

### **HIV and ViiV Healthcare**

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#### **Overview**



- 1. ViiV Healthcare vision
- 2. ViiV Healthcare history and operating model
- 3. HIV market
- 4. Dolutegravir (DTG)
- 5. R&D strategy
- 6. Concluding remarks



### **ViiV Healthcare vision**

#### An ambitious vision



Establish ViiV Healthcare as the leading company in the HIV market in innovation, sales and reputation



# ViiV Healthcare history and operating model

#### A rich HIV history joined under a unique model

Highly reliant

on GSK

infrastructure

R&D

**Manufacturing** 

Distribution

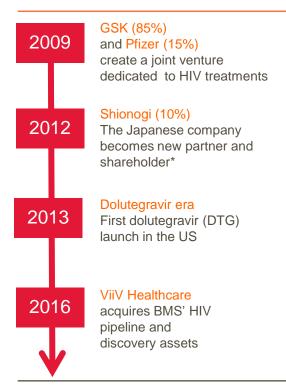
(Alliance markets)

Administrative and

functional (HR, IT,

Legal, Finance)





#### ViiV Healthcare shareholding









Strategy
Drug discovery and
development
Medical affairs
Marketing
Sales
Public affairs
Global operations
Resource management
Performance management

External support from Pfizer and Shionogi

R&D support Manufacturing

# End to end operation reliant on the scale and infrastructure of large Pharma shareholders





3

regions – North America, Europe and International



15

affiliates and a presence in more than 50 countries through GSK



900+

employees worldwide



**150** 

employees working in Alliance markets\*



244

employees working for GSK in R&D for ViiV Healthcare



**222** 

employees working for ViiV Healthcare through shared service agreements



450+

planned, concluded and active clinical trials since creation, including BMS acquisitions

## ViiV Healthcare success to date has evolved in two phases – First Phase: 2009 - 2013



2009

#### Re-energised commercial operation and R&D

2013

1. Led the Epzicom/Kivexa turnaround



2. Created an unprecedented development programme to catapult DTG's success



# ViiV Healthcare success to date has evolved in two phases – Second Phase: 2013 - Today

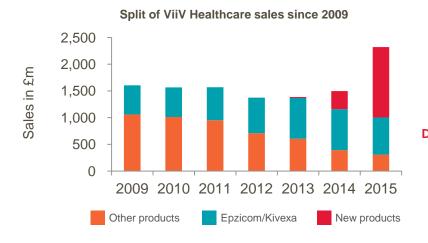


2013

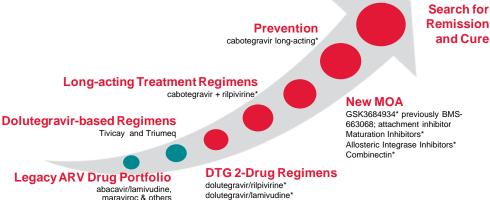
#### Emerging Leadership: market growth and innovation

Today

1) DTG success fuelling ViiV Healthcare growth



2) Commitment to true innovation that delivers real patient benefit



Source: Reported Financial Results

<sup>\*</sup> Note, therapies denoted with an (\*) are investigational; safety and efficacy in treating/preventing HIV has not been established



### The HIV market

## The HIV epidemic remains a substantial challenge of our time



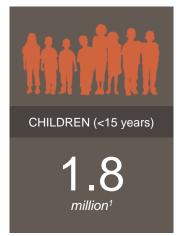
36.7<sub>m</sub> people living with HIV worldwide<sup>1</sup>

2.1m infections and 1.1m
AIDS-related deaths per year globally<sup>1</sup>

2.4m people living with HIV in Western and Central Europe and North America<sup>1</sup>







Patients are living longer and infection rates have begun to rise again

Treatment rate in developed markets is only 50-70%<sup>2,3</sup>

IAS July 2016 recommends that all people living with HIV should receive treatment

#### A highly dynamic market

HIV market valued at £16 billion in 2015



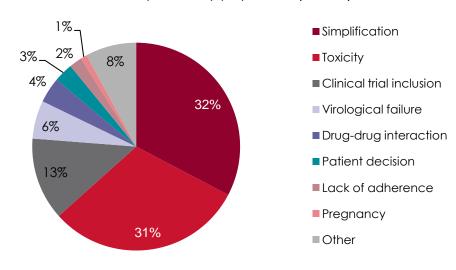
Dynamic Segment ~15-35% of the market per year

Initiation (naive) ~5-10%

Switch ~10-25%

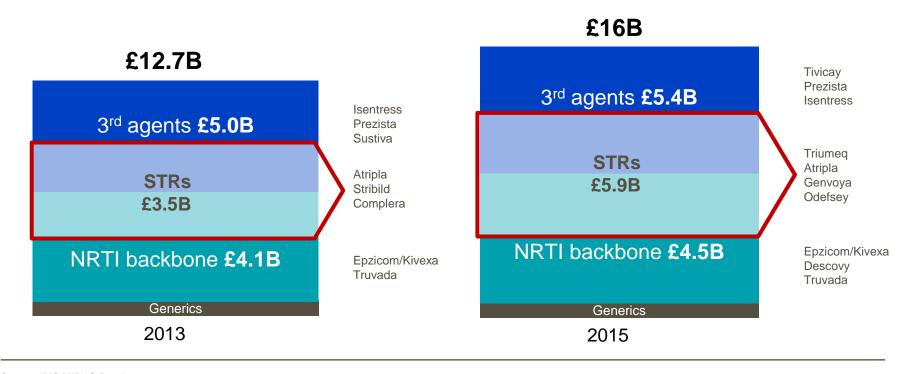
Stable segment ~65-85%

Reported reason for patients switching to a new therapy as reported by physicians (N=246)



# The market has been receptive to innovation and remains a strong opportunity for growth





Source: IMS MIDAS Database

#### **Guideline updates drive market evolution**

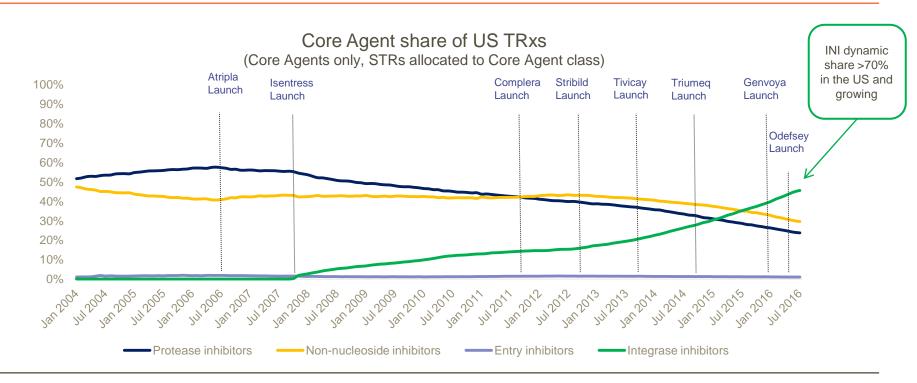


2013	2014	2015	2016
October 2013 DHHS recommends ntegrase inhibitor- pased regimens ncluding DTG repzicom or ruvada as preferred for ART naive patients	November 2014 EACS added DTG + Epzicom/Kivexa or +Truvada for ART naive patients	November 2015 WHO added DTG as alternative first line treatment	July 2016 IAS recommends initial regimens consisting of an integrase inhibitor plus two NRTIs

#### We have now entered the integrase inhibitor era



INIs represent 46% of the TRx market, a figure that will continue to grow



Source: IMS NPA Monthly Jul 2016



### Dolutegravir

#### Amongst integrase inhibitors, DTG stands out

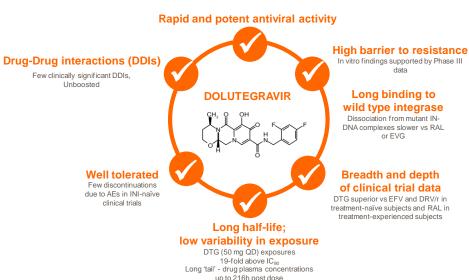


### Unprecedented and unmatched clinical trial results

	efavirenz	raltegravir	darunavir	atazanavir
dolutegravir	SUPERIOR (naive) SINGLE	SUPERIOR (experienced) SAILING	SUPERIOR (naive)	SUPERIOR (women/naive)
		NON INFERIO (naive) SPRING <sup>2</sup>	R	
elvitegravir/ cobicistat	NON INFERIOR (naive) NON INFERIOR			SUPERIOR (women/naive) NON INFERIOR
raltegravir	(naive)			(naive)

SINGLE, FLAMINGO, SPRING 2, SAILING and ARIA were non-inferiority studies with a pre-specified analysis for superiority Chart shows primary endpoint outcomes

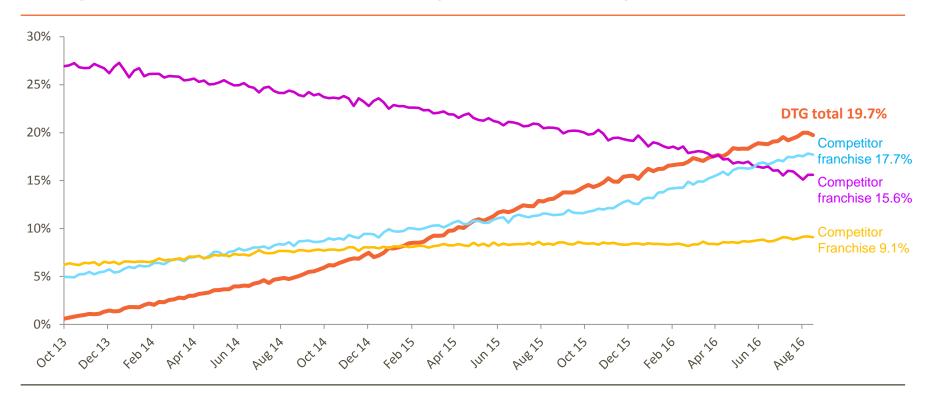
#### Unique product characteristics



#### Dolutegravir leads the market as the #1 core agent

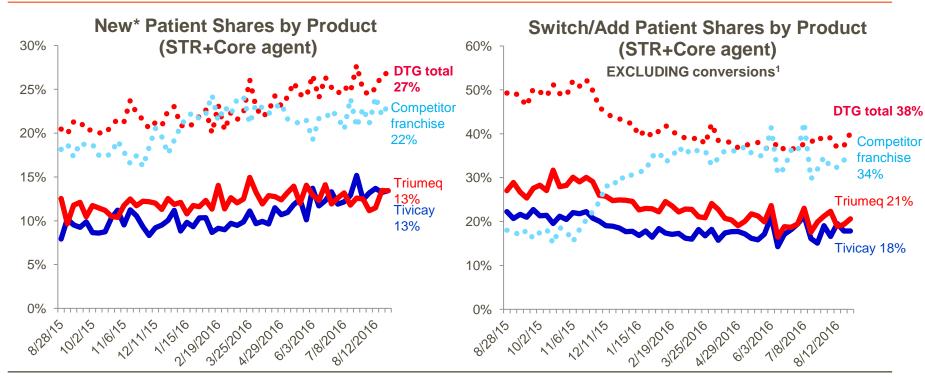


Weekly US TRx market share (STR + core agent) – since Tivicay launch



#### And the #1 agent in dynamic share in the US





<sup>1</sup> Conversions = switches from Truvada+Sustiva to Atripla, Truvada+Edurant to Complera, Tivicay+Epzicom to Triumeq, Prezista to Prezcobix, Reyataz to Evotaz, Stribild to Genvoya, Complera to Odefsey. \*\* IMS "New" metric is a proxy for naïve patients. It represents a longitudinal IMS panel of patients with no prior HIV therapy RX in the last 12 months, and overstates true naïve volume slightly.

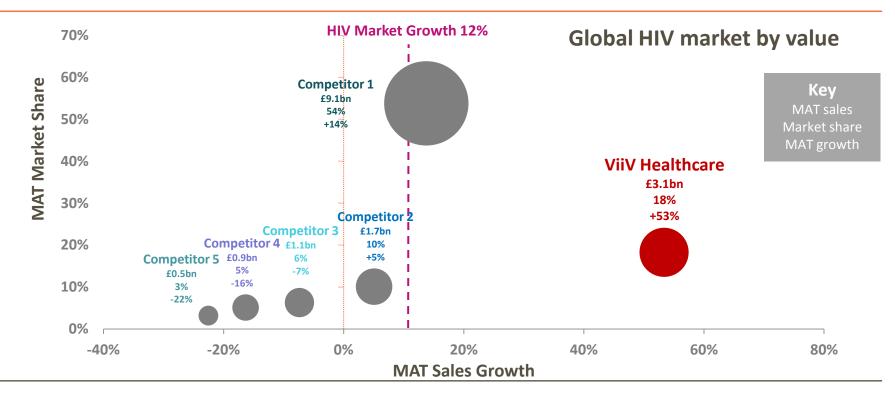
# Already #1 agent in dynamic share in many other key markets



	# 1 in Naïve	#1 in Switch
France	<b>✓</b>	$\checkmark$
Germany	$\checkmark$	$\checkmark$
Italy	$\checkmark$	$\checkmark$
Spain	$\checkmark$	$\checkmark$
UK	$\checkmark$	$\checkmark$
Canada	$\checkmark$	$\checkmark$
Japan	$\checkmark$	$\checkmark$

## ViiV Healthcare is the only company with increasing growth in HIV over the past 12 months (from +34% to +53%)





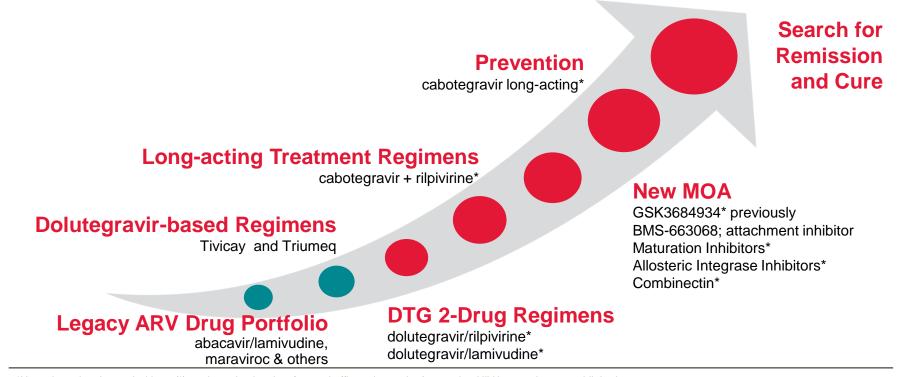
Source: IMS Health MAT June 2016



### R&D strategy

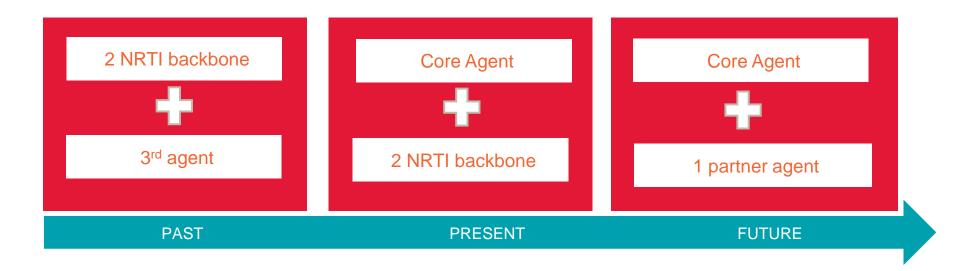
#### Committed to innovation and leadership in HIV





#### Our belief in the market evolution





#### Why can 2-drug regimens (2DR) succeed?



Scientifically viable	DTG/CAB uniquely positioned for 2DRs
	Encouraging clinical data
Unmet medical need	Long term treatments with improved adverse event profile
	Ageing HIV patient population with co-morbidities
Market demand	Persistent interest in 2DR research
	Market receptive to new treatment advances

2DRs have the potential to challenge therapy standard

# ViiV Healthcare integrase inhibitors at the forefront of the 2DR paradigm shift



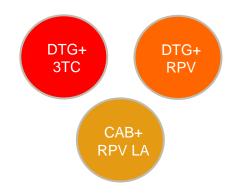
Establish DTG as the leading core agent in the market







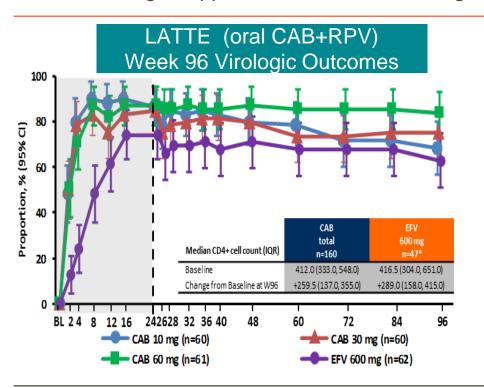




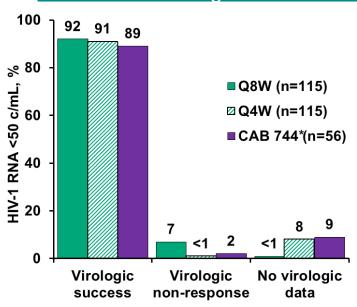
#### **Cabotegravir LATTE and LATTE-2 Studies**



Durable virologic suppression with oral and long-acting (LA) 2DR



### LATTE-2 (LA inj. CAB+RPV) Week 48 Virologic Outcomes



#### **Investigator initiated 2DR studies**



**GARDEL** 

LPV/r+3TC

SALT

ATV/r + 3TC

ASPIRE LAMIDOL

LAMIDOL ACTG 5353

**PADDLE** 

DTG+3TC

**DUALIS** 

DTG+ DRV/r

**DOLATAV** 

DTG+ATV/r

#### DTG + RPV

#### Phase III started May 2015



SWORD 1 and 2	
Indication	Maintenance therapy for adult patients with HIV-1 infection
Number of patients	1,000 virologically suppressed patients
Study design	Phase III, randomised, open-label study to assess the safety and efficacy of switching to DTG + RPV versus continuing current antiretroviral regimen
Primary endpoint	The primary endpoint is proportion of patients with plasma HIV-1 RNA <50 copies per milliliter (c/mL) at week 48. Key secondary endpoints include evaluation of the development of viral resistance, measurements of safety and tolerability, and changes in renal, bone and cardiovascular biomarkers
Expected readout date	End of 2016
Expected launch date	H1 2018

#### DTG + 3TC

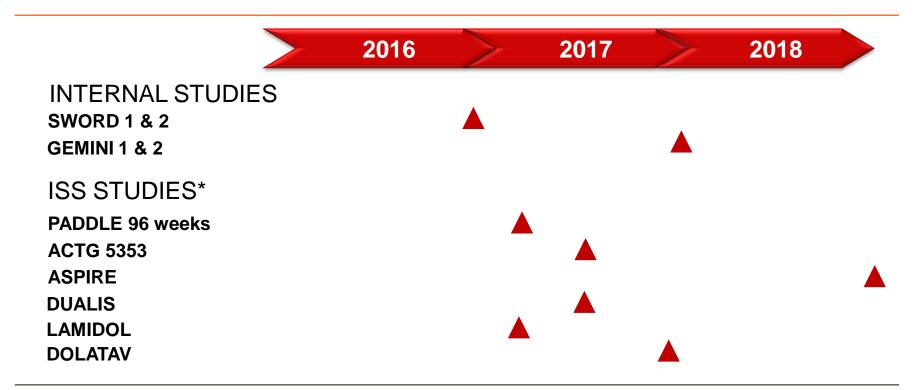
#### Phase III started August 2016



GEMINI 1 and 2	
Indication	Treatment for HIV-1 infection in adults who have not received prior antiretroviral therapy
Number of patients	1,400 naive patients
Study design	Phase III, randomised, multicentre, non-inferiority studies to evaluate the efficacy, safety, and tolerability of DTG + 3TC QD versus DTG + TDF/FTC FDC over 148 weeks
Primary endpoint	The primary endpoint for these studies is non-inferior antiviral activity measured by the proportion of participants with plasma HIV-1 RNA <50 copies/mL (c/ML) at week 48
Expected readout date	2018
Expected launch date	H1 2019

#### A growing body of evidence to support 2DR



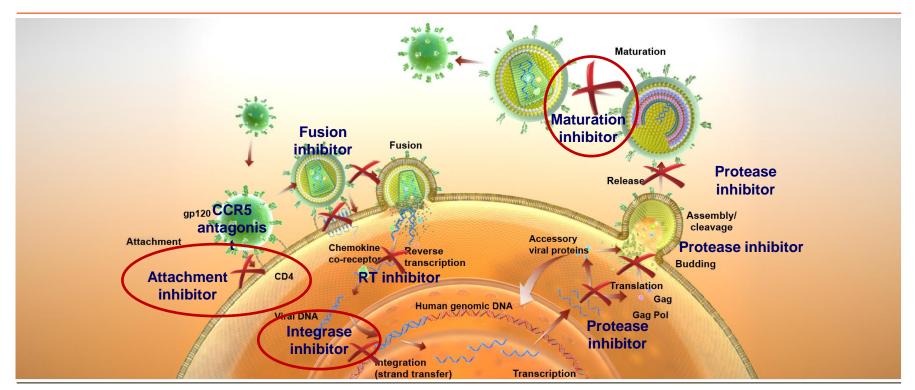


Forward-looking, dependant on data availability

<sup>\*</sup>ISS abstract are best estimates only and subject to change based on investigator decision

#### Why innovation should remain a priority in HIV





Reference: Lataillade et al. CROI 2015, Abstract 114LB



### **Concluding remarks**

### Our strategic priorities to ensure near and long term success



Continue to drive share in traditional 3 drug regimens through strength of DTG

Create a new paradigm in oral treatment through 2DR

Create a new paradigm in treatment through long-acting therapy

Continue to lead HIV innovation with research that delivers new mechanisms offering new options for patients most in need



Q&A