

# Fuelling our future growth

ViiV Healthcare: Update on our pipeline progression





# WELCOME



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# CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This presentation may contain 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 '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, and financial results.

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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 presentation, 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 FY 2017. 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. These measures are defined and reconciliations to the nearest IFRS measure are available in our third quarter 2018 earnings release and Annual Report on Form 20-F for FY 2017.

All expectations and targets regarding future performance should be read together with "Assumptions related to 2018 guidance and 2016-2020 outlook" on page 38 of our third quarter 2018 earnings release.



TO LEAVE NO PERSON LIVING WITH HIV BEHIND





### **OUR PIPELINE**

### NEW TREATMENT PARADIGM TWO-DRUG REGIMENS

Juluca (dolutegravir/rilpivirine)

Dovato (dolutegravir/lamivudine)

Long-acting treatment regimens

cabotegravir + rilpivirine

#### **PREVENTION**

cabotegravir (744LAP) †

#### SEARCH FOR REMISSION AND CURE Collaborations

#### New MOA

Combinectin (GSK3732394)\*‡
Maturation inhibitor portfolio\*‡
Allosteric integrase inhibitor \*‡
Capsid inhibitor\*‡

#### **LEGACY ARV PORTFOLIO**

**Epzicom/Kivexa** (abacavir/lamivudine) **Celsentri/Selzentry** (maraviroc)



**Tivicay** (dolutegravir)

**THERAPEUTICS** 



Triumeq (dolutegravir/abacavir/lamivudine)

Attachment inhibitor for highly experienced patients†

Medicines approved for prescription

† Investigational assets not currently approved for prescription





### The US Food and Drug Administration (FDA) approved Dovato

An innovative treatment powered by dolutegravir at the core for treatment-naïve PLHIV

Dovato offers PLHIV efficacy non-inferior to a three-drug regimen with fewer drugs that is TAF, TDF, abacavir and booster-free

**Label:** no limitations on viral load





# NO ONE SHOULD TAKE MORE MEDICINES THAN THEY NEED

Reducing long term effect of HIV medication on the body ranked as the most important improvement among people living with HIV (PLHIV)

PLHIV worry about longterm effects of HIV treatments<sup>1</sup> PLHIV would consider reducing the number of drugs in their regimen to the minimum<sup>1</sup>

"With this approval, patients who have never been treated have the option of taking a two-drug regimen in a single tablet while eliminating additional toxicity and potential drug interactions from a third drug."<sup>2</sup>

Debra Birnkrant, director of the FDA's division of antiviral products

"This is good news for patients and providers looking to avoid side effects with the use of a third drug...and should be viewed favorably by insurers"<sup>3</sup>

Lynda Dee, Fair Pricing Coalition member and former co-chair

https://fairpricingcoalition.org/2019/04/09/dovato-approval-price



Positive Perspectives survey, 2017 DOF. Marcotullio S, et al. EACS 2017, poster PE25/9

https://www.fda.gov/news-events/press-announcements/fda-approves-first-two-drug-complete-regimen-hiv-infected-patients-who-have-never-received



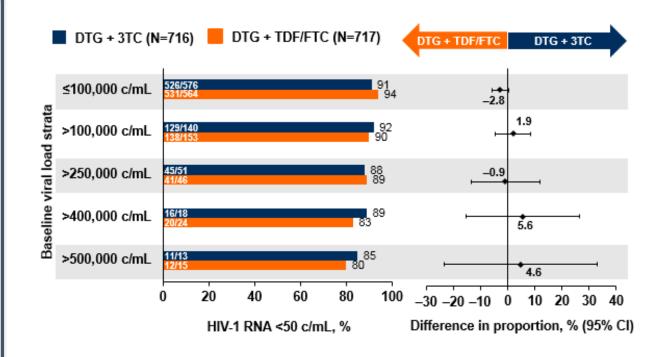
# GEMINI 1 & 2 PHASE III STUDIES: PIVOTAL 48-WEEK DATA FOR APPROVAL AND LAUNCH

Noninferior virologic efficacy for the 2DR of DTG + 3TC vs the three-drug regimen of DTG + TDF/FTC

Low rates of confirmed virologic withdrawals - no treatment-emergent INSTI or NRTI mutations

Overall safety and tolerability profile at Week 48 was comparable between the two regimens

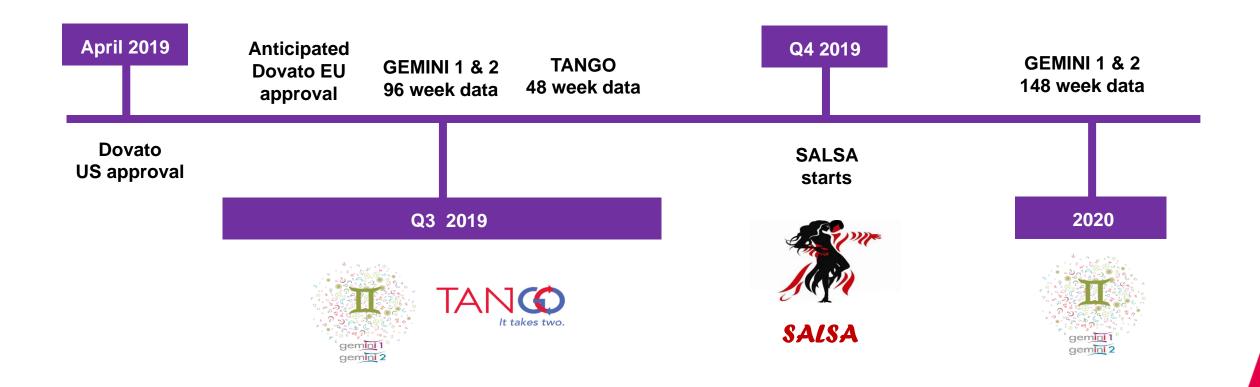
- / Fewer drug-related AEs with DTG + 3TC
- / Change in renal and bone biomarkers significantly favors DTG + 3TC



<sup>&</sup>lt;sup>a</sup>Based on Cochran-Mantel-Haenszel stratified analysis adjusting for the following baseline stratification factors: plasma HIV-1 RNA (≤100,000 c/mL vs >100,000 c/mL), CD4+ cell count (≤200 cells/mm³ vs >200 cells/mm³), and study (GEMINI-1 vs GEMINI-2). <sup>b</sup>PP, per protocol: population consisted of participants in the ITT-E population except for significant protocol violators, which could potentially affect efficacy outcomes as determined by the medical monitor prior to database lock.



# DOVATO: EVIDENCE GENERATION CONTINUES





# GIVING TREATMENT A SHOT: cabotegravir + rilpivirine long acting injectable (investigational)

#### POTENTIAL INDICATIONS

**HIV treatment** (long acting injectable)

- / CAB LA + RPV LA every 4 week IM injection as a two-drug maintenance regimen
- / For virologically suppressed patients who don't want a daily reminder of HIV, reducing the number of treatment days they have from 365 to 12 per year

### **HIV PrEP** (CAB monotherapy)

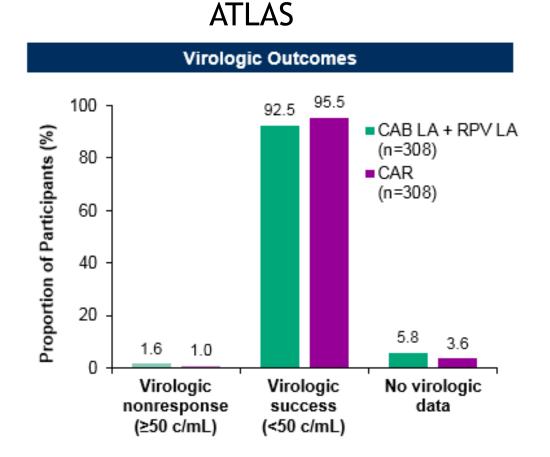
- / CAB LA IM once every two months (combined with safer sex practices)
- / Potential to deliver with long acting contraception in family planning setting

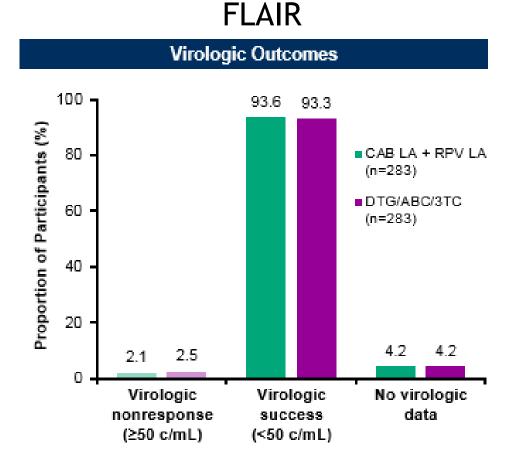




# ATLAS/FLAIR MEET PRIMARY ENDPOINTS: Cabotegravir and rilpivirine monthly injectable demonstrates non-inferiority to oral three-drug regimen









STRONG PATIENT PREFERENCE FOR MONTHLY INJECTABLE OVER DAILY ORAL REGIMEN

Question: Today we would like you to compare your experience on the Long Acting injections with the oral medication you received during the study. Which therapy do you prefer?

ATLAS: 266 of 273 (97%) preferred the LA regimen over previous oral therapy

FLAIR: 257 of 259 (99%) preferred the LA regimen over previous oral therapy





### **REACTION TO ATLAS/FLAIR**

# RollingStone

HOME > CULTURE > CULTURE NEWS

IARCH 19, 2019 2:45PM ET

# Monthly HIV Injection Treatments Could Soon Become Available

Two clinical trials indicate that we may have a new course of treatment on the horizon

One of the toughest things about taking daily medications is actually remembering to take the damn things. Studies have consistently shown that **many people frequently forget to take their meds**, and that's a big problem, particularly if they're living with HIV and rely on antiretroviral therapy (ART) to keep the virus in check.

That's why the health care company Viiv Healthcare has just announced the completion of two clinical trials involving more than 1,0000 people for a **monthly injectable antiretroviral medication**, which they say works just as well as the standard course of daily, pill-based treatment for people with HIV.

"If approved, this two-drug regimen would give people living with HIV one month between each dose of antiretroviral therapy, changing HIV treatment from 365 dosing days per year, to just 12" John Pottage, VHC



# Media headlines and commentary cemented positive reception

HIV Drug Aiming to Free Patients From Daily Doses Nears Market **Bloomberg** 

The success of the two injectabledrug studies — named Atlas and Flair — raised hopes among H.I.V. experts that these shots may eventually be used to protect the uninfected

The New York Times

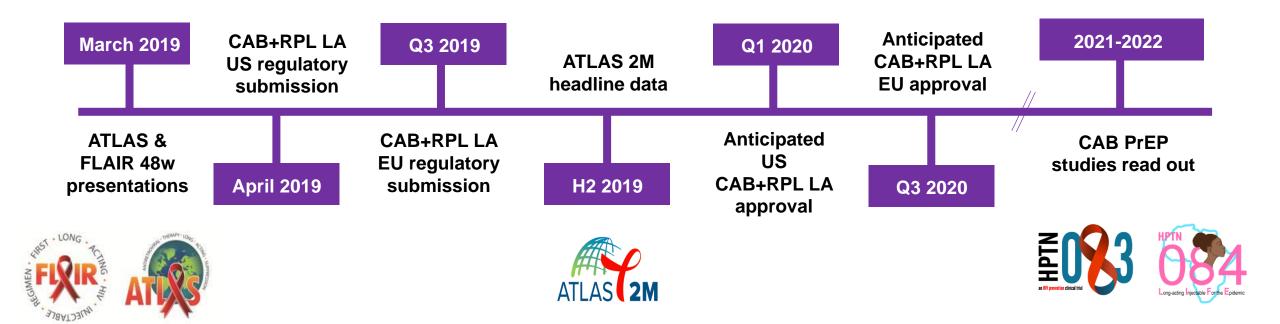
If the injectable monthly regimen makes it to the market, Gilead's crown may be more vulnerable than ever

**ENDPOINTS NEWS** 

Monthly HIV Injection Could Free Patients From Grueling Drug Regime nature



# CABOTEGRAVIR: EVIDENCE GENERATION AND MILESTONES





# FOSTEMSAVIR: a life-saving investigational medicine for patients with few or no treatment options left

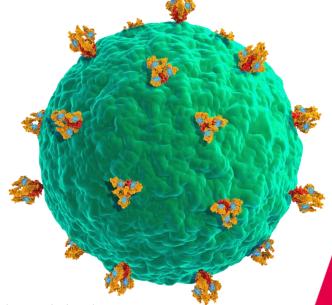
First-in-class - unique mechanism blocking CD4 binding<sup>1</sup>

No cross-resistance to other antiretrovirals<sup>1,3</sup>

FDA breakthrough therapy designation<sup>2</sup> US regulatory filing planned for 2H2O19

In BRIGHTE study, 54% of heavily treatment-experienced patients achieved virologic suppression at 48 weeks and had continued increase in CD4+ t-cell counts<sup>4</sup>





<sup>1.</sup> Nowicka-Sans B, et al. Antimicrob Agents Chemother. 2012;56:3498–350 2. https://news.bms.com/press-release/bristol-myers-squibb-receives-us-fda-breakthrough-therapy-designation-investigational- 3. Li Z, et al. Antimicrob Agents Chemother. 2013;57:4172–4180. 4. Aberg J et al. HIV Drug Therapy Glasgow 2018, 28 – 31 October 2018. Oral abstract O344A. (URLs accessed November 2018).



### **CONTINUING TO DISRUPT** AND INNOVATE

#### **NEW TREATMENT PARADIGM** TWO-DRUG REGIMENS

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**THERAPEUTICS** 

### **DOLUTEGRAVIR REGIMENS**

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Q&A





