

ViiV Healthcare investor & analyst update

15 February 2017

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An ambitious vision



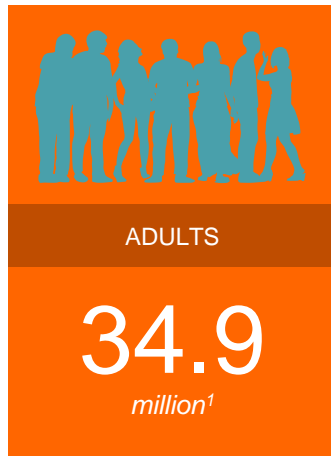
Establish ViiV Healthcare as the leading company in the HIV market in innovation, sales and reputation

The HIV epidemic remains a substantial challenge of our time

36.7 m people living with HIV worldwide¹

2.1m infections and **1.1m** AIDS-related deaths per year globally¹

2.4m people living with HIV in Western and Central Europe and North America¹



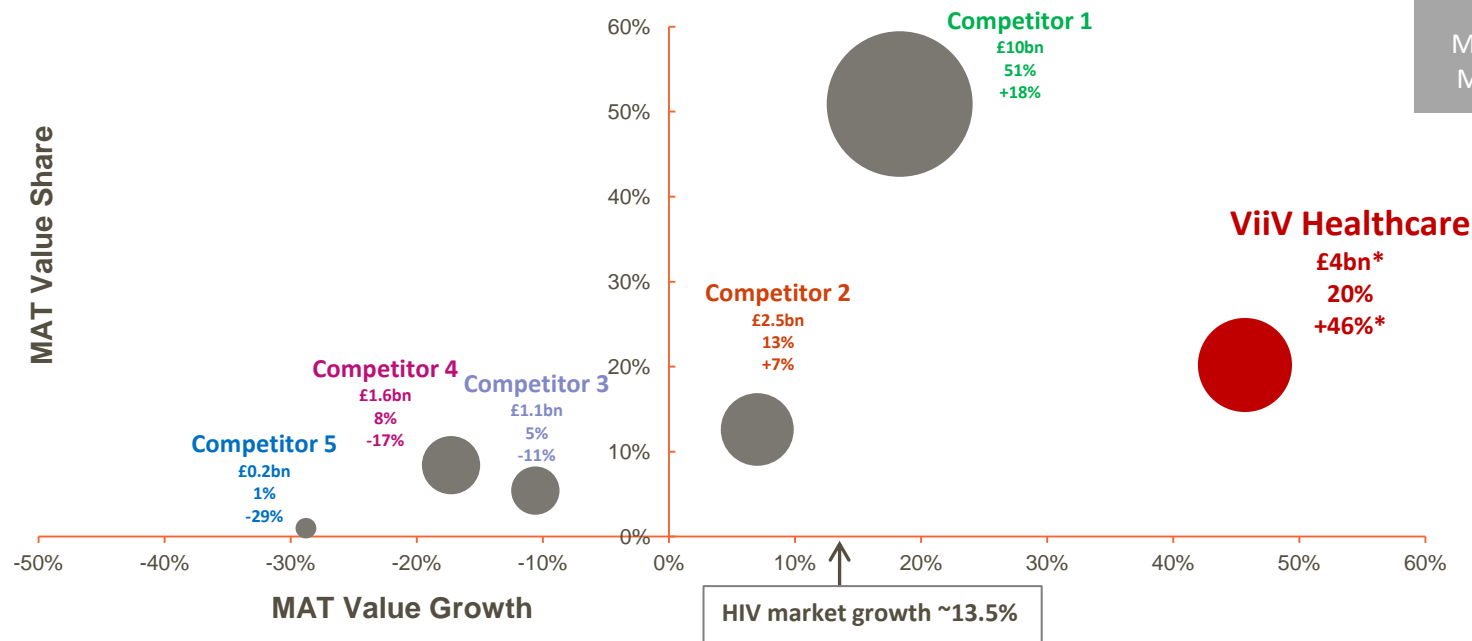
Patients are living longer and infection rates have begun to rise again
Treatment rate in developed markets is only 50-70%^{2,3}
IAS July 2016 recommends that all people living with HIV should receive treatment

ViiV is the second largest HIV company globally, and the fastest-growing



£19.7 bn global HIV market

Total HIV market performance by company

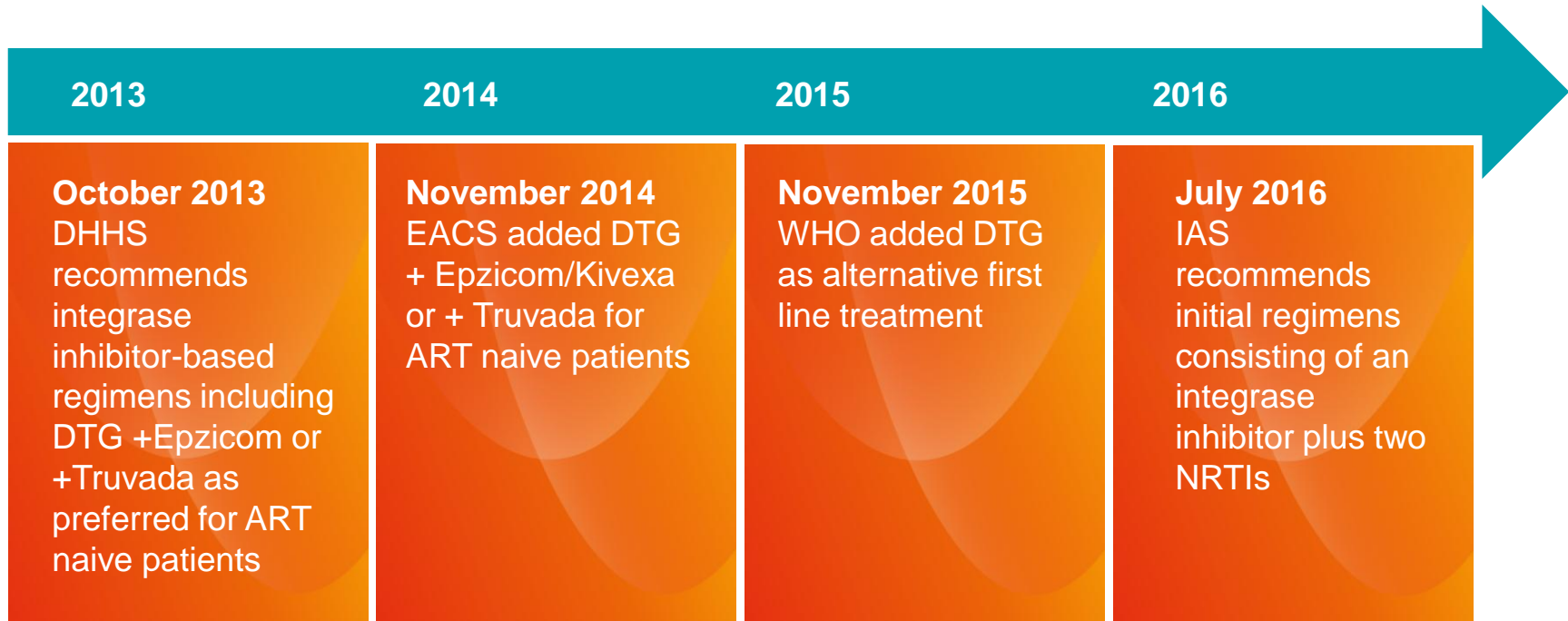


Source(s): IMS Monthly (Oct'16); IMS LoC (Nov'16); FiROM (Nov'16); IMS Dataview (Oct'16); Cegeidim Hospital (Nov'16);

*GSK reported HIV turnover of £3.6bn +37% CER growth for FY 2016 (8 Feb 2017)

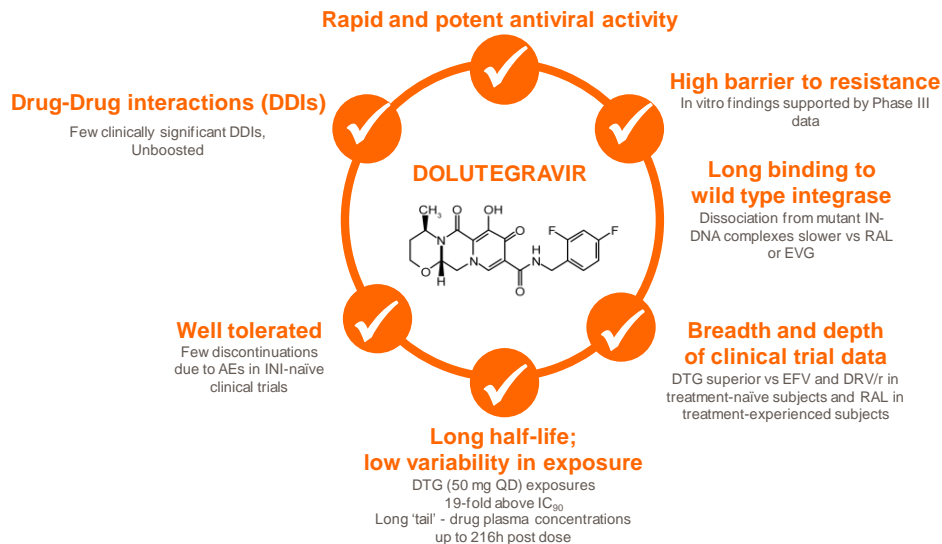
Guideline updates drive market evolution

Dolutegravir (DTG) now widely recognised as leading core agent



Amongst integrase inhibitors, dolutegravir stands out

Unique product characteristics



Unprecedented and unmatched clinical trial results in HIV

vs. efavirenz	vs. raltegravir	vs. darunavir	vs. atazanavir
SUPERIOR (naïve)	SUPERIOR (experienced)	SUPERIOR (naïve)	SUPERIOR (women/naïve)
	 NON INFERIOR (naïve)		

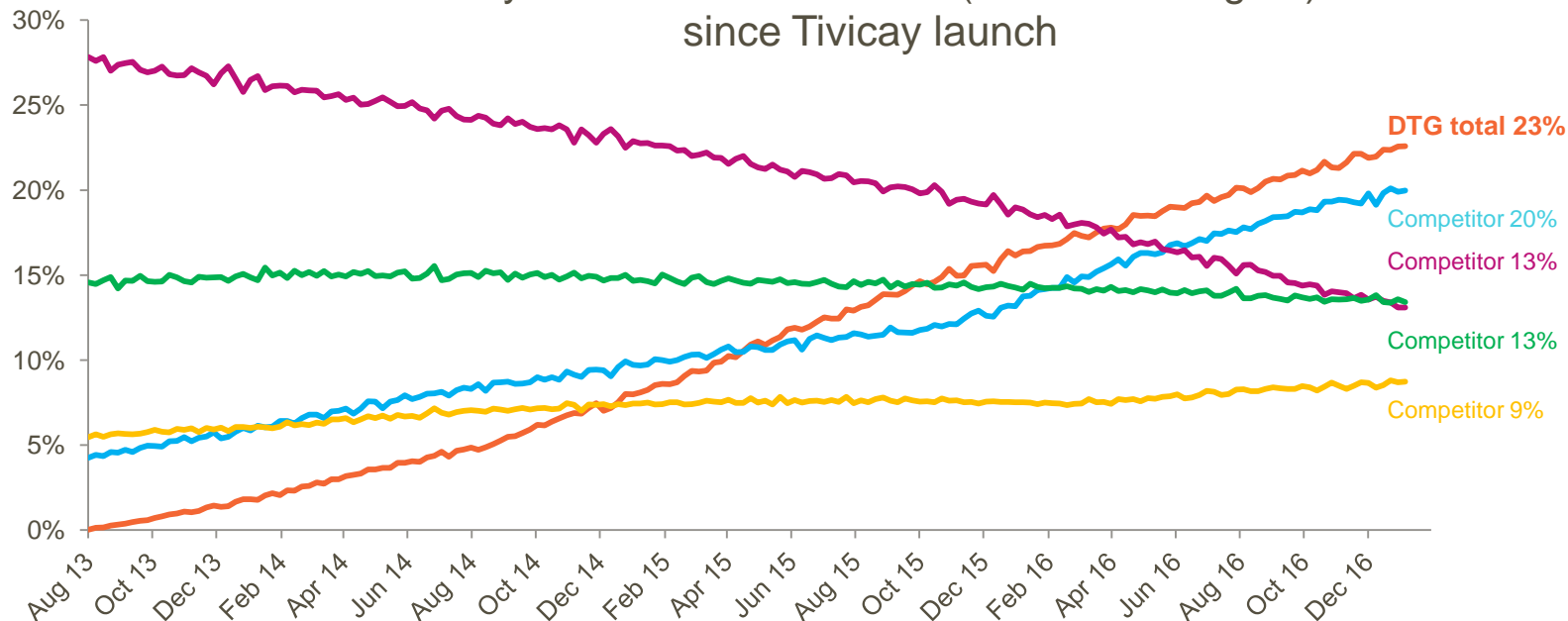
SINGLE, FLAMINGO, SPRING 2, SAILING and ARIA were non-inferiority studies with a pre-specified analysis for superiority. Chart shows primary endpoint outcomes.

Positive results from dolutegravir + rilpivirine two drug regimen Phase III SWORD studies, supports filing in 2017

DTG leads the market as the #1 core agent in the US



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

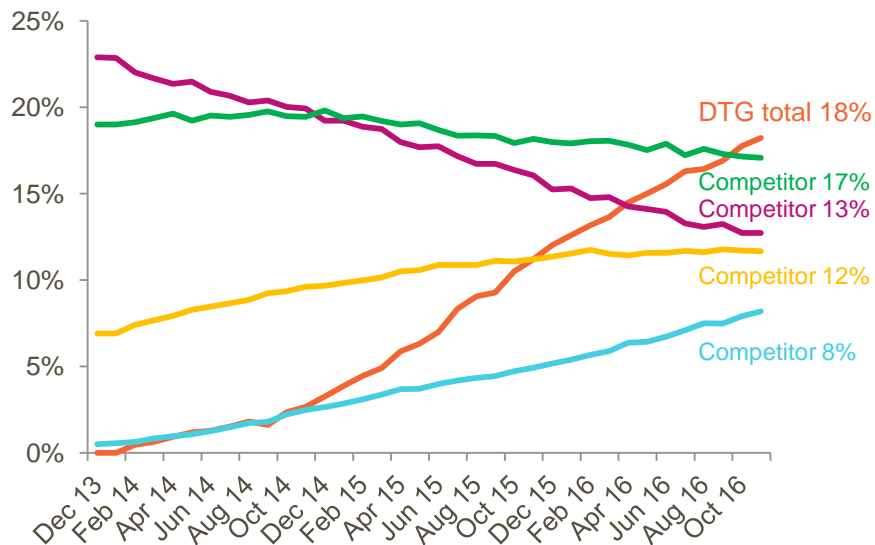


Source: IMS data to 27 January 2017. #1 meaning most prescribed

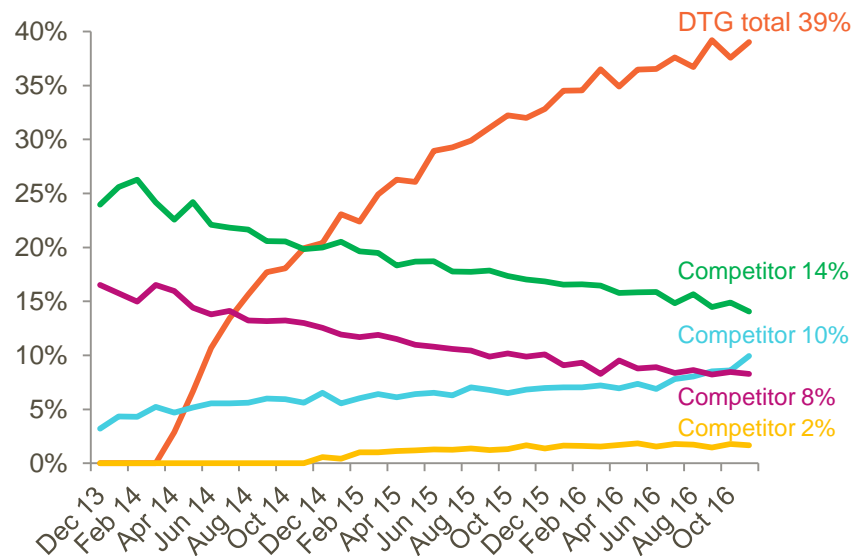
DTG leads the market as the #1 core agent in the top 5 European markets and Japan



EU5 total volume (DoT) share (STR + core agent) – since Tivicay launch



Japan total volume (DoT) share (STR + core agent) – since Tivicay launch



Source: IMS data to November 2016; France data GERS November 2016

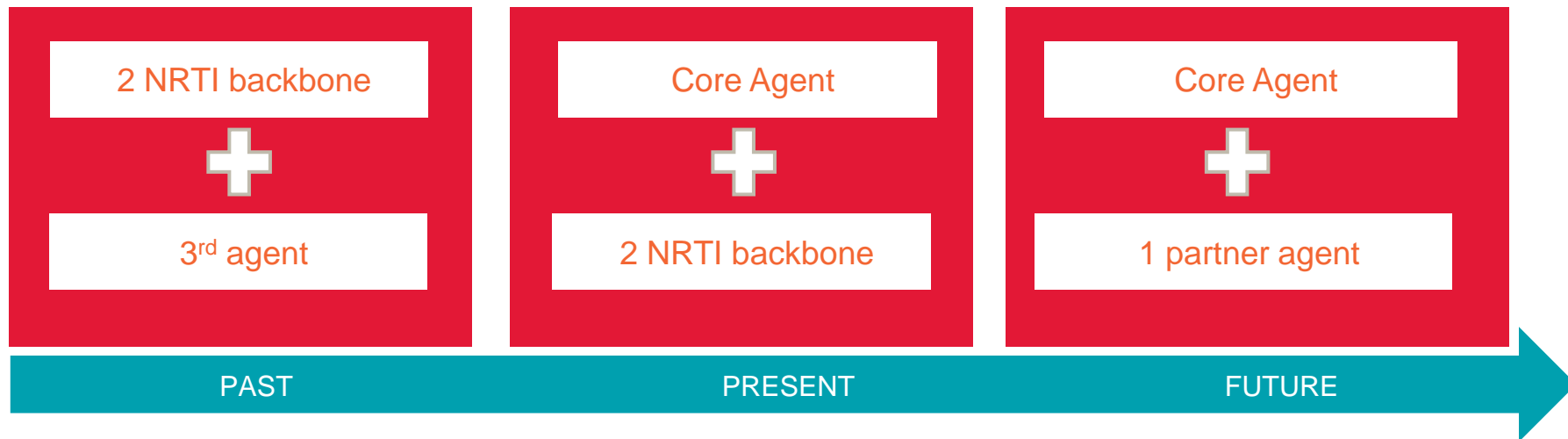
A growing body of evidence to support two drug regimens (2DR)



Scientifically viable	DTG/CAB uniquely suited for 2DRs
	Encouraging initial 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

Our belief in the market evolution



Phase III SWORD 1 & 2:

Switch to DTG + RPV

Maintains virologic suppression through 48 weeks

Introduction

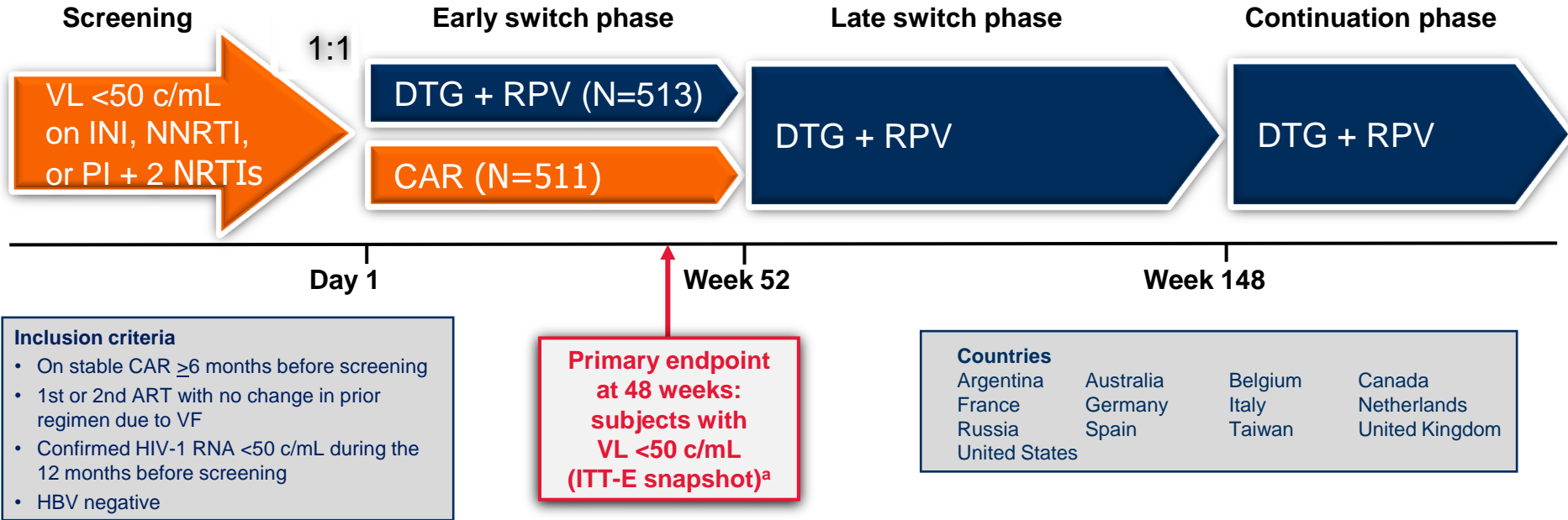
- The requirement for life-long antiretroviral therapy (ART) for HIV infection has highlighted a need to minimize cumulative drug exposure
- The potency, safety, and resistance barrier of dolutegravir (DTG) make it an ideal core agent for two-drug regimen (2DR)
- The safety, tolerability, and efficacy of rilpivirine (RPV) make it an optimal partner
- The SWORD-1&2 studies evaluated whether a 2DR of DTG + RPV once daily was as effective as a 3- or 4DR for the maintenance of virologic suppression

1. Raffi et al. *HIV Med.* 2016;17(suppl 5):3-16. 2. Ford et al. *Antimicrob Agents Chemother.* 2013;57:5472-5477. 3. Palella et al. *AIDS.* 2014;28:335-344.

Libre et al. CROI 2017; Seattle, WA. Abstract 2421.

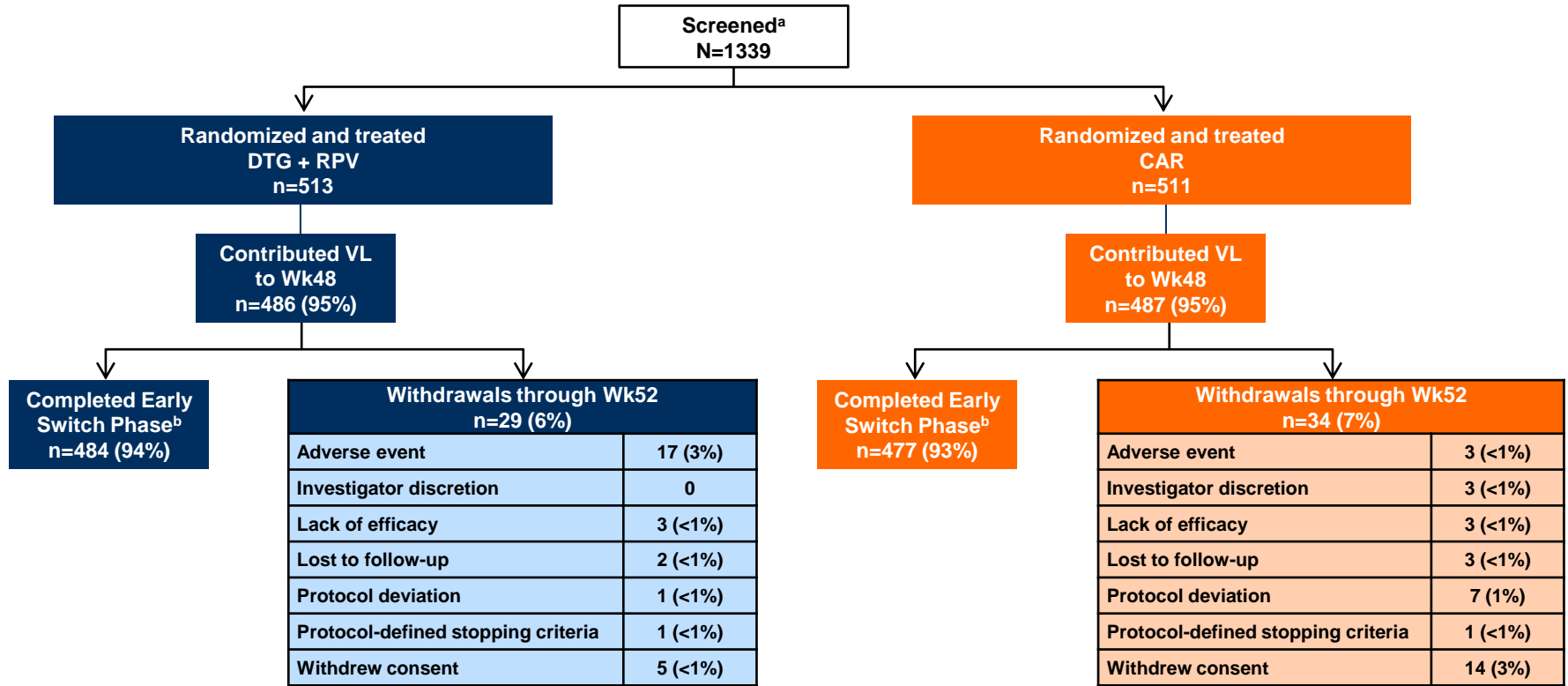
SWORD-1 and SWORD-2 Phase III Study Design

Identically designed, randomized, multicenter, open-label, parallel-group, non-inferiority studies



^a-8% non-inferiority margin for pooled data. -10% non-inferiority margin for individual studies

Subject Disposition: Early Switch Phase (Through Wk 52)



^aData pooled across SWORD-1 and SWORD-2. ^bEarly switch phase ends at Week 52.

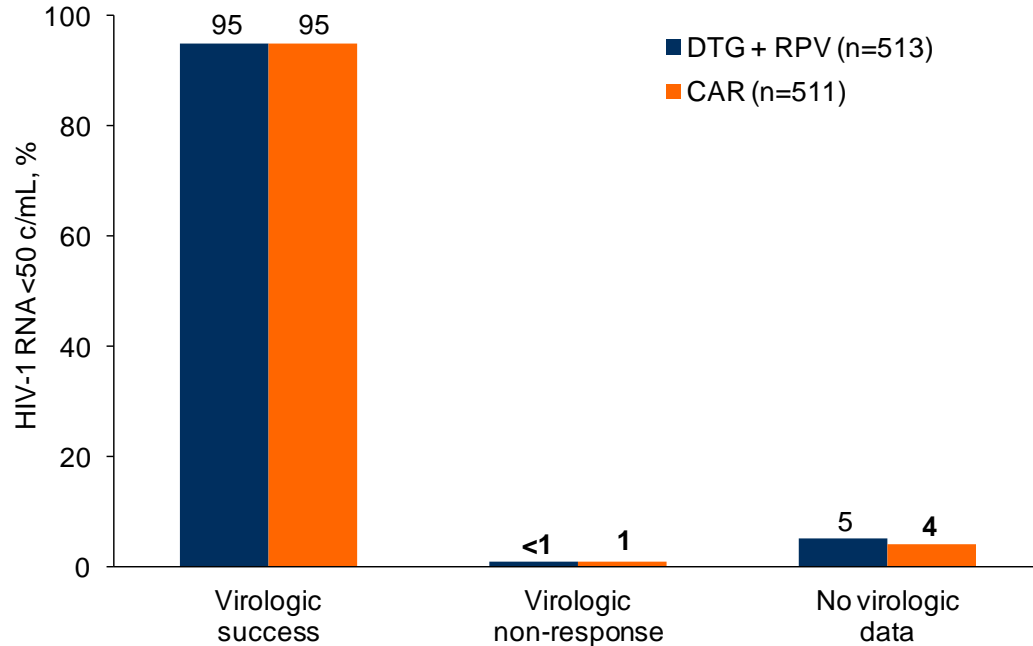
Demographics and Baseline Characteristics^a

	DTG + RPV (n=513) n (%)	CAR (n=511) n (%)
Age, mean (SD)		
≥50 years	43 (11.1)	43 (10.2)
Female	120 (23)	108 (21)
Race, non-white	92 (18)	111 (22)
CD4+ cell count, cells/mm³ (median)	611	638
≤500	165 (32)	149 (29)
>500	348 (68)	362 (71)
Baseline 3rd-agent class		
PI	133 (26)	136 (27)
NNRTI	275 (54)	278 (54)
INI	105 (20)	97 (19)
Baseline TDF use	374 (73)	359 (70)
Duration of ART prior to Day 1, median, months	51	53

^aData pooled across SWORD-1 and SWORD-2.

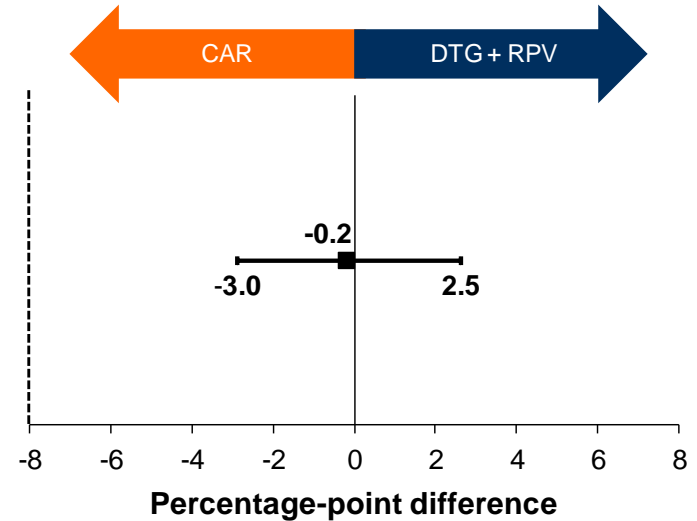
Snapshot Outcomes at Week 48 (Pooled)

Virologic outcomes



^aAdjusted for age and baseline 3rd agent.

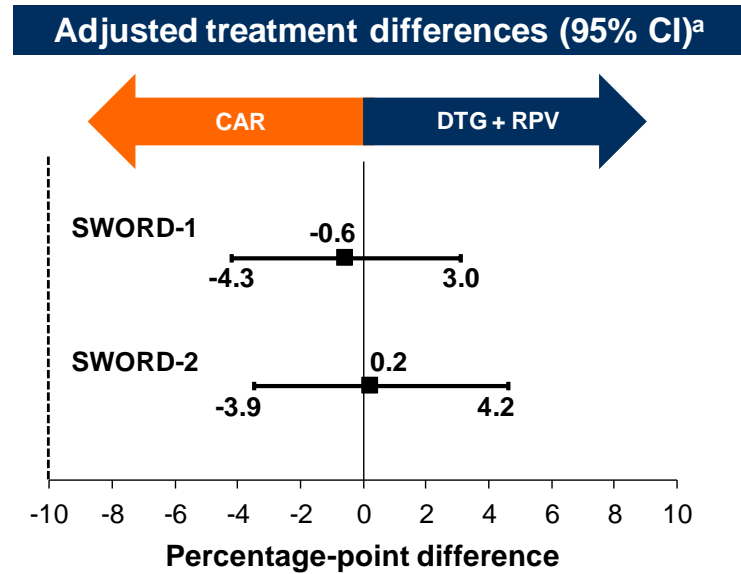
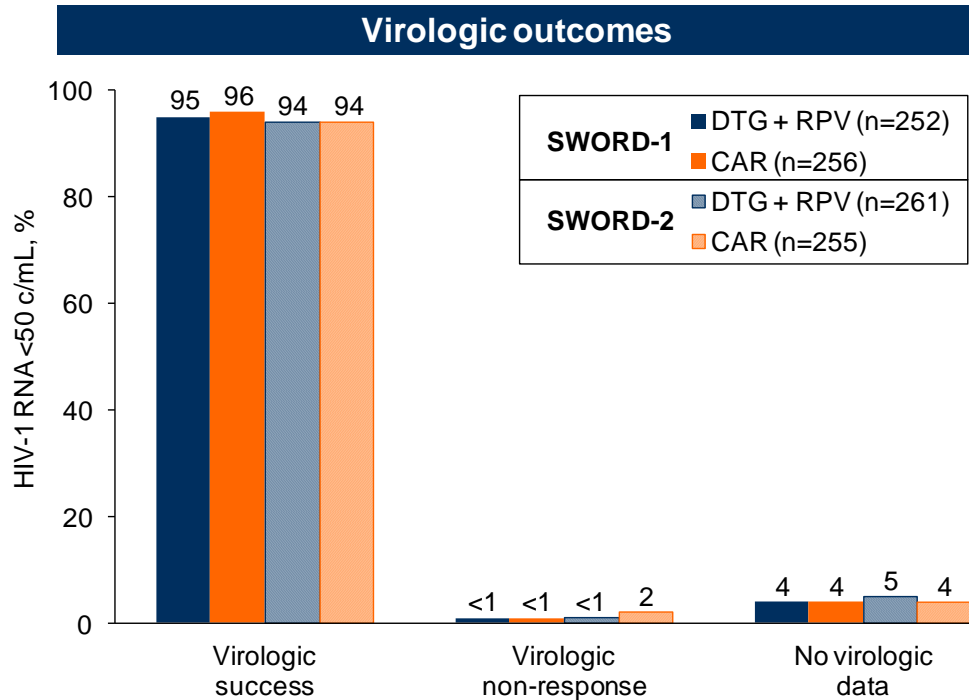
Adjusted treatment difference (95% CI)^a



DTG + RPV is **non-inferior** to CAR with respect to snapshot in the ITT-E population (<50 c/mL) at Week 48

Libre et al. CROI 2017; Seattle, WA. Abstract 2421.

Snapshot Outcomes at Week 48 (SWORD-1&2)



^aAdjusted for age and baseline 3rd agent.

Snapshot Outcomes at Week 48

	Early switch phase ^a	
	DTG + RPV n=513 n (%)	CAR n=511 n (%)
Virologic success	486 (95)	485 (95)
Virologic non-response	3 (<1)	6 (1)
Data in window not <50 c/mL	0	2 (<1)
Discontinued for lack of efficacy	2 (<1)	2 (<1)
Discontinued while VL not <50 c/mL	1 (<1)	1 (<1)
Change in ART	0	1 (<1)
No virologic data	24 (5)	20 (4)
Discontinued due to AE or death ¹	17 (3)	3 (<1)
Discontinued for other reasons	7 (1)	16 (3)
Missing data during window but on study	0	1 (<1)

¹ Two deaths in the study, both unrelated to study drug. DTG+RPV Kaposi's Sarcoma (N=1), CAR Lung cancer (N=1)

^aData pooled across SWORD-1 and SWORD-2.

Confirmed Virologic Withdrawals

	Early switch phase ^a	
	DTG + RPV n=513 n (%)	CAR n=511 n (%)
Confirmed Virologic Withdrawal (CVW) ^b	2 (<1)	2 (<1)

- One subject on DTG + RPV meeting virologic withdrawal criteria had identified an NNRTI resistance–associated mutation (K101K/E)
- No INI resistance–associated mutations were identified

^aData pooled across SWORD-1 and SWORD-2. ^bCVW – Current “retest” HIV-1 RNA ≥ 200 c/mL, prior ≥ 50 c/mL.

Adverse Events with Onset through Week 52

	Early switch phase ^a	
	DTG + RPV (n=513) n (%)	CAR (n=511) n (%)
Any AE	395 (77)	364 (71)
AEs occurring in ≥5% of subjects in either group		
Nasopharyngitis	49 (10)	50 (10)
Headache	41 (8)	23 (5)
Upper respiratory tract infection	24 (5)	37 (7)
Diarrhea	32 (6)	27 (5)
Back pain	15 (3)	31 (6)
Any Serious AEs¹	27 (5)	21 (4)
Drug-related AEs		
Grades 1-2	89 (17)	8 (2)
Grades 3-4	8 (2)	1 (<1)
AEs leading to withdrawal from the study	21 (4)	3 (<1)
CNS AEs leading to withdrawal	9 (2)	1 (<1)

^aData pooled across SWORD-1 and SWORD-2.

¹Two deaths in the study, both unrelated to study drug. DTG+RPV Kaposi's Sarcoma (N=1), CAR Lung cancer (N=1).

Adverse Events Leading to Withdrawal

	DTG + RPV ^{a,b} (n=513) n (%)
Subjects with AEs leading to withdrawal from the study	21 (4)
Events Leading to Withdrawal (subject may report >1 AE)	
Anxiety	4 (<1)
Depression	3 (<1)
Abdominal distention	2 (<1)
Dyspepsia	2 (<1)
Insomnia	2 (<1)
Depressed mood	1 (<1)
Drug-induced liver injury	1 (<1)
Eosinophilic pneumonia, acute	1 (<1)
Gastrointestinal haemorrhage	1 (<1)
Headache	1 (<1)
Hodgkin's disease	1 (<1)
Kaposi's sarcoma	1 (<1)
Pancreatitis, acute	1 (<1)
Panic attack	1 (<1)
Peptic ulcer	1 (<1)
Plasmablastic lymphoma	1 (<1)
Tremor	1 (<1)
Suicidal ideation	1 (<1)

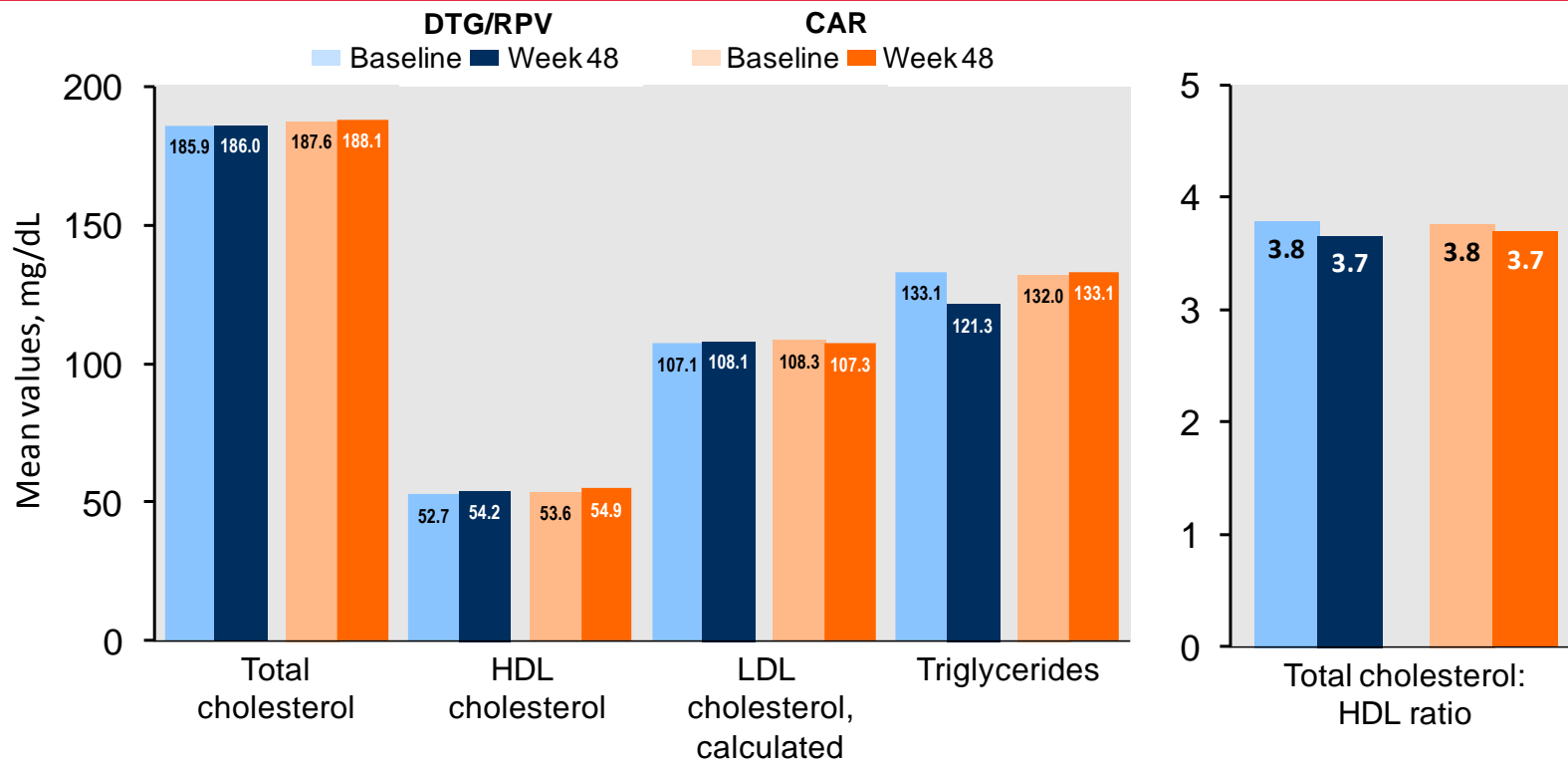
^aData pooled across SWORD-1 and SWORD-2.

^bCAR AEs leading to withdrawal: 1 subject each with lung cancer, breast cancer, suicide attempt.

Libre et al. CROI 2017; Seattle, WA. Abstract 2421.

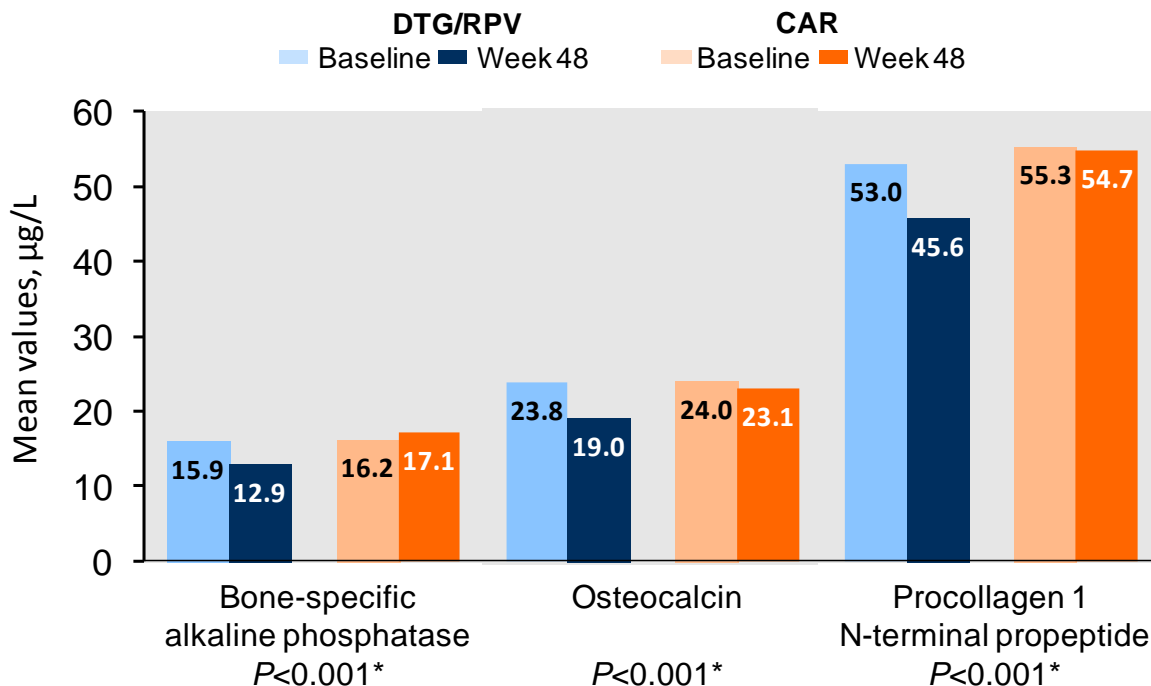
Change in Serum Lipids at Week 48

Pooled Data Early Switch Phase



Change in Bone Markers at Week 48

Pooled Data Early Switch Phase



*Adjusted for baseline third agent, age, sex, body mass index, smoking status, and baseline biomarker level. Statistical model uses log-transformed data.

Conclusions

- A switch to a novel, once-daily 2DR of DTG + RPV demonstrated high efficacy and was non-inferior to the continuation of a 3- or 4DR in virologically suppressed HIV-1–infected adults
- The safety profiles of both DTG and RPV were consistent with their respective labels
- Switching to DTG+RPV had a neutral effect on lipids, while significantly improving bone turnover biomarkers
- These data support the use of DTG+RPV as a 2DR for streamlining therapy for maintenance of suppression
- These data support
 - Regulatory filing for DTG/RPV
 - Exploration of additional regimens in the 2DR paradigm

Emerging clinical support on 2DR



INTERNAL STUDIES

SWORD 1 & 2 (DTG+RPV switch)

GEMINI 1 & 2 (DTG+3TC naïve)

ATLAS & FLAIR (CAB+RPV naïve & switch)

INVESTIGATOR INITIATED STUDIES*

PADDLE 96 weeks (DTG+3TC naïve)

ACTG 5353 (DTG+3TC naïve)

ASPIRE (DTG+3TC switch)

DUALIS (DTG+DRV/r switch)

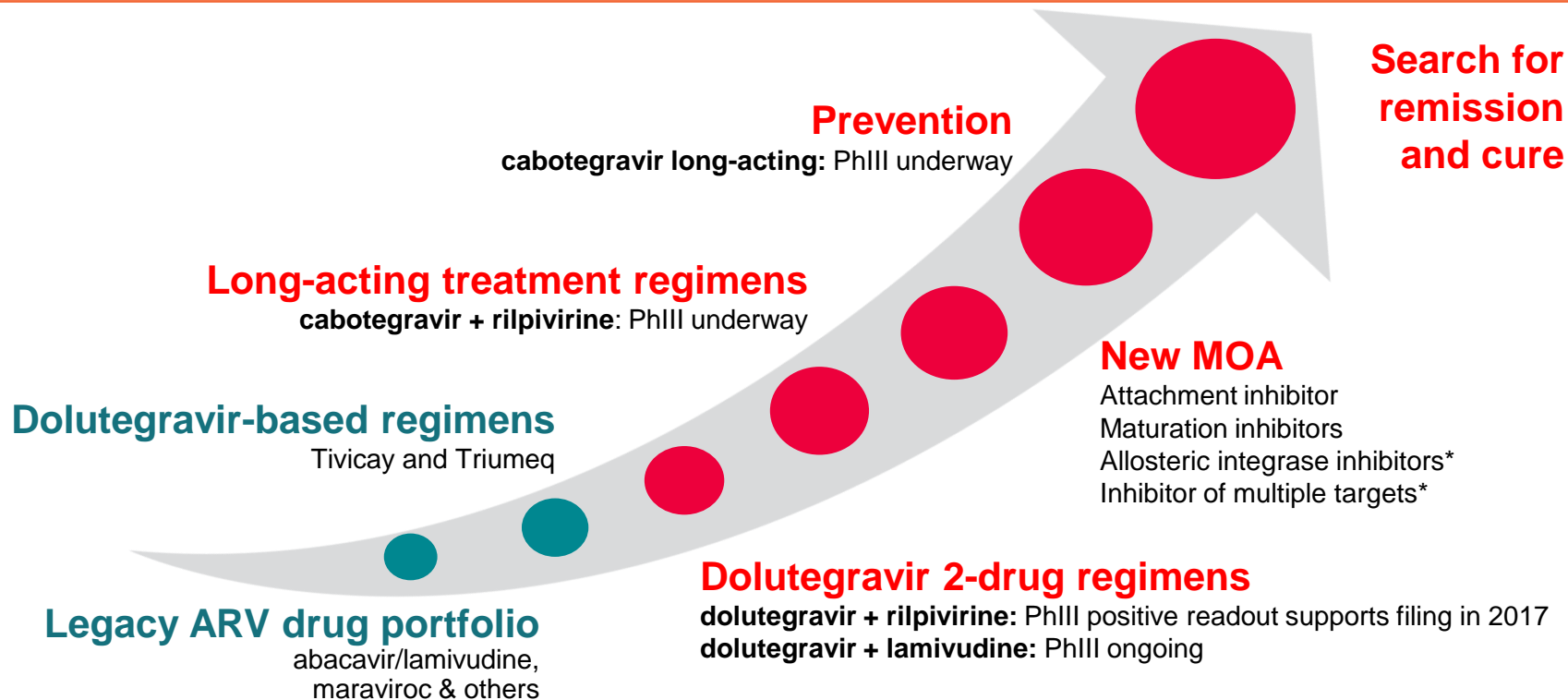
LAMIDOL (DTG+3TC switch)

DOLATAV (DTG+ATV/r naïve)



Next available congress presentation = 

Innovative pipeline addressing unmet patient needs



*Denotes preclinical asset

Ongoing studies: DTG+3TC GEMINI studies started Aug 2016; CAB+RPV ATLAS and FLAIR studies started Nov 2016; CAB monotherapy HPTN083 study started Dec 2016

Two Drug Regimen Phase III treatment study designs

DTG + RPV

Phase III started May 2015



SWORD 1 and 2	
Population	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 millilitre (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	Headlined Dec 2016; Presented Feb 2017
Expected filing date (STR)	H1 2017

DTG + 3TC

Phase III started August 2016



GEMINI 1 and 2	
Population	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 versus DTG + TDF/FTC over 148 weeks in patients with a screening HIV-1 RNA of 1,000 to $\leq 500,000$ copies/mL (c/mL)*.
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 filing date (STR)	2018

*~93% of the HIV-1 patient population has RNA levels between 1,000 and 500,000 copies/ml. Based on GSK data on file.

CAB + RPV

Phase III started November 2016



FLAIR and ATLAS	
Population	Maintenance therapy for adult patients with HIV-1 infection
Number of patients	1,200 virologically suppressed patients
FLAIR study design	<p>Phase III, randomised, open-label, multicentre, parallel-group, non-inferiority study designed to assess the antiviral activity and safety of a 2-drug regimen of intramuscular, long-acting, injectable cabotegravir and rilpivirine in treatment-naïve adults living with HIV.</p> <p>The primary endpoint is the proportion of participants with a ‘virologic failure’ endpoint as per FDA Snapshot algorithm at week 48 (Missing, Switch, or Discontinuation = Failure, Intent-to-Treat Exposed [ITT-E] population). 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.</p>
ATLAS study design	<p>Phase III, open-label, active-controlled, multicentre, parallel-group, non-inferiority study designed to assess the antiviral activity and safety of a 2-drug regimen of long-acting, injectable cabotegravir and rilpivirine dosed every 4 weeks, compared to continuation of current ART of two NRTI plus an INSTI, NNRTI, or PI.</p> <p>The primary endpoint for ATLAS is the proportion of participants with a ‘virologic failure’ endpoint as per FDA Snapshot algorithm at Week 48 (Missing, Switch, or Discontinuation = Failure, ITT-E population).</p>
Expected readout date	2018
Expected filing date	2019

Q&A