SHIONOGI & CO. LTD.

Q1 Financial Results Briefing for the Fiscal Year Ending March 2021 Conference Call

July 31, 2020

Hanasaki: I will explain Q1 financial results.



Please look at page two. Here, we have reposted our 2030 vision announced on June 1. We are working towards enacting a transformation from a discovery-based pharmaceutical company centered on existing prescription drugs to a healthcare provider offering healthcare service, thus creating the future of healthcare through new platforms.

From the New Mid-term Business Plan STS2030 (partially modified) Start of New M Business Plan	edium-term						
Strategy to achieve 2030 Vision STS2030 - Shionogi Transformation Strategy 2030 -							
STS	2030						
STS Phase1 ('20 -'24)⇒ New medium-term business planRealizing our transformation202020	STS Phase2 ('25 -) ⇒ Next medium-term business plan Growth from transformation 25 2030						
SHIONOGI	3						

Next, look at page three. As a strategy to achieve this vision, we formulated Shionogi Transformation Strategy 2030, or STS2030. In this strategy, we particularly intend to overcome the patent cliff in HIV products set to come around 2028 and achieve further growth. Towards this end, we have drawn out a new growth strategy achieved through business transformation. In the first 5 years out of the 10 years, or Phase I, we aim to realize this transformation.



On page four, we describe the basic policy in Phase I. Specifically, we include the initiatives we will take in our R&D strategy and top-line strategy toward creating new value, as we work to embody the transformation towards realizing sustainable growth as a total healthcare company.

We intend to work resolutely towards creating a management foundation strategy as we advance this strategy. In this fiscal year, particularly in response to the state-of-emergency declaration under the COVID-19 crisis, we have reviewed the way we work. We have deemed this as an opportunity to raise our productivity, and we are currently working towards evolving our growth platform. In particular, we are reviewing our decision-making process and activities to further accelerate the speed of transformation, and we are making company-wide efforts to create a "discontinuous evolution."

Today, Hosogai will give a summary of the financial results for Q1, and in the latter half, I will explain about the progress towards STS Phase I through actions taken over the last three months.

Now, Hosogai will explain the summary of the financial results for Q1.

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



* See Appendix p.26, ** See Appendix p.27, *** See Appendix p.33, 34

7

Hosogai: This is Hosogai. I will now give an explanation.

First, on page seven, we summarized the overview of COVID-19's impact on our business.

We described three points. First, we outlined the impact on our supply chain. Regarding the procurement of raw ingredients for products, no major hindrances have been observed. However, some production has been pushed ahead of schedule, and imported raw ingredients have been secured.

As for information provision activities, we refrained from visiting medical institutions. And, instead, we have been providing information through web lectures and e-detail. Meanwhile, some visits have resumed following the gradual lifting of activity restrictions. On the other hand, we're continuing to carry out digital measures. As part of our disease strategy, we are conducting educational activities on a range of diseases even if, for instance, we are working from home.

Concerning the third point, R&D, progress in the eight projects is being made without any major delays. But, in addition to that, initiatives are being taken by allocating resources to R&D related to COVID-19. This completes the explanation for this section.

Financial Results (Consolidated)

					(Unit: B yen)		
		FY2	020	FY2019	Y2019 Y to Y		
	Forec	asts	AprJun.	Progress	AprJun.	Change	Change
	Full year	1H	results	vs. forecasts	results*	(%)	(B yen)
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 			Ex	change Rat (average)	te FY2 fore	casts	FY2020 AprJun. results
			USD) (\$) – JPY	(¥)	107	107.64
			GBP	• (£) – JPY	(¥)	130	133.63
progressing smo	othly		EUR	t (€) – 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 genupment, etc.)

Next, moving on to page eight, I would like to give a general overview of the consolidated financial results.

We describe the results for the April-June period shown inside the red border. Revenue came to JPY71.4 billion, which represents 45.9% of the 1H forecast, down JPY9.4 billion YoY. Operating profit was JPY25.6 billion, which represents 47.6% of the 1H forecast, down JPY6.1 billion YoY. As for core operating profit, the trend was roughly the same as operating profit. Regarding profit attributable to owners of parent, on the very bottom, the result was JPY21.5 billion, which is 48.0% of the 1H forecast, down JPY5.6 billion YoY.

Of course, there was an impact on sales as described on the bottom left, as COVID-19 caused the market to shrink. On a profit basis, as I will explain later, R&D expenses have been spent above the standard level. Taking this into consideration, progress in profits is likely to be roughly standard. Another point described on the bottom left is our various initiatives toward the new medium-term targets, as explained by Hanasaki earlier. We wrote that actions are progressing smoothly in consideration of the steady progress being made. We will give more details later.

As for the foreign exchange rate, the yen depreciated against the British pound slightly more than we anticipated.

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Statement of Profit and Loss (Consolidated)

						(Un	it: B yen)
	FY2020				FY2019	Y to Y	
	Fore	casts	AprJun.	Achievement	AprJun.	Change	Change
	Full year	1H	results	(%)	results*	(%)	(B yen)
Revenue	323.5	155.6	71.4	45.9	80.8	(11.6)	(9.4)
Cost of sales	55.7	25.7	16.1	44.7	15.7	(9.3)	(1.2)
Gross profit	267.8	129.9	59.9	46.1	68.1	(12.0)	(8.2)
Selling general &	32.1	33.2	30.4		29.6	, ,	
administrative expenses	103.7	51.6	21.7	42.0	23.9	(9.2)	(2.2)
	15.5	14.8	17.0		14.5	1	
R&D expenses	50.2	23.0	12.2	52.8	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)

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* Converted from JGAAP to IFRS 9

Moving on to page nine, I will give an explanation of the consolidated profit and loss statement.

As explained earlier, revenue came to JPY71.4 billion, reflecting 45.9% of the 1H forecast. I will give the details in a page we will cover later. As for the cost of sales, slight improvements have been made in the cost ratio attributable to the drug mix. Gross profit was JPY59.9 billion, reflecting 46.1% of the 1H forecast.

As for expenses, SG&A expenses amounted to JPY21.7 billion, representing 42.0% of the 1H forecast. We will be covering this more a little later, but due to the impact of restrictive orders on our activity bases, the figures reflect the impact of these activity bases undershooting expectations. Meanwhile, R&D expenses were JPY12.2 billion, representing 52.8% of the 1H forecast. As mentioned earlier, steady progress is being made in each project, and additional R&D expenses related to COVID-19 are also included.

Based on the above, operating profit was JPY25.6 billion, reflecting 47.6% of the 1H forecast. Core operating profit was JPY25.9 billion, reflecting 48.0% of the 1H forecast. Profit attributable to owners of parent totaled JPY21.5 billion, representing 48.0% of the 1H forecast. The YoY figures are described on the very right, and we will omit an explanation here because we will once again review all these figures later.

Revenue by Segment



(I Init: D von

	EV2020				EV2010	V on V	
	Forec	asts*	020		<u>F12015</u>		
	E	411	AprJun.	Achievem	AprJun.	Change	Change (B
	Full year	18	results	ent (%)	results*	(%)	yen)
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)

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* Converted from JGAAP to IFRS 10

The breakdown of revenue is described on page 10, so we hope you will look at this information.

In the middle, on the very bottom, we described that the total was 71.4 billion yen. This breaks down as 22.4 billion yen in prescription drugs, or 42.1% of the 1H forecast. We will look at revenue by drug later.

Below that are overseas subsidiaries and exports, Shionogi Inc. made more progress than we expected, driven by revenues from Osphena and the newly launched antibacterial drug Fetroja. Meanwhile, C&O came in slightly below expectations chiefly Rabeprazole, in part due to the impact of COVID-19.

In contract manufacturing, revenue was 2.9 billion yen, reflecting 36.5% of the 1H forecast. Progress has been slightly slow in this business, too. But this is due to the impact of a slight delay in the contract manufacturing of Xofluza for Roche. In OTC and quasi-drug, revenue was 2.3 billion yen, reflecting 46.5% of the 1H forecast, and we consider progress to be roughly in line with expectations.

Royalty income related to HIV franchise amounted to 31.0 billion yen, representing 48.2% of the 1H forecast. Revenue was down 0.8 billion yen YoY, so it appears a little weak, but there is a reason for this. COVID-19 had an impact during the January to March period, resulting in a slight accumulation of market inventory. On a volume basis, this impact emerged a little in the April to June period. Also, compared to the previous year, the yen slightly appreciated, so this impact is also factored in.

This is the status of the breakdown of revenues.

Revenue of Prescription Drugs in Japan



					(Unit:	B yen)	
		FY2	2020	FY2019	Y on Y		
	Foreca Full year	asts 1H	AprJun. results	Achieve ment (%)	AprJun. results*	Change (%)	Change (B yen)
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 disease="" drugs="" in="" included="" infectious=""> Xofluza[®] FINIBAX[®] Seftem[®] Baktar[®] ISODINE[®] Shiomarin[®] Flagyl[®] Brightpoc[®]Flu·Neo Flomox[®] Vancomycin Fluconazole </products>							

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11

Moving on to page 11, this page shows the breakdown of revenue by prescription drug. As explained earlier, prescription drug revenue came to 22.4 billion yen, or 42.1% of the 1H forecast, down 4.0 billion yen YoY.

By prescription drug, revenue for Cymbalta was 6.9 billion yen, or 49.8% of the 1H forecast, suggesting steady progress towards the target. Revenue for Intuniv was 2.6 billion yen, or 38.4% of the 1H forecast, and we consider this figure to be very weak. We believe this was partly attributable to the reduction of medical examinations caused by the COVID-19 impact.

Two lines below that are infectious disease drugs that posted total revenue of 2.1 billion yen. Figures for these drugs have been described in this way since the previous reporting period. We believe the 2.1 billion yea, representing 30.1% of 1H forecast, is attributable to the impact of the market shrinking. In particular, we think there was a significant impact on antibacterial drugs. Likewise, in the Others category, we think there was an impact depending on the drug. If you look at the very bottom on the right, it says prescription drugs revenue fell by 4.0 billion yen YoY. If you look at the breakdown of this figure, 1.5 billion yen is attributable to infectious disease drugs, and 2.9 billion yen is due to Others. Of course, the impact wasn't the same across all drugs, but they ware long-listed products, particularly for antibiotic drugs and Others. This figure factors in the impact of drug prices, but we also believe the market impacted it.

On page 12, we show a summary of the total.

As for the breakdown of the 9.4 billion yen YoY decline in revenue, there were three major impacts: a onetime payment for Symproic was booked in the US in the previous fiscal year, drug price revisions, and market changes stemming from COVID-19. As for the market impact, we already explained the impact on the business in Japan and China and US, and the royalty income related to HIV franchise . We described these impacts on this page.

SG&A expenses declined by 2.2 billion yen YoY, which is the result of reflecting the undershoot at activity bases. In China, there was an impact from reduced expenses resulting from a decline in sales of Rabeprazole.

R&D expenses increased by 0.5 billion yen YoY for the reasons explained earlier.

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

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Please turn to page 13. Given these conditions, in which we describe the various activities we are examining in light of our experience in Q1. In Q2, based on this experience, we look to review various activities and examine the level of impact or the changes in activities. We are considering examining these activities and putting them to action in Q2.

Before I end, I would like to make one last point. We have not changed our earnings forecasts for 1H or the full year. This is because even though Q1 results have already come out, we are unable to get an accurate outlook on the impact of COVID-19 on the market, as well as the review of resources, which I just mentioned. After carefully examining the impact of these factors on our future business plan, we are considering to once again issue our forecasts.

This concludes my section.

13



Hanasaki: Now, I will explain the initiatives taken in the Q1 and progress in STS Phase I.

On page 15, we have reposted the material we disclosed in our medium-term business plan. What we aim for is to sell pharmaceuticals by our own business. We aim to enhance our ability to earn by our own business, especially in Japan, the US, and China, and aim to develop products and services other than prescription drugs, OTC drugs, and vaccines, which are independent on patents, and well as a contract production business. By balancing sale by our own business and alliances business, as well as patented pharmaceutical business and other businesses, we aim to realize high profitability and a stable management foundation.

On page 16, as we push forward on these initiatives, we first explain our initiatives against COVID-19 where we are currently placing foremost priority as part of our R&D strategy.

First, we are working to discover of novel therapeutic drugs. We aim to identify therapeutic drugs specifically for COVID-19 by leveraging our strengths in drug discovery that we have cultivated through Xofluza and other antiviral drugs, rather than repositioning. Upon tackling this initiative, we are collaborating with Hokkaido University and National Institutes of Biomedical Innovation, Health and Nutrition, utilizing the AMED research grant. Currently, we aim to start clinical trials by the end of the fiscal year, and we are in the stage of screening candidates, including their efficacy, safety, and manufacturing method, toward the final selection of a development candidate.

We are also offering tests and diagnostic kits.

In June, we launched an IgG/IgM antibody-test kit as a reagent for use in epidemiological studies. Meanwhile, we are currently making earnest efforts in collaboration with Nihon University, Gunma University, and Tokyo Medical University toward the practical application of the SATIC method, which is a rapid diagnostic method.

Below, we have described the features of the SATIC method. While the detection sensitivity is about the same level as the PCR method, detection is possible from samples that are easy to collect, such as saliva and sputum. Furthermore, no detection equipment is required. Although the PCR method requires a dedicated measuring instrument, the SATIC method, as described on the right, has the characteristic of enabling visual detection of the presence of aggregates in a very short period of 25 minutes at 37 degrees Celsius after pretreatment at 95 degrees Celsius.

We are aiming to start providing this SATIC method from September 2020, and we are currently preparing for approval application as an in-vitro diagnostic drug and striving for commercialization. Also, we are making earnest efforts to accelerate development and production scale-up studies for early provision of kits that enable easier and quicker diagnosis of multiple samples.



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UNIGEN Inc.: http://www.unigen-bio.com/ API Co., Ltd.: https://www.api3838.co.jp/en/index.html 17

Next, on page 17, we explain the development status of prophylactic vaccines.

We are developing a gene recombinant protein vaccine in collaboration with the National Institute of Infectious Diseases and Kyushu University based on UMN Pharma's BEVS technology. Non-clinical trials and studies of the manufacturing method for the antigen candidates are currently being conducted toward launching clinical trials by year-end. In particular, immunogenicity tests are currently in progress to select antigen and adjuvant candidates. We are also utilizing the AMED research grants for this purpose.

We have briefly included the schedule on the bottom. Clinical trials will be launched by the end of the year, in November or December, and flash reports on the clinical trials will be available in February. We aim to complete building the supply system from March onwards. As for the production system to proceed with this, we will be developing the first production system withinFY2020, in collaboration with UNIGEN and API. We will utilize the grants for this by the Ministry of Economy, Trade and Industry. Also, to strengthen the production system, we are considering further expanding capital investment to secure vaccines for over 30 million people by the end of 2021.

As described above, we intend to provide total care ranging from diagnosis, prevention to treatment, for COVID-19. Utilizing this vaccine business as an opportunity, we hope to expand our business model by full-scale entry into vaccine business.

R&D Strategy: S-005151 [Redasemtide] Change the paradigm of regenerative medicine Promote tissue regeneration Suggested action of redasemtide In vivo self-regeneration mechanism discovered by collaborative research Signed a new contract with StemRim. MSC with academia and venture (June 30, 2020) e damag Regeneration Dr inducing factor seeds Utilize evidence from non-clinical studies redasemtide MSC administratio that StemRim accumulated through joint Bone marrow Damaged tissue blood peripheral research with several academia groups rulati for starting Investigator-Initiated clinical Mesenchymal stromal cells (MSC) trials for new 3 indications S2 StemRIM New development for indications of 3 diseases Chronic liver Cardio-Epidermolysis bullosa Acute stroke Osteoarthritis disease myopathy

Confirmed efficacy in
investigator-initiated
clinical trial
Preparing for applicationPhase 2 study in
progress
Non-clinical study: Confirmed
efficacy by administration at 6
hours after infarctionInvestigator-initiated
clinical trial
Scheduled to start in 2020Investigator-initiated
initiated
clinical trial
Planned

Steady progress in LCM^{*} strategy to maximize compound value

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* LCM: Life cycle management 18

Next, on page 18, we indicate the status of progress on S-005151.

As disclosed, this is an HMGB1 peptide that we are promoting with academia. Through the administration of this drug, mesenchymal stromal cells are drawn from the blood produced from bone marrow under a mechanism in which damaged tissues are accumulated, repaired, and regenerated. As for epidermolysis bullosa, efficacy has been confirmed in an investigator-initiated clinical study, and an application is under preparation.

Regarding acute stroke, Phase 2 study are currently in progress. By using non-clinical evidence that has been newly accumulated through joint research between StemRim and several academic groups, we have signed an agreement to promote investigator-initiated clinical studies for three diseases in June.

Out of these diseases, preparations for investigator-initiated clinical studies are being made in terms of knee osteoarthritis and chronic liver diseases, and the studies are scheduled to start by the end of this year. In this way, we aim to steadily expand the lifecycle management to maximize the value of a compound.

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

CDR-SB >=3.5 (median)



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

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* ClinicalTrials.gov Identifier: NCT03817684 19

Next, on page 19, we indicate the status of progress on BPN14770.

In the Phase 2 trial conducted in the US by Tetra targeting patients with early-stage Alzheimer's dementia, we were unable to achieve the primary endpoint. In a score that evaluates the general clinical efficacy, including both cognitive function and daily activities, called CDR-SB, we conducted an analysis focusing on the patient segment above the median value. As shown in the figure on the right, we obtained results in which changes in the score from the baseline, especially significant improvements in 25mg BID, were observed.

Meanwhile, regarding safety, side effects that would particularly not be a problem, including vomiting, were not observed. In order to further identify the potential of this compound, we intend to proceed with further analysis in the future, including changing the dose and period of administration.

Also, we made Tetra a wholly-owned subsidiary on May 26, thereby acquiring its global rights for all compounds, as we aim to further utilize its drug discovery know-how related to the central nervous system.

R&D Strategy: SDT-001



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

Early detection Accurate diagnosis	Service pla AD	tform for	Support social activities of patients
Tre	eatment	New treatment options	
Drug with MoA	Basic drug	SDT-001	
We will support recog	gnition of disea	ise, treatment, and	social activities

thereby contributing to improved social productivity.

SHIONOGI * Certification mark that indicates the product has been assessed to meet safety requirements sold within the European Economic Area. ** MoA: Mechanism of Action 20

Next, on page 20, we describe the status of progress on the digital treatment app that we name SDT-001. We are currently conducting Phase 2 study in Japan targeting ADHD patients aged 6 to 17, and we are aiming to provide treatment options that are different from conventional pharmaceutical compounds.

Meanwhile, Akili in the US has received approval for the world's first game-based digital therapeutic for improving attention function in children with ADHD. Also, in Europe, progress has been made through the acquisition of the CE mark.

At Shionogi, we currently have two drug offerings for ADHD, including intuniv and vyvanse. By providing a digital treatment app as a new treatment option, we intend to expand the scope of treatment options. Also, we are working to create a platform that would enable the provision of total services for ADHD from the early detection and diagnosis of ADHD to support social activities of patients. By doing so, we hope to help relieve the difficulties in their lives and contribute to improve of social productivity.



Next, from page 21, we explain our top-line strategy.

In Japan, we will build strong cooperation between the Integrated Disease Care Division and Commercial Division. In so doing, we hope to meet the needs of individual doctors through the communication of relevant information on diseases, rather than just conveying information on existing products. Towards that end, we will distribute effective information through Web-conferences conducted by Key Opinion Leaders. In addition, we are working to communicate with doctors by web or face-to-face where visitations have been resumed. Consequently, we will be disseminating information using e-detail to foster understanding of diseases among doctors and work towards raising their willingness to prescribe our drugs.

Next, on page 22. We have established joint ventures with Ping An Insurance as part of our overseas top-line strategy. We plan to establish a joint venture in Shanghai called Ping An-Shionogi Co., Ltd., and another joint venture in Hong Kong. We plan to launch these two companies with a stake of 51% SHIONOGI and 49% Ping An. We have just established a subsidiary in Hong Kong in July, to control and support these two JVs locally.

Also, the chairman and CEO of these two JVs will be appointed from Shionogi, while the selection of board members is scheduled to comprise three members from SHIONOGI and two members from Ping An. Meanwhile, roughly 2% of our company shares will be sold to Ping An through private placement, as part of our efforts to manage these JVs under an equal partnership.

As for the input of Shionogi products into these JVs, high-quality generic drugs from C&O and Japanese brand products from Shionogi Healthcare will be transferred from FY2020 to contribute to revenues. Furthermore, we will obtaine approval for cefiderocol, naldemedine, and COVID-19 related products, and transfer them to JV by inputting them at these JVs at the appropriate timing.



SHIONOGI * RWD: Real World Data ** 平安好医生 (Good Doctor): Mobile medical application with the largest number of users in China. A 23 healthcare ecosystem that comprehensively provides services such as online medical treatment, prescription, and drug delivery.

Next, please look at page 23.

We describe our future vision in our partnership with Ping An insurance. We look to effectively link the diagnosis and treatment data of Ping An's Good Doctor with its real-world data, such as various video data during medical examinations, activities in smart cities or at home, and lifestyle data. As a result, we hope to create a diagnostic algorithm that can provide optimal healthcare solutions to each individual. Based on this, we look to select and offer the optimal drug for each individual. In so doing, we hope to input our existing drugs or input transferred products or the like as a menu.

Meanwhile, for domains in which the optimal drugs do not exist, we intend to conduct new drug discovery research and cultivate new solutions to fill these unmet needs.

Progress of HIV Franchise by ViiV



SONG

* CABENUVA: Product name in Canada ** CAB/RPV: cabotegravir/rilpivirine *** FTC/TDF: emtricitabine/tenofovir disoproxil fumarate **** DSMB: Data and Safety Monitoring Board 24

On page 24, we summarize the progress of the HIV Franchise by ViiV. The three-drug regimen consisted of Tivicay or Triumeq have been shifted to a two-drug regimen of Juluca and Dovato. Progress is also being made in CAVENUVA as the first long-acting injection. While CMC-related issues have halted progress to an extent, reapplication was made in the US in July, and the market launch is planned in January to March next year. We believe there will be a shift from daily oral administration to monthly or bimonthly injection.

On the other hand, cabotegravir is also developed for a preventive indication as the first long-acting injection as a preventive drug. From HPTN 083 study, It was confirmed in July that preventive effects of a cabotegravir injection once every two months exceed once a day oral administration of FTC/TDF by 66%. Furthermore, a recommendation for early completion was received from the Data and Safety Monitoring Board. As a result, the trial was completed earlier than scheduled, and we believe that an expansion to prevention is progressing well.

At SHIONOGI, we aim to create the best-in-class oral compound or long-acting injectable drug. Currently, we are making earnest efforts to develop S-648414 with a novel mechanism of action. Furthermore, we are currently tackling at our research laboratories to realize cure.

This concludes our report on the financial summary for Q1 and the progress on STS2030.

Question & Answer

Kyokawa: Thank you. We will now move on to the Q&A session.

The first question will be from Mr. Yamaguchi of Citigroup Global Markets Japan.

Yamaguchi: Thank you. I have a few questions about COVID-19 vaccine. First, you provided the schedule for clinical trials in Japan. However, unlike in overseas countries, I believe it's difficult to conduct Phase III trials in Japan, and there is also not enough time for them. I understand that, under the current conditions, an application can be made based on the results from the initial test. Has there been any change to this situation? That is my first question.

Sawada: We believe the situation can be changed depending on the environment. It would be difficult at this stage to say that an application will definitely be made based on those results.

However, setting aside whether the vaccine will be approved based on those results, discussions will likely take place about implementing it so that the vaccine can be used by people who really need it, going beyond the ordinary process. Whether it would be the official approval or a different one will probably depend on the situation of the infections at that time.

Yamaguchi: So, under current conditions, even if you say it will be a small group at this timing, it will not be that small of a group, right?

Sawada: We cannot gather so many cases.

Yamaguchi: Right.

Sawada: It will be impossible by March next year.

Yamaguchi: That's the schedule in which current plans are being made, right?

Sawada: Yes. That's right.

Yamaguchi: Okay. Non-clinical trials have already begun, and a code number has already been assigned to the vaccine candidate. You mentioned that a clinical trial will start in November or December, and you have been saying it will start by the end of the year. I have no intention of picking on the details. But I believe you also suggested the possibility that the timing to start a clinical trial could be earlier in the best-case scenario. What are the current conditions, including the research at the National Institute of Infectious Diseases? Is there a possibility that it will be earlier in the best-case scenario? Is it correct to understand that there has particularly been no change to the original guidance?

Sawada: Yes, I believe you can understand that there has been no particular change. We have issued this schedule based on exerting a large amount of pressure on our capacity.

Yamaguchi: Right.

Sawada: In that sense, there has been no change to the schedule at this point.

Yamaguchi: Okay. Thank you.

Kyokawa: Thank you. The next question will be from Mr. Ueda of Goldman Sachs Japan.

Ueda: This is Ueda of Goldman Sachs. First, I would like to ask about the trends in the domestic business. It appears that progress is very slow versus the forecast. I would like to know whether there has been a large impact from COVID-19 on the certain disease area, such as antibacterial agents or CNS, where SHIONOGI plays a central role. In addition, you explained that the company forecast had been left unchanged, given the uncertainties.

Could you comment on whether you really have no idea about what results would be like? Or do you think that profits will likely come within the range of guidance for this fiscal year, given that profits are likely to be fairly steady due to the slower usage of expenses?

Hosogai: Yes. I will answer.

As you pointed out, we will need to examine the impact a little more, as we consider the degree of that impact to vary depending on the drug. As you said, the results in Q1 reflect the impact of COVID-19.

Also, concerning future initiatives, I would like to add a little to the comment made earlier. It doesn't mean that everything's okay, because sales have declined, but expenses have fallen, too. We're not talking about reaching an equilibrium based on downsized operations. Various new initiatives based on the new medium-term plan, as well as reordering of these initiatives, need to be conducted to increase sales. We would like to make further considerations, including those factors. That is all.

Ueda: Thank you. My second question is regarding BPN14770, which you introduced on page 19. Should we understand that the data for low dose have not shown an effect due to the dosage being too low? Given that the drug has little side effects, I think your policy is to consider a relatively high dose in the future. Could you tell us about your future development policies, including these matters?

Sawada: I will answer. As you say, we think that the dosage was too low. Looking at the clinical trial results, we think it's possible to increase the dosage, and we would like to try raising the dosage by a little in the next trial.

Ueda: I understand. Thank you. That is all.

Kyokawa: Thank you. The next question will be from Mr. Hashiguchi of Daiwa Securities.

Hashiguchi: This is Hashiguchi of Daiwa Securities. Thanks. My question is about page 22, regarding the transfer of SHIONOGI's drug pipeline into the JV.

It's written here that SHIONOGI's drug discovery assets will be transferred from FY2022 onwards. Does this mean that the licensing to the JV will be from FY2022, or do you mean that the drugs will be launched in FY2022 and after? Also, it's written on the bottom left in blue font that contributions to the top line will occur from FY2020. Does this mainly mean that sales will be booked as compensation for the licenses, or does it point to sales of products?

Hanasaki: As for your first question, the input of SHIONOGI's drug discovery assets from FY2022 mean the approval of new drugs in China and their market launch. Also, with regard to revenues from FY2020, it means that we will be selling generic drugs and Japanese brand drugs in the Chinese market to increase sales.

Hashiguchi: In other words, that would mean that the conclusion of a license contract for SHIONOGI's drug discovery assets is not that far away, as written in a press release issued last month, correct?

Hanasaki: Yes, that's right.

Hashiguchi: As compensation, I believe there is a likelihood that there would be some kind of a one-time payment for the license. Have you already included those payments in your forecast? Should I understand that you might review guidance in the future?

Hanasaki: We haven't set any one-time payment for it. We've written that we'll work to increase sales through the market launch of new drugs.

Hashiguchi: Does that mean you won't be receiving compensation at the time of the license contract?

Hosogai: Right, we are not considering such payments.

Hashiguchi: Okay. That's all. Thank you.

Kyokawa: Thank you. The next question will be from Mr. Kohtani of Nomura Securities.

Kohtani: This is Kohtani of Nomura Securities. My question is also about the COVID-19 vaccine. You've decided on investing JPY41.7 billion in production facilities for the vaccine. Even with the government grant, you would still need to have an idea of how to win. You need to think about the competition. Currently, there has been detailed data on vaccines issued by AstraZeneca on ChAdOx1-S/AZD1222, Moderna on mRNA-1273, and Pfizer on BNT-162b1. Neutralizing antibodies are already confirmed and antibodies around the same level as recovered sera have been identified, but the assay method is different throughout the company, making them impossible to compare. Do you have anything to comment about these vaccines? Today, AstraZeneca held a conference call, and they were talking that the recovered sera are also different. Is there anything that you can say about these competitors at this point?

Also, I would like to confirm about clinical trials of vaccines in Japan. It seems to be the case that even vaccines from overseas must complete a Phase I trial in Japan. Given that J&J has stated that it would conduct a Phase I trial in Japan during the second half of FY2020, it's probably likely that all of them would conduct a Phase I trial. What I would like to confirm is whether it is your understanding that you are in the lead in terms of vaccine development other than AnGes. And my last question regarding COVID-19 is to confirm that there isn't a framework to obligate vaccines in Japan. In that case, the administration of a vaccine will depend on the decision of doctors. What are your views on the likelihood that Japanese doctors would use an mRNA vaccine or vector vaccine that do not have any guarantee of ensuring long-term safety? Could you tell us a little more about this?

Sawada: You've asked a very difficult question. AstraZeneca, Moderna, and Pfizer have all confirmed neutralizing activity. However, there is no data on how long that neutralizing activity lasted. As you mentioned, they have included neutralizing activity in patients who have recovered in the control group, but it's unclear what kind of patients they've selected or the number of patients in the trial. At Moderna, where the number of patients is the lowest, it is 3 cases, so to be honest, there is no way of telling how much trust can be placed on the data. Thus, our understanding is that we have no choice but to set our own criteria and carry out trials based on those criteria.

Ultimately, we have heard that the duration of the neutralizing antibody itself is very short. So, we believe it will become crucial to induce not only the neutralizing antibody but also the cellular immunity. Although progress is being made on this front at AstraZeneca, we would like to select in view of both of these approaches.

I think you're probably true that the oversea products have to conduct clinical trials in Japan. It'll probably remain unclear why the percentages of both onset and severity vary, whether it depends on national borders or ethnicity. Given that the conditions vary considerably depending on the country, we think it'll probably be quite difficult to administer vaccines without any trials conducted in each country.

With regard to your question about AnGes, are you asking about how much progress we have made in comparison with AnGes?

Kohtani: It's clear that AnGes is ahead of you in vaccine development, but I'd like to know whether SHIONOGI comes next. I'd like to confirm that point.

Sawada: Domestically, we are second only to AnGes, but in reality, there are companies overseas with development candidates. So, once the companies complete procedures, we think there's a possibility that they would start clinical trials before us.

But the vaccines themselves are different at each company. One of the issues at this point is that no one can honestly answer which mechanism or approach is correct. But unless we push forward with each of our

respective approaches, we wouldn't be able to develop the vaccine that would ultimately be necessary. Regardless of whether others are ahead of us, all we will be doing is carrying out the development steadily.

Kohtani: In Japan, all drugs are very sensitive about safety. But when you look at the mRNA vaccine or vector vaccine, there are barely any long-term data. Do you still think these vaccines will be used in Japan?

Sawada: Grade 1 or 2 side effects have been observed in 60% to 70% of patients. Meanwhile, out of the people who contract the virus, around 20% have no symptoms, while symptoms are mild to moderate in around 80%. So, if you were to consider the degree to which the Japanese market would accept adverse effects of the vaccine, it's probably unlikely that the administration of a vaccine will be enforced on all people. In other words, it's unlikely for a vaccine of this level of safety to be administered to everyone without even data that confirm long-term safety.

Kohtani: Just to add to that, Moderna has announced that they confirmed 1 case of grade 3 side effects of fever in its Phase I trial.

Sawada: I think that was a dosage that they discontinued from the Phase II trials.

Kohtani: Right. Lastly, I'd like to ask about Ping An. I've had various discussions with investors about this, but everyone seems a little confused by this move because there aren't that many examples of a pharmaceutical company creating a JV in China. When looking at similar cases at medical device companies, the results have been miserable. Even in light of other Asian companies that have taken such steps, I've heard of almost no company that's succeeded by forming a JV in China. So, I wonder why you chose to take this step. Presumably, there aren't that many benefits to be shared or win-win conditions. Could you give us an explanation why this would be successful under SHIONOGI's business scheme? This is my last question.

Sawada: It's a little difficult to answer that question because we haven't succeeded in it yet. But a point that's clearly different from others is that our areas of specialization stand in stark contrast to each other. That is an area where there is a large difference from JVs that have been formed in the past, because the division of responsibilities is clear. I think there are many cases where companies clash with each other when they have expertise in a similar field. In that sense, I think the greatest difference with others is that we both recognize to complement each other.

Kohtani: My impression is that president Teshirogi's connections with people at Ping An will be very important. Or do you think it's not that important?

Sawada: No, I think we've built a very good relationship. When there's an issue where we are at crosspurposes, we've agreed that the decision on the issue would ultimately be escalated to the top. This tends to be a particularly important issue in China, so we think this will be crucial.

Kohtani: Okay. Thank you.

Kyokawa: It's now 2:50 PM, which is the time we initially scheduled to end the meeting, but we'd like to extend the meeting until 2:55 PM. The next question will be from Mr. Wakao of Mitsubishi UFJ Morgan Stanley Securities.

Wakao: This is Wakao of Mitsubishi. Thanks. A brief answer is fine. On page 17, I'd like to confirm a point, which Mr. Yamaguchi also asked about in his question. My understanding is that clinical trials will initially be conducted at a small scale, and if the results are favorable, they will be supplied for limited usage at medical institutions.

According to today's presentation material, it appears that the clinical trial plan is based on supplying the vaccine to 30 million people. But is it correct to understand that the clinical trial required to supply the vaccine to 30 million people could potentially be just the Phase I trial conducted in the future?

Sawada: No, that's not correct. A Phase II trial will, of course, be necessary. This also depends on consultations with authorities regarding whether trials will be expanded or not afterward. But we believe there should be at least several thousand more cases that have been accumulated before the end of 2021.

Wakao: Did you just say several thousand?

Sawada: I think it will be more than 10,000 cases.

Wakao: Cases? Several thousand cases in Japan?

Sawada: Yes, at least several thousand cases in Japan.

Wakao: I see. So that would mean you are going to be conducting a trial of a moderately large size in Japan.

Sawada: Yes.

Wakao: I understand.

Sawada: We believe it will be relatively easy to accumulate these cases. But, of course, this would depend on the results of the Phase I trial.

Wakao: Okay, I understand. Also, you mentioned that you aim to secure vaccines for 30 million people. Based on my understanding, this number of people would vary depending on the dosage amount and the number of times the vaccine needs to be administered. You've already announced your vaccines will be for 30 million people, but is it correct to understand that you already have a general idea of how many times the vaccines will be administered as well as their dosage?

Sawada: Unfortunately, the number of supply will vary if the underlying assumptions were to change. If the number of administrations is within our current assumptions of two times, then it should go as planned.

Wakao: So, it'll be administered two times. I understand. Thank you. I'd like to ask one more question. Let's hypothetically assume that the government was to purchase the vaccines from oversea companies eg AstraZeneca. Of course, that would depend on the efficacy of the vaccines themselves and how much the doctors would tolerate them. However, if these purchases were to be made, even if your vaccines are aided by government grants, there hasn't been any clarity over whether they will be purchased. So, in the case that the government chooses to purchase the vaccines of other countries, then would you say that could be negative for your company?

Sawada: As I mentioned earlier, we actually do not think that the COVID-19 vaccines will merely require one administration or one cycle. In that sense, even if the vaccines of other companies were to be purchased, we think it's unlikely that those vaccines can be used indefinitely.

As for the vaccine that uses adenovirus vectors, there is a considerable risk of antibodies to adenovirus vectors, so we believe it will likely be an issue whether the vaccine can be administered repeatedly to the same person.

Wakao: I understand. Okay. Thank you.

Kyokawa: Mr. Sakai of Credit Suisse, please go ahead.

Sakai: Thanks. I'd like to ask this question to Ms. Sawada. My question is about the seasonal flu season this year. If the flu will end up having to coexist with COVID-19, which seems to be the case if nothing changes, then the natural course would be that a seasonal flu vaccine needs to be administered first. I think this pattern will always continue as long as the flu coexists with COVID-19. Do you think this understanding is correct? Also, I'd like to know more about how UNM will be used going forward. Unfortunately, the previous vaccine that the Rhabdovirus issue was unsuccessful, but you will be investing more than JPY40 billion on theCOVID-19. Does this conversely mean that you will be converting or diverting resources to the seasonal flu? Is it possible that you will be adopting a flexible structure like this? Please tell us a little more about this.

Sawada: Yes, it is possible.

Sakai: It's possible?

Sawada: Yes.

Sakai: It's not just COVID-19. I will take it to mean that your answer was "yes." Thank you.

Kyokawa: Of course, the answer was yes.

We will now close the conference call for Q1 of the financial period ending March 31, 2021, of SHIONOGI & Co., Ltd. Thank you, everyone, for joining despite your busy schedules.

Sawada: Thank you.

[END]