Supplemental material for financial results for the 1st quarter of fiscal year 2020

July 31, 2020
Shionogi & Co., Ltd.

1. Revenue by segment

(Billions of yen)

	FY2020 1H forecast	FY2020 forecast	FY2020 1Q actual	FY2019 1Q actual	change	Progress% vs. 2020 1H forecast
Prescription drugs	53.1	123.9	22.4	26.3	(4.0)	42.1
change %	-	*16.6*	*(15.1)*	-		
CYMBALTA	13.9	28.6	6.9	6.7	0.2	49.8
INTUNIV	6.8	16.7	2.6	1.8	0.8	38.4
VYVANSE	0.2	0.8	0.0	-	0.0	11.3
Infectious Disease Drugs	7.1	26.5	2.1	3.6	(1.5)	30.1
OXYCONTIN Franchise	2.9	5.6	1.4	1.7	(0.3)	47.3
SYMPROIC	1.3	2.9	0.5	0.5	(0.0)	36.6
ACTAIR	0.2	0.3	0.1	0.1	0.0	36.9
MULPLETA	0.1	0.1	0.0	0.0	(0.0)	42.5
PIRESPA	2.9	4.9	1.4	1.7	(0.3)	49.6
Others	17.7	37.5	7.3	10.2	(2.9)	41.1
CRESTOR	4.2	8.3	1.5	2.4	(0.8)	37.3
IRBETAN Franchise	1.8	3.7	0.8	1.2	(0.4)	47.0
Overseas subsidiaries/Export	11.3	24.0	5.5	10.7	(5.3)	48.5
change %	-	*(21.9)*	*(49.1)*	-		
Shionogi Inc.	2.6	5.1	1.7	5.3	(3.6)	64.1
C&O	5.7	11.9	2.4	3.8	(1.4)	41.4
Contract manufacturing	7.9	15.4	2.9	2.4	0.4	36.5
change %	-	*(12.2)*	*17.6*	-		
OTC and quasi-drugs	4.9	10.4	2.3	1.8	0.5	46.5
change %	-	*7.6*	*26.1*	-		
Royalty income	77.8	148.3	38.0	38.9	(0.9)	48.8
change %	-	*(11.1)*	*(2.4)*	-		
HIV Franchise	64.2	126.3	31.0	31.7	(0.8)	48.2
CRESTOR	11.1	16.9	5.6	5.7	(0.1)	50.0
Others	2.5	5.2	1.5	1.5	(0.1)	60.3
Others	0.7	1.3	0.4	0.5	(0.1)	65.8
change %	-	*(39.0)*	*(17.2)*	-		
Total	155.6	323.5	71.4	80.8	(9.4)	45.9
change %	-	*(3.0)*	*(11.6)*	-		

Note: Change % shows changes from the same period of the previous fiscal year.

Sales of prescription drugs are shown on non-consolidated basis.

Products included in infectious disease drugs are bellow.

・Xofluza ・Rapiacta ・Brightpoc Flu Neo ・Finibax ・Flumarin ・Flomox

・Seftem ・Shiomarin ・Vancomycin ・Baktar ・Flagyl ・Fluconazole ・Isodine

2 - 1. Quarterly trend for FY2019 and FY2020 (Revenue by segment)

Fiscal year ended March 31, 2020 *(Billions of yen)*

FY2019	FY2019 1Q actual	Y on Y change%
Prescription drugs	26.3	-
CYMBALTA	6.7	-
INTUNIV	1.8	-
VYVANSE	-	-
Infectious Disease Drugs	3.6	-
OXYCONTIN Franchise	1.7	-
SYMPROIC	0.5	-
ACTAIR	0.1	-
MULPLETA	0.0	-
PIRESPA	1.7	-
Others	10.2	-
CRESTOR	2.4	-
IRBETAN Franchise	1.2	-
Overseas subsidiaries/Export	10.7	-
Shionogi Inc.	5.3	-
C&O	3.8	-
Contract manufacturing	2.4	-
OTC and quasi-drugs	1.8	-
Royalty income	38.9	-
HIV Franchise	31.7	-
CRESTOR	5.7	-
Others	1.5	-
Others	0.5	-
Total	80.8	-

Note: Sales of prescription drugs are shown on non-consolidated basis.

Fiscal year ending March 31, 2021

FY2020	FY2020 1Q actual	Y on Y change%
Prescription drugs	22.4	(15.1)
CYMBALTA	6.9	2.9
INTUNIV	2.6	42.2
VYVANSE	0.0	-
Infectious Disease Drugs	2.1	(40.7)
OXYCONTIN Franchise	1.4	(17.3)
SYMPROIC	0.5	(7.9)
ACTAIR	0.1	3.4
MULPLETA	0.0	(26.3)
PIRESPA	1.4	(17.1)
Others	7.3	(28.4)
CRESTOR	1.5	(35.3)
IRBETAN Franchise	0.8	(30.5)
Overseas subsidiaries/Export	5.5	(49.1)
Shionogi Inc.	1.7	(68.6)
C&O	2.4	(37.5)
Contract manufacturing	2.9	17.6
OTC and quasi-drugs	2.3	26.1
Royalty income	38.0	(2.4)
HIV Franchise	31.0	(2.4)
CRESTOR	5.6	(1.6)
Others	1.5	(3.6)
Others	0.4	(17.2)
Total	71.4	(11.6)

Note: Sales of prescription drugs are shown on non-consolidated basis.

2 - 2. Quarterly trend for FY2019 and FY2020 (Consolidated statements of profit or loss)

Fiscal year ended March 31, 2020 *(Billions of yen)*

FY2019	FY2019 1Q actual	Y on Y change %
Revenue	**80.8**	-
Cost of sales	15.7 (12.7)	-
Gross profit	**68.1**	-
SG & A expenses	28.6 (23.1)	-
R & D expenses	14.5 (11.7)	-
Amortization of intangible assets associated with products	1.0 (0.8)	-
Other income & expenses	(0.9)	-
Operating profit	**39.2** **31.7**	-
Finance income & costs	3.7	-
Profit before tax	**43.8** **35.3**	-
Income tax expense etc.	(8.2)	-
Profit attributable to owners of parent	**33.6** **27.1**	-

Fiscal year ending March 31, 2021

FY2020	FY2020 1Q actual	Y on Y change %
Revenue	**71.4**	**(11.6)**
Cost of sales	16.1 (11.5)	(9.3)
Gross profit	**59.9**	**(12.0)**
SG & A expenses	29.2 (20.9)	(9.5)
R & D expenses	17.0 (12.2)	4.2
Amortization of intangible assets associated with products	1.1 (0.8)	(0.1)
Other income & expenses	(0.5)	(49.0)
Operating profit	**35.9** **25.6**	**(19.1)**
Finance income & costs	4.4	21.1
Profit before tax	**42.1** **30.1**	**(14.9)**
Income tax expense etc.	(8.5)	3.8
Profit attributable to owners of parent	**30.2** **21.5**	**(20.6)**

3. Pipeline (as of July 31, 2020)

Areas	Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Infectious disease	S-649266 (Cefiderocol Tosilate Sulfate Hydrate) [US:Fetroja®] [EU：Fetcroja®]	Cell-wall synthesis inhibition (injection)	USA:Complicated urinary tract infections, including pyelonephritis and nosocomial pneumonia with no or limited treatment options Europe:Infections due to aerobic gram-negative bacteria in adult patients with limited treatment options	Global:PhaseIII (pediatric) USA:Approval (cUTI) (Nov.2019), NDA submission (Nosocomial nuemonia) (Mar.2020) Europe: Approval (Apr.2020)	In-house	In-house
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Cap-dependent endonuclease inhibition (oral, granule)	Influenza virus infection	Japan:Approval (body weight ≧20kg) (Sep.2018) Japan:NDA submission (body weight <20kg) (Aug.2018) Japan:PhaseIII(high dosage for children)	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Cap-dependent endonuclease inhibition (oral)	Influenza virus infection (prophylaxis)	Japan:NDA submission (Oct.2019)	In-house	Shionogi/Roche (Switzerland)
	S-648414	Not disclosed (oral)	HIV infection	USA,Japan:PhaseI	In-house	In-house
Pain/CNS	S-297995 (naldemedine tosilate) [US/Japan:Symproic®] [EU:Rizmoic®]	Peripheral opioid receptor antagonist (oral, granule)	Opioid-induced constipation(pediatric)	Europe:PhaseI/II	In-house	In-house
	S-297995 (naldemedine tosilate)	Peripheral opioid receptor antagonist (oral,)	Postoperative ileus	USA:PhaseII	In-house	In-house
	S-120083	Not disclosed (oral)	Inflammatory pain	Japan:PhaseI USA:PhaseII	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-010887	Not disclosed (oral)	Neuropathic pain	Japan:PhaseI	In-house	In-house
	S-117957	Not disclosed (oral)	Insomnia	USA:PhaseI	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-600918	$P2X_3$ receptor antagonist (oral)	Neuropathic pain	Japan:PhaseI	In-house	In-house
	S-600918	$P2X_3$ receptor antagonist (oral)	Refractory/unexplained chronic cough	Global:PhaseII	In-house	In-house
	S-600918	$P2X_3$ receptor antagonist (oral)	Sleep Apnea Syndrome	Japan:PhaseII	In-house	In-house
	S-637880	Not disclosed (oral)	Neuropathic pain	Japan:PhaseI	In-house	In-house
	LY248686 (duloxetine hydrochloride) [Cymbalta®]	SNRI (Serotonin–norepinephrine reuptake inhibitors) (oral)	Depression (pediatric)	Japan:PhaseIII	Eli Lilly (USA)	Shionogi/Eli Lilly Japan K.K.
	S-812217 (Zuranolone)	GABAA receptor positive allosteric modulator (oral)	Depression	Japan:PhaseII	Sage (USA)	Shionogi/Sage
	SDT-001	Treatment digital application based on cerebral mechanism	Inattention symptom in ADHD patients (pediatric)	Japan:PhaseII	Akili (USA)	Shionogi/Akili
Metabolic disorder	S-237648	Neuropeptide Y Y5 receptor antagonist (oral)	Obesity	Japan:PhaseII USA:PhaseI	In-house	In-house
	S-707106	Insulin sensitizer (oral)	Type 2 diabetes	USA:PhaseIIa	In-house	In-house
	ADR-001	Human mesenchymal stem cells（injection）	Decompensated liver cirrhosis	Japan:PhaseI/II	Rohto	Shionogi/Rohto
Frontier	S-588410	Cancer peptide vaccine (injection)	Esophageal cancer	Japan:PhaseIII	OncoTherapy Science, Inc. (Japan)	In-house
	S-588410	Cancer peptide vaccine (injection)	Bladder cancer	Japan,Europe:PhaseII	OncoTherapy Science, Inc. (Japan)	In-house

Areas	Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Frontier	S-488210	Cancer peptide vaccine (injection)	Head and neck squamous cell carcinoma	Europe:PhaseI/II	OncoTherapy Science, Inc.(Japan)	In-house
	S-588210	Cancer peptide vaccine (injection)	Solid tumor	UK:PhaseI	OncoTherapy Science, Inc.(Japan)	In-house
	S-222611 (epertinib)	HER2/EGFR dual inhibitor (oral)	Malignant tumor	Europe:PhaseI/II	In-house	In-house
	S-770108	Antifibrotic (inhalation)	Idiopathic pulmonary fibrosis	Japan:PhaseI	In-house	In-house
	SR-0379	Promote granulation formation (topical)	Cutaneous ulcer (Pressure ulcer, Diabetic ulcer)	Japan:PhaseII	FunPep (Japan)	In-house
	S-005151 (Redasemtide Trifluoroacetate)	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Stroke	Japan:PhaseII	StemRIM (Japan)	In-house
	S-005151 (Redasemtide Trifluoroacetate)	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Epidermolysis bullosa	Japan:PhaseII (preparing NDA submission)	StemRIM (Japan)	In-house

<Out-Licensing Activity>

Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
S/GSK1349572 (dolutegravir)	Integrase inhibitor (oral)	For the treatment of HIV infection	(DTG*1/3TC*2 2-drug fixed dose combination tablet) USA:Approval(naïve patients) (Apr.2019) Europe:Approval(naïve and switch patients) (Jul.2019) Japan:Approval(naïve patients)(Jan. 2020) Global:NDA submission(switch patients)	Shionogi-ViiV Healthcare LLC	Viiv Healthcare Ltd. (UK)
S/GSK1265744 LAP*3 (cabotegravir)	Integrase inhibitor (injection)	For the treatment and prevention for HIV infection	(CAB*4 LAP+RPV*5 LAP 2-drug regimen for treatment) Canada:Approval(Mar.2020) USA:NDA re-submission(Jul.2020) Europe:MAA submission(Jul.2019) (CAB LAP for prevention) Global:PhaseIII	Shionogi-ViiV Healthcare LLC	ViiV Healthcare Ltd. (UK) for treatment Collaboration among ViiV,HPTN,NIAID and Gilead Sciences, Inc.(USA)for prevention
S-0373	Non-peptide mimetic of TRH (oral)	Spinocerebellar ataxia	Japan:PhaseIII	In-house	Kissei Pharmaceutical Co., Ltd. (Japan)
S-033188 (baloxavir marboxil) [USA:Xofluza™]	Cap-dependent endonuclease inhibition (oral)	Influenza virus infection	USA:Approval(Oct.2018) USA:Approval(high risk patients) (Oct.2019) USA:NDA submission(pediatric,≧ 1 year old) (Mar.2020) USA:NDA submission (Granule)(Mar.2020) USA:NDA submission (Phophylaxis) (Mar.2020) Europe:MAA submission(treatment, prophylaxis)(Nov.2019) Global:PhaseIII(severe influenza virus infection) Global:PhaseIII(pediatric, < 1 year old) Global:PhaseIII(transmission)	In-house	Shionogi/Roche (Switzerland)

*1: Dolutegravir, *2: Lamivudine, *3: Long acting parenteral formulation, *4: Cabotegravir, *5: Rilpivirine

<Drugs to acquire new indication requested by the Ministry of Health, Labour and Welfare>

Generic name [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Oxycodone hydrochloride hydrate [OxyContin®]	Natural opium alkaloids (oral)	For the treatment of moderate to severe chronic pain	Japan;NDA re-submission(May.2019)	Napp Pharmaceuticals Limited (UK)	In-house

Since May 11, 2020

Change of phase	S-648414:USA PhaseI→USA,Japan:PhaseI
	S-005151(Epidermolysis bullosa):Japan PhaseII→NDA submission(in preparation)
	S/GSK1349572:USA PhaseIII→Additional submission