3rd Quarter of Fiscal 2020 Financial Results

Conference Call

February 1, 2021

SHIONOGI

Agenda

1. Overview of Q3 FY2020 Financial Results (P.4-10)
2. FY2020 Financial Forecasts (P.12-17)
3. Actions in FY2020 for Future Growth (P.19-25)

1. Overview of Q3 FY2020 Financial Results

Business Impact of COVID-19

Impact of COVID-19 on 3Q FY2020 and Our Response

- **Supply chain**
  - Continued to secure inventory, and increased monitoring of manufacturing of active pharmaceutical ingredients (APIs) and products by suppliers and CMOs so as to be prepared for major environmental changes stemming from the spread of COVID-19
  - From a national security standpoint, participated in a project to promote the domestic manufacture of raw ingredients of pharmaceutical agents for which Japan is currently heavily dependent on overseas production (received a grant from the Ministry of Health, Labour and Welfare to ensure stable supplies of pharmaceuticals)
- **Promotion**
  - At the clinic, the proportion of face-to-face meetings with physicians has recovered to around 70% of the pre-COVID-19 level, but it remained at a low level at large hospitals so far
  - Providing information virtually, in an efficient manner, through web-conferences and e-details, in combination with face-to-face or online meetings, depending upon the needs of each medical institution
  - Continuing to train sales reps for comprehensive understanding of disease, in collaboration with the Integrated Disease Care Division
- **R&D**
  - Focused resources on COVID-19-related projects, and commenced clinical trials of vaccine as planned
  - No significant impact on development timeline for 8 core projects* and, or for any other projects, in the 3rd quarter**

* See Appendix p.19 ** See Appendix p.35-37

Financial Results (Consolidated)

(Unit: B yen)

	FY2020			FY2019	Y on Y	
	Full year forecasts (revised on Oct. 30)	Apr.-Dec. results	Achievement (%)	Apr.-Dec. results*	Change (%)	Change (B yen)
Revenue	318.1	**224.4**	70.5	254.8	(11.9)	(30.3)
Operating profit	133.2	**102.2**	76.7	106.7	(4.2)	(4.5)
Core operating profit**	108.5	**80.0**	73.7	104.4	(23.4)	(24.5)
Profit before tax	159.6	**116.8**	73.2	123.6	(5.5)	(6.8)
Profit attributable to owners of parent	119.7	**86.1**	71.9	94.3	(8.7)	(8.2)

- **Sales of infectious disease drugs, mainly influenza franchise, decreased but that of other products were almost as expected**
- **Sales and profits decreased year on year due to aggressive investment in R&D in addition to the impact of transient earnings of the previous year and foreign exchange**

Exchange Rate (average)	FY2020 forecasts (Oct. 30)	FY2020 Apr.-Dec. results
USD ($) – JPY (¥)	107.00	106.11
GBP (£) – JPY (¥)	135.00	136.29
EUR (€) – JPY (¥)	120.00	122.45

* Converted from JGAAP to IFRS
** Operating income adjusted for one-time factors (impairment losses, gains on sale of property, plant and equipment, etc.)

Statement of Profit and Loss (Consolidated)

(Unit: B yen)

	FY2020			FY2019	Y on Y	
	Full year forecasts (revised on Oct. 30)	Apr.-Dec. results	Achievement (%)	Apr.-Dec. results*	Change (%)	Change (B yen)
Revenue	318.1	**224.4**	**70.5**	254.8	**(11.9)**	**(30.3)**
Cost of sales	17.3 55.1	16.0 **35.9**	**65.3**	16.0 40.7	**(11.7)**	**(4.8)**
Gross profit	263.0	**188.5**	**71.7**	214.0	**(11.9)**	**(25.6)**
Selling general & administrative expenses	31.5 100.2	30.6 **68.6**	**68.5**	28.7 73.1	**(6.1)**	**(4.5)**
R&D expenses	16.4 52.0	17.5 **39.2**	**75.4**	13.7 34.9	**12.6**	**4.4**
Other income	25.5	**23.3**	**91.4**	3.0	**687.4**	**20.4**
Other expenses	3.1	**1.7**	**55.8**	2.4	**(27.3)**	**(0.6)**
Operating profit**	41.9 133.2	45.5 **102.2**	**76.7**	41.9 106.7	**(4.2)**	**(4.5)**
Core operating profit	34.1 108.5	35.6 **80.0**	**73.7**	41.0 104.4	**(23.4)**	**(24.5)**
Finance income	28.3	**15.9**	**56.1**	18.5	**(14.0)**	**(2.6)**
Finance costs	1.9	**1.3**	**66.0**	1.5	**(18.0)**	**(0.3)**
Profit before tax	50.2 159.6	52.1 **116.8**	**73.2**	48.5 123.6	**(5.5)**	**(6.8)**
Profit attributable to owners of parent	119.7	**86.1**	**71.9**	94.3	**(8.7)**	**(8.2)**

* Converted from JGAAP to IFRS

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

Revenue by Segment

(Unit: B yen)

	FY2020			FY2019	Y on Y	
	Full year forecasts (revised on Oct. 30)	Apr.-Dec. results	Achievement (%)	Apr.-Dec. results*	Change (%)	Change (B yen)
Domestic Prescription drugs	115.3	**71.8**	**62.3**	80.3	**(10.5)**	**(8.4)**
Overseas subsidiaries/export	24.0	**17.5**	**72.7**	24.0	**(27.2)**	**(6.5)**
Shionogi Inc.	6.2	**5.4**	**87.0**	8.5	**(36.5)**	**(3.1)**
C&O	10.5	**6.9**	**66.1**	10.2	**(32.0)**	**(3.3)**
Contract manufacturing	17.1	**10.3**	**60.1**	12.0	**(14.3)**	**(1.7)**
OTC and quasi-drug	11.9	**8.8**	**74.2**	7.0	**25.5**	**1.8**
Royalty income	148.3	**114.8**	**77.4**	129.8	**(11.5)**	**(14.9)**
HIV franchise	126.3	**95.1**	**75.3**	97.8	**(2.8)**	**(2.7)**
Crestor®	16.9	**16.6**	**98.3**	16.7	**(0.9)**	**(0.2)**
Others	5.2	**3.2**	**61.9**	15.3	**(79.1)**	**(12.1)**
Others	1.5	**1.2**	**80.0**	1.7	**(29.1)**	**(0.5)**
Total	**318.1**	**224.4**	**70.5**	**254.8**	**(11.9)**	**(30.3)**

* Converted from JGAAP to IFRS

Revenue of Prescription Drugs in Japan

(Unit: B yen)

	FY2020			FY2019	Y on Y	
	Full year forecasts (revised on Oct. 30)	Apr.-Dec. results	Achievement (%)	Apr.-Dec. results*	Change (%)	Change (B yen)
Cymbalta®	28.2	**20.5**	**72.7**	20.2	**1.5**	**0.3**
Intuniv®	15.9	**9.6**	**60.4**	7.1	**35.5**	**2.5**
Vyvanse®**	0.7	**0.2**	**26.2**	0.0	**-****	**-****
Infectious disease drugs	22.8	**7.6**	**33.3**	12.8	**(40.7)**	**(5.2)**
Influenza franchise	12.9	**0.2**	**1.9**	2.1	**(88.2)**	**(1.8)**
OxyContin® franchise	5.4	**4.1**	**75.1**	4.7	**(13.4)**	**(0.6)**
Symproic®	2.7	**1.7**	**61.9**	1.5	**7.6**	**0.1**
Actair®	0.3	**0.2**	**71.1**	0.2	**30.5**	**0.1**
Mulpleta®	0.1	**0.1**	**67.9**	0.1	**(25.0)**	**(0.0)**
Pirespa®	4.8	**4.0**	**83.1**	5.0	**(19.0)**	**(0.9)**
Others	34.4	**23.9**	**69.6**	28.7	**(16.6)**	**(4.8)**
Crestor®	7.8	**5.1**	**65.2**	6.6	**(22.5)**	**(1.5)**
Irbetan® franchise	3.6	**2.6**	**70.7**	3.2	**(20.7)**	**(0.7)**
Prescription drugs	**115.3**	**71.8**	**62.3**	**80.3**	**(10.5)**	**(8.4)**

<Products included in infectious disease drugs>

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

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Influenza franchise

* Converted from JGAAP to IFRS

** Launched in Dec. 2019

Year-on-Year Comparison

- **Revenue (-30.3 B yen [-11.9%]** reference: -15.2 B yen at 1H **)**
  - **Domestic Prescription drugs (-8.4 B yen [-10.5%])**
    - > Increase: Sales of Intuniv®
    - > Decrease: Sales of Infectious disease drugs and impact of price revision (long-listed products in "Infectious disease drugs" and "Others")
  - **Overseas subsidiaries/export (-6.5 B yen [-27.2%])**
    - > Increase: US: Steady progress of cefiderocol
    - > Decrease: US: One-time payment received from BDSI* for Symproic® in FY2019 (one-time income of 1Q)
      China: sales of rabeprazole in the hospital market
  - **Contract manufacturing (-1.7 B yen [-14.3%])**
    - > Increase: Recording of contract manufacturing revenue of Nagase Medicals
    - > Decrease: Temporal reduction of dolutegravir API supply, due to manufacturing process improvements (already included in the original forecast)
      Export of Xofluza® based on this season's influenza epidemic situation
  - **OTC and quasi-drug (1.8 B yen [25.5%])**
    - > Increase: Infectious disease-related products
  - **Royalty revenue (-14.9 B yen [-11.5%])**
    - > Decrease: One-time payment received from Roche for Xofluza® in FY2019 (one-time income of 3Q)
      Exchange rate impact on royalty income from HIV franchise (£/$, £/¥)

* BioDelivery Sciences International, Inc.

Year-on-Year Comparison

- **Cost of sales (-4.8 B yen [-11.7%]** reference: -4.8 B yen at 1H**)**
  - Increase: Sales of OTC and quasi-drugs and addition of Nagase Medicals
  - Decrease: Sales of medical drugs (as the one-time income was royalty income, there is no cost reduction effect due to the decrease in income in FY2019)
- **Selling general & administrative expenses (-4.5 B yen [-6.1%]** reference: -3.5 B yen at 1H**)**
  - Increase: Initiating business of Ping An JV and investing in Nagase Medicals
  - Decrease: Cost due to decreasing opportunities to visit medical institutions
- **R&D expenses (4.4 B yen [12.6%]** reference: 1.5 B yen at 1H**)**
  - Increase: Accelerating progress of COVID-19 related projects, and 8 core projects including S-600918 and S-005151
- **Other income (20.4 B yen [687.4%]** reference: 0.0 B yen at 1H**)**
  - Increase: Gain on exchange of Shionogi Shibuya Building (one-time income of 3Q)

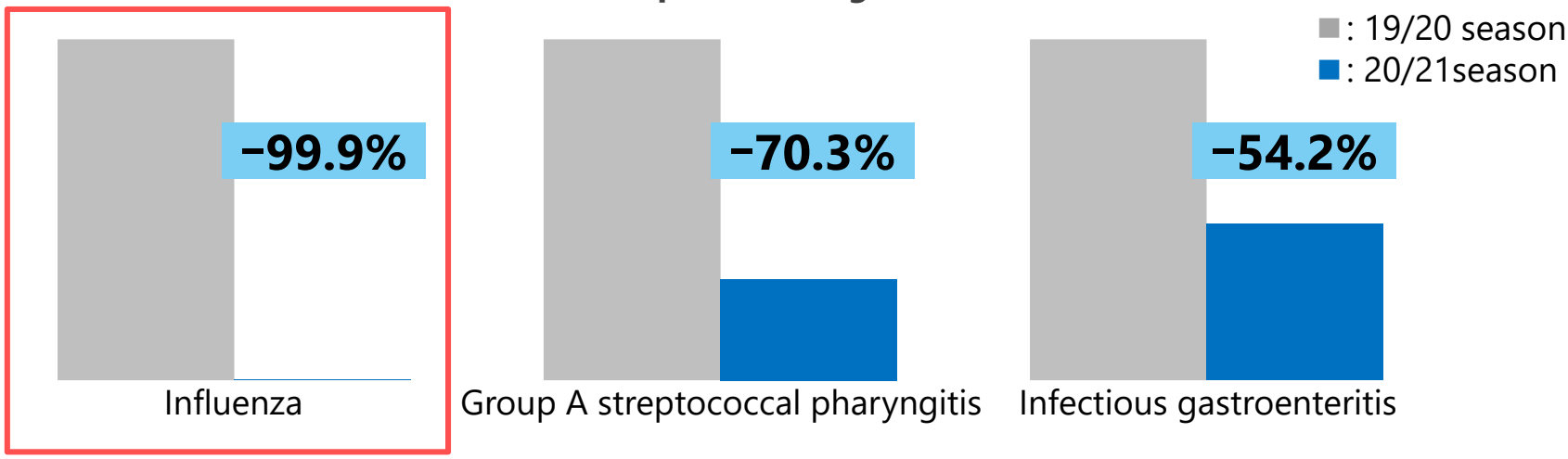
2. FY2020 Financial Forecasts

Impact of COVID-19 on Infectious disease drug market

- Many infectious diseases dropped dramatically as people took steps to prevent COVID-19 infection
- The impact of a prolonged pandemic on the infectious disease drug market should continue to be carefully estimated.

Downward revisions to forecasts for influenza-related products, considering the latest epidemic situation

Rate of decline from previous season in the number of patients with the main infectious diseases spread during the winter



Prepared from Infectious Diseases Weekly Report Japan: Cumulative number of domestic fixed-point reports (Oct.-Dec.)

Impact of Exchange fluctuation

- Sales of HIV products in the U.S. are recognized by ViiV after being translated from dollars into pounds
- In 3Q, the pound appreciated substantially against the dollar, so the amount of royalty revenue received declined
  - **Sales by ViiV remained strong as expected**

Downward revision of HIV franchise* royalty revenue forecast

Dolutegravir -related products(2020/1-9)
Total sales : £3,477m (+3% CER)**

Sales（US）($)

US sales : £2,155m (+0% CER)

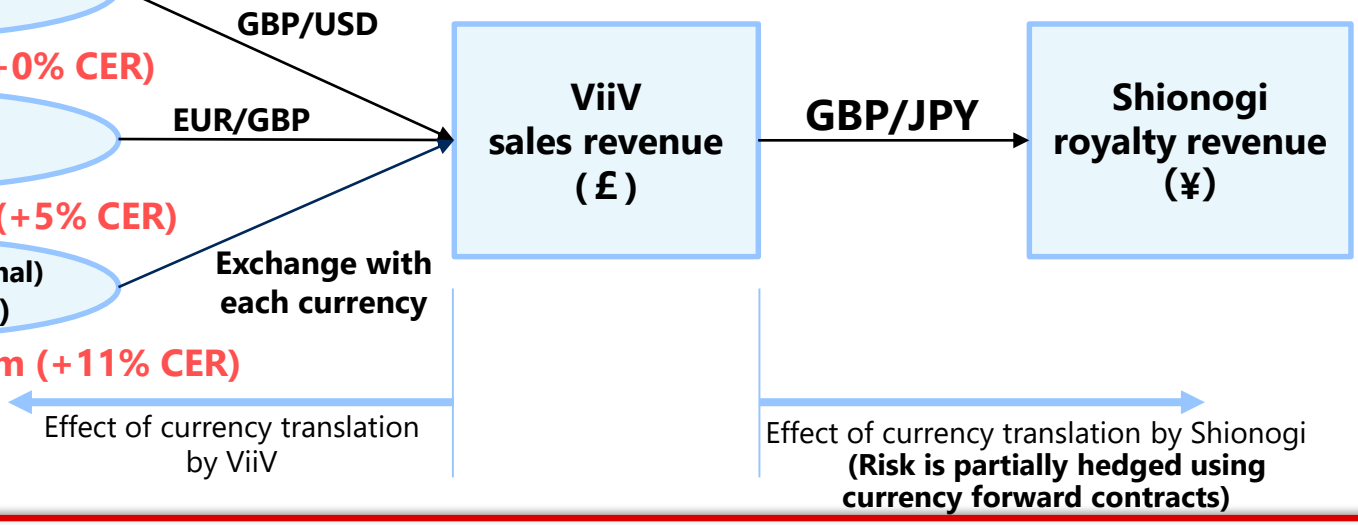
Sales（EU）(EUR)

Europe sales : £848m (+5% CER)

Sales (International) (each currency)

International sales : £474m (+11% CER)

Relationship between exchange rates and amount of royalties received



* HIV franchise: Tivicay®、Triumeq®、Juluca®、Dovato®

** Constant exchange rate growth

Revision of earnings forecast
Revenue of Prescription Drugs in Japan

(Unit: B yen)

	FY2020 Full year forecast				FY2019	Y on Y*	
	Forecasts (May 11)	Forecasts (revised on Oct. 30)	Forecasts (revised on Feb. 1)	Revised amount	Results**	Change (%)	Change (B yen)
Cymbalta®	28.6	28.2	**27.4**	**(0.7)**	26.2	**4.7**	**1.2**
Intuniv®	16.7	15.9	**14.0**	**(1.9)**	10.6	**31.2**	**3.3**
Vyvanse®* **	0.8	0.7	**0.5**	**(0.2)**	0.0	**–*** **	**0.4**
Infectious disease drugs	26.5	22.8	**10.6**	**(12.2)**	16.0	**(33.6)**	**(5.4)**
Influenza franchise	13.3	12.9	**0.7**	**(12.2)**	2.4	**(69.6)**	**(1.7)**
OxyContin® franchise	5.6	5.4	**5.5**	**0.1**	5.8	**(5.2)**	**(0.3)**
Symproic®	2.9	2.7	**2.3**	**(0.4)**	2.1	**8.7**	**0.2**
Actair®	0.3	0.3	**0.3**	**–**	0.3	**23.2**	**0.1**
Mulpleta®	0.1	0.1	**0.1**	**–**	0.1	**(9.9)**	**(0.0)**
Pirespa®	4.9	4.8	**5.2**	**0.4**	6.8	**(22.5)**	**(1.5)**
Others	37.5	34.4	**32.3**	**(2.0)**	38.3	**(15.5)**	**(5.9)**
Crestor®	8.3	7.8	**6.9**	**(0.9)**	8.6	**(20.1)**	**(1.7)**
Irbetan® franchise	3.7	3.6	**3.4**	**(0.2)**	4.2	**(19.4)**	**(0.8)**
Prescription drugs	**123.9**	**115.3**	**98.3**	**(16.9)**	**106.3**	**(7.5)**	**(7.9)**

<Products included in infectious disease drugs>

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

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Influenza franchise

* Comparison to revised forecast (2/1)
** Converted from JGAAP to IFRS
*** Launched in Dec. 2019

Revision of earnings forecast
Sales by Segment

(Unit: B yen)

	FY2020 Full year forecasts				FY2019	Y on Y*	
	Forecasts (May 11)	Forecasts (revised on Oct. 30)	Forecasts (revised on Feb. 1)	Revised amount	Results**	Change (%)	Change (B yen)
Domestic Prescription drugs	123.9	115.3	**98.3**	**(16.9)**	106.3	**(7.5)**	**(7.9)**
Overseas subsidiaries/export	24.0	24.0	**24.5**	**0.5**	30.8	**(20.3)**	**(6.3)**
Shionogi Inc.	5.1	6.2	**7.0**	**0.8**	10.1	**(31.1)**	**(3.2)**
C&O	11.9	10.5	**10.1**	**(0.4)**	13.1	**(23.1)**	**(3.0)**
Contract manufacturing	15.4	17.1	**19.0**	**1.9**	17.6	**7.8**	**1.4**
OTC and quasi-drug	10.4	11.9	**11.9**	**–**	9.7	**22.3**	**2.2**
Royalty income	148.3	148.3	**146.2**	**(2.1)**	166.9	**(12.4)**	**(20.7)**
HIV franchise	126.3	126.3	**124.3**	**(2.0)**	128.1	**(3.0)**	**(3.8)**
Crestor®	16.9	16.9	**16.9**	**–**	22.3	**(24.2)**	**(5.4)**
Others	5.2	5.2	**5.0**	**(0.2)**	16.5	**(69.8)**	**(11.5)**
Others	1.3	1.5	**1.5**	**(0.0)**	2.2	**(28.9)**	**(0.6)**
Total	**323.5**	**318.1**	**301.4**	**(16.7)**	**333.4**	**(9.6)**	**(32.0)**

The revised forecast includes Ping An-Shionogi's revenue forecast. The impact will be minor due to short accounting recognition period.

* Comparison to revised forecast (2/1)

** Converted from JGAAP to IFRS

Revision of earnings forecast
Statement of Profit and Loss (Consolidated)

(Unit: B yen)

	FY2020 Full year forecasts				FY2019	Y on Y*	
	Forecasts (May 11)	Forecasts (revised on Oct. 30)	Forecasts (revised on Feb. 1)	Revised amount	Results**	Change (%)	Change (B yen)
Revenue	323.5	318.1	**301.4**	**(16.7)**	333.4	**(9.6)**	**(32.0)**
Cost of sales	17.2 55.7	17.3 55.1	18.1 **54.5**	**(0.6)**	17.0 56.8	**(4.0)**	**(2.3)**
Gross profit	267.8	263.0	**246.9**	**(16.1)**	276.6	**(10.7)**	**(29.7)**
Selling general & administrative expenses	32.1 103.7	31.5 100.2	31.3 **94.4**	**(5.8)**	29.5 98.4	**(4.0)**	**(4.0)**
R&D expenses	15.5 50.2	16.4 52.0	17.3 **52.0**	**–**	14.4 47.9	**8.4**	**4.1**
Other income	0.5	25.5	**25.5**	**–**	4.3	**494.2**	**21.2**
Other expenses	4.0	3.1	**3.1**	**–**	4.0	**(21.5)**	**(0.9)**
Operating profit	34.1 110.3	41.9 133.2	40.8 **122.9**	**(10.3)**	39.2 130.6	**(5.9)**	**(7.7)**
Core operating profit	34.1 110.3	34.1 108.5	32.4 **97.7**	**(10.8)**	38.2 127.4	**(23.3)**	**(29.6)**
Finance income	27.5	28.3	**28.3**	**-**	30.5	**(7.2)**	**(2.2)**
Finance costs	1.6	1.9	**1.9**	**-**	2.6	**(27.2)**	**(0.7)**
Profit before tax	42.1 136.3	50.2 159.6	49.5 **149.3**	**(10.3)**	47.5 158.5	**(5.8)**	**(9.2)**
Profit attributable to owners of parent	103.6	119.7	**113.7**	**(6.0)**	122.2	**(7.0)**	**(8.5)**

The revised forecast includes Ping An-Shionogi's revenue forecast.
The impact will be minor due to short accounting recognition period.

* Comparison to revised forecast (2/1)
** Converted from JGAAP to IFRS

Revision of earnings forecast (Announced on February 1, 2021)

(Unit: B yen)

	FY2020 Full year forecasts				FY2019	Y on Y*	
	Forecasts (May 11)	Forecasts (revised on Oct. 30)	Forecasts (revised on Feb. 1)	Revised amount	Results**	Change (%)	Change (B yen)
Revenue	323.5	318.1	**301.4**	**(16.7)**	333.4	**(9.6)**	**(32.0)**
Operating profit	110.3	133.2	**122.9**	**(10.3)**	130.6	**(5.9)**	**(7.7)**
Core operating profit* **	110.3	108.5	**97.7**	**(10.8)**	127.4	**(23.3)**	**(29.6)**
Profit before tax	136.3	159.6	**149.3**	**(10.3)**	158.5	**(5.8)**	**(9.2)**
Profit attributable to owners of parent	103.6	119.7	**113.7**	**(6.0)**	122.2	**(7.0)**	**(8.5)**

Exchange Rate (average)	FY2020 forecast (May.11)	FY2020 forecast (revise on Oct.30)	FY2020 forecast (revise on Feb.1)	FY2020 Apr.-Dec. results
USD ($) –JPY(¥)	107.00	107.00	**105.50**	**106.11**
GBP (£) –JPY(¥)	130.00	135.00	**137.50**	**136.29**
EUR (€) –JPY(¥)	120.00	120.00	**123.00**	**122.45**

Forecast excluding a gain on exchange of Shionogi Shibuya Building (22.9 B yen) is in Appendix p.27

* Comparison to revised forecast (2/1) ** Converted from JGAAP to IFRS *** Operating income adjusted for one-time factors (impairment losses, gains on sale of property, plant and equipment, etc.)

3. Actions in FY2020 for Future Growth

Core 8 Projects Update

	Pipeline	Indication	Status
Infectious disease	**S-540956**	HIV infection, cancer	Non-clinical studies are progressing to support initiation of Phase I study in FY2020 4Q
Psycho-neurological diseases	**S-600918**	① Refractory chronic cough ② sleep apnea syndrome	① Phase 2b: **completed enrollment** ⇒topline results are anticipated in FY2021 1Q ② Phase 2a in progress (Japan)⇒topline results are anticipated in FY2021 1Q
	S-637880	Neuropathic low back pain	Phase 2a in progress (Japan)
	zuranolone [S-812217]	Depression	Phase 2 in progress (Japan)
	BPN14770	① Alzheimer's disease ② Fragile X Syndrome	① Phase 1 in progress (Japan) ② Preparations for Phase 3
	S-874713	Psycho-neurological diseases	Non-clinical studies are progressing to support initiation of Phase I study in FY2020 4Q
New growth areas	**S-531011**	Solid tumor	Non-clinical studies are progressing to support initiation of Phase I study in FY2021 2Q
	redasemtide [S-005151]	① Epidermolysis bullosa ② Acute stroke ③ Osteoarthritis ④ Chronic liver disease	① Preparing for application ② Phase 2 in progress (Japan) ③ Phase 2 in progress (Japan)（Investigator initiated clinical trial） ④ Phase 2 in progress (Japan)（Investigator initiated clinical trial）

Steady progress of R&D activity centered on core 8 projects*

As a Leading Company in the Infectious Disease Field

Strengthen efforts for total care of infectious diseases

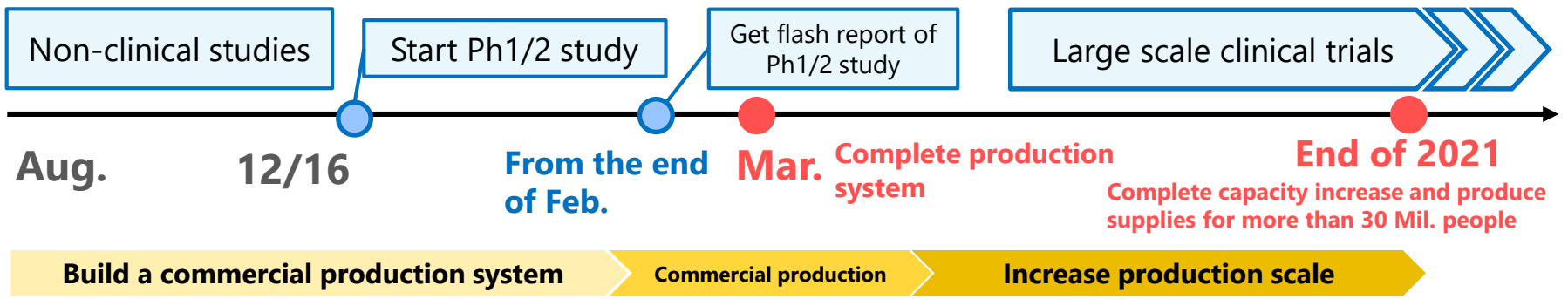
Prevention	Diagnosis	Treatment	Exacerbation suppression
			
Immunity acquisition	**Appropriate diagnosis**	**Elimination/reduction of pathogens**	**Control of host response**
Contribute to reducing spread of infection		Contribute to offering of optimal treatment options	

Providing comprehensive infectious disease care to address medical and societal needs

Our Efforts to Fight COVID-19

Development of Prophylactic Vaccine (S-268019)

- **Developing a recombinant protein vaccine** based on established technology
- Selection of the antigen and the adjuvant
  - Confirmed efficacy of vaccination in preventing exacerbation in an animal study
- Ph1/2 clinical trial* started in December 2020
  - No major safety concerns so far
  - In discussion with regulatory authorities to start global Ph3 trials later this year, considering further plans
- **Complete production system** in collaboration with UNIGEN (antigen production) and API (formulated product manufacturing) **within FY2020**



* Randomized double-blind placebo controlled trial involving 200 or more Japanese adults
In two parts of clinical trials, Ph1 for confirmation of safety and tolerability, and Ph2 for the second to investigate the optimal dose
The vaccine was administered two times with a gap of three weeks between inoculations, and safety, tolerability, and immunogenicity were assessed for a period of one year post-inoculation

Our Efforts to Fight COVID-19

Business alliance to control exacerbation

- **Conclusion of basic agreement with BioAge aiming to suppress the exacerbation of infectious diseases with S-555739**
  - ✓ Shionogi granted BioAge the exclusive US and European rights to develop and commercialize S-555739 for COVID-19 treatment
  - ✓ Shionogi granted BioAge the exclusive rights to negotiate a license for further indications
  - – **BioAge Labs, Inc.**
    - > Clinical-stage biotechnology company that develops drugs to treat aging and aging-related diseases
    - > Building a biology platform to map out the key molecular pathways that impact healthy human aging, based on proprietary human aging cohorts that have blood samples collected up to 45 years ago with participant-omics data
  - – **S-555739（BioAge code: BGE-175）**
    - > Prostaglandin D2 DP1 receptor antagonist which conducted Ph3 study with allergic rhinitis as an indication*
    - > Improvement of allergic symptoms in animal model and high affinity for DP1 receptor had confirmed in non-clinical studies
    - > Proven good tolerability and safety in clinical trials**

Discovery of Therapeutic Drugs

- Abandoned the initial goal of starting clinical study within FY2020 as more efficacy and safety studies are needed
- **We are continuing our drug discovery efforts not only for SARS-CoV-2 but also for other corona viruses to prepare for the potential for future corona virus pandemics**
- Producing more effective and safer drug by taking advantage of various modalities

Offering Test/Diagnosis Kit***

- Reviewing the release target date of the initial product and formulating a new development plan
- **In parallel, accelerating studies for early provision of kits that enable easier and quicker diagnosis of multiple samples**

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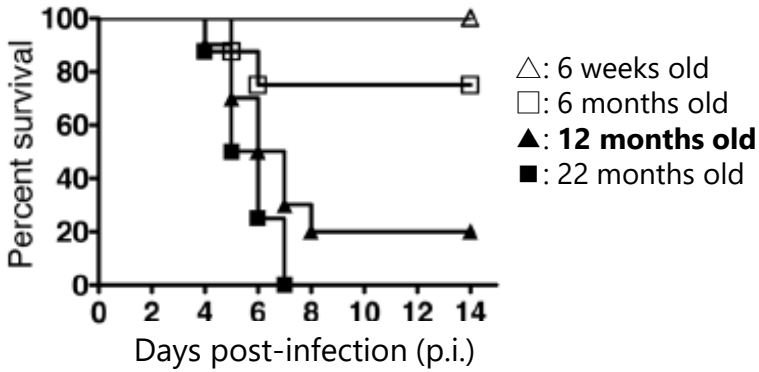
* Development for this indication was halted in November 2016

** See Appendix p.29

*** R&D involving the SATIC method conducted jointly with Nihon University, Gunma University, and Tokyo Medical University

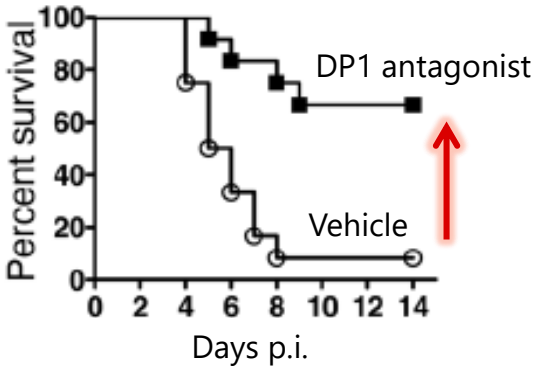
Mortality Reduction by Inhibition of PGD_2 DP1 in Elderly Mice Infected with SARS-CoV

Comparison of mortality rates of various aged mice infected with SARS-CoV*



Increase in mortality rates with aging

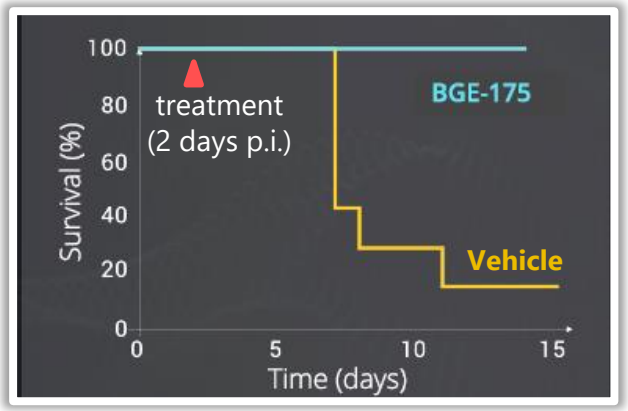
Mortality suppression through DP1 antagonist in **12 months old mice**



DP1 antagonist reduces mortality rate in elderly mice

J. Clin. Invest., 2011;121(12):4921-4930

BGE-175 reduced mortality rate of 8 months old mice infected with SARS-CoV (conducted by BioAge)



- DP1 antagonist promotes the acquisition of immunity in elderly mice
  - → **Possibility of suppressing exacerbation of COVID-19 and other infectious diseases**
  - → **BioAge plans to start Phase 2 trial for COVID-19 from Feb. 2021**

* A strain adapted from the SARS coronavirus strain that was prevalent in 2002 for use in animal studies

Progress of cefiderocol

A new model to obtain stable return*

- United Kingdom
  - **Adopted for subscription-type reimbursement model** (12/18)
    - > A system where the government pays the company a fixed amount of compensation regardless of the amount of antimicrobial drugs prescribed, and the government can ensure availability of the antimicrobial drugs needed
    - > Subscription payment contract period is scheduled to start in April 2022
- Sweden
  - **Started supply as a delinked incentive model target** (1/1)
    - > A system where payment for a minimum amount is guaranteed, and if the amount supplied exceeds the minimum, revenue for that is also earned

Expand sales to EU

- Germany
  - Available from 1/15
    - > New health reimbursement evaluation method will be introduced
- Preparing for release in France, Italy and Spain

* See Appendix p.30

Progress of HIV Franchise by ViiV

- 「Growth through 2 Drug Regimens (DRs)」, 「Prevention Market transformation」 -

Strong momentum and development progress on 2DRs

Juluca (DTG/RPV*1) Dovato (DTG/3TC*2) CABENUVA (CAB/RPV*3)

- **Juluca and Dovato drive growth in HIV franchise**
  - Increase notable especially in US DTG NBRx*4 share
- **Dovato**
  - Increased share in switch market（U.S. Approved Aug. 2020: switch patients）
  - Long-term safety and efficacy results from TANGO study 96w, GEMINI study 144w
- **Cabotegravir**：Cabenuva（U.S., Canada）、Vocabria+Rekambys（Europe）
  - U.S. ,Canada, Europe Approved、**Scheduled for market launch in Feb. 2021**
  - New treatment can enable people living with HIV to reduce the days they receive treatment from **365 to 12** (U.S. ,Canada, Europe) or **6** per year (Europe)
  - Improvement of QOL:「Convenience」、「Medication Adherence」、「Reduce daily awareness of HIV」、「Privacy」
  - Efficacy and safety were confirmed in 5 years of continuous dosing
  - Strong patient preference:>97% of patients in pivotal ATLAS and FLAIR studies preferred LA regimen vs daily oral therapy

Prevention market transformation by cabotegravir

- **US submission expected mid-2021**
  - 66% more effective for men and 89% more effective for women than FTC/TDF*5 in preventing HIV infection
  - Received FDA Breakthrough Therapy Designation
  - $2bn market (>200k US PrEP patients) today, but up to 1.2m could benefit

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*1 DTG/RPV: dolutegravir/ rilpivirine *2DTG/3TC: dolutegravir/lamivudine *3 CAB/RPV: cabotegravir/rilpivirine
*4 New-to-Brand Prescriptions *5 FTC/TDF: emtricitabine/tenofovir disoproxil fumarate

Appendix

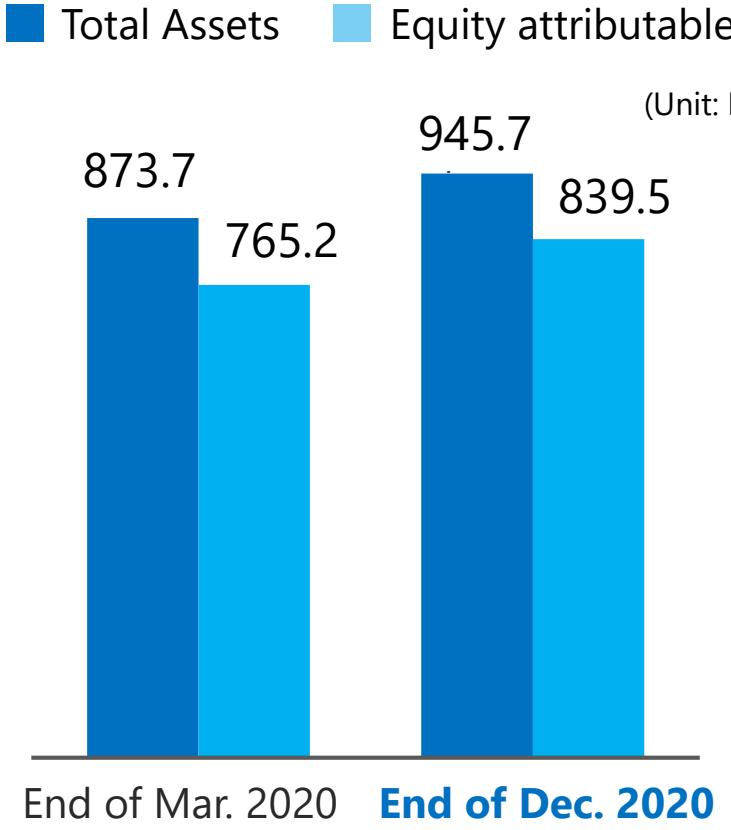
Revision of earnings forecast
(excluding a gain on exchange of Shibuya Building (22.9 B yen))

(Unit: B yen)

	FY2020 Full year forecasts				FY2019	Y on Y*	
	Forecasts (May 11)	Forecasts (revised on Oct. 30)	Forecasts (revised on Feb. 1)	Revised amount	Results**	Change (%)	Change (B yen)
Revenue	323.5	318.1	**301.4**	**(16.7)**	333.4	**(9.6)**	**(32.0)**
Operating profit	110.3	110.3	**100.0**	**(10.3)**	130.6	**(23.4)**	**(30.6)**
Core operating profit* **	110.3	108.5	**97.7**	**(10.8)**	127.4	**(23.3)**	**(29.6)**
Profit before tax	136.3	136.7	**126.4**	**(10.3)**	158.5	**(20.3)**	**(32.1)**
Profit attributable to owners of parent	103.6	103.6	**97.8**	**(5.7)**	122.2	**(20.0)**	**(24.4)**

* Comparison to revised forecast (2/1) ** Converted from JGAAP to IFRS *** Operating income adjusted for one-time factors (impairment losses, gains on sale of property, plant and equipment, etc.)

Financial Position (Consolidated, IFRS)



Unit: B yen		End of Mar. 2020	End of Dec. 2020	Change
Total Assets	Non-current Assets	357.7	401.6	43.9
	Current Assets	516.0	544.1	28.1
Equity attributable to owners of parent		765.2	839.5	74.4
Total Liabilities	Non-current Liabilities	27.4	23.1	(4.3)
	Current Liabilities	81.1	72.4	(8.7)

	Mar. 2020	Dec. 2020
Ratio of equity attributable to owners of parent to total assets	87.6%	**88.8%**

S-555739：previously conducted clinical trials

- **Clinical trials have been conducted in Japan, US and Europe (more than 10 trials in total)**
  - Japan: Completed Phase 3 trials (2013)
  - US: Completed Phase 2a trials (2013)
  - Europe: Completed Phase 2a trials (2009)

Region	Stage	Major clinical trials conducted in the past	Description
JP	Ph2a	Phase IIa Study of S-555739 in Patients with Perennial Allergic Rhinitis	JapicCTI-090875
	Ph2a	Phase IIa Study of S-555739 in Patients with Seasonal Allergic Rhinitis	JapicCTI-101361
	Ph2b	Phase IIb Study of S-555739 in Patients with Seasonal Allergic Rhinitis	JapicCTI-111698
	Ph2	Phase II Study of S-555739 in Patients with Japanese Cedar Pollinosis in an Environmental Challenge Chamber	JapicCTI-121981
	Ph3	Phase III Study of S-555739 in Patients with Seasonal Allergic Rhinitis	JapicCTI-132046
	Ph3	A multicenter double blind randomized controlled trial to investigate the efficacy of S-555739 in perennial allergic rhinitis	JapicCTI-132222
US	Ph2a	Combination Study Of S-555739/Cetirizine HCl In Adult Patients With Seasonal Allergic Rhinitis	ClinicalTrials.gov Identifier: NCT01651871
Europe	Ph2a	A randomized, double blind, placebo-controlled, 2-period cross over study to evaluate effects of S-555739 on prostaglandin D2 (PGD2) induced nasal airway resistance in healthy adult volunteers	EudraCT Number: 2008-006787-11
	Ph2a	A randomised, double-blind, placebo-controlled, 2-period crossover study to evaluate effects of multiple oral doses of S-555739 on nasal allergen challenge in subjects with intermittent grass pollen sensitive allergic rhinitis.	EudraCT Number: 2008-006788-35

So far, more than 2,000 patients have been treated with S-555739, but no S-555739-specific safety concerns have been identified.

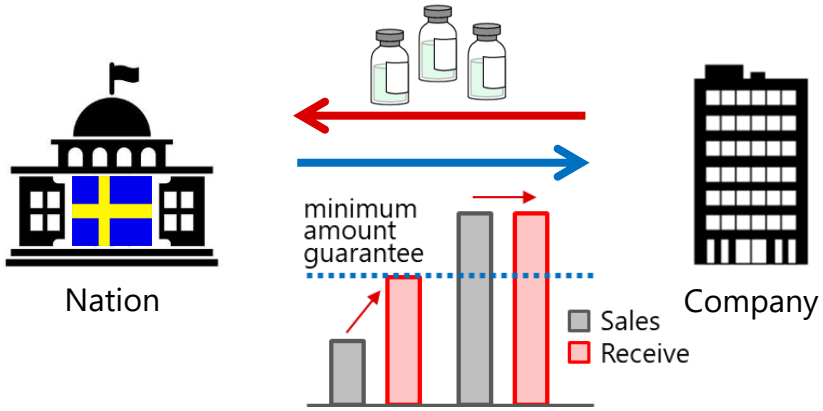
Cefiderocol: subscription-type reimbursement model

【UK model】

A system where the government pays the company a fixed amount of compensation regardless of the amount of antimicrobial drugs prescribed, and the government can obtain the antimicrobial drugs needed

【Swedish model】

A system where payment for a minimum amount is guaranteed, and if the amount supplied exceeds the minimum, revenue for that is also earned



subscription-type reimbursement model

- Adopted antimicrobial drugs
  - Fetcroja（cefiderocol）
  - ceftazidime/avibactam（Zavicefta: Avycaz）
- Subscription payment contract period is scheduled to start in April 2022

delinked incentive model

- Adopted antimicrobial drugs
  - Zerbaxa（ceftolozan-tazobactam）
  - Recarbrio（imipenem-cilastatin-relebactam）
  - Fetcroja（cefiderocol）
  - Vaborem（meropenem-vaborbactam）
  - Fosfomycin infectopharm（fosfomycin）

Pipeline: Infectious Disease

as of Feb 1, 2021

Preclinical	Phase 1	Phase 2	Phase 3	Submission
S-872600 Influenza prophylactic vaccine	**S-268019*** COVID-1 prophylactic vaccine **Up**	**Cefiderocol** cUTI*	**Cefiderocol** Nosocomial pneumonia	**Xofluza®** Influenza virus infection (Prophylaxis) **Approved**
	* Phase 1/2 on-going		**Xofluza®** Influenza virus infection (High-dose for children)	**Xofluza®** Influenza virus infection (Granules, < 20 kg)
: Global development	**S-648414** HIV infection		**Cefiderocol** Aerobic Gram-negative bacterial infection (Pediatric)	**Xofluza® (Taiwan)** Influenza virus infection (Prophylaxis) **Approved**

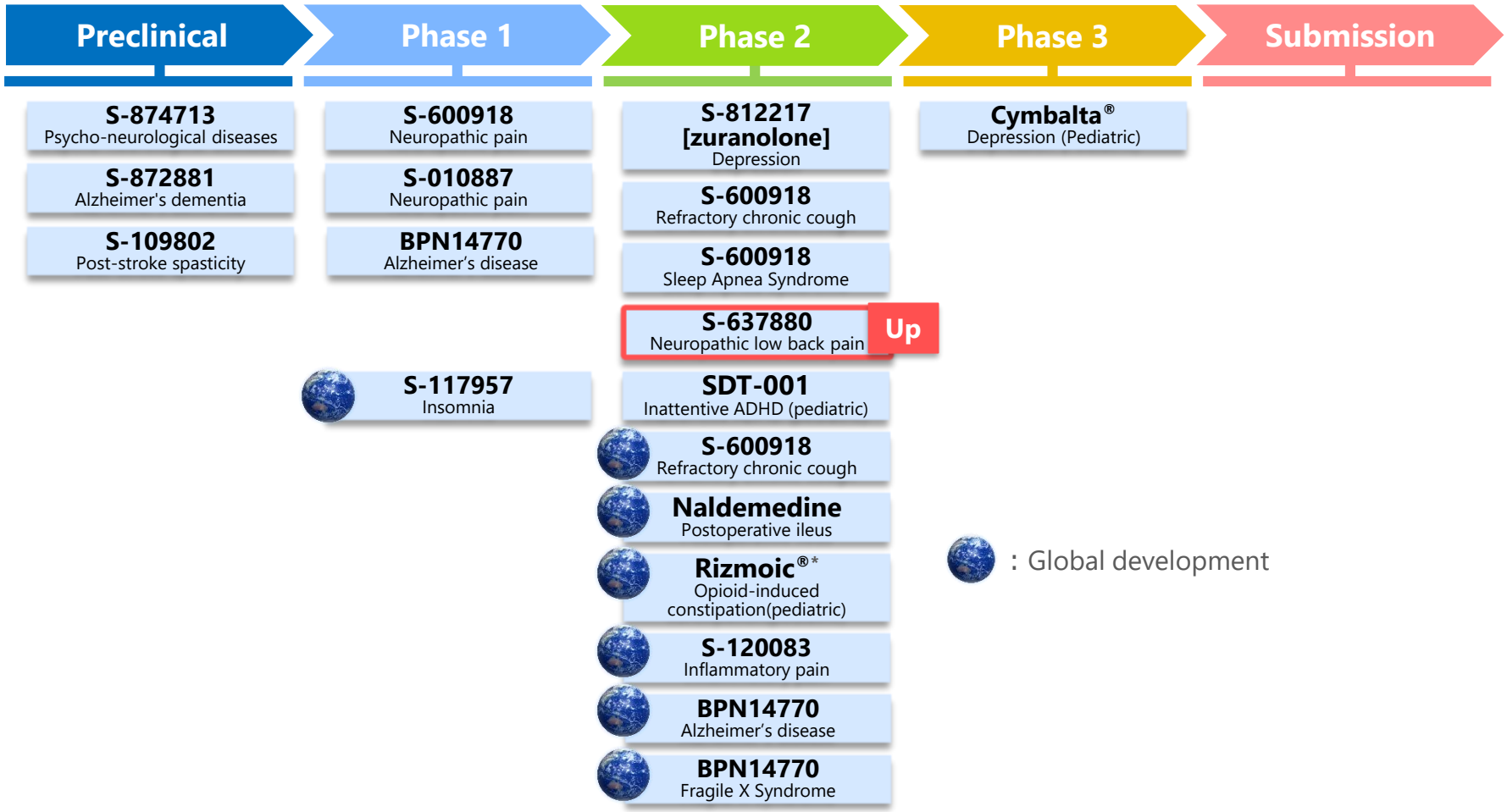
Out license

S-555739 Treatment by suppressing aggravation of COVID-19 **New**	**Cabotegravir LAP** Prophylaxis of HIV infection	**Xofluza® (EU)** Influenza virus infection (Treatment [healthy, high risk], prophylaxis) **Approved**
	Xofluza® Influenza virus infection (Severe hospitalised)	**Xofluza® (US)** Influenza virus infection (Prophylaxis) **Approved**
	Xofluza® Influenza virus infection (Pediatric, < 1 year old)	**Xofluza® (US)** Influenza virus infection (Pediatric, over 1 year old)
	Xofluza® Influenza virus infection (Transmission)	**Xofluza® (US)** Influenza virus infection (Granules) **Approved**
		CAB+RPV LAP（US,EU） HIV infection **Approved**

Stage change (Changes from Oct. 31, 2020)
Xofluza® (Treatment): Approved (EU) Xofluza® (Prophylaxis): Approved (Japan, US, EU, Taiwan) Xofluza® (Granules): Approved （US） S-268019 (COVID-1 prophylactic vaccine): Phase ½ start (Japan) S-555739 (Treatment by suppressing aggravation of COVID-19): Non-clinical

Pipeline: Psycho-neurological Disease

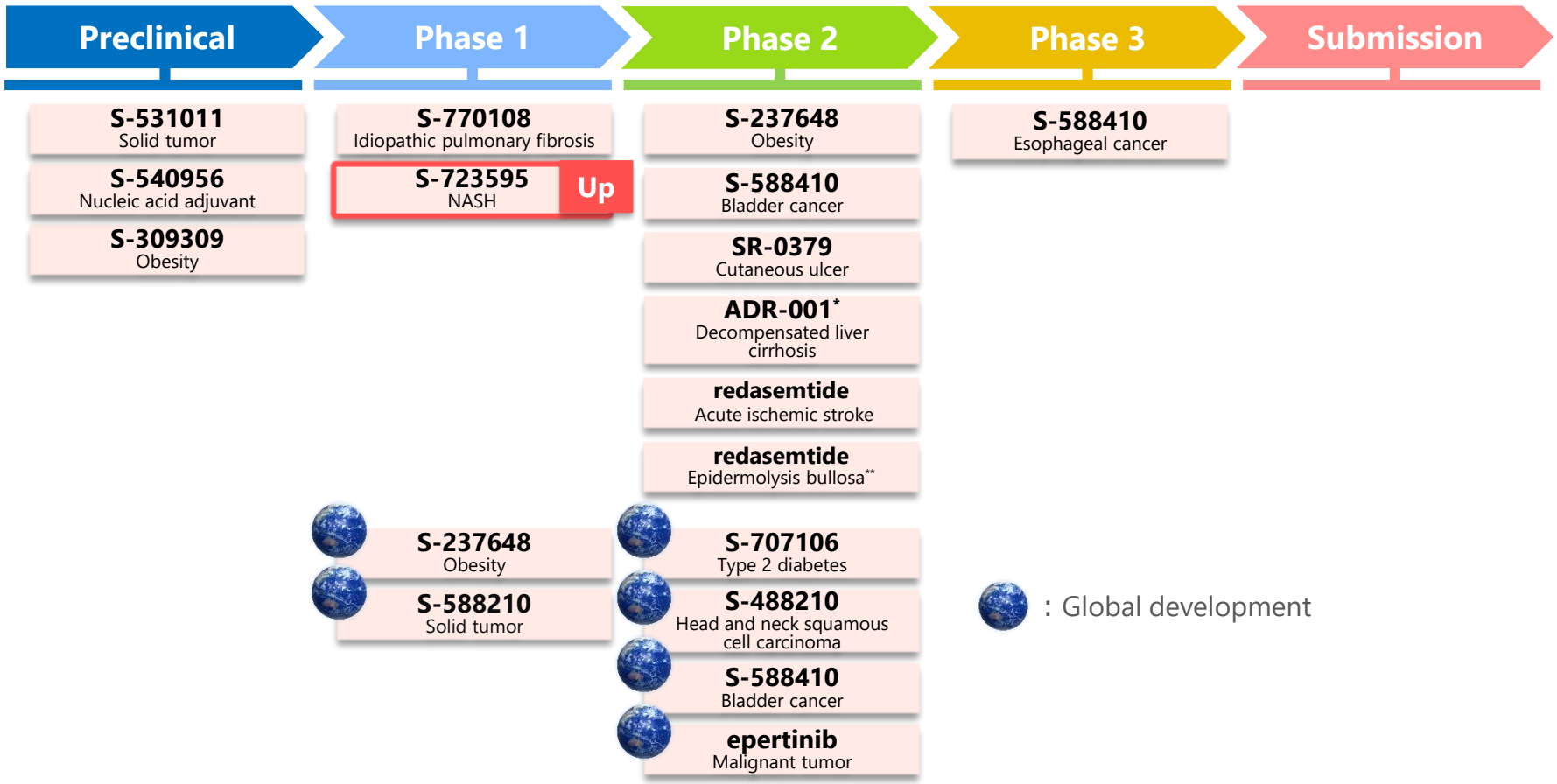
as of Feb 1, 2021



Stage change (Changes from Oct. 31, 2020)
S-673880 (Neuropathic low back pain): Phase 2 start

Pipeline: New Growth Area

as of Feb 1, 2021



Stage change (Changes from Oct. 31, 2020)
S-723595 (NASH): Phase1 start (Japan)

FY2020 Pipeline Target Milestones

Phase	Pipeline	Indication	Milestone ✓ : achieved
Submission~ Approval	Fetroja® (cefiderocol)	Nosocomial pneumonia*	US: supplemental approval ✓
	Fetcroja® (cefiderocol)	Aerobic Gram-negative bacterial infection*	EU: Approval ✓
	Xofluza®granules	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 MAD ✓
	S-637880**	Neuropathic low back pain**	Japan: Initiation of Phase 2 (PoC) ✓
	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	US: Initiation of Phase 1
	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 ✓

* Patients 18 years of age or older who have limited or no alternative treatment options

** Due to a change in the development policy, S-637880 alone was developed for neurological low back pain from a clinical trial that evaluates S-637880 and S-600918 within the same study

Key Events for Major Pipeline Compounds

as of Feb 1, 2021

Pipeline	Mar. 2020	FY2020	FY2021	FY2022
S-648414 HIV infection	Ph1 on-going		Ph2a start (4Q) ★ Ph2a topline results (2Q)	
S-540956 HIV infection, cancer	Non-clinical		Ph1 start (4Q)	Ph1 topline results (3Q)
S-268019 COVID-19 prophylactic vaccine	Non-clinical	Ph1/2 start (4Q)	★ topline results are anticipated sequentially（4Q～）	Ph3 start time is under discussion with authorities

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

Key Events for Major Pipeline Compounds

as of Feb 1, 2021

Pipeline	Mar. 2020	FY2020	FY2021	FY2022
zuranolone Depression	Ph2 start		Ph2 topline results (3Q)	
S-600918 Refractory chronic cough	Ph2b on-going		Ph2b topline results (1Q)	
S-600918 Sleep apnea syndrome	Ph2a start	Ph1 topline results (2Q) Ph2a start (3Q)	Ph2a topline results (1Q)	
S-637880 Neuropathic low back pain*	Ph1 on-going			Ph2a topline results (4Q)
BPN14770 Alzheimer's disease	US Ph2 topline results	Ph1 start (2Q)	Ph1 topline Results (4Q) Ph2 start (2Q)	
BPN14770 Fragile X Syndrome	Ph2b on-going	Ph2 topline Results (2Q)	Ph3 start (2Q)	
S-874713 Psycho-neurological diseases	Non-clinical		Ph1 start (4Q) Ph1 topline results (4Q)	Ph2 start (1Q)
SDT-001 ADHD	Ph2 on-going		Ph2 topline results (3Q)	
S-109802 Post-stroke spasticity	Non-clinical			Ph1 start (3Q)
S-872881 Alzheimer's disease	Non-clinical			Ph1 start (1Q)

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

→Changes from 1st half of fiscal 2020 financial results presentation material (Oct. 30, 2020)

* Due to a change in the development policy, S-637880 alone was developed for neurological low back pain from a clinical trial that evaluates S-637880 and S-600918 within the same study

Key Events for Major Pipeline Compounds

as of Feb 1, 2021

Pipeline	Mar. 2020	FY2020	FY2021	FY2022
redasemtide Epidermolysis bullosa	Sponsor investigator top-line results		Launch	
redasemtide Ischemic stroke	Ph2 on-going		Ph2 topline results (3Q)	
S-531011 Solid tumor	Non-clinical		Ph1 start (2Q)	
S-588410 Esophagus cancer	Ph3 on-going		Ph3 topline (1Q)	
S-588210 Solid tumor	Ph1 on-going		Ph1 topline (3Q)	
S-770108 Idiopathic pulmonary fibrosis	Preparation for lung deposition study (LD study)	LD study start (2Q)	LD study topline results (4Q) / Ph2/3 start (2Q)	
S-723595 NASH	Non-clinical	Ph1 start (3Q)	Ph1 start (3Q)	Ph2a start (3Q)
S-309309 Obesity	Non-clinical		Ph1 start (2Q)	Ph1 start (2Q) / Ph2a start (4Q)

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

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