

1st Quarter of Fiscal 2019 Financial Results

Conference Call

July 29, 2019

SHIONOGI

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1. Overview of Q1 FY2019 Financial Results

Q1 FY2019 Financial Results

1. **Overview of Q1 FY2019 Financial Results**
2. **Actions and Progress in Q1 FY2019**

Financial Results (Consolidated)

(Unit: B yen)

	FY2019				FY2018	Y on Y	
	Forecasts		Apr.-Jun. results	Progress vs. forecasts	Apr.-Jun. results	Change (%)	Change (B yen)
	Full year	1H					
Sales	365.5	159.0	**79.2**	49.8%	88.5	(10.5%)	(9.3)
Operating income	147.0	52.0	**29.0**	55.7%	27.6	4.7%	1.3
Ordinary income	170.5	63.0	**32.4**	51.4%	37.9	(14.6%)	(5.5)
Profit attributable to owners of parent	133.0	49.0	**24.4**	49.8%	31.9	(23.4%)	(7.5)

- **Sales and each profit measure have smoothly progressed toward 1H forecasts**
- **Operating income was higher than that in Apr.-Jun. FY2018**

Exchange Rate (average)	FY2019 forecasts	FY2019 Apr.-Jun. results
USD ($) – JPY (¥)	110.0	**109.91**
GBP (£) – JPY (¥)	145.0	**141.18**
EUR (€) – JPY (¥)	130.0	**123.50**

Statement of Income

(Unit: B yen)

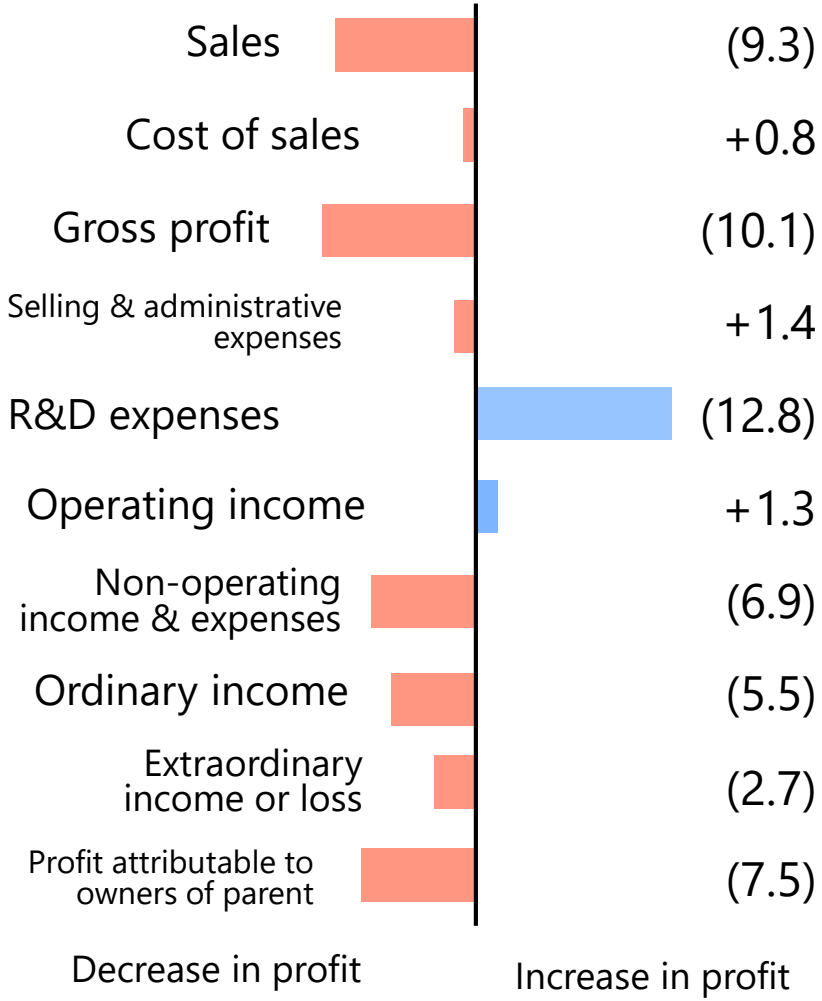
	FY2019 Forecasts Full year	FY2019 Forecasts 1H	FY2019 Apr.-Jun. results	Achievement (%)	FY2019 Apr.-Jun. results	Y on Y Change (%)	Y on Y Change (B yen)
Sales	**365.5**	**159.0**	**79.2**	49.8	88.5	(10.5)	(9.3)
	14.6	16.0	16.1		13.5		
Cost of sales	**53.5**	**25.5**	**12.7**	49.9	11.9	6.9	0.8
Gross profit	**312.0**	**133.5**	**66.5**	49.8	76.6	(13.2)	(10.1)
	45.1	51.3	47.4		55.3		
SG&A expenses	**165.0**	**81.5**	**37.5**	46.1	49.0	(23.3)	(11.4)
	31.6	35.5	32.4		27.4		
Selling & administrative expenses	**115.5**	**56.4**	**25.7**	45.5	24.3	5.8	1.4
	13.5	15.8	15.0		27.9		
R&D expenses	**49.5**	**25.1**	**11.9**	47.3	24.7	(51.9)	(12.8)
Ordinary R&D expenses *	**49.5**	**25.1**	**11.9**	47.3	13.7	(13.2)	(1.8)
Strategic investment	**-**	**-**	**-**	-	11.0	-	(11.0)
	40.2	32.7	36.6		31.2		
Operating income	**147.0**	**52.0**	**29.0**	55.7	27.6	4.7	1.3
Non-operating income & expenses	**23.5**	**11.0**	**3.4**	31.3	10.3	(66.6)	(6.9)
	46.6	39.6	40.9		42.9		
Ordinary income	**170.5**	**63.0**	**32.4**	51.4	37.9	(14.6)	(5.5)
Profit attributable to owners of parent	**133.0**	**49.0**	**24.4**	49.8	31.9	(23.4)	(7.5)

* Ordinary R&D expenses: Total R&D expenses excluding strategic investment

Y on Y Comparison and Main Variation Factors (Statements of Income)

- **Y on Y comparison**

(Unit: B yen)



Main Variation Factors (Y on Y)

- **Sales**
  - FY2018: Income from Roche for Xofluza™*
- **Cost of sales**
  - Sales growth of drugs
- **SG & A expenses**
  - **Selling & administrative expenses**
    - › Increase according to sales growth of drugs
  - **R&D expenses**
    - › FY2018: Strategic investment (11.0 B yen)
- **Non-operating income & expenses**
  - FY2018: One-time dividend from ViiV
  - Exchange-rate fluctuations
- **Extraordinary income or loss**
  - FY2018: Sale of the Nanjing factory of C&O in China

* Royalty income from Roche as milestones of R&D achievement

Sales by Segment

(Unit: B yen)

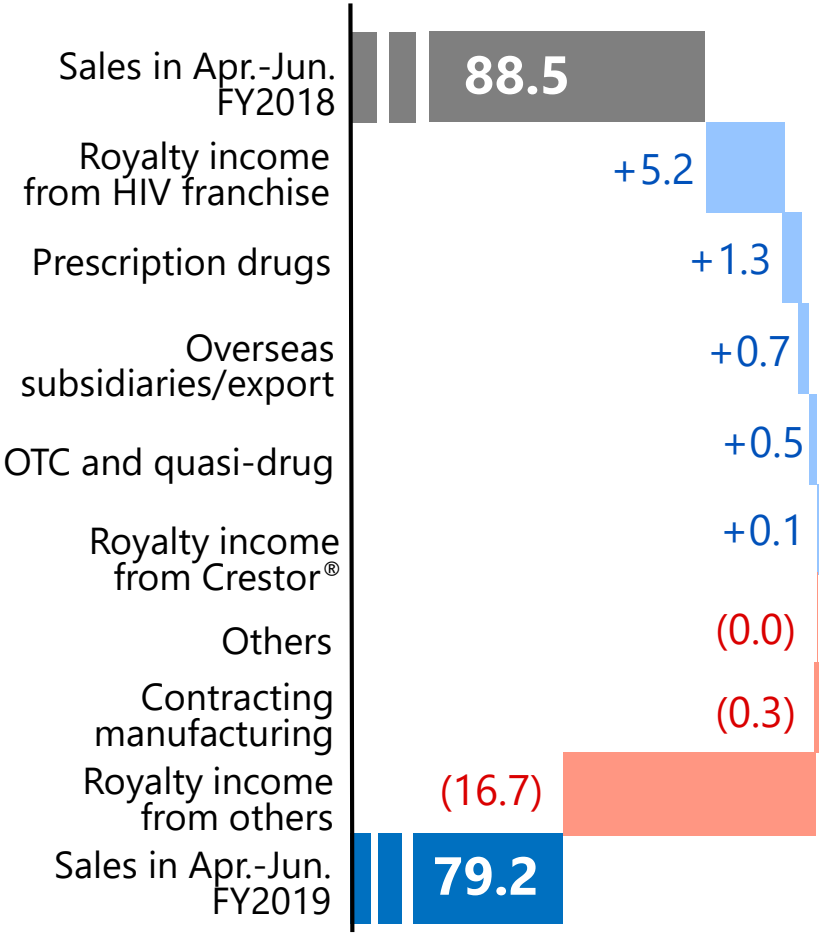
	FY2019				FY2018	Y on Y	
	Forecasts*		Apr.-Jun. results	Achievement (%)	Apr.-Jun. results	Change (%)	Change (B yen)
	Full year	1H					
Prescription drugs	**144.1**	**53.7**	**26.7**	49.7	25.4	5.0	1.3
Overseas subsidiaries/export	**31.4**	**16.0**	**10.6**	66.6	9.9	7.4	0.7
Shionogi Inc.	**9.9**	**6.3**	**5.2**	83.3	6.1	(14.0)	(0.9)
Mulpleta®	**1.0**	**0.25**	**0.15**	61.2	-*	-	0.2
C&O	**14.6**	**6.8**	**3.8**	55.2	2.3	61.1	1.4
Contract manufacturing	**14.3**	**9.1**	**2.4**	27.0	2.8	(12.1)	(0.3)
OTC and quasi-drug	**9.7**	**4.6**	**2.1**	44.5	1.6	29.4	0.5
Royalty income	**163.6**	**74.3**	**36.9**	49.6	48.3	(23.6)	(11.4)
HIV franchise	**126.5**	**61.3**	**29.7**	48.5	24.5	21.4	5.2
Crestor®	**22.0**	**11.0**	**5.6**	50.5	5.5	1.1	0.1
Others	**15.1**	**2.1**	**1.6**	79.1	18.3	(91.0)	(16.7)
Others	**2.4**	**1.2**	**0.54**	45.0	0.58	(5.9)	(0.0)
Total	**365.5**	**159.0**	**79.2**	**49.8**	88.5	**(10.5)**	**(9.3)**

*The full-scale promotion was initiated in Dec. 2018.

Y on Y Comparison and Main Variation Factors (Sales by Segment)

- **Y on Y comparison**

(Unit: B yen)



Main Variation Factors Occurring in Apr.-Jun. (Y on Y)

- **Royalty income**
  (Increase factor)
  - <HIV franchise> Sales growth and termination of the threshold period

  (Decrease factor)
  - <Others> FY2018: Income from Roche for Xofluza™*
- **Prescription drugs**
  - Sales increase of Cymbalta® and Intuniv®
- **Overseas subsidiaries/export**
  - C&O: Sales increase of Rabeprazole

* Royalty income from Roche as milestones of R&D achievement

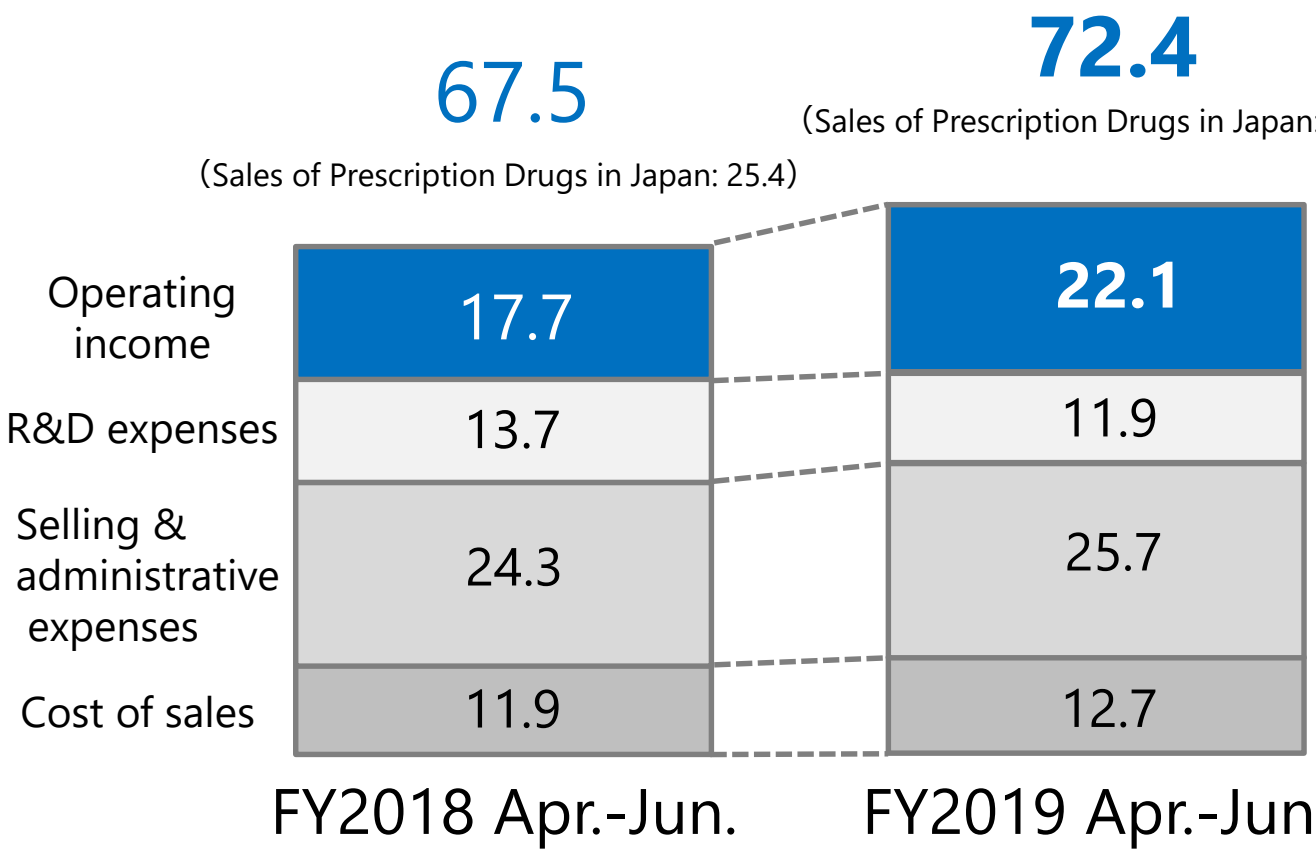
Sales of Prescription Drugs in Japan

(Unit: B yen)

	FY2019				FY2018	Y on Y	
	Forecasts		Apr.-Jun. results	Achievement (%)	Apr.-Jun. results	Change (%)	Change (B yen)
	Full year	1H					
Cymbalta®	29.3	13.0	6.7	51.6	6.1	10.3	0.6
Intuniv®	13.6	4.6	1.8	39.9	1.1	65.6	0.7
Xofluza®	28.0	0.28	0.00	0.0	0.03	(100.0)	(0.0)
Rapiacta®	2.6	0.05	0.00	2.6	0.01	(89.4)	(0.0)
Brightpoc® Flu	1.8	0.18	0.01	5.1	0.01	97.7	0.0
Total of strategic products	75.7	18.2	8.6	47.1	7.3	18.1	1.3
OxyContin® franchise	6.7	3.6	1.7	46.7	2.0	(15.5)	(0.3)
Symproic®	2.3	1.1	0.53	48.6	0.31	70.6	0.2
Actair®	0.27	0.12	0.06	45.8	0.04	42.1	0.0
Mulpleta®	0.33	0.17	0.03	19.7	0.05	(31.2)	(0.0)
Pirespa®	6.9	3.5	1.7	49.8	1.4	26.2	0.4
Total of new products	92.2	26.7	12.6	47.3	11.0	14.4	1.6
Crestor®	10.0	5.2	2.4	46.9	2.6	(7.8)	(0.2)
Irbetan® franchise	4.9	2.6	1.2	47.0	1.9	(35.5)	(0.7)
Others	36.9	19.2	10.4	54.0	9.8	5.8	0.6
Prescription drugs	**144.1**	**53.7**	**26.7**	**49.7**	25.4	**5.0**	**1.3**

Year-On-Year Comparisons Excluding One-time Factors

Sales (Unit: B yen)



<Main One-time Factors>

FY2018：
- Income from Roche for Xofluza™*
- One-time payment from Purdue
- Strategic investment

FY2019：
- Termination of the threshold period for the calculation of royalty payment of HIV franchise by ViiV
- One-time payment from BDSI*

Our business is progressing steadily including the sales of new products, excluding one-time factors

* BioDelivery Sciences International Inc.

2. Actions and Progress in Q1 FY2019

1st Quarter of Fiscal 2019 Financial Results

1. Overview of Q1 FY2019 Financial Results
2. **Actions and Progress in Q1 FY2019**

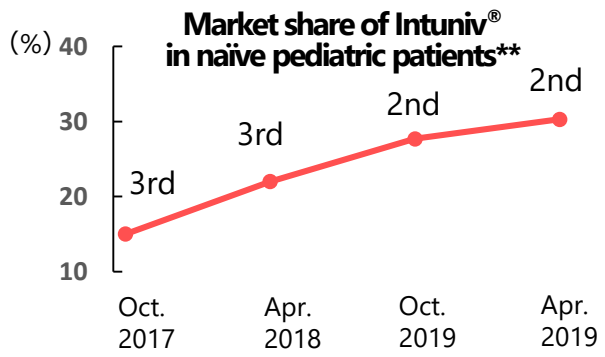
Progress in Growth of Strategic Products

Cymbalta®

- **Smooth progress in the achievement of FY2019 targets with focused resources (Q1: Progress vs. 1H FY2019 forecasts was more than 50%)**
- Effectively communicated that the analgesic effects of Cymbalta® are direct, rather than through the mediation of its antidepressant effects, resulting in recommendations in guidelines
  - **Guidelines for the Management of Low Back Pain 2019 (issued in May 2019): recommended as an analgesic for the treatment of both Chronic low back pain and Sciatic nerve pain***
  - Guidelines for the treatment of Chronic Pain (issued in March 2018): recommended as an analgesic for the treatment of both Musculoskeletal pain and Neuropathic pain*

ADHD family (Intuniv® , Vyvanse®)

- **Intuniv®: Growth for first-line drug**
  - **Pediatric patients:**
    - > Maintained top share in switch and add-on patient market
    - > Aim to expand share in naïve patient market by making the mechanism and efficacy fully understood
  - **Adult patients:**
    - > **Supplementally approved for the treatment of adult patients on Jul. 18, 2019**
    - > Immediately increase market share for adult patients, which is as large as pediatric market, by communicating the profile of Intuniv®



- **Vyvanse®: Preparation for proper use after the launch**
  - Promoting understanding of the efficacy and safety profile and establishing distribution management system

*Indication: Pain due to diabetic neuropathy, fibromyalgia, chronic low back pain, or osteoarthritis

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Progress in Growth of Strategic Products

XOFLUZA™

- BLOCKSTONE study:
  XOFLUZA™ showed a significant prophylactic effect against influenza infection after a single oral dose in people exposed to an infected family member during a 10 days observation period.
- Collection and analysis of the data regarding PA/I38 variants for 2019/2020 season.

Status	Clinical assessments	(★) Data to be shown prior to 2019/2020 flu season	Presentation schedule
Ongoing	**Additional analysis for the completed clinical studies** • Including next generation sequencing	Additional analysis on PA/I38 variants for the completed clinical studies (CAPSTONE-1, CAPSTONE-2, pediatric studies). (★)	**CAPSTONE-1: ECCMID (done)** **CAPSTONE-2 and pediatric study: OPTIONS X**
Ongoing	**Post exposure prophylaxis**	Assessing prophylactic efficacy of baloxavir and the risk of transmission of PA/I38 variants. (★)	**OPTIONS X or IDWeek**
Ongoing	**Drug susceptibility surveillance**	Resistance monitoring in the clinical setting. (★)	**OPTIONS X**
Ongoing	**Global pediatric patients**	Assessing safety, efficacy and pharmacokinetics of baloxavir compared with oseltamivir, including the emergence of PA/I38 variants. (★)	**OPTIONS X**
Ongoing	**Pediatric studies at higher doses**	Assesses safety, PK and efficacy at higher dose.	To be determined
Ongoing	**Severely ill & hospitalized patients**	Explores combination therapy with NAIs and multiple dosing in hospitalized patients.	To be determined
Planned	**Reduced transmission**	Clinical assessment for reduced transmission to household contacts from patients treated with baloxavir and possible risk of transmission of PA/I38 variants.	To be determined

Status	Non-clinical assessment		Presentation schedule
Ongoing	**Transmission study in ferret models**	Explores effect of baloxavir on transmission and assess risk of transmission of I38 variants in ferrets	To be determined

ECCMID: Apr.13-16, 2019
OPTIONS X: Aug. 29-Sep 1, 2019
IDWeek: Oct. 2-9, 2019

HIV Franchise: Progress of 2-Drug Regimens

Tivicay®, Triumeq® **Launch: 2013~**
Key drug for 3-drug regimen

Juluca® (DTG/RPV) **Launch: 2017~**
First 2-drug regimen for switch patients

Dovato® (DTG/3TC) **Launch: 2019~**
First 2-drug regimen for naïve patients
- Sep. 2018: MAA submission in EU (naïve patients)
- Apr. 2019: Approved in US (naïve patients)
- **Jul. 2019: Approved in EU (naïve and switch patients)**
- **Jul. 2019: TANGO 48-week positive results (switch patients)**
  GEMINI 96-week positive results (naïve patients)

Oct. to Dec. 2019: Start SALSA (switch patients)

CAB+RPV **Launch: early 2020~**
- **First long acting injection** (monthly or bimonthly)
- Apr. 2019: NDA submission in US (monthly injection)
  PDUFA date: Dec. 29, 2019 (priority review designated)
- Jul. to Sep. 2019: MAA submission in EU (monthly injection)
  : ATLAS 2M results (bimonthly injection for switch patients)

CAB prophylaxis **Launch: 2021~**
- **First long-acting injectable for prophylaxis** (bimonthly injection)

Progress from May 10, 2019 to Jul. 29. 2019

DTG: dolutegravir, RPV: rilpivirine, 3TC: lamivudine , CAB: cabotegravir

HIV Franchise: Dovato® (DTG/3TC)

*Source: ViiV Healthcare analyst call**

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)

Dovato® meets needs of patients who worry about the impact of long-term treatment and/or the number of drugs

72% PLHIV worry about long-term effects of HIV treatments[1]

56% PLHIV would consider reducing the number of drugs in their regimen to the minimum[1]

1 Positive Perspectives survey, 2017 DOF. MarcotullioS, et al. EACS 2017, poster PE25/9

Successful progress of clinical studies

<GEMINI-1&2 96-week>

◆ **Outline of study design**

- Efficacy and safety profiles were **compared between DTG+3TC and DTG+TDF/FTC in naïve patients** .

◆ **Outline of study results**

- Efficacy: **Non-inferiority to DTG+TDF/FTC** was maintained.
- Resistance: **No cases of treatment emergent resistance**
- Safety: Drug-related AEs occurred less frequently in patients treated with DTG+3TC.

<TANGO 48-week>

◆ **Outline of study design**

- Efficacy and safety profiles were compared between patients who switched from TAF-containing regimen of at least 3 drugs to DTG/3TC and patients who maintained TAF-containing regimen.

◆ **Outline of study results**

- Efficacy: **Non-inferiority to TAF-containing regimen**
- Resistance: **No cases of treatment emergent resistance**
- Safety: Consistent with the product labelling

Efficacy of Dovato® was non-inferior to 3 drug regimen, and no cases of treatment emergent resistance was observed after 2-year treatment

*ViiV Healthcare analyst call on Apr 30, 2019 https://www.gsk.com/media/5411/fuelling-our-future-growth-slides.pdf

Appendix

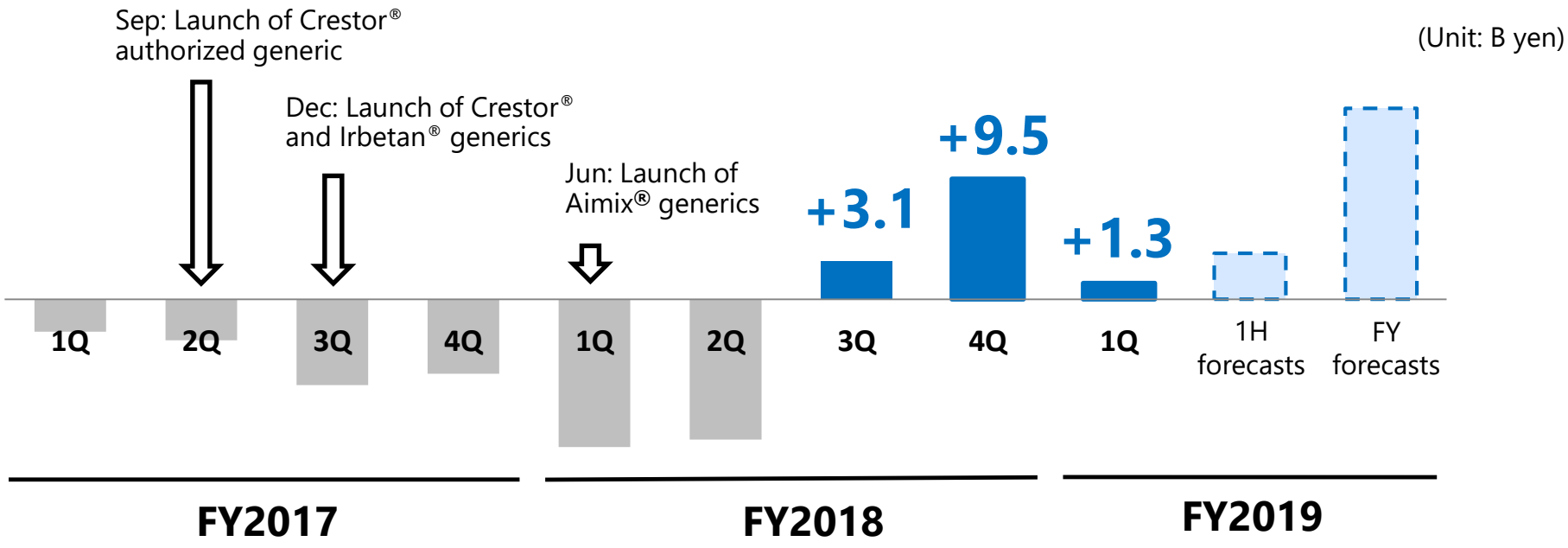
- Japanese Business: Sales Y on Y Comparison -
- Financial Statements (Consolidated) -
- Major progress in Q1 FY2019 -
- Target Milestones for FY2019 -
- Progress of Pipeline -
- Target Milestones for Launch of Products -
- Definition of New Products -
- Conference Presentation Slides by ViiV –
- Shionogi Pharma -

Japanese Business: Sales Y on Y Comparison

Sales of prescription drugs in Japan (Y on Y comparison)

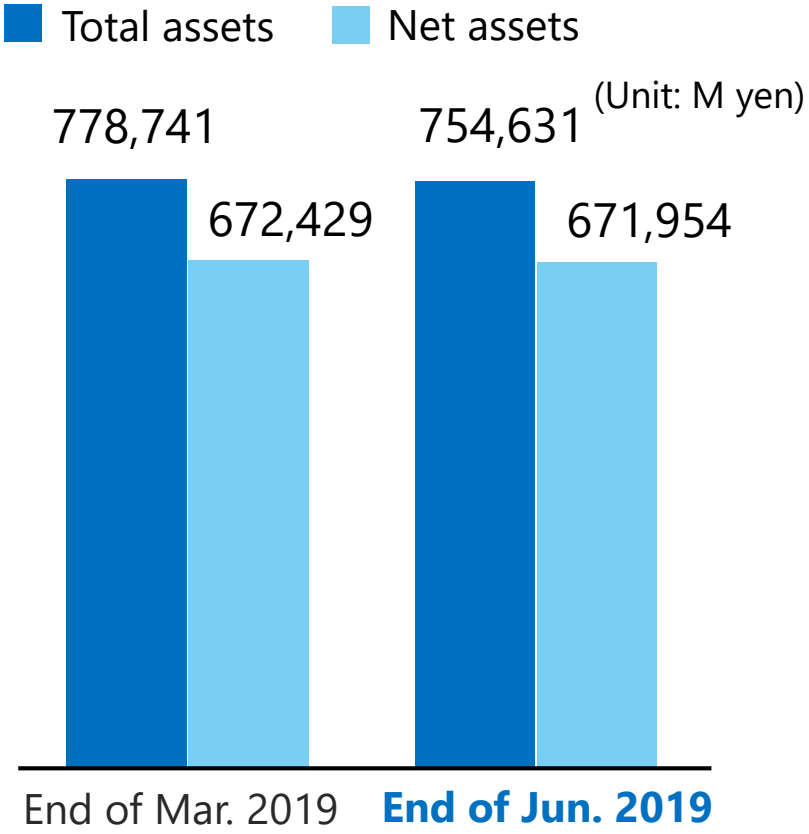
The impact of share capture by generic competitors hit a plateau in 1H FY2018

Sales-growth phase by our own earning power



Achieved profit increase for three consecutive quarters

Financial Statements (Consolidated)



Unit: M yen		End of Mar. 2019	End of Jun. 2019	Change
Total assets	Current assets	461,743	443,535	(18,207)
	Non-current assets	316,997	311,096	(5,901)
Liabilities	Current liabilities	89,107	64,855	(24,252)
	Non-current liabilities	17,203	17,822	618
Net assets	Shareholders' equity	652,371	661,332	8,960
	Others	20,058	10,622	(9,436)

	End of Mar. 2019	End of Jul. 2019
Shareholders' equity ratio	85.7%	**88.4%**

Major Progress in Q1 FY2019* (Pipeline)

	Phase I	Phase II	Phase III	Submission	Approval, Launch
Global					
In Japan			**Xofluza™** ・Positive top-line results in prophylaxis study		**Intuniv®** ・Supplementally approval for adult patients
Out-licensed			**DOVATO®** ・Positive results in TANGO (48-week treatment for experienced patients)		**DOVATO®** ・Approval in EU (naïve and experienced patients)

Infections disease
Pain/CNS
Frontier

* Progress from May 10, 2019 to Jul. 29. 2019
DTG: dolutegravir 3TC: lamivudine

Major Progress in Q1 FY2019* (Others)

- **May**
  - Contract agreement with Molteni for the commercialization of Rizmoic® (naldemedine), an opioid-induced constipation therapeutic agent in Italy and Poland
- **June**
  - Purchase all outstanding shares of Pionnier following the conclusion of the joint study
  - Contract agreement with Ferrer for the commercialization of Rizmoic® (naldemedine), an opioid-induced constipation therapeutic agent in Spain
  - Out-licensing agreements with Eddingpharm and EOC Pharma for lusutrombopag, a thrombopoietin receptor agonist and Epertinib, an HER2/EGFR Inhibitor
- **July**
  - Out-licensing agreement with AMR Centre on COT-143, a humanized monoclonal antibody targeting the PcrV protein of *Pseudomonas aeruginosa*

* Progress from May 10, 2019 to Jul. 29, 2019

Target Milestones for FY2019 : Approval and Submission

Product (indication)	Phase I	Phase II	Phase III	Submission	Approval
Vyvanse® (ADHD(pediatric))			**Achieved** (Mar.)	Japan(2017.4)	Japan
Intuniv® (ADHD(adult))			**Achieved** (Jul.)	Japan(2018.8)	Japan
Cefiderocol (US: Complicated urinary tract infections, including pyelonephritis , EU: Multidrug-resistant Gram-negative bacterial infections)	CR study: completion of enrolment HAP/VAP/HCAP study: completion of enrolment		Global: CR study completion Global: HAP/VAP/HCAP study completion	US(2018.12) EU(2019.3)	US EU
Xofluza® (Influenza virus infection) ①granule (weight under 20kg) ②granule (new dosage for children (weight under 20kg) ③prophylaxis	Prophylaxis study: top-line results has been disclosed		Japan： High-dose study for children completion Prophylaxis study completion	①Japan(2018.8) ②Japan ③Japan	①Japan
OxyContin®TR (Treatment of moderate to severe chronic pain)	**Achieved** (May)		Japan： completion	Japan	

Target Milestones for FY2019 : Phase I~III

Product (indication)	Phase I	Phase II	Phase III	Submission	Approval
S-812217 (Depression)	Japan: Single and multiple dose study completion	Completion of enrolment ⇨	Japan: initiate		
Rizmoic® (Opioid-induced constipation(pediatric))	EU: Phase I/II study Initiate				
Cefiderocol (Multidrug-resistant Gram-negative bacterial infections(pediatric))			Global: Safety and PK study initiate		
S-600918 (Neuropathic pain or Refractory Chronic Cough)		Japan: POC* study completion Global: Dose-finding Study initiate			
SR-0379 (Skin ulcers (Pressure ulcers, diabetic ulcers, etc))	Completion of enrolment	Japan: POC* study completion			
S-770108 (Idiopathic Pulmonary Fibrosis)	UK: Lung deposition study initiate				

* Proof of concept ⇨ Planned

Target Milestones for FY2019 : Phase I~III

Product (indication)	Phase I	Phase II	Phase III	Submission	Approval
S-005151 (stroke)	Japan：Study in Healthy adults (Including the elderly) completion	Japan：initiate	Achieved (Q1)		
S-637880 (Neuropathic pain)	Japan：Multiple dose study completion	Global：initiate			
Naldemedine (POI*)		Global：initiate			
Novel HIV Drug (HIV virus infection)	US：initiate				
SDT-001 (ADHD)		Japan：initiate			

* Post operative ileus

Planned

Completed

Pipeline (as of Jul. 29, 2019)

SONG for you!

Preclinical (target indication*)	Phase I	Phase II	Phase III	Submission
Influenza virus infection	**Global**			
HIV virus infection	**S-004992**** Tuberculosis	**S-120083** Inflammatory pain	**Cefiderocol** Multidrug-resistant Gram-negative bacterial infections	**Cefiderocol (US)** Complicated Urinary Tract Infections (cUTI), including Pyelonephritis
RS virus infection	**S-117957** Insomnia	**S-707106** Type2 diabetes		**Cefiderocol (EU)** Multidrug-resistant Gram-negative bacterial infections
Bacterial infection	**S-237648** Obesity	**S-488210** Head and neck squamous cell carcinoma		**Baloxavir Marboxil (Taiwan)** Influenza virus infection
Mycobacterium disease	**S-588210** Solid tumor	**epertinib** Malignant tumor		
Fungus infection	**Rizmoic®** Opioid-induced constipation (pediatric)	**S-588410** Bladder cancer		
Vaccine for prevention				
Peptide	**In Japan**			
ADHD	**S-812217** Depression	**Cefiderocol** Multidrug-resistant Gram-negative bacterial infections	**Cefiderocol** Multidrug-resistant Gram-negative bacterial infections	**Oxycontin®TR** Moderate to severe chronic pain
Opioid	**S-600918** Neuropathic pain	**S-600918** Refractory/unexpected chronic cough	**Xofluza™** Influenza virus infection (prophylaxis)	
Alzheimer's disease	**S-637880** Neuropathic pain	**S-005151** Acute ischemic stroke	**Xofluza™** Influenza virus infection (New dosage for children)	
Cognitive and memory deficits	**S-010887** Neuropathic pain	**S-237648** Obesity	**Cymbalta®** Depression (pediatric)	
Post-stroke spasticity	**S-770108** Idiopathic pulmonary fibrosis	**S-525606** Allergic rhinitis caused by Japanese cedar allergen	**S-588410** Esophageal cancer	
Peptide		**S-588410** Bladder cancer		
Obesity		**SR-0379** Cutaneous ulcer		
S-723595 NASH		**ADR-001***** Decompensated liver cirrhosis		
Cancer metastasis				
S-540956 Nucleic acid adjuvant				
Peptide				

- **Infectious diseases**
- **Pain/CNS**
- **Other**

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Progress from May 10, 2019 to Jul. 29, 2019

* Target indication may include some projects

** In preparation for Phase I

*** In Phase I/II

Pipeline
- Major Out-Licensed Pipeline (as of Jul. 29, 2019)

Preclinical	Phase I	Phase II	Phase III	Submission
	GSK3342830 Multidrug-resistant Gram-negative bacterial infections		**Dovato®** Treatment for HIV infection TANGO study (maintenance)	**Xofluza™** Influenza virus infection (High risk patients)
			CAB LAP Prevention for HIV infection	**CAB+RPV LAP** Treatment for HIV infection
			Xofluza™ Severe influenza virus infection	
			Xofluza™ Influenza virus infection (pediatric)	

- **Infectious diseases**
- **Pain/CNS**
- **Others**

Stage progression (from Mar. 9 2019)	OxyContin®TR (chronic pain): Phase III→Re-submission (Japan) Intuniv® (adult patients): Submission→Approval (Japan) Dovato®: Submission→Approval (EU)

DTG: dolutegravir 3TC: lamivudine CAB：cabotegravir RPV: rilpivirine

Target Milestones for Launch of Products

FY2017 (Achieved)	FY2018 (Achieved)	FY2019
In Japan		
Symproic® **Intuniv®** ADHD (pediatric) **Oxycodone** Tamper resistant formulation **Actair®** Pediatric allergic rhinitis caused by house-dust mite allergen **Xofluza® (adult, pediatric)**		**Intuniv®** ADHD (adult) **Launched** **Vyvanse®** ADHD (pediatric) **Xofluza® (granule)**
Global		
Symproic® (US)	**Mulpleta®** (US)	**Cefiderocol (US)** **Lusutrombopag (EU)** **Baloxavir marboxil (Taiwan)** **Rizmoic® (EU)**
Out-licensed		
Juluca® (DTG/RPV)(US)	**Juluca® (DTG/RPV)** (EU) **Osphena®** (US) Vaginal dryness associated with postmenopausal VVA **Xofluza™** (US, OwH*)	**Dovato® (DTG/3TC)** (US, EU) **Launched (US)** **CAB+RPV** (US) **Xofluza™** (US, HR**)

DTG: dolutegravir, RPV: rilpivirine, 3TC: lamivudine

*OwH: Otherwise healthy patients ** HR: High risk (patients at high risk for influenza-related complications)

Definition of New Products (in Updates to SGS2020)

Pain/ CNS

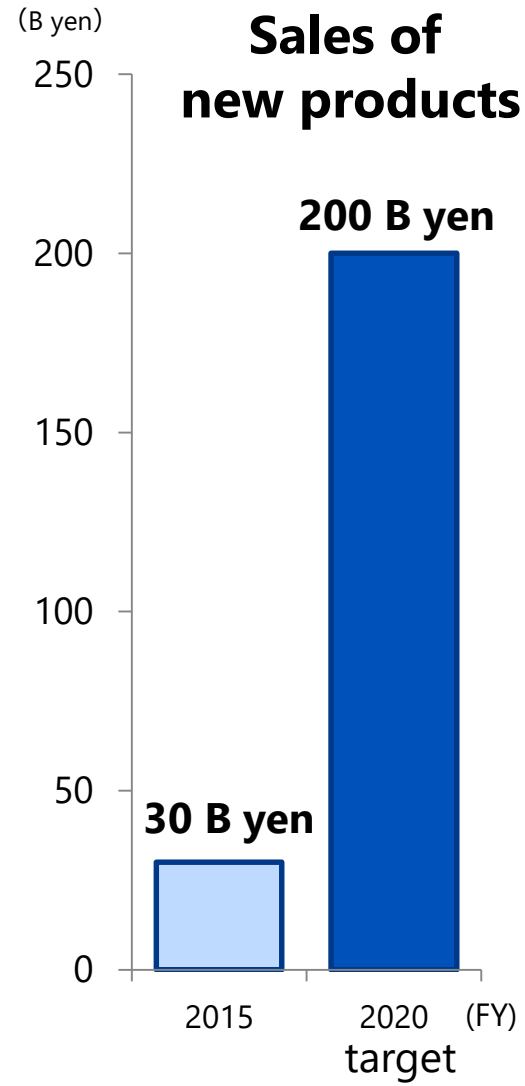
- Cymbalta®
- OxyContin® tamper resistant formulation, OxiNorm®, OxiFast®
- Naldemedine*
- Intuniv®, Vyvanse®

Infectious diseases

- Xofluza™
- Cefiderocol
- Rapiacta®, flu diagnosis kit

Others

- Pirespa®
- Mulpleta®
- Actair®
- Osphena® (Senshio®)



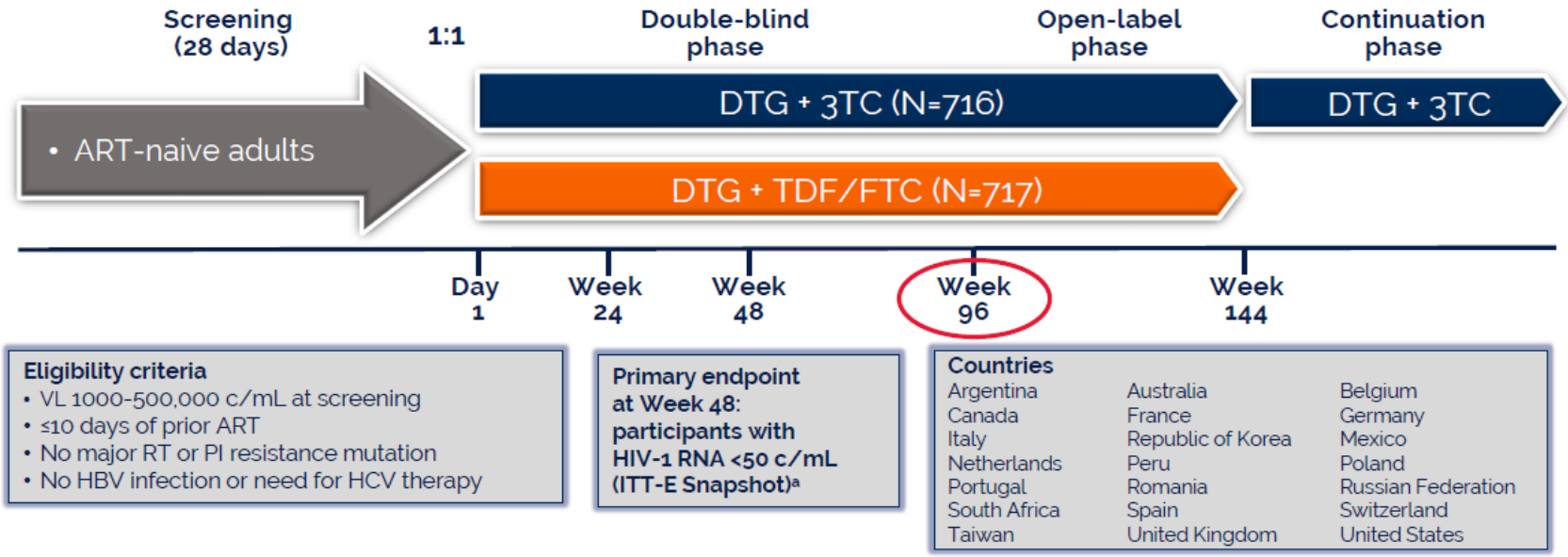
* Product name of naldemedine: Symproic® in Japan and US, Rizmoic ® in EU

GEMINI-1&2 Study Design

Source: Presentation by ViiV at 10th International AIDS Society Conference on HIV Science (IAS 2019) on Jul. 21-24, 2019

GEMINI-1 AND GEMINI-2 PHASE III STUDY DESIGN

Identically designed, randomized, double-blind, parallel-group, multicenter, non-inferiority studies



Eligibility criteria
- VL 1000-500,000 c/mL at screening
- ≤10 days of prior ART
- No major RT or PI resistance mutation
- No HBV infection or need for HCV therapy

Primary endpoint at Week 48: participants with HIV-1 RNA <50 c/mL (ITT-E Snapshot)[a]

Countries

Argentina	Australia	Belgium
Canada	France	Germany
Italy	Republic of Korea	Mexico
Netherlands	Peru	Poland
Portugal	Romania	Russian Federation
South Africa	Spain	Switzerland
Taiwan	United Kingdom	United States

Baseline stratification factors: plasma HIV-1 RNA (≤100,000 vs >100,000 c/mL) and CD4+ cell count (≤200 vs >200 cells/mm^3).

[a]–10% non-inferiority margin for individual studies.

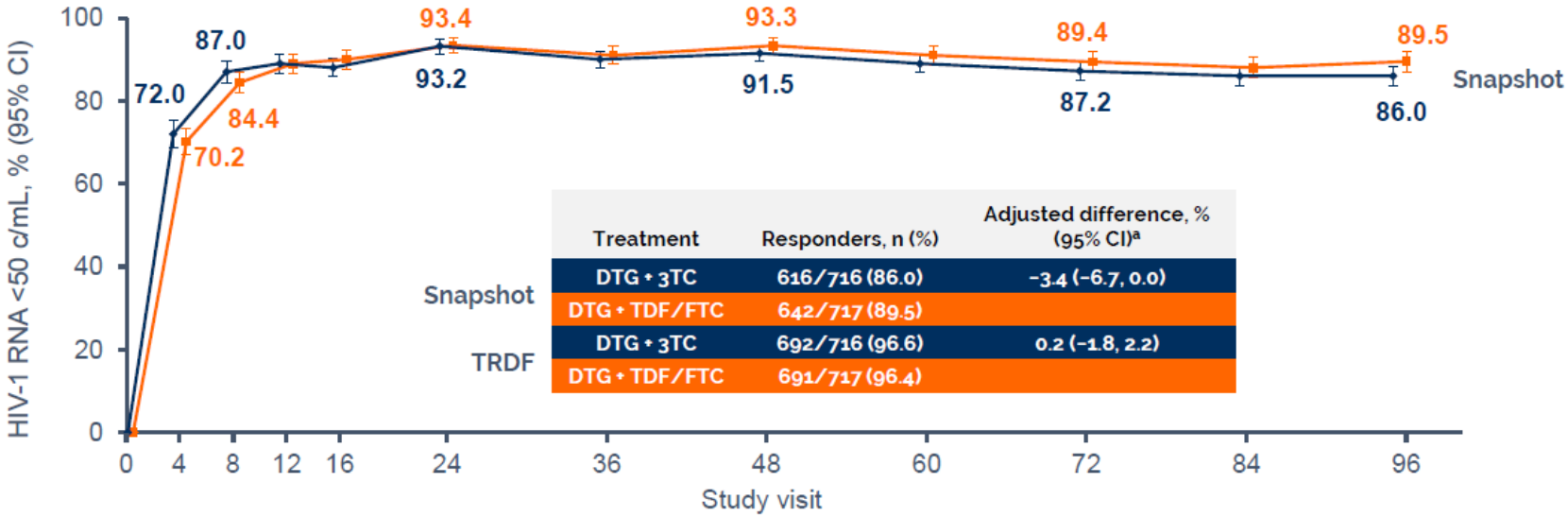
Cahn et al. IAS 2019; Mexico City, Mexico. Slides WEAB0404LB.

DTG: dolutegravir、3TC: lamivudine、TDF: tenofovir disoproxil fumarate、FTC: emtricitabine

GEMINI-1&2 Week 96 Data

Source: Presentation by ViiV at 10th International AIDS Society Conference on HIV Science (IAS 2019) on Jul. 21-24, 2019

DTG + 3TC IS NON-INFERIOR TO DTG + TDF/FTC IN SNAPSHOT HIV-1 RNA <50 C/ML AT WEEK 96



	Treatment	Responders, n (%)	Adjusted difference, % (95% CI)[a]
Snapshot	DTG + 3TC	616/716 (86.0)	−3.4 (−6.7, 0.0)
	DTG + TDF/FTC	642/717 (89.5)	
TRDF	DTG + 3TC	692/716 (96.6)	0.2 (−1.8, 2.2)
	DTG + TDF/FTC	691/717 (96.4)	

- **Non-inferiority criteria were met for GEMINI-1, GEMINI-2, and the pooled analysis**
- **Treatment related discontinuation = failure (TRDF) population accounts for confirmed virologic withdrawal, withdrawal due to lack of efficacy, withdrawal due to treatment-related AE, and participants who met protocol-defined stopping criteria**

[a]Based on Cochran-Mantel-Haenszel stratified analysis adjusting for the following baseline stratification factors: plasma HIV-1 RNA (≤100,000 vs >100,000 c/mL), CD4+ cell count (≤200 vs >200 cells/mm³), and study (GEMINI-1 vs GEMINI-2). The upper limit of the 95% CI for the pooled analysis was 0.0007%. TRDF (unadjusted difference) was a pre-planned analysis at Week 96.
[b]In GEMINI-1, HIV-1 RNA <50 c/mL (95% CI) was achieved in 300/356 participants (84.3% [80.5-88.1]) in the DTG + 3TC group and 320/358 (89.4% [86.2-92.6]) in the DTG + TDF/FTC group (adjusted treatment difference [95% CI], −4.9% [−9.8, 0.03]). In GEMINI-2, the corresponding values were 316/360 (87.8% [84.4-91.2]) and 322/359 (89.7% [86.5-92.8]), respectively (adjusted treatment difference [95% CI], −1.8% [−6.4, 2.7]).

Cahn et al. IAS 2019; Mexico City, Mexico. Slides WEAB0404LB.

GEMINI-1&2 Week 96 Data

Source: Presentation by ViiV at 10th International AIDS Society Conference on HIV Science (IAS 2019) on Jul. 21-24, 2019

NO TREATMENT-EMERGENT RESISTANCE WAS OBSERVED AMONG PARTICIPANTS WHO MET CONFIRMED VIROLOGIC WITHDRAWAL CRITERIA

		GEMINI-1		GEMINI-2		Pooled	
	Variable, n (%)	DTG + 3TC (N=356)	DTG + TDF/FTC (N=358)	DTG + 3TC (N=360)	DTG + TDF/FTC (N=359)	DTG + 3TC (N=716)	DTG + TDF/FTC (N=717)
Week 48	CVW	4 (1.1)	2 (0.6)	2 (0.6)	2 (0.6)	6 (0.8)	4 (0.6)
Week 96	CVW	5 (1.4)	4 (1.1)[a]	6 (1.7)	3 (0.8)	11 (1.5)	7 (1.0)[a]
	Treatment-emergent resistance	**0**	**0**	**0**	**0**	**0**	**0**

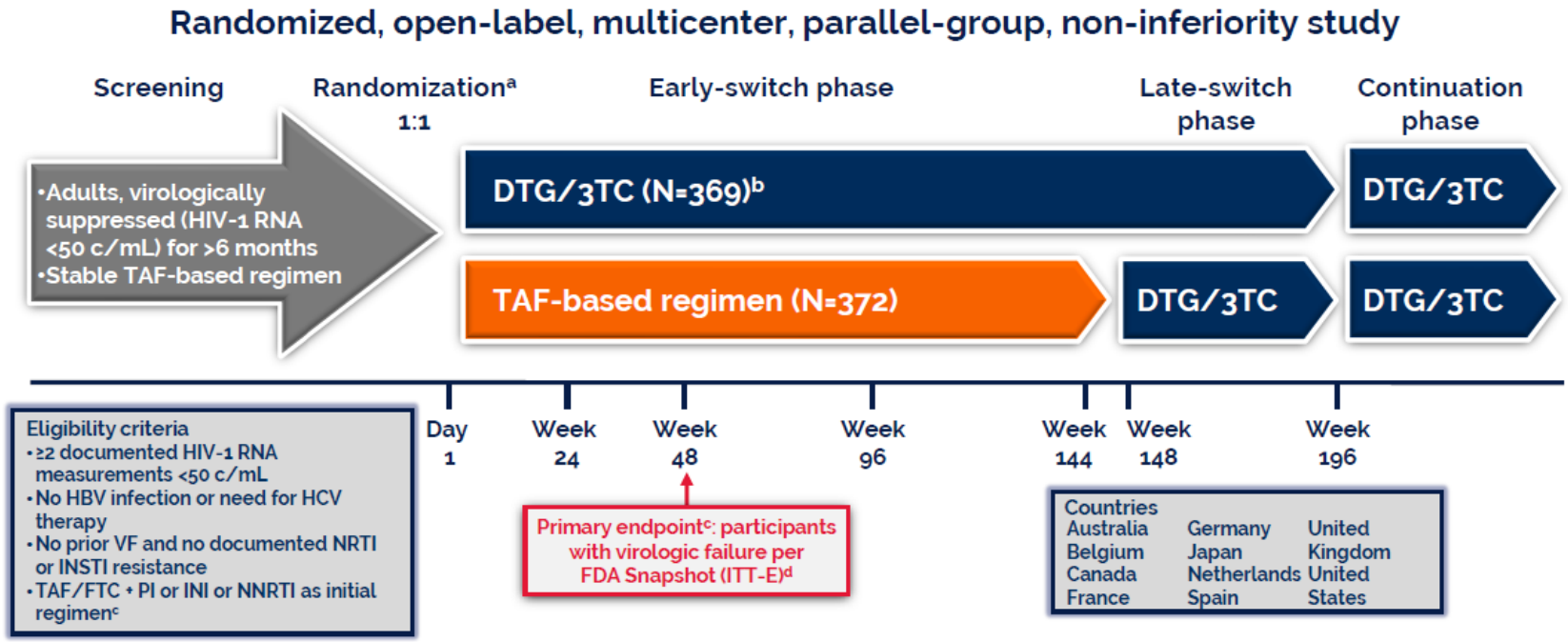
[a]One participant met the criteria for CVW at Week 12 but was not reported at the Week 48 analysis because of a laboratory reporting error identified after the Week 48 analysis.

Cahn et al. IAS 2019; Mexico City, Mexico. Slides WEAB0404LB.

TANGO Study Design

Source: Presentation by ViiV at 10th International AIDS Society Conference on HIV Science (IAS 2019) on Jul. 21-24, 2019

TANGO PHASE III STUDY DESIGN



[a]Stratified by baseline third agent class (PI, INI, or NNRTI). [b]Two patients excluded who were randomized but not exposed to study drug. [c]Participants with initial TDF treatment who switched to TAF ≥3 months before screening, with no changes to other drugs in their regimen, were also eligible. [d]4% non-inferiority margin. [e]Includes participants who changed a background therapy component or discontinued study treatment for lack of efficacy before Week 48, or who had HIV-1 RNA ≥50 c/mL in the 48-week window.

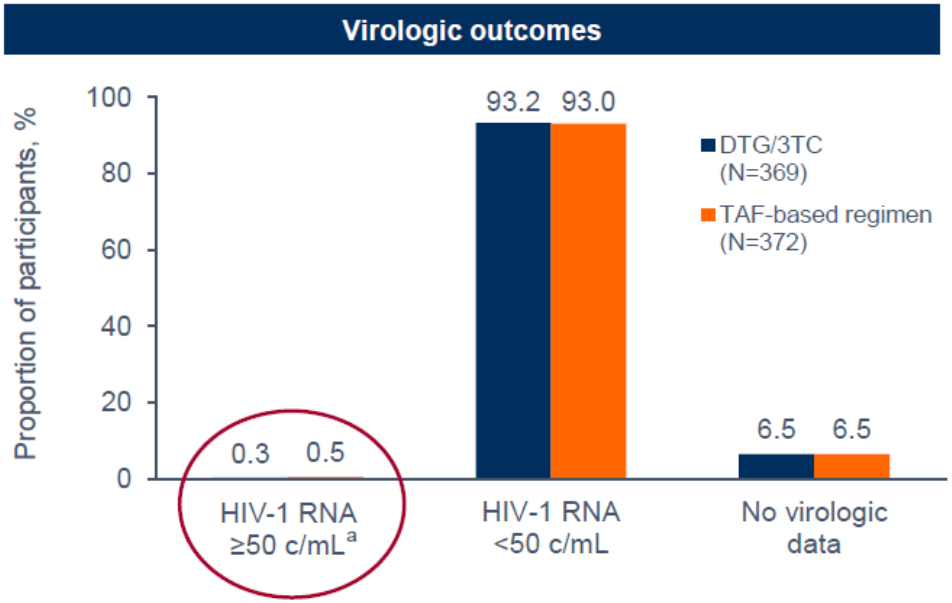
van Wyk et al. IAS 2019; Mexico City, Mexico. Slides WEAB0403LB.

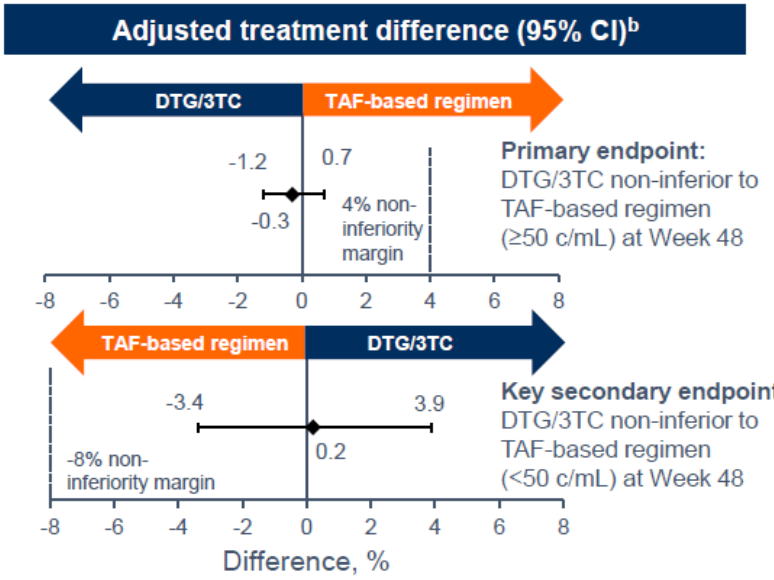
DTG: dolutegravir、3TC: lamivudine、TAF: tenofovir alafenamide fumarate

TANGO Week 48 Data

Source: Presentation by ViiV at 10th International AIDS Society Conference on HIV Science (IAS 2019) on Jul. 21-24, 2019

DTG/3TC IS NON-INFERIOR TO TAF-BASED REGIMEN AT WEEK 48





- In the per-protocol population, 0/352 participants in the DTG/3TC group and 2/358 participants in the TAF-based regimen group had HIV-1 RNA ≥50 c/mL at Week 48 (adjusted difference, −0.6; 95% CI, −1.3 to 0.2)[b]

[a]Primary endpoint (Snapshot virologic non-response, ITT-E). [b]Based on Cochran-Mantel-Haenszel stratified analysis adjusting for baseline third agent class.

van Wyk et al. IAS 2019; Mexico City, Mexico. Slides WEAB0403LB.

TANGO Week 48 Data

Source: Presentation by ViiV at 10th International AIDS Society Conference on HIV Science (IAS 2019) on Jul. 21-24, 2019

NO CONFIRMED VIROLOGIC WITHDRAWALS WITH DTG/3TC THROUGH WEEK 48

n (%)	DTG/3TC (N=369)	TAF-based regimen (N=372)
Confirmed virologic withdrawal (CVW)[a]	0	1 (<1)[b]
Observed resistance mutation at failure[c]	0	0

[a]One assessment with HIV-1 RNA ≥200 c/mL after Day 1 with an immediately prior HIV-1 RNA ≥50 c/mL.
[b]Treatment interrupted before suspected virologic withdrawal (VL, 38,042 c/mL) and resumed 3 weeks before VL retest (297 c/mL).
[c]Plasma HIV-1 RNA resistance genotype at failure is compared with baseline PBMC pro-viral resistance genotype.

van Wyk et al. IAS 2019; Mexico City, Mexico. Slides WEAB0403LB.

Shionogi Pharma

Shionogi Company Policy: Evolve "research, produce, and promote"

Shionogi Pharma founded

Taking over Shionogi's production technologies and quality
Moving toward further advancement

シオノギファーマ株式会社

Produce at affordable prices

Proactively introduce new technologies

Aspire to become top-level CDMO* in Japan

Flexibly respond to changes in product LCM**

Ensure stable supply for the global market

Aiming to improve product value through technology development, Shionogi group will continue to produce pharmaceuticals and healthcare products, and contribute to the maintenance and promotion of people's health

* CDMO: Contract Development Manufacturing Organization
** LCM: Life Cycle Management

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