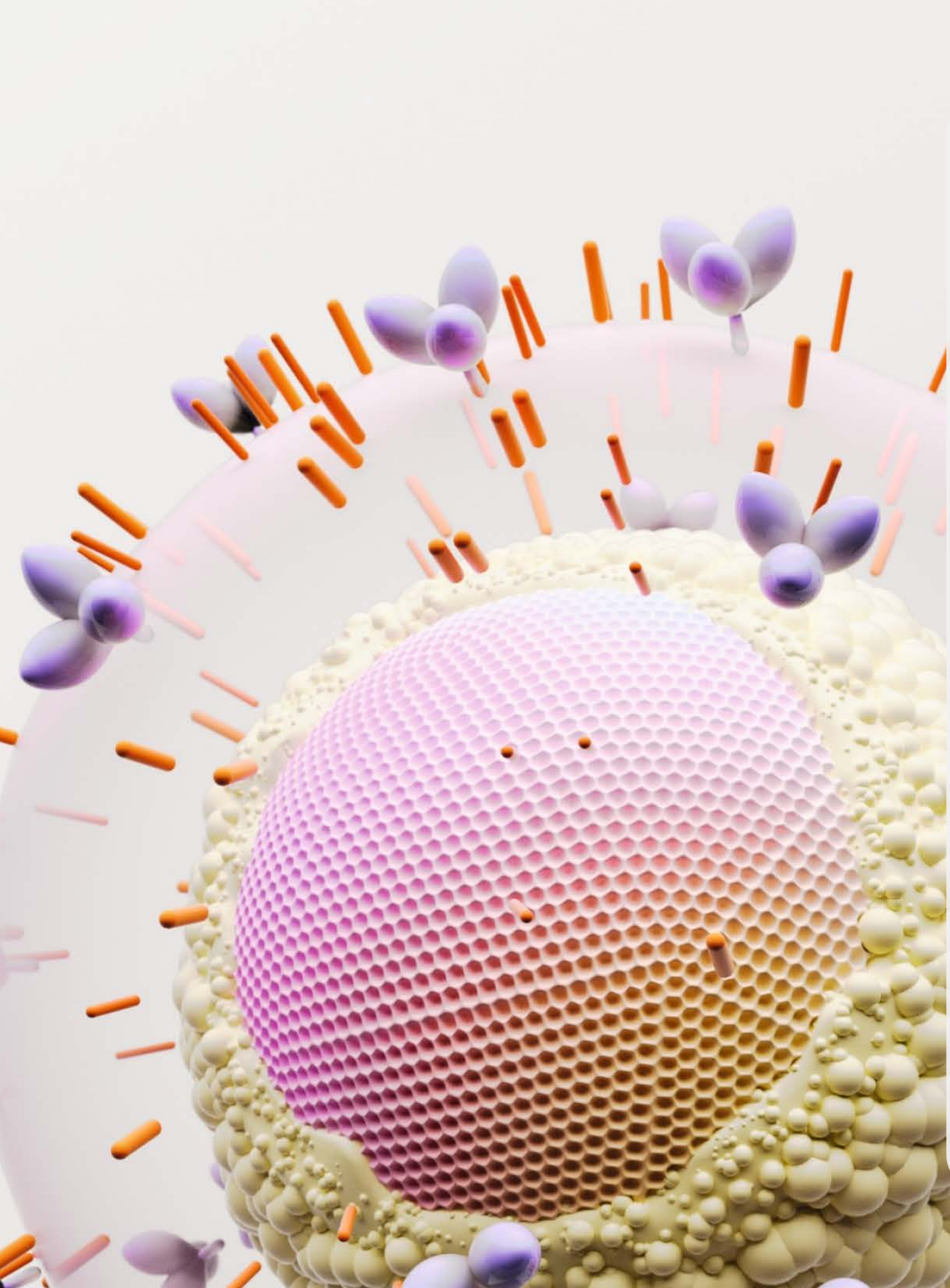
LA is the key to ending the HIV epidemic  
ViiV Healthcare continues to lead the way



# Reshaping the HIV treatment and prevention market

**Deborah Waterhouse**

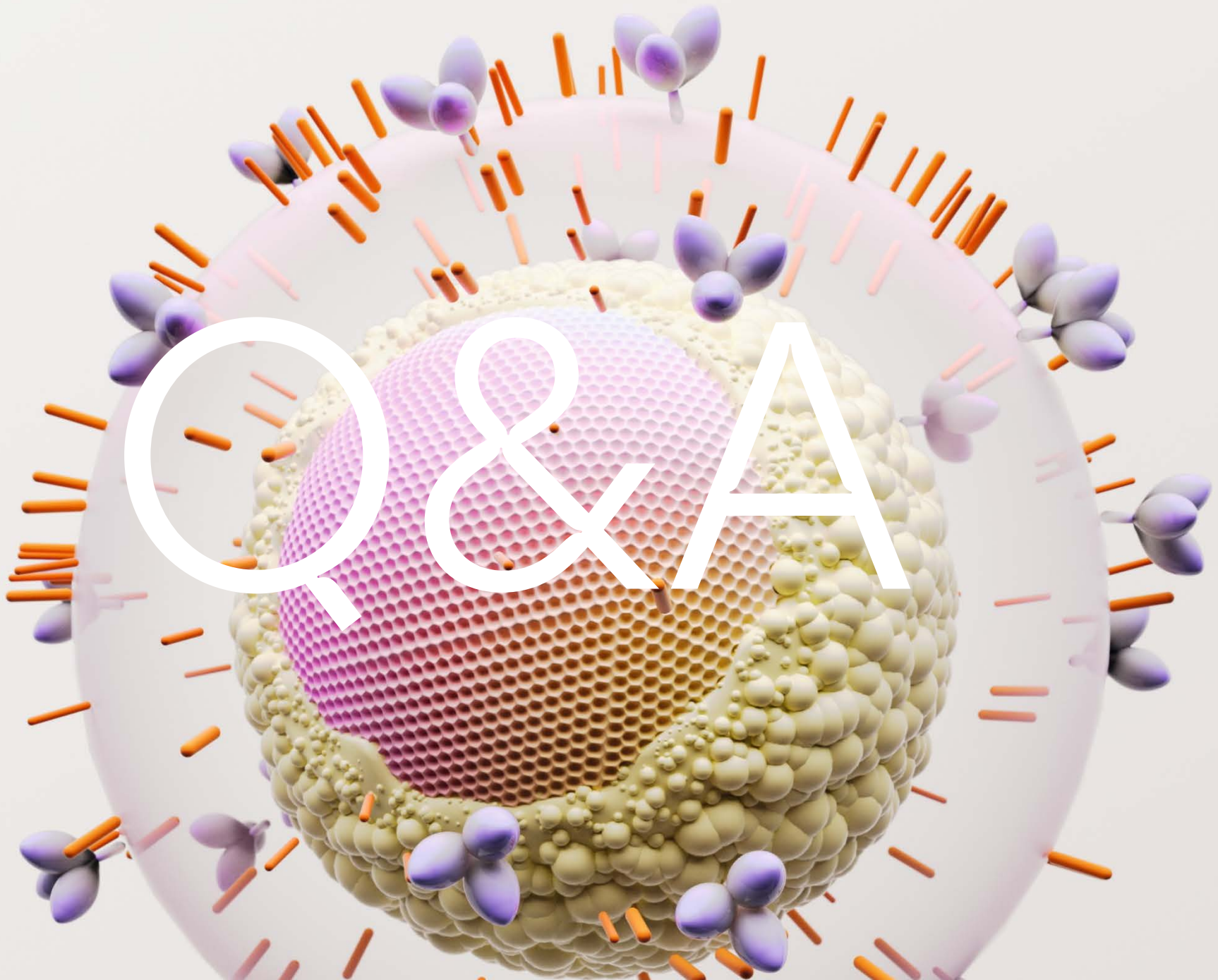
CEO, ViiV Healthcare and President Global Health, GSK



## 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



Q&A