Supplemental material for financial results for the 1st quarter of fiscal year 2019

July 29, 2019
Shionogi & Co., Ltd.

1. Sales of segments

(Billions of yen)

	FY2019 1H forecast	FY2019 forecast	FY2019 1Q actual	FY2018 1Q actual	change	Progress% vs. 2019 1H forecast
Prescription drugs	53.7	144.1	26.7	25.4	1.3	49.7
change %	*7.5*	*12.0*	*5.0*	*(31.9)*		
CYMBALTA	13.0	29.3	6.7	6.1	0.6	51.6
INTUNIV	4.6	13.6	1.8	1.1	0.7	39.9
XOFLUZA	0.3	28.0	0.0	0.0	(0.0)	0.0
RAPIACTA	0.1	2.6	0.0	0.0	(0.0)	2.6
BRIGHTPOC Flu	0.2	1.8	0.0	0.0	0.0	5.1
Total of strategic products	18.2	75.7	8.6	7.3	1.3	47.1
OXYCONTIN Franchise	3.6	6.7	1.7	2.0	(0.3)	46.7
SYMPROIC	1.1	2.3	0.5	0.3	0.2	48.6
ACTAIR	0.1	0.3	0.1	0.0	0.0	45.8
MULPLETA	0.2	0.3	0.0	0.0	(0.0)	19.7
PIRESPA	3.5	6.9	1.7	1.4	0.4	49.8
Total of new products	26.7	92.2	12.6	11.0	1.6	47.3
CRESTOR	5.2	10.0	2.4	2.6	(0.2)	46.9
IRBETAN Franchise	2.6	4.9	1.2	1.9	(0.7)	47.0
Other	19.2	36.9	10.4	9.8	0.6	54.0
Overseas subsidiaries/Export	16.0	31.4	10.6	9.9	0.7	66.0
change %	*4.3*	*6.6*	*7.4*	*49.3*		
Shionogi Inc.	6.3	9.9	5.2	6.1	(0.9)	83.3
Mulpleta	0.3	1.0	0.2	-	0.2	61.2
C&O	6.8	14.6	3.8	2.3	1.4	55.2
Contract manufacturing	9.1	14.3	2.4	2.8	(0.3)	27.0
change %	*58.4*	*(3.0)*	*(12.1)*	*(20.5)*		
OTC and quasi-drugs	4.6	9.7	2.1	1.6	0.5	44.5
change %	*22.3*	*19.7*	*29.4*	*1.3*		
Royalty income	74.3	163.6	36.9	48.3	(11.4)	49.6
change %	*(19.4)*	*(9.2)*	*(23.6)*	*89.7*		
HIV Franchise	61.3	126.5	29.7	24.5	5.2	48.5
CRESTOR	11.0	22.0	5.6	5.5	0.1	50.5
Other	2.1	15.1	1.6	18.3	(16.7)	79.1
Others	1.2	2.4	0.5	0.6	(0.0)	45.0
change %	*5.9*	*(3.2)*	*(5.9)*	*1.8*		
Total	159.0	365.5	79.2	88.5	(9.3)	49.8
change %	*(5.5)*	*0.5*	*(10.5)*	*18.0*		

Note: Change % shows changes from the same period of the previous fiscal year.
Sales of prescription drugs are shown on non-consolidated basis.

2 - 1. Quarterly trend for FY2018 and FY2019 (Sales of segments)

Fiscal year ended March 31, 2019 *(Billions of yen)*

FY2018	FY2018 1Q actual	Y on Y change %	FY2018 2Q actual	Y on Y change %	FY2018 3Q actual	Y on Y change%	FY2018 4Q actual	Y on Y change%
Prescription drugs	25.4	(31.9)	24.6	(31.5)	38.3	8.8	40.4	31.0
CYMBALTA	6.1	6.1	5.8	(2.2)	6.7	2.1	5.5	4.2
INTUNIV	1.1	209.9	1.3	284.8	1.6	194.4	1.4	100.1
XOFLUZA	0.0	-	0.4	-	9.5	-	16.4	578.7
RAPIACTA	0.0	(76.4)	(0.0)	(131.8)	0.8	(33.9)	1.3	(39.9)
BRIGHTPOC Flu	0.0	(90.5)	0.2	168.5	0.3	(11.6)	0.6	(0.9)
OXYCONTIN Franchise	2.0	(15.2)	1.8	(16.8)	2.0	(18.7)	1.5	(11.6)
SYMPROIC	0.3	526.3	0.4	257.6	0.5	123.0	0.4	72.2
Total of strategic products	9.6	11.0	10.0	14.8	21.2	88.9	27.0	107.7
ACTAIR	0.0	47.4	0.0	63.3	0.1	61.0	0.0	51.4
MULPLETA	0.0	0.6	0.0	3.0	0.0	(2.2)	0.0	(21.6)
PIRESPA	1.4	(5.1)	1.5	(10.5)	1.6	(10.8)	1.2	(22.2)
Total of new products	11.0	8.8	11.6	10.8	23.0	74.7	28.2	93.6
CRESTOR	2.6	(78.1)	2.5	(74.6)	2.7	(38.1)	2.0	(31.9)
IRBETAN Franchise	1.9	(48.5)	1.1	(71.5)	1.3	(67.7)	1.0	(63.8)
Other	9.8	(13.8)	9.3	(18.6)	11.4	(16.7)	9.1	(13.4)
Overseas subsidiaries/Export	9.9	49.3	5.5	(1.1)	6.7	27.5	7.3	18.8
Shionogi Inc.	6.1	75.7	1.3	(49.7)	2.0	(14.6)	2.4	8.3
Osphena	0.8	(32.7)	0.7	(21.4)	1.0	(0.1)	0.6	(17.6)
C&O	2.3	31.0	2.7	69.2	3.2	125.0	3.3	57.7
Contract manufacturing	2.8	(20.5)	2.9	(40.1)	3.4	2.7	5.6	8.3
OTC and quasi-drugs	1.6	1.3	2.2	21.9	2.5	7.1	1.8	18.8
Royalty income	48.3	89.7	43.9	(9.2)	45.3	2.3	42.8	15.7
HIV Franchise	24.5	31.4	32.6	18.2	32.8	18.1	34.5	17.3
CRESTOR	5.5	(4.3)	5.4	(3.9)	5.5	(1.4)	5.5	(1.9)
Others	18.3	-	5.9	(61.1)	6.9	(36.0)	2.7	43.6
Others	0.6	1.8	0.6	(14.5)	0.8	(0.5)	0.6	(9.1)
Total	88.5	18.0	79.7	(18.0)	97.0	6.4	98.5	21.1

Fiscal year ending March 31, 2020

FY2019	FY2019 1Q actual	Y on Y change%
Prescription drugs	26.7	5.0
CYMBALTA	6.7	10.3
INTUNIV	1.8	65.6
XOFLUZA	0.0	(100.0)
RAPIACTA	0.0	(89.4)
BRIGHTPOC Flu	0.0	97.7
Total of strategic products	8.6	18.1
OXYCONTIN Franchise	1.7	(15.5)
SYMPROIC	0.5	70.6
ACTAIR	0.1	42.1
MULPLETA	0.0	(31.2)
PIRESPA	1.7	26.2
Total of new products	12.6	14.4
CRESTOR	2.4	(7.8)
IRBETAN Franchise	1.2	(35.5)
Other	10.4	5.8
Overseas subsidiaries/Export	10.6	7.4
Shionogi Inc.	5.2	(14.0)
Mulpleta	0.2	-
C&O	3.8	61.1
Contract manufacturing	2.4	(12.1)
OTC and quasi-drugs	2.1	29.4
Royalty income	36.9	(23.6)
HIV Franchise	29.7	21.4
CRESTOR	5.6	1.1
Others	1.6	(91.0)
Others	0.5	(5.9)
Total	79.2	(10.5)

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

2 - 2. Quarterly trend for FY2018 and FY2019 (Consolidated statements of income)

Fiscal year ended March 31, 2019 *(Billions of yen)*

FY2018	FY2018 1Q actual	Y on Y change %	FY2018 2Q actual	Y on Y change %	FY2018 3Q actual	Y on Y change %	FY2018 4Q actual	Y on Y change %
Net sales	88.5	18.0	79.7	(18.0)	97.0	6.4	98.5	21.1
Cost of sales	13.5 11.9	(40.2)	16.1 12.8	(35.1)	16.1 15.7	(8.2)	14.7 14.5	(15.6)
Gross profit	76.6	39.0	66.9	(13.6)	81.4	9.8	84.0	31.0
SG & A expenses	55.3 49.0	25.2	46.7 37.2	(1.1)	42.5 41.3	3.8	43.5 42.9	9.8
Selling & administrative expenses	24.3	9.7	23.3	(5.2)	26.9	10.9	27.5	11.6
R & D expenses	24.7	45.3	13.9	6.5	14.3	(7.4)	15.3	6.8
Operating income	31.2 27.6	72.9	37.2 29.7	(25.4)	41.3 40.1	16.7	41.7 41.1	63.8
Non-operating income & expenses	10.3		2.5		5.5		9.8	
Ordinary income	42.9 37.9	80.1	40.3 32.1	(27.8)	47.0 45.6	14.3	51.7 50.9	53.3
Extraordinary income & losses	2.1		(0.0)		0.7		1.0	
Income before income taxes	40.1		32.1		46.2		51.9	
Income taxes and etc.	8.2		6.1		9.8		13.5	
Profit attributable to owners of parent	36.0 31.9	99.2	32.6 26.0	(24.2)	37.6 36.4	24.0	39.0 38.4	31.8

Fiscal year ending March 31, 2020

FY2019	FY2019 1Q actual	Y on Y change %
Net sales	**79.2**	**(10.5)**
Cost of sales	16.1 12.7	6.9
Gross profit	66.5	(13.2)
SG & A expenses	47.4 37.5	(23.3)
Selling & administrative expenses	25.7	5.8
R & D expenses	11.9	(51.9)
Operating income	**36.6** **29.0**	**4.7**
Non-operating income & expenses	3.4	
Ordinary income	**40.9** **32.4**	**(14.6)**
Extraordinary income & losses	(0.5)	
Income before income taxes	31.9	
Income taxes and etc.	7.5	
Profit attributable to owners of parent	**30.8** **24.4**	**(23.4)**

3. Pipeline (as of July 29, 2019)

Areas	Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
Infectious disease	S-649266 (Cefiderocol Tosilate Sulfate Hydrate)	Cephem antibiotic (injection)	USA: Complicated urinary tract infections, including pyelonephritis Europe: Multidrug-resistant gram-negative bacterial infections	Global: Phase III USA: NDA submission (Dec.2018) Europe: MAA submission (Mar.2019)	In-house	In-house
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Anti-influenza virus infection (oral)	Influenza virus infection	Japan: Approval (Feb.2018) Taiwan: NDA submission (Jun.2018)	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Anti-influenza virus infection (oral, granule)	Influenza virus infection	Japan: Approval (body weight ≧20kg) (Sep.2018) Japan: NDA submission (body weight <20kg) (Aug.2018) Japan: Phase III (new dosage for children)	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Anti-influenza virus infection (oral)	Influenza virus infection (prophylaxis)	Japan: Phase III	In-house	Shionogi/Roche (Switzerland)
Pain/CNS	S-297995 (naldemedine tosilate) [US/Japan:Symproic®] [EU: Rizmoic®]	Peripheral opioid receptor antagonist (oral, granule)	Opioid-induced constipation(pediatric)	Japan: Phase I	In-house	In-house
	S-877503 (guanfacine hydrochloride) [Intuniv®]	Alpha-2A-adrenergic receptor agonist (oral)	ADHD (adult)	Japan:Approval (Jun.2019)	Shire (Ireland)	Shionogi/Shire
	S-120083	Analgesic agent for inflammatory pain (oral)	Inflammatory pain	Japan: Phase I USA: Phase II	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-010887	Analgesic agent for neuropathic pain (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
	S-117957	Agent for insomnia (oral)	Insomnia	USA: Phase I	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-600918	Analgesic agent for neuropathic pain (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
	S-600918	Antitussive agent (oral)	Refractory/unexplained chronic cough	Japan: Phase II	In-house	In-house
	S-637880	Analgesic agent for neuropathic pain (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
	LY248686 (duloxetine hydrochloride) [Cymbalta®]	SNRI (Serotonin–norepinephrine reuptake inhibitors) (oral)	Depression (pediatric)	Japan: Phase III	Eli Lilly (USA)	Shionogi/Eli Lilly Japan K.K.
	S-812217	GABAA receptor positive allosteric modulator (oral)	Depression	Japan: Phase I	Sage (USA)	Shionogi/Sage
Metabolic disorder	S-237648	Neuropeptide Y Y5 receptor antagonist (oral)	Obesity	Japan: Phase II USA: Phase I	In-house	In-house
	S-707106	Insulin sensitizer (oral)	Type 2 diabetes	USA: Phase IIa	In-house	In-house
	ADR-001	Human mesenchymal stem cells(injection)	Decompensated liver cirrhosis	Japan: Phase I/II	Rohto	Shionogi/Rohto
Frontier	S-588410	Cancer peptide vaccine (injection)	Esophageal cancer	Japan: Phase III	OncoTherapy Science, Inc. (Japan)	In-house
	S-588410	Cancer peptide vaccine (injection)	Bladder cancer	Japan, Europe: Phase II	OncoTherapy Science, Inc. (Japan)	In-house

Areas	Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
Frontier	S-525606	Sublingual tablet of Japanese cedar allergen extracts for immunotherapy (sublingual)	Allergic rhinitis caused by Japanese cedar allergen	Japan: Phase II	Stallergenes (France)	In-house
	S-488210	Cancer peptide vaccine (injection)	Head and neck squamous cell carcinoma	Europe: Phase I/II	OncoTherapy Science, Inc. (Japan)	In-house
	S-588210	Cancer peptide vaccine (injection)	Solid tumor	UK: Phase I	OncoTherapy Science, Inc. (Japan)	In-house
	S-222611 (epertinib)	HER2/EGFR dual inhibitor (oral)	Malignant tumor	Europe: Phase I/II	In-house	In-house
	S-770108	Anti-fibrosis (inhalation)	Idiopathic pulmonary fibrosis	Japan: Phase I	In-house	In-house
	SR-0379	Cutaneous ulcer (topical)	Cutaneous ulcer (Pressure ulcer, Diabetic ulcer)	Japan: Phase II	FunPep (Japan)	In-house
	S-005151	Stroke (injection)	Stroke	Japan: Phase Ⅱ	StemRIM (Japan)	In-house

<Out-Licensing Activity>

Code No. (Generic name) [Product name]	Category (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 (Apr.2019, naïve patients) Europe: Approval (Jul.2019, naïve and switch patients) Global: Phase III (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) USA: NDA submission (Apr.2019) (CAB LAP for prevention) Global: Phase III	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: Phase III	In-house	Kissei Pharmaceutical Co., Ltd. (Japan)
S-033188 (baloxavir marboxil) [USA: Xofluza™]	Anti-influenza virus infection (oral)	Influenza virus infection	USA: Approval (Oct.2018) USA: sNDA submission acceptance (high risk patients, Mar.2019) Global: Phase III (severe influenza virus infection) Global: Phase III (pediatric)	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]	Category (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 9, 2019

Change of phase	S-877503 (adult) : Japan:NDA submission (Aug.2018) →Japan:Approval (Jun. 2019)
	ADR-001 : Added to the list
	S/GSK1349572(DTG/3TC 2-drug fixed dose combination tablet) : Europe:MAA submission (Sep.2018)→Europe:Approval (Jul.2019)
	Oxycodone hydrochloride hydrate : Japan:NDA submission (Nov.2016)→Japan:NDA re-submission (May 2019)
Compound erased from the list	S-297995 (adult) : USA, Japan: Approval (Mar.2017), Europe: Approval (Feb.2019)
	S-877489 : Japan: Approval (Mar.2019)
	S-888711 : Japan: Approval (Sep.2015), USA: Approval (Jul.2018), Europe: Approval (Feb.2019)