



1st Quarter of Fiscal 2020 Financial Results *Conference Call*

July 31, 2020
Shionogi & Co., Ltd.



Vision 2030

Building Innovation Platforms to Shape the Future of Healthcare

As Shionogi family we promise to:

- Imagine new ways to deliver innovation, and catalyze the formation of new healthcare platforms
- Create innovative products and deliver them worldwide compliantly with high quality at a fair price
- Embrace social responsibility and contribute to longer, healthier lives everywhere

Start of New Medium-term Business Plan

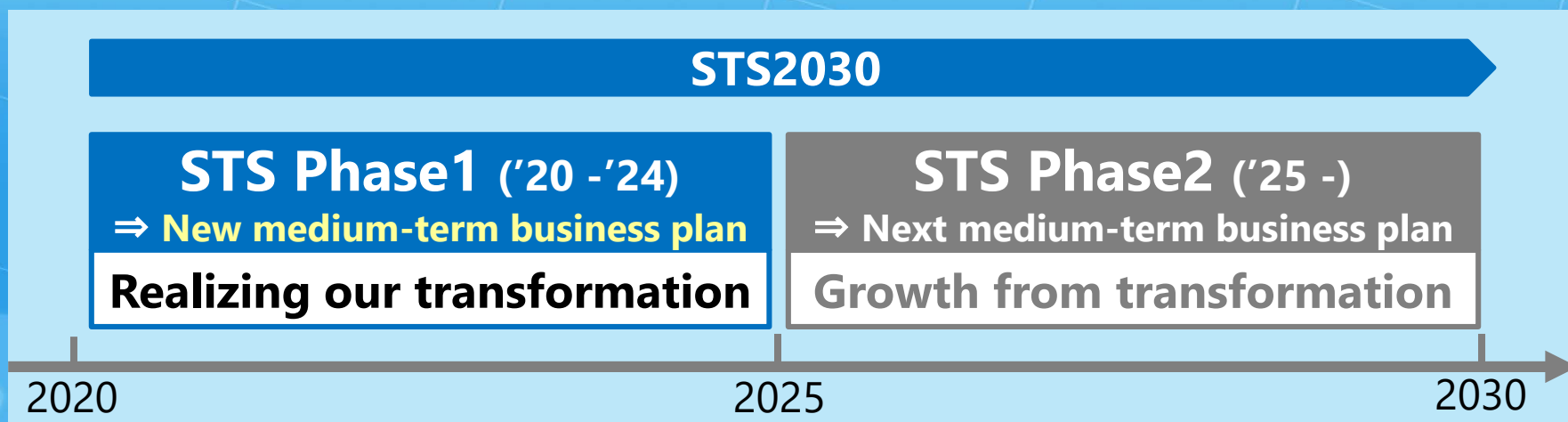


Strategy to achieve 2030 Vision

STS2030

- **Shionogi Transformation Strategy 2030** -

New growth achieved through business transformation



Positioning of FY2020 in STS Phase1

STS Phase1 Basic Policy

Realize transformation to a new growth as a total healthcare company

New value creation

i. R&D strategy



Development of innovative pipeline

- Overcome the “2028 patent cliff” and develop multiple pipeline assets

ii. Top-Line Strategy



Business growth through creation of diverse businesses

- Strengthen our ability to sell our own products overseas
- Address social needs with new business models
- Build an foundation for new platform businesses

Infrastructure building

iii. Management Foundation Strategy



Building framework for new value creation

- Able to respond flexibly to sudden changes in external/internal environment
- Implement a fundamental internal transformation to establish a robust financial foundation

FY2020

Capturing the emergency response to COVID-19 as an opportunity to improve productivity and promoting the enhancement of the foundation for growth

**"Discontinuous evolution" and "Rapid transformation"
by revision of decision-making processes and actions**

- 1. Overview of Q1 FY2020 Financial Results (P.6-13)**
- 2. Actions in Q1 FY2020 and Progress of STS Phase1 (P.14-24)**

1. Overview of Q1 FY2020 Financial Results

Business Impact of COVID-19



Impact of COVID-19 on Q1 FY2020 and Our Response

- **Supply chain**

- No impact on procurement of raw ingredients etc., production, or inventory – no hindrance to stable supply
- Accelerate (or advance) production of some products and secure inventory of materials imported from overseas

- **Promotion**

- Provide information through web-conferences and e-details responding to a request to refrain from visiting medical institutions
 - > After the easing of the request, partially resumed visits according to the needs of medical institutions, and continuing to strengthen digital activities
- As part of disease strategy, strengthen training of sales reps with comprehensive information about diseases in collaboration with the Integrated Disease Care Division*
 - > Infectious diseases, including COVID-19, and psycho-neurological disease

- **R&D**

- Focus resources on COVID-19 related projects
- No significant impact on the development timeline of 8 core projects**
- Some development timelines for non-core projects were shifted (c.a. 3-6 months)***
 - > Enrollment and trial start is delayed in some clinical studies

Financial Results (Consolidated)



(Unit: B yen)

	FY2020				FY2019	Y to Y	
	Forecasts		Apr.-Jun. results	Progress vs. forecasts	Apr.-Jun. results*	Change (%)	Change (B yen)
	Full year	1H					
Revenue	323.5	155.6	71.4	45.9	80.8	(11.6)	(9.4)
Operating profit	110.3	53.8	25.6	47.6	31.7	(19.1)	(6.1)
Core operating profit**	110.3	53.8	25.9	48.0	31.9	(18.8)	(6.0)
Profit before tax	136.3	61.6	30.1	48.8	35.3	(14.9)	(5.3)
Profit attributable to owners of parent	103.6	44.9	21.5	48.0	27.1	(20.6)	(5.6)

- Each aspect of profit has been steadily progressing, though the COVID-19 pandemic has shrunk the pharmaceutical market
- Actions in STS Phase1 are progressing smoothly

Exchange Rate (average)	FY2020 forecasts	FY2020 Apr.-Jun. results
USD (\$) – JPY (¥)	107	107.64
GBP (£) – JPY (¥)	130	133.63
EUR (€) – JPY (¥)	120	118.59

* Converted from JGAAP to IFRS

** Operating income adjusted for one-time factors (asset impairment, gains on sale of property, plant and equipment, etc.)

Statement of Profit and Loss (Consolidated)



(Unit: B yen)

	FY2020				FY2019		Y to Y	
	Forecasts		Apr.-Jun. results	Achievement (%)	Apr.-Jun. results*	Change (%)	Change (B yen)	
	Full year	1H						
Revenue	323.5	155.6	71.4	45.9	80.8	(11.6)	(9.4)	
Cost of sales	17.2 55.7	16.5 25.7	16.1 11.5	44.7	15.7 12.7	(9.3)	(1.2)	
Gross profit	267.8	129.9	59.9	46.1	68.1	(12.0)	(8.2)	
Selling general & administrative expenses	32.1 103.7	33.2 51.6	30.4 21.7	42.0	29.6 23.9	(9.2)	(2.2)	
R&D expenses	15.5 50.2	14.8 23.0	17.0 12.2	52.8	14.5 11.7	4.2	0.5	
Other income	0.5	0.3	0.1	31.0	0.1	(43.1)	(0.1)	
Other expenses	4.0	1.6	0.5	32.8	1.0	(48.2)	(0.5)	
Operating profit	34.1 110.3	34.6 53.8	35.9 25.6	47.6	39.2 31.7	(19.1)	(6.1)	
Core operating profit	34.1 110.3	34.6 53.8	36.2 25.9	48.0	39.4 31.9	(18.8)	(6.0)	
Finance income	27.5	8.4	4.9	58.2	5.7	(14.5)	(0.8)	
Finance costs	1.6	0.6	0.4	73.2	2.1	(78.2)	(1.6)	
Profit before tax	42.1 136.3	39.6 61.6	42.1 30.1	48.8	43.8 35.3	(14.9)	(5.3)	
Profit attributable to owners of parent	103.6	44.9	21.5	48.0	27.1	(20.6)	(5.6)	

Revenue by Segment



(Unit: B yen)

	FY2020				FY2019	Y on Y	
	Forecasts*		Apr.-Jun. results	Achievement (%)	Apr.-Jun. results*	Change (%)	Change (B yen)
	Full year	1H					
Prescription drugs	123.9	53.1	22.4	42.1	26.3	(15.1)	(4.0)
Overseas subsidiaries/export	24.0	11.3	5.5	48.5	10.7	(49.1)	(5.3)
Shionogi Inc.	5.1	2.6	1.7	64.1	5.3	(68.6)	(3.6)
C&O	11.9	5.7	2.4	41.4	3.8	(37.5)	(1.4)
Contract manufacturing	15.4	7.9	2.9	36.5	2.4	17.6	0.4
OTC and quasi-drug	10.4	4.9	2.3	46.5	1.8	26.1	0.5
Royalty income	148.3	77.8	38.0	48.8	38.9	(2.4)	(0.9)
HIV franchise	126.3	64.2	31.0	48.2	31.7	(2.4)	(0.8)
Crestor®	16.9	11.1	5.6	50.0	5.7	(1.6)	(0.1)
Others	5.2	2.5	1.5	60.3	1.5	(3.6)	(0.1)
Others	1.3	0.7	0.4	65.8	0.5	(17.2)	(0.1)
Total	323.5	155.6	71.4	45.9	80.8	(11.6)	(9.4)

Revenue of Prescription Drugs in Japan



(Unit: B yen)

	FY2020				FY2019	Y on Y	
	Forecasts		Apr.-Jun. results	Achievement (%)	Apr.-Jun. results*	Change (%)	Change (B yen)
	Full year	1H					
Cymbalta®	28.6	13.9	6.9	49.8	6.7	2.9	0.2
Intuniv®	16.7	6.8	2.6	38.4	1.8	42.2	0.8
Vyvanse®	0.8	0.2	0.0	11.3	-	-**	0.0
Infectious disease drugs	26.5	7.1	2.1	30.1	3.6	(40.7)	(1.5)
OxyContin® franchise	5.6	2.9	1.4	47.3	1.7	(17.3)	(0.3)
Symproic®	2.9	1.3	0.5	36.6	0.5	(7.9)	(0.0)
Actair®	0.3	0.2	0.1	36.9	0.1	3.4	0.0
Mulpleta®	0.1	0.1	0.0	42.5	0.0	(26.3)	(0.0)
Pirespa®	4.9	2.9	1.4	49.6	1.7	(17.1)	(0.3)
Others	37.5	17.7	7.3	41.1	10.2	(28.4)	(2.9)
Crestor®	8.3	4.2	1.5	37.3	2.4	(35.3)	(0.8)
Irbetan® franchise	3.7	1.8	0.8	47.0	1.2	(30.5)	(0.4)
Prescription drugs	123.9	53.1	22.4	42.1	26.3	(15.1)	(4.0)

<Products included in infectious disease drugs>

- Xofluza®
- Rapiacta®
- Brightpoc® Flu・Neo
- FINIBAX®
- Flumarin®
- Flomox®
- Seftem®
- Shiomarin®
- Vancomycin
- Baktar®
- Flagyl®
- Fluconazole
- ISODINE®

Summary of 1st Quarter



Year-on-Year Comparison

- **Revenue (-9.4 B yen)**
 - US: One-time payments from BDSI for Symproic® in FY2019
 - Japan: Impact of price revision
 - Changes in the domestic and overseas market due to COVID-19 pandemic
 - > Japan: Significant reduction in meeting acceptance by many medical departments
 - > China: Decrease in sales of rabeprazole
 - > US: Decrease in Mulpleta® sales
 - > Decline in royalty income from HIV franchise
 - = Rebound from ViiV's accelerated shipment in the previous quarter
 - = Delay in Dovato® share expansion
- **Selling general & administrative expenses (-2.2 B yen)**
 - Decrease in costs due to refraining from visiting and changes to promotion using digital tools
 - China: Decrease in costs due to decline in sales of rabeprazole
- **R&D expenses (0.5 B yen)**
 - Aggressive investment in COVID-19 related projects and 8 core projects

Summary of 1st Quarter



- **Emergency response is a good opportunity to optimize resource allocation in STS Phase1**
- **Opportunity for proactive assessment of "stopping, accelerating, and starting"**
 - In response to changes in the market due to COVID-19 pandemic, consider optimal resource allocation
 - Invest in efforts that need to be accelerated in order to achieve the 2030 Vision such as R&D and improvement of management foundation, etc.

Q1 (Trial)

Confirmed changes in post corona market. Based on these changes, reviewed activities and ways of working, and investigated the impact on costs.

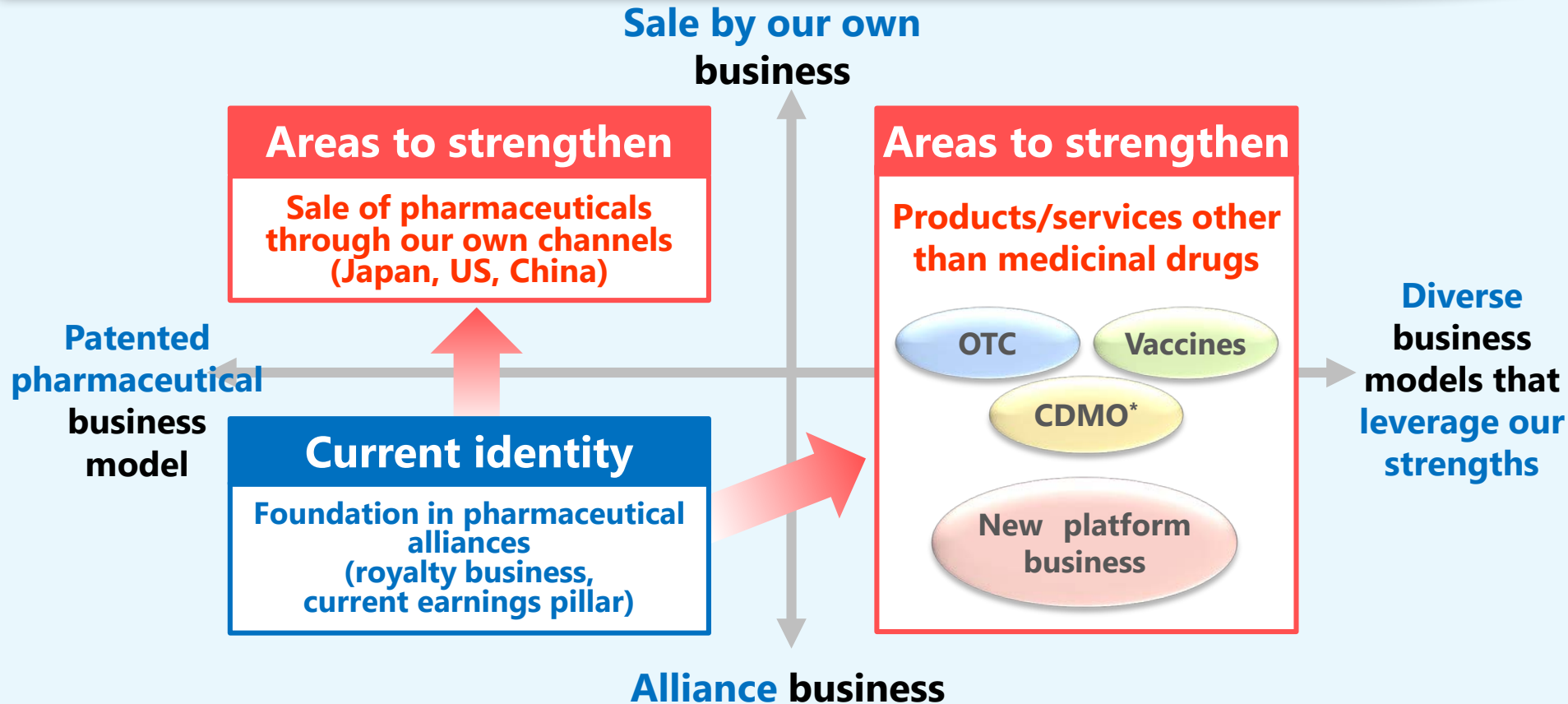


Q2 (Validation -> Action)

Review the appropriate resource allocation based on the revised action plan, and estimate and respond to the impact on the full-year results as soon as possible.

Rapid business transformation to achieve the 2030 Vision

2. Actions in Q1 FY2020 and Progress of STS Phase1



Ensure both high profit margins and a stable financial foundation through multiple new business models

- Balance our own sales capabilities with sales through alliance partners
- Balance “businesses that utilize patents” and “non-patent businesses that utilize strengths”

R&D Strategy: Our Efforts to Fight COVID-19 (1/2)



Discovery of Novel Therapeutic Drugs

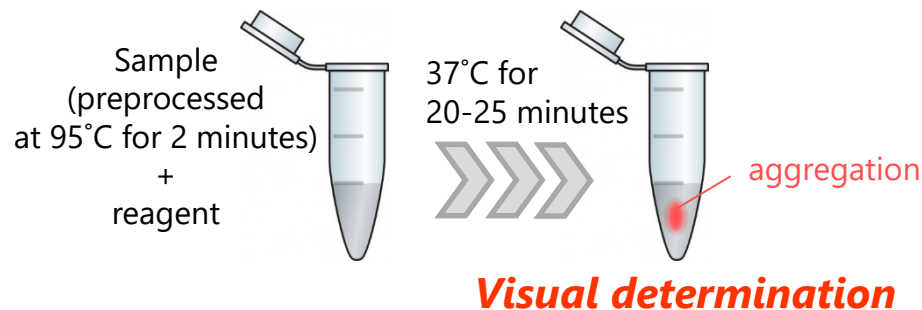
- Advancing collaborative research with Hokkaido Univ. and National Institutes of Biomedical Innovation, Health and Nutrition, utilizing AMED* fund
- Screening to select candidates is progressing well **with the goal of initiating clinical trials in FY2020**

Offering Test/Diagnosis Kit

- Launched IgG/IgM Antibody-test Kit as a research reagent (June 3, 2020)
- License agreement regarding **developing a new rapid diagnostic method (SATIC** method)** with 3 Univ.***
 - Preparation for approval application as in-vitro diagnostic drug and striving for commercialization with the goal of availability in September 2020
 - Acceleration of development and production scale-up studies for early provision of kits that enable easier and quicker diagnosis of multiple samples

Features of SATIC method

Easy and reliable sample collection , saliva etc.	No need for detection equipment
25 minutes Rapid diagnosis	High sensitivity equivalent to that of a PCR method

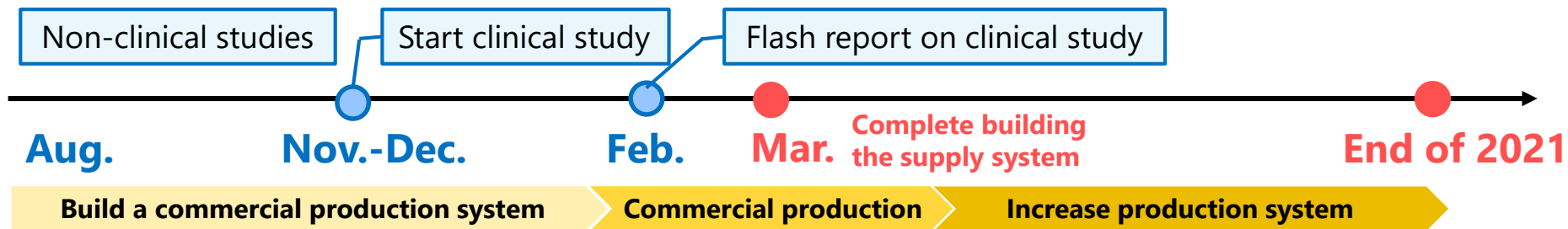


R&D Strategy: Our Efforts to Fight COVID-19 (2/2)



Discovery of Prophylactic Vaccine

- **Developing a recombinant protein vaccine** with the National Institute of Infectious Diseases and the Kyushu University
- Non-clinical studies and manufacturing method for antigen candidate are evaluating to **initiation of clinical trials in 2020**
 - Immunogenicity test in progress to select candidate antigen and adjuvant
 - Utilize AMED research grants
- Build the first production system in collaboration with UNIGEN (API manufacturing) and API (Pharmaceutical manufacturing) within FY2020
 - Utilize the “Grant to Promote the Domestic Investment Project to Combat the Supply Chain” by the Ministry of Economy, Trade and Industry
 - Plan for further investment (Target supply: more than 30 M people at the end of FY2021)

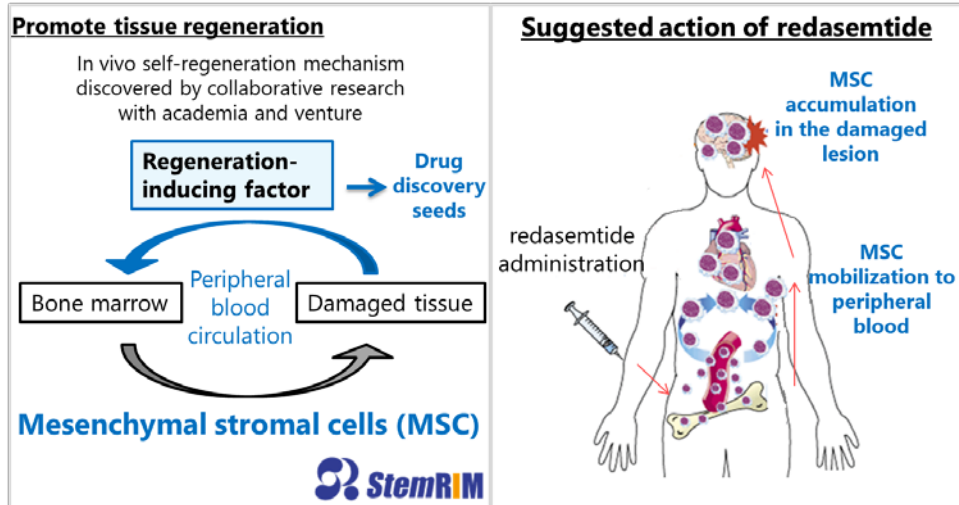


Provide total care for COVID-19 infection and expand our business model by full-scale entry into vaccine business

R&D Strategy: S-005151 [Redasemtide]



Change the paradigm of regenerative medicine



Signed a new contract with StemRim.
(June 30, 2020)

Utilize evidence from non-clinical studies that StemRim accumulated through joint research with several academia groups for starting Investigator-Initiated clinical trials for new 3 indications

New development for indications of 3 diseases

Epidermolysis bullosa

Confirmed efficacy in investigator-initiated clinical trial

Preparing for application

Acute stroke

Phase 2 study in progress

Non-clinical study: Confirmed efficacy by administration at 6 hours after infarction

Osteoarthritis

Investigator-initiated clinical trial

Scheduled to start in 2020

Chronic liver disease

Cardiomyopathy

Investigator-initiated clinical trial, Planned

Steady progress in LCM* strategy to maximize compound value

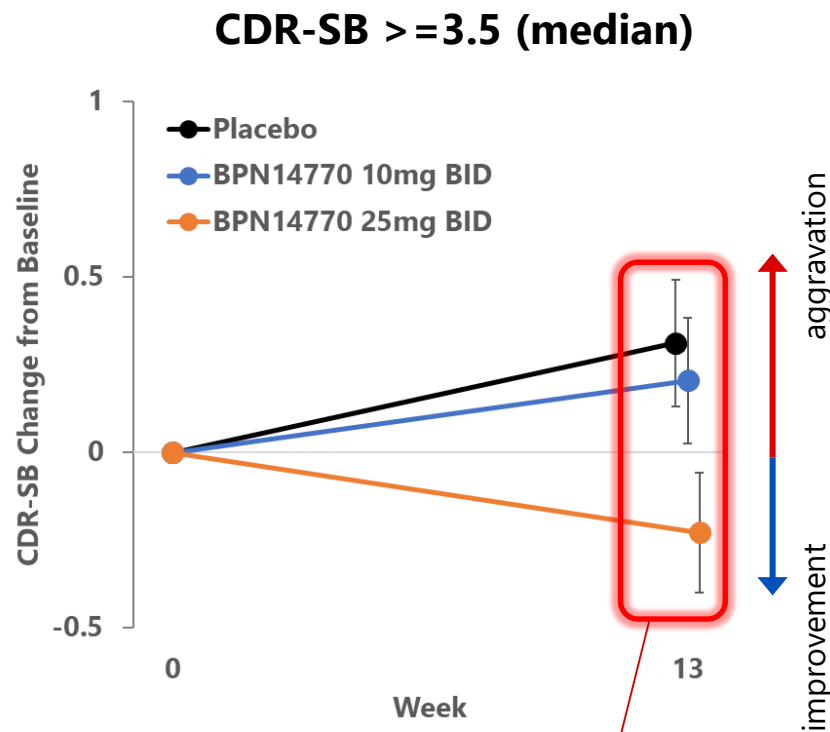
R&D Strategy: BPN14770



For maximization of the value of BPN14770, cognitive function improving drug

- **US Phase 2 test results in early Alzheimer's disease patients***
 - Efficacy: Trend toward improvement in cognitive function
 - Safety: No problematic side effects, including vomiting
- **Global rights to BPN14770 and all compounds currently held by Tetra Therapeutics**
- **Tetra's know-how to conduct drug discovery for central nervous system**

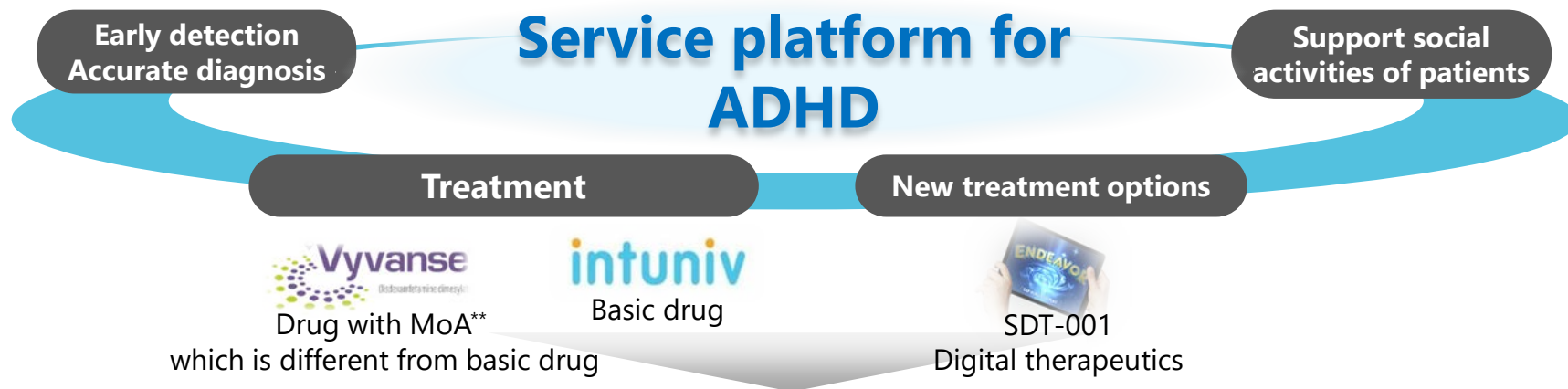
**Made Tetra a wholly owned subsidiary
(May 26, 2020)**



	Change from Baseline at week 13	vs. Placebo
Placebo	0.312	
10mg	0.204	-0.11 (p=0.668)
25mg	-0.228	-0.54 (p=0.0295)

Progress of application for ADHD digital therapeutics

- Shionogi: SDT-001
 - New treatment option which distinct from treatment with pharmaceutical products
 - > Domestic phase 2 study is ongoing in ADHD patients 6 to 17 years old.
- Akili: AKL-T01
 - World's first game-based digital therapeutic for improving attention function in children with ADHD
 - > US: Received FDA approval, Europe: CE mark* approval



We will support recognition of disease, treatment, and social activities, comprehensively, in order to free patients from difficulties in their lives, thereby contributing to improved social productivity.

Top-Line Strategy (Japan):

Cooperation Between Integrated Disease Care Division and Commercial Division



**Deep knowledge
about products**

**Cooperation between
both Divisions**

**Analysis of
doctors' needs**

**Broad knowledge
about diseases**

**Web-conference from
KOL***
(providing message effectively)



**Communication between sales
reps and doctors**
(face to face, Web)



e-detail
(providing message
comprehensively)



Evolution of promotion by providing information about products and diseases
Create more opportunities for 1 on 1 meetings by utilizing web



Understanding diseases, motivated to prescribe

Top-Line Strategy (overseas):

Joint-Venture establishments with Ping An Insurance (Group) Company of China



Establish three group companies including two Joint-Ventures

- Jul. 2020 : Shionogi (Hong Kong) Limited
- Aug. 2020 : Joint-venture "Ping An-Shionogi Co., Ltd*"
- Aug. 2020 : Joint-venture "Ping An-Shionogi (Hong Kong) Limited*"

	Ping An-Shionogi	Ping An-Shionogi (Hong Kong)
Chairman & CEO	Shionogi	Shionogi
Directors of the Board	Shionogi-3 (including Chairman) Ping An-2	Shionogi-3 (including Chairman) Ping An-2

Transfer Shionogi products and pipeline to Joint-Venture companies

**High quality
generic drugs
from C&O
(FY2020)**

**Contribution to Top-Line
from FY2020**

**Branded products
from Shionogi
Healthcare Co., Ltd.
(FY2020)**

Shionogi pipeline
Cefiderocol
Naldemedine
Covid-19 related products
(FY2022~)

**Development of Shionogi
pipeline in China**

Top-Line Strategy (overseas):

Joint-Venture establishments with Ping An Insurance (Group) Company of China



Provide individually optimized healthcare solutions by R&D utilizing RWD* to solve unmet medical needs, and cooperate with "Good Doctor"

Video recording

- ✓ Voice
- ✓ Movement
- ✓ Posture



Smart city/behavior at home

- ✓ Life pattern
- ✓ Walk distance/velocity
- ✓ Sleep quality/quantity

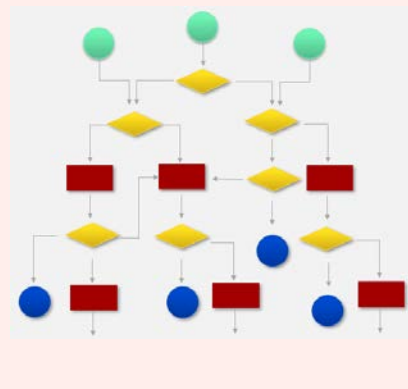


RWD



平安好医生**

Diagnosis Algorithm



(OTC)

No good Solution

- Introduce current Shionogi products and pipeline
- In-license assets from third party companies actively

Individually Optimized Healthcare Solutions

R&D utilizing RWD

- Identify unmet needs
- New drug discovery projects
- New healthcare solutions



Progress of HIV Franchise by ViiV



Commitment of Shionogi

- Combination of two oral drugs that will be the pillar of next-generation HIV treatment
- Creation of the best in class of long-acting injections
- Challenge to cure HIV infection

2020~
“everyday” to
“monthly or bimonthly”

Towards “Cure”

 **CABENUVA*** (CAB/RPV**)

First long-acting injection

- Jul. 2020: Resubmission in the US (1 dose/month)
→ Scheduled for market launch in Jan.-Mar. 2021

“3 drug regimen”
to “2 drug regimen” 2019

 **Dovato**

2021~
expansion to
“prevention”

 **Triumeq**
 **Tivicay**

2013

 **Juluca**
2017

CAB prophylaxis

First long-acting injection for prophylaxis

- HPTN 083 study:
65% more effective than FTC/TDF* in preventing HIV infection**
⇒ Advised to terminate study earlier than DSMB****

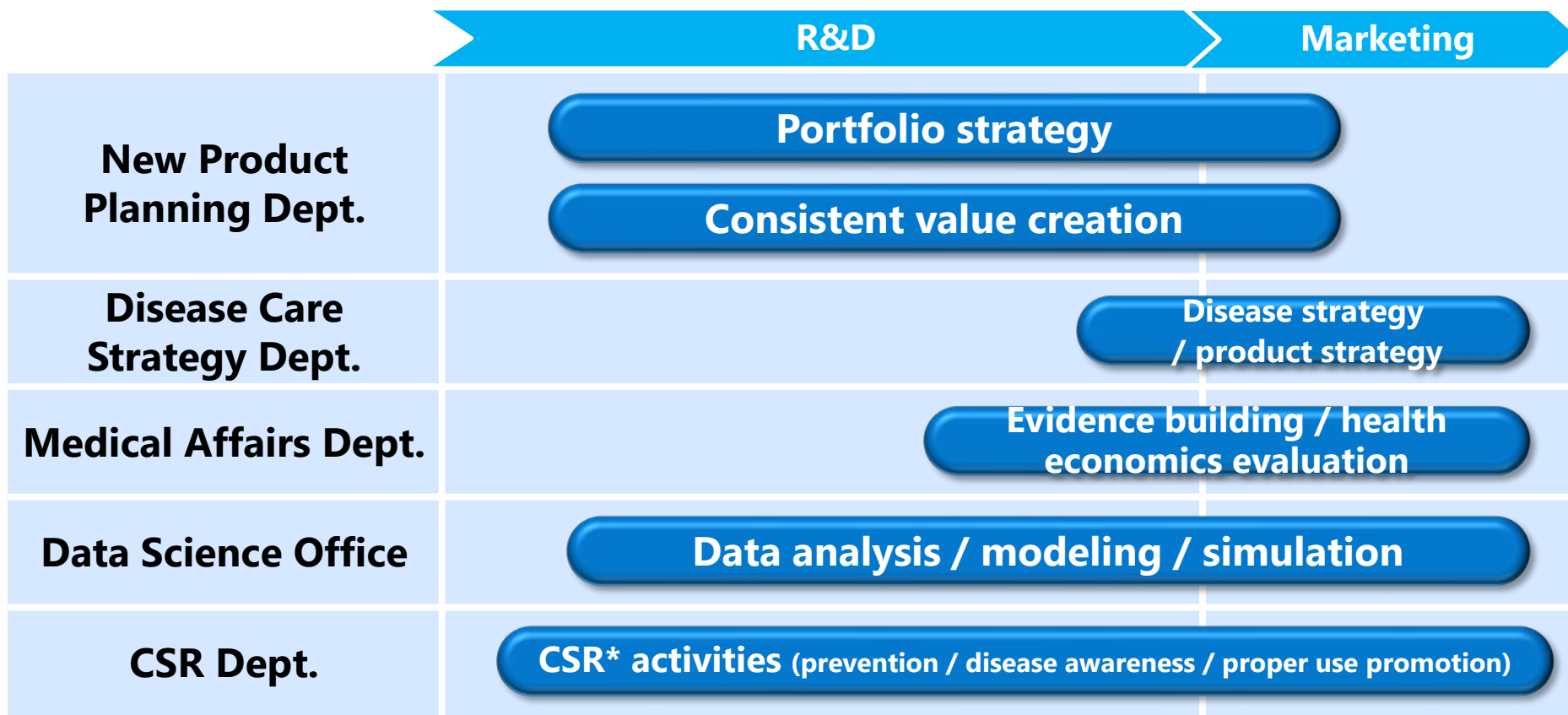
Appendix

Establishment of Integrated Disease Care Division

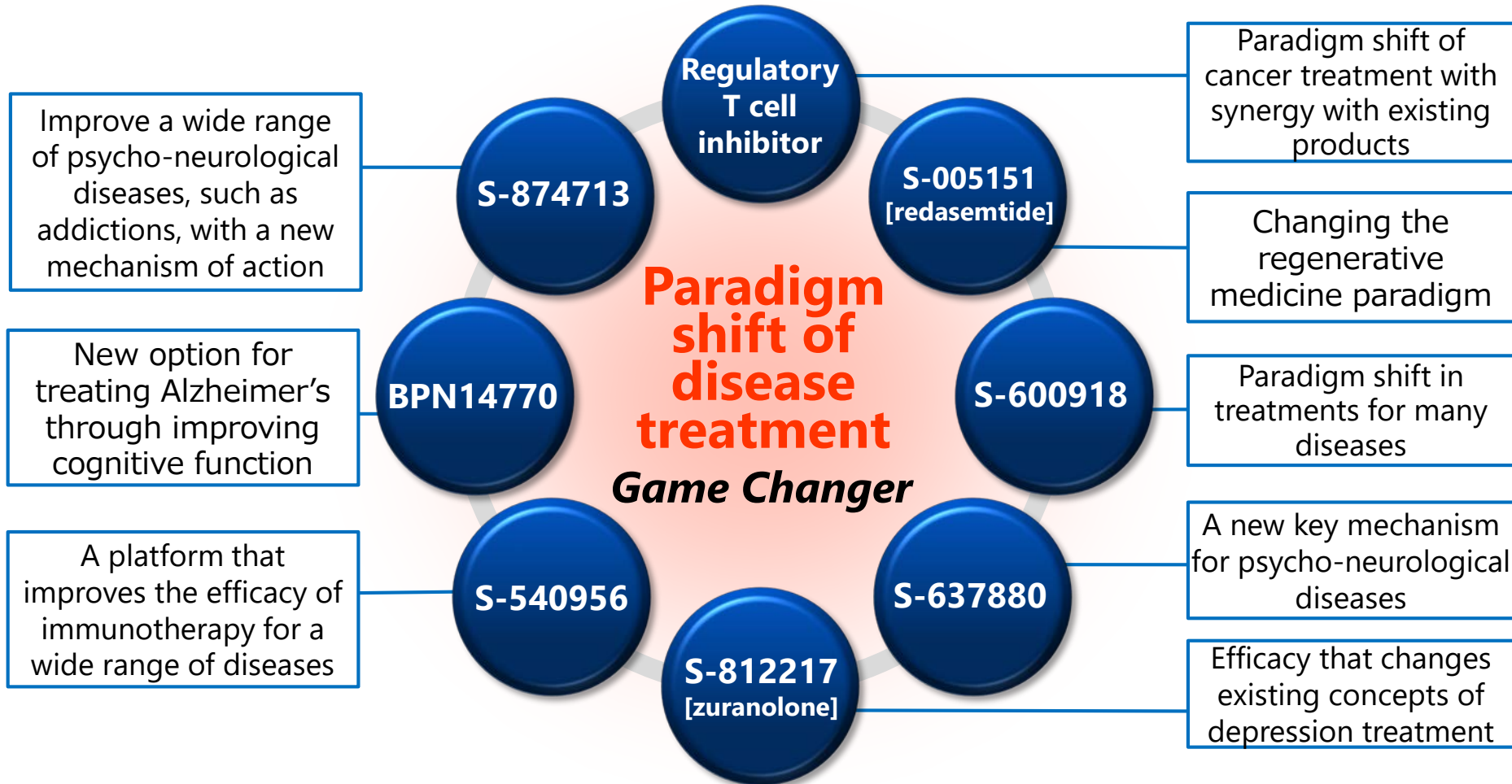


Structured to effectively deliver required products/information to more people globally

➤ Cross-value chain, customer-oriented, evidence-focused, data-driven



The Outcome We Envision from our Core Pipeline



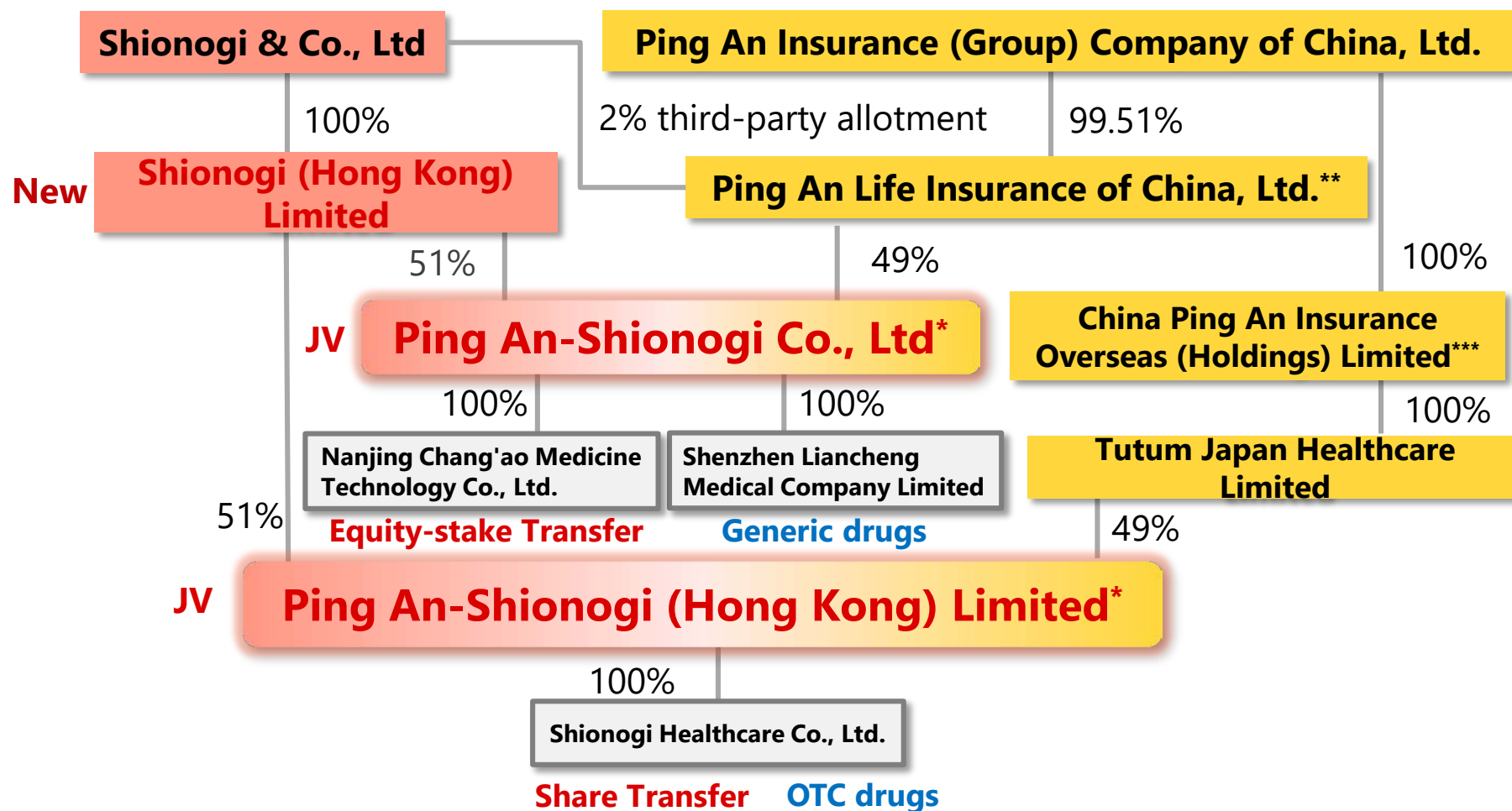
**Creating products and services for diseases
with high unmet medical needs**

Top-Line Strategy (overseas):

Joint-Venture establishments with Ping An Insurance (Group) Company of China



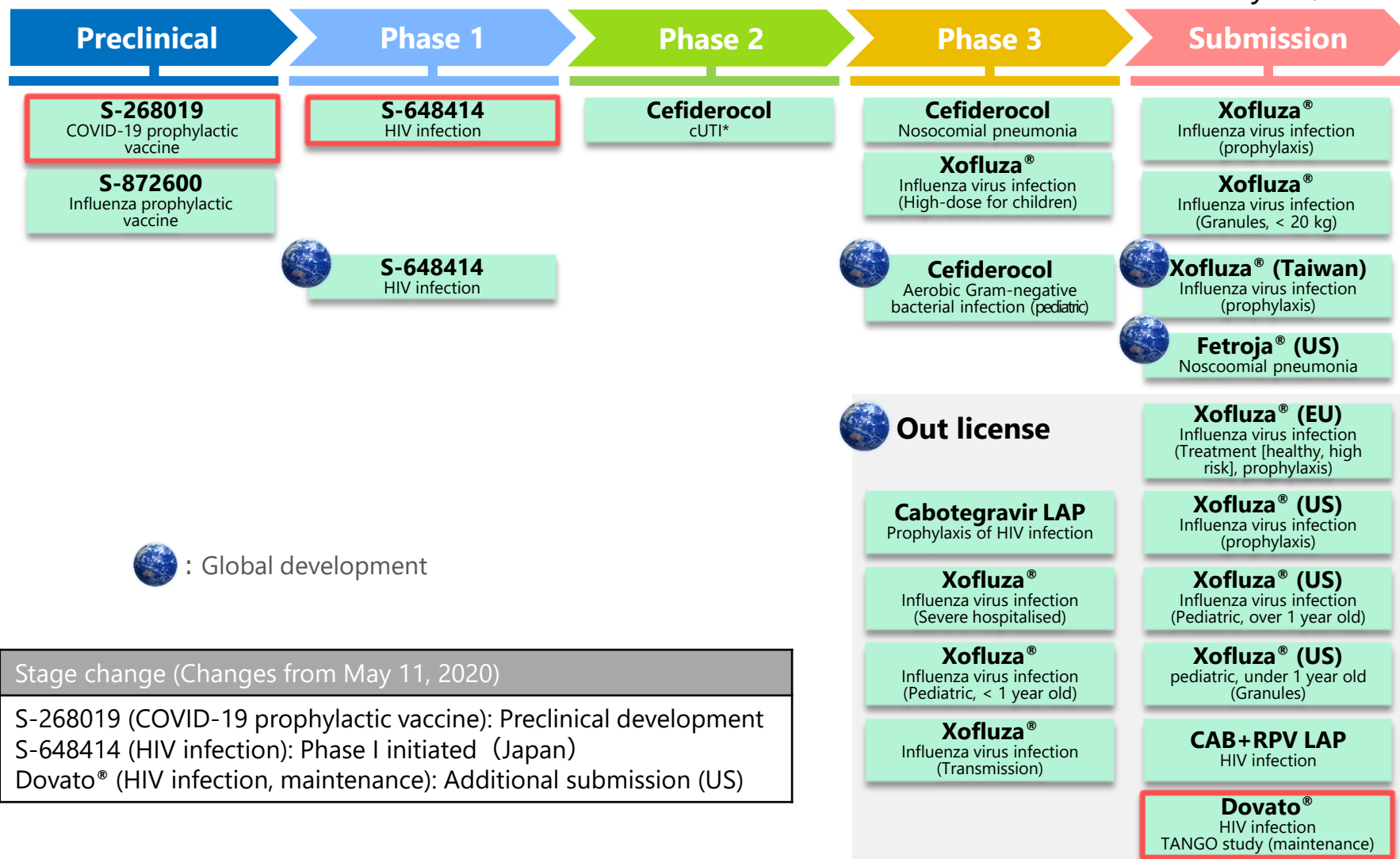
- Capital ties of joint ventures



Pipeline: Infectious Disease



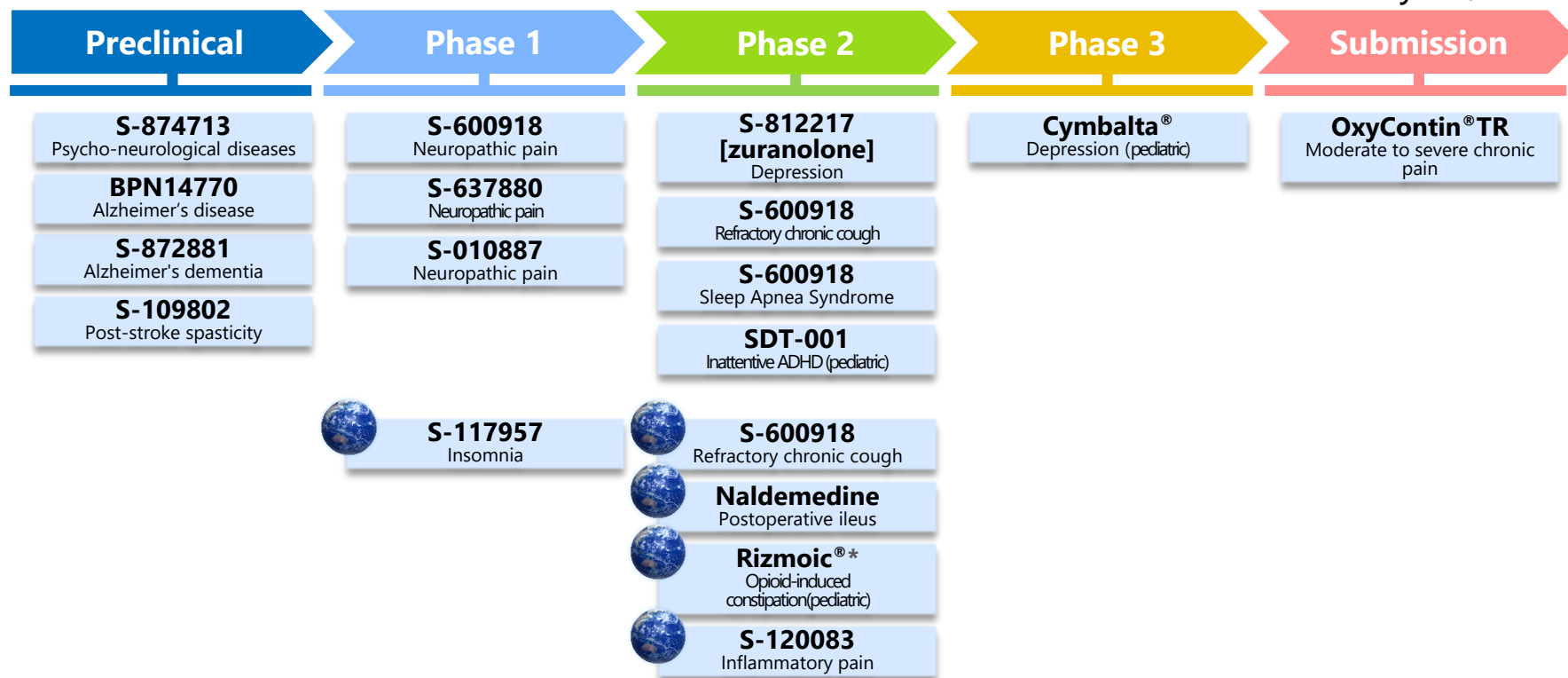
as of July 31, 2020



Pipeline: Psycho-neurological Disease



as of July 31, 2020

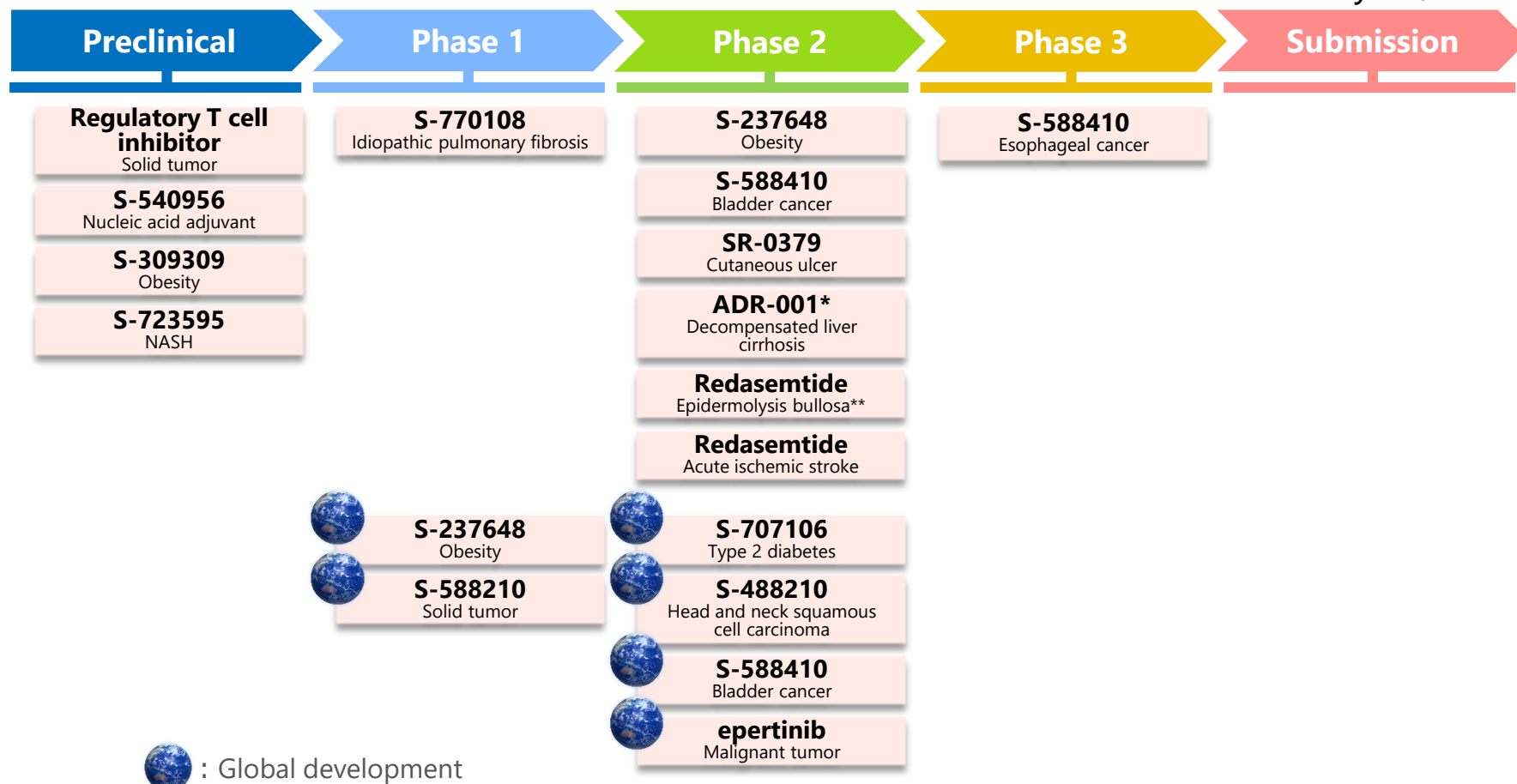


: Global development

Pipeline: New Growth Area



as of July 31, 2020

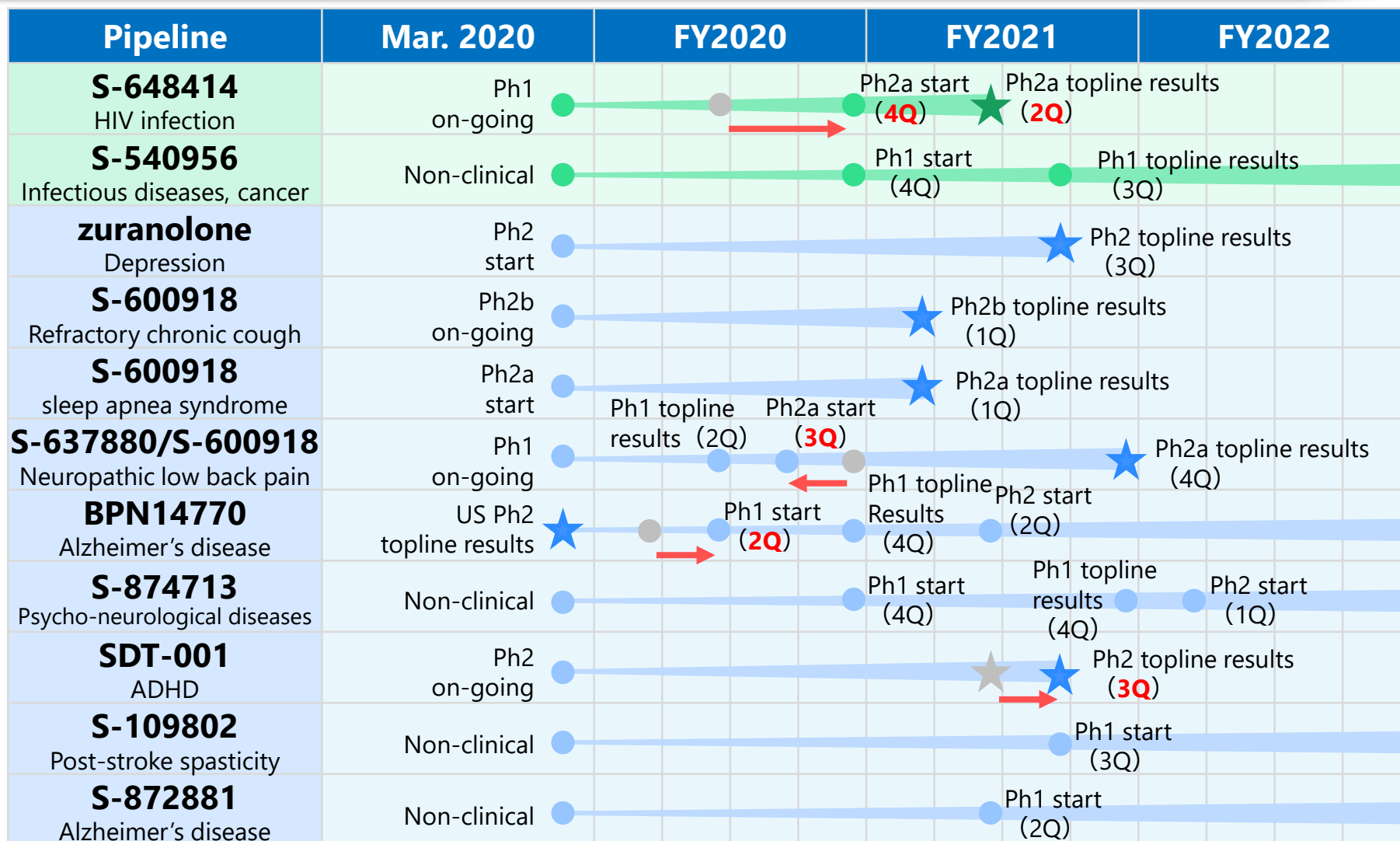


FY2020 Pipeline Target Milestones



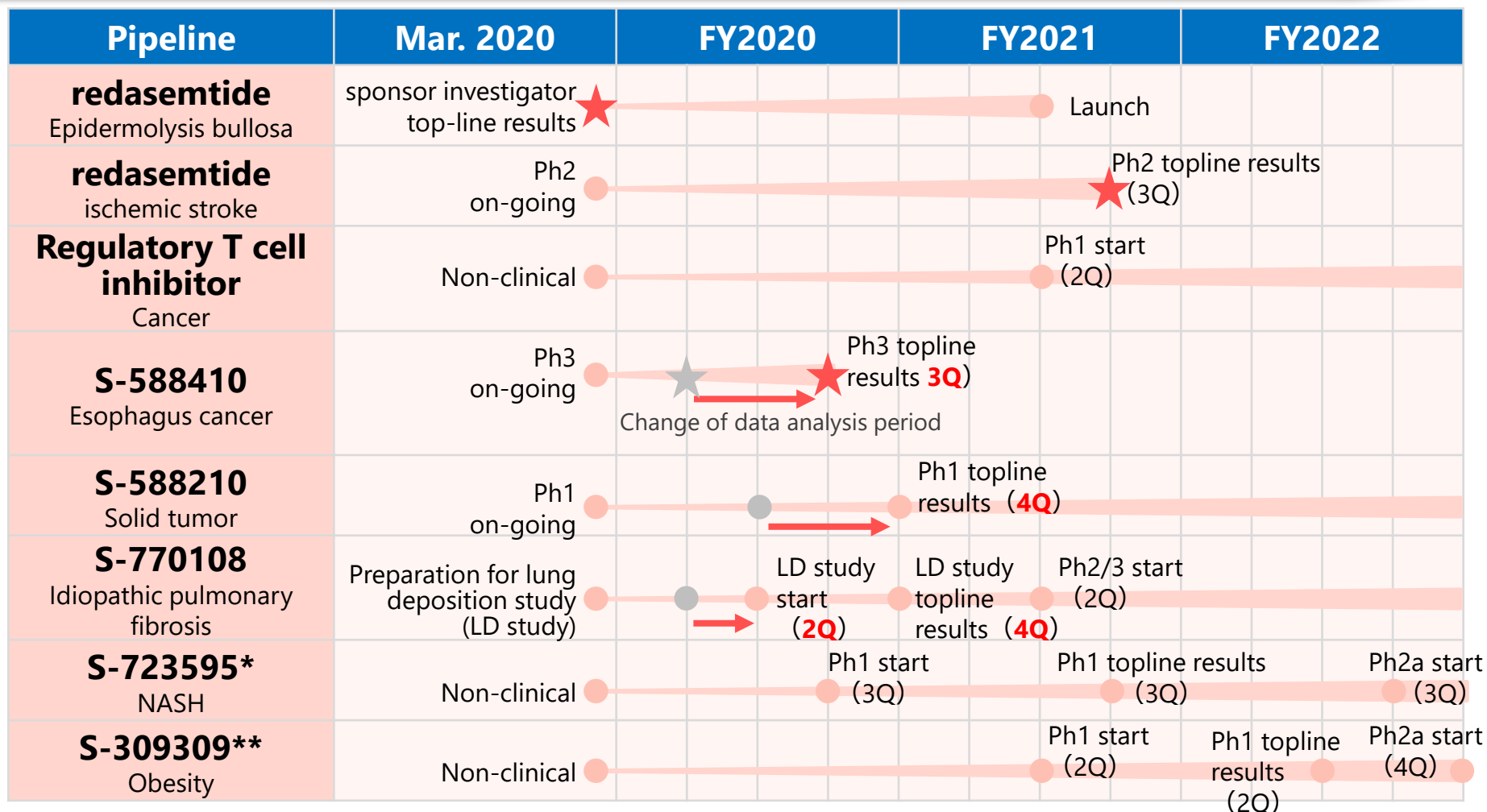
Phase	Pipeline	Indication	Milestone	✓ : achieved
Submission~ Approval	Fetroja® (cefiderocol)	Nosocomial pneumonia*	US: supplemental approval	
	Fetroja® (cefiderocol)	Aerobic Gram-negative bacterial infection*	EU: Approval ✓	
	Xofluza® granule	Influenza virus infection (pediatric, <20 kg)	Japan: supplemental approval	
	Xofluza®	Influenza virus infection (prophylaxis)	Japan: supplemental approval	
	Oxycontin® TR	Analgesia in chronic pain	Japan: supplemental approval	
	Cymbalta®	Depression (pediatric)	Japan: Submission	
Phase 1~3	S-637880	Neuropathic pain	Japan: Completion of Phase 1 MAD	
	S-600918/S-637880	Neuropathic pain	Japan: Initiation of Phase 2	
	S-648414	HIV infection	US: Initiation of Phase 2 (PoC)	
	S-770108	Idiopathic pulmonary fibrosis	UK: Initiation of lung deposition study	
	S-540956	HIV infection, cancer	Initiation of Phase 1 (Region Not Decided)	
	S-874713	Psycho-neurological disease	Japan: Initiation of Phase 1	
	BPN14770	Alzheimer's disease	Japan: Initiation of Phase 1	
	S-723595	NASH	Japan: Initiation of Phase 1	

Key Events for Major Pipeline Compounds



★ Ph2 or Ph3 topline results are anticipated (Disclosure timing and way are considered separately)

Key Events for Major Pipeline Compounds



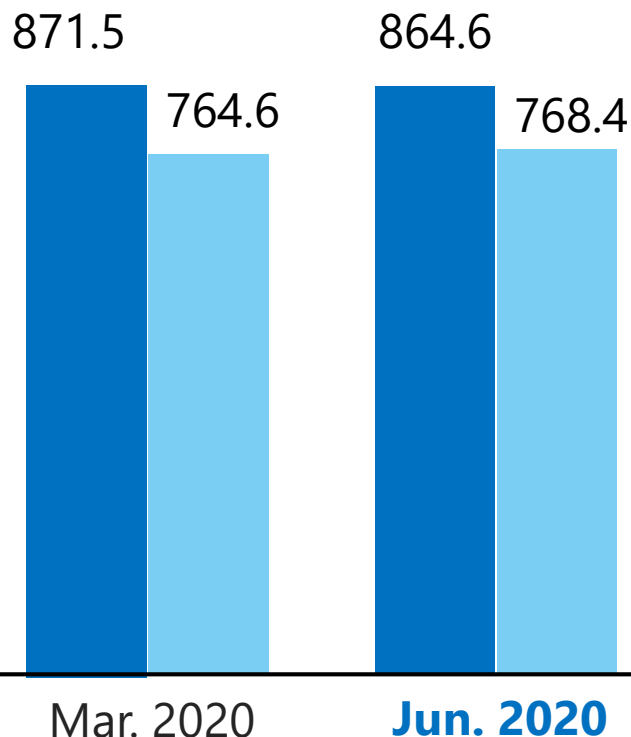
★ Ph2 or Ph3 topline results are anticipated (Disclosure timing and way are considered separately)

Financial Position (Consolidated, IFRS)



■ Total Assets ■ Equity attributable to owners of parent

(Unit: B yen)



Unit: B yen		End of Mar. 2020	End of Jun. 2020	Change
Total Assets	Non-current Assets	355.5	368.1	12.6
	Current Assets	516.0	496.5	(19.5)
Equity attributable to owners of parent		764.6	768.4	3.9
Total Liabilities	Non-current Liabilities	25.8	25.1	(0.7)
	Current Liabilities	81.1	71.0	(10.1)

	Mar. 2020	Jun. 2020
Ratio of equity attributable to owners of parent to total assets	87.7%	88.9%

Cabotegravir Prophylaxis Study: HPTN 083



From ViiV Conference call on July 9, 2020

THE PREP LANDSCAPE WORLDWIDE

- 200,000 people currently taking PrEP in US
- US Government believes 1.2 million could benefit
- Circa 500,000 MSM in Europe could benefit from PrEP but barriers to access remain high
- In Africa HIV infections are growing among adolescent girls and young women who could benefit from PrEP
- Some people express dissatisfaction at taking daily PrEP pills as reinforcing self stigma
- CAB LA could present a new option, dosed every two months

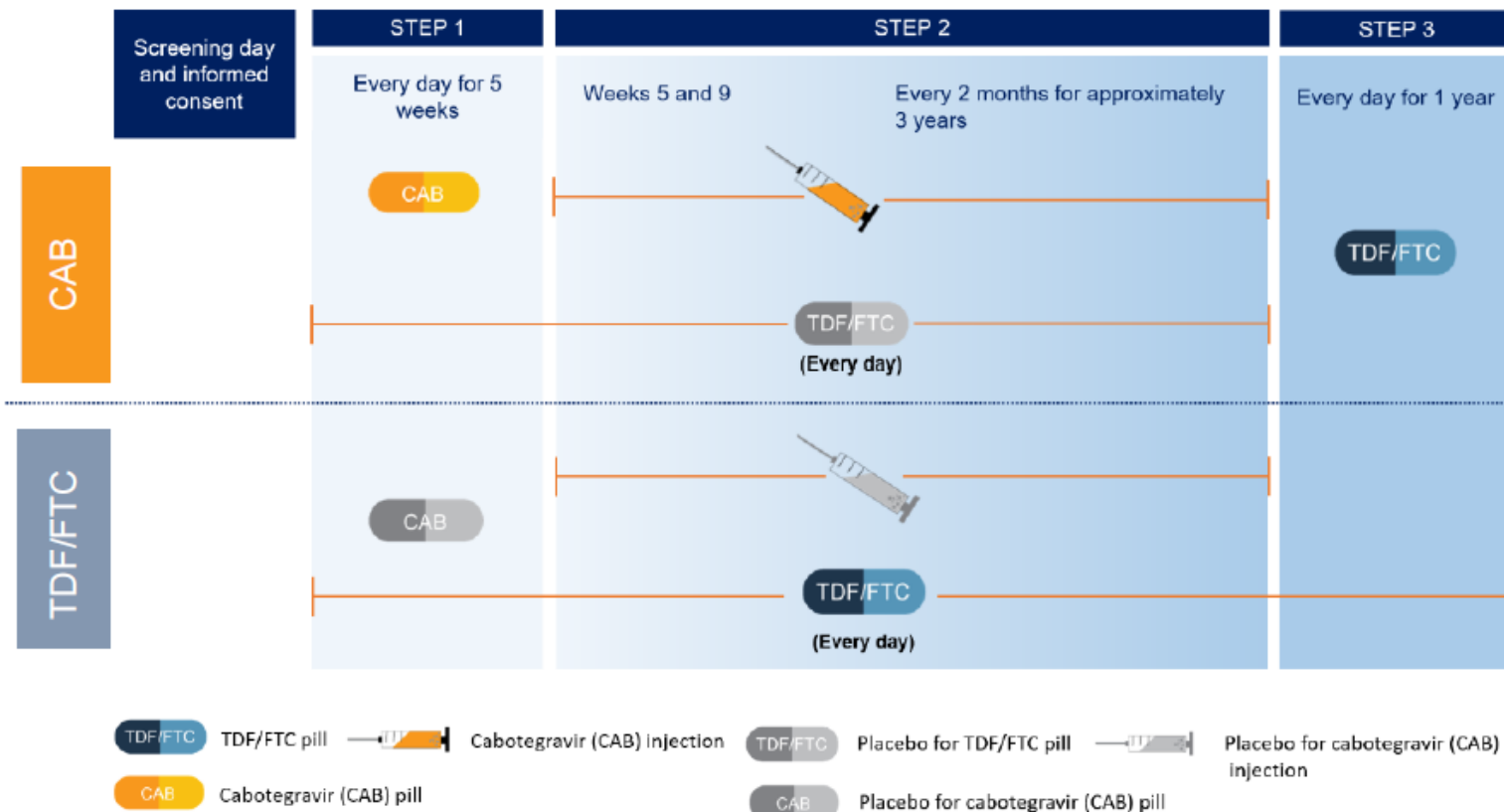
US market value

Circa \$2bn today
and growing

Cabotegravir Prophylaxis Study: Study design

From ViiV Conference call on July 9, 2020

HPTN 083 STUDY DESIGN



Landovitz RJ et al. AIDS 2020, #OAXLB01

Cabotegravir Prophylaxis Study: Efficacy Data



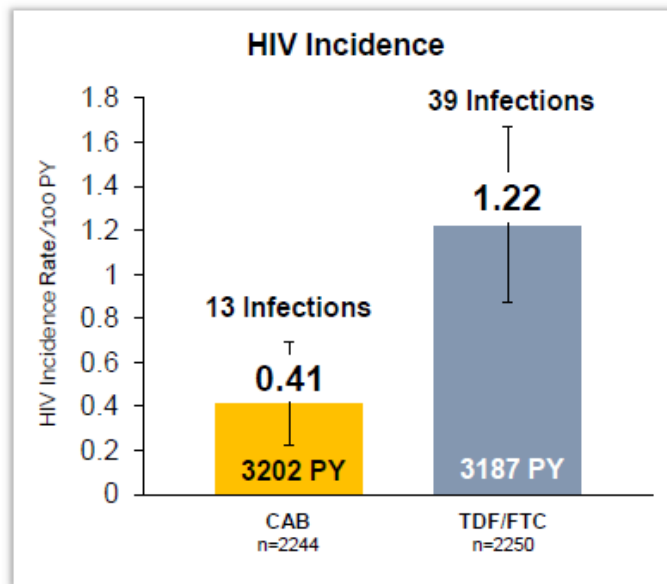
From ViiV Conference call on July 9, 2020



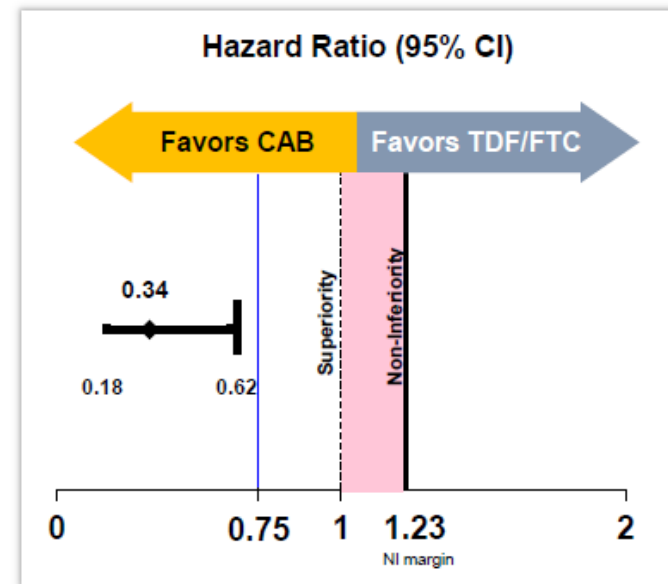
HIV INCIDENCE: CAB VS. TDF/FTC



52 HIV infections in 6389 PY of follow-up
1.4 (IQR 0.8-1.9) years median per-participant follow-up
Pooled incidence 0.81 (95%CI 0.61-1.07) per 100 PY



CI, confidence interval



Landovitz RJ et al. AIDS 2020, #OAXLB01

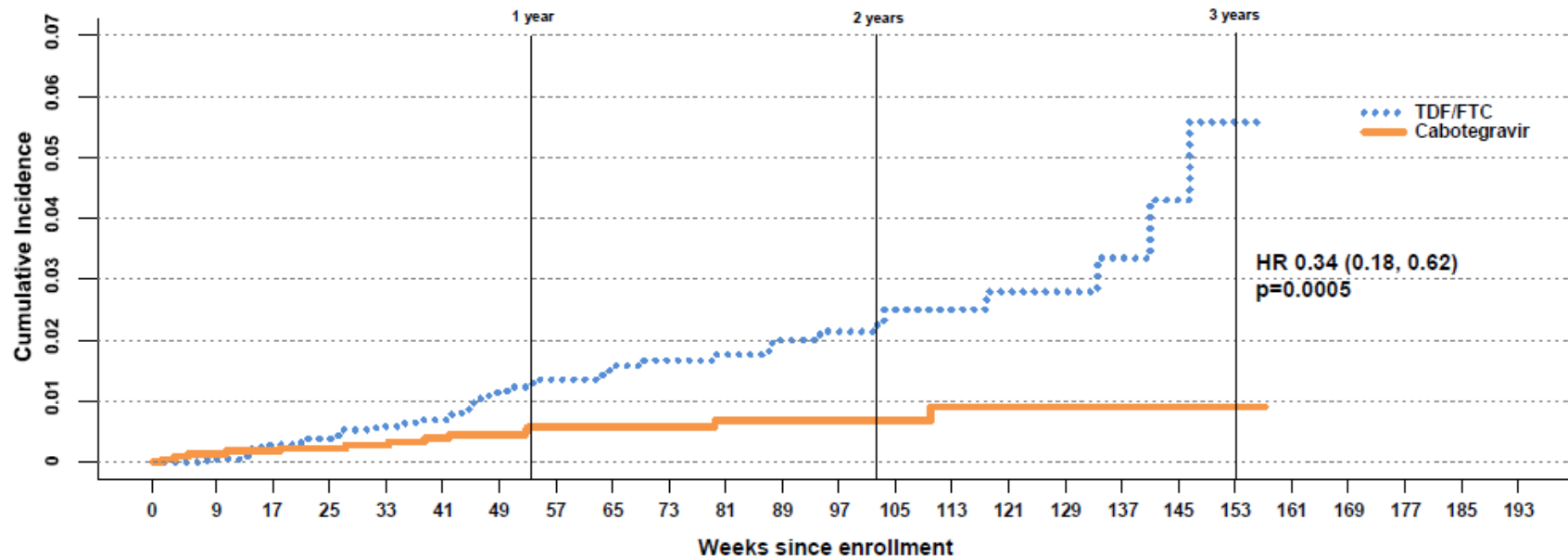
Cabotegravir Prophylaxis Study: Efficacy Data



From ViiV Conference call on July 9, 2020



HIV INCIDENCE – ITT



Number at risk

TDF/FTC	2247	2133	2081	2019	1913	1764	1624	1494	1294	1132	965	816	643	516	400	310	230	149	85	33	0	0	0	0	0
Cabotegravir	2243	2138	2092	2032	1921	1776	1632	1488	1312	1119	957	795	644	503	401	318	243	172	111	42	0	0	0	0	0

Cumulative number of events

TDF/FTC	0	1	6	8	12	14	22	25	27	29	30	32	33	35	35	36	36	37	38	39	0	0	0	0	0
Cabotegravir	0	3	4	5	6	8	9	11	11	11	12	12	12	12	13	13	13	13	13	13	0	0	0	0	0

Landovitz RJ et al. AIDS 2020, #OAXLB01

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