Outline of Consolidated Financial Results for the 1st Quarter Ended June 30, 2020

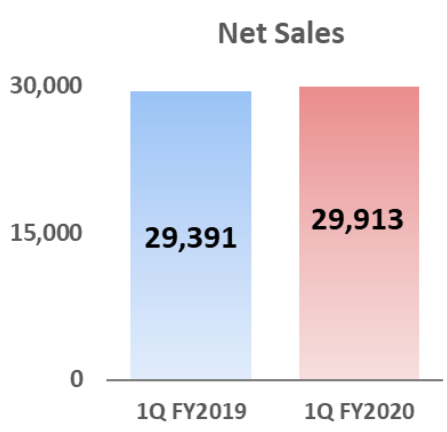
August 11, 2020
NIPPON SHINYAKU CO., LTD.

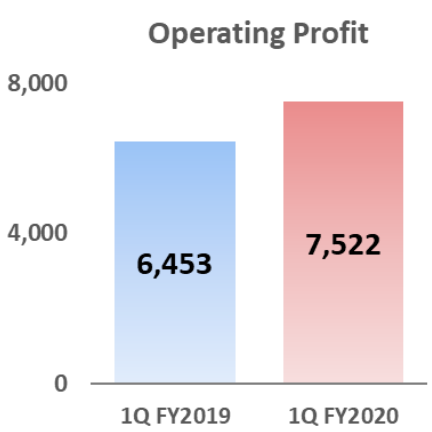
NIPPON SHINYAKU CO., LTD.

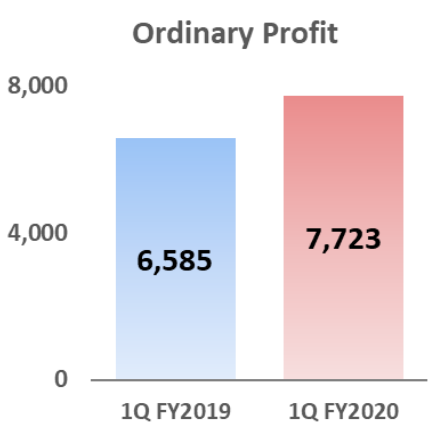
1Q FY2020 Summary

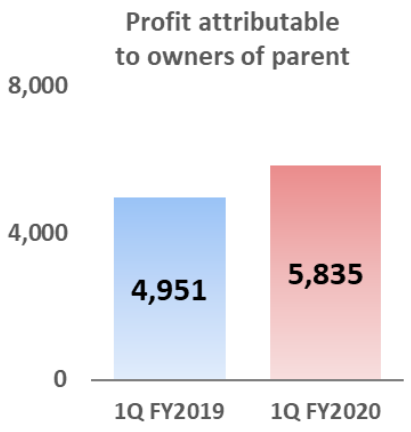
- **Net sales** : 29,913 million yen (+1.8%)
- **Operating profit** : 7,522 million yen (+16.6%)
- **Ordinary profit** : 7,723 million yen (+17.3%)
- **Profit attributable to owners of parent** : 5,835 million yen (+17.9%)

(Million yen)

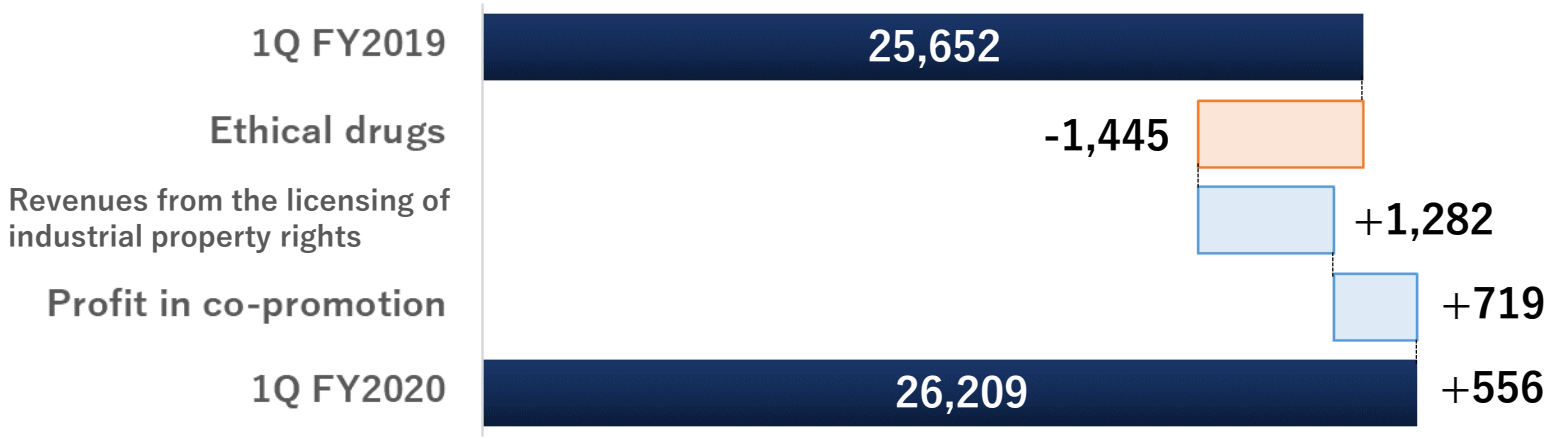








Segmental Review - Pharmaceuticals -



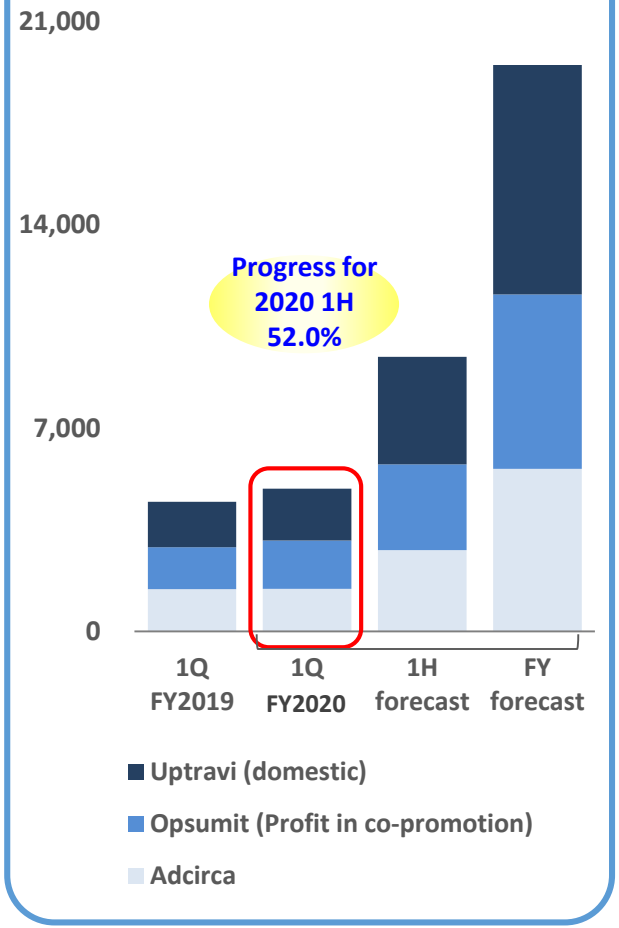
(Million yen)	1Q FY2019		1Q FY2020		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	20,365	79.4%	18,919	72.2%	-1,445	-7.1%
Revenues from the licensing of industrial property rights	3,822	14.9%	5,105	19.5%	+1,282	+33.6%
Profit in co-promotion	1,464	5.7%	2,184	8.3%	+719	+49.1%
Net sales	25,652	100.0%	26,209	100.0%	+556	+2.2%

Net sales increased by 2.2% through revenues from the licensing of industrial property rights and profit in co-promotion.

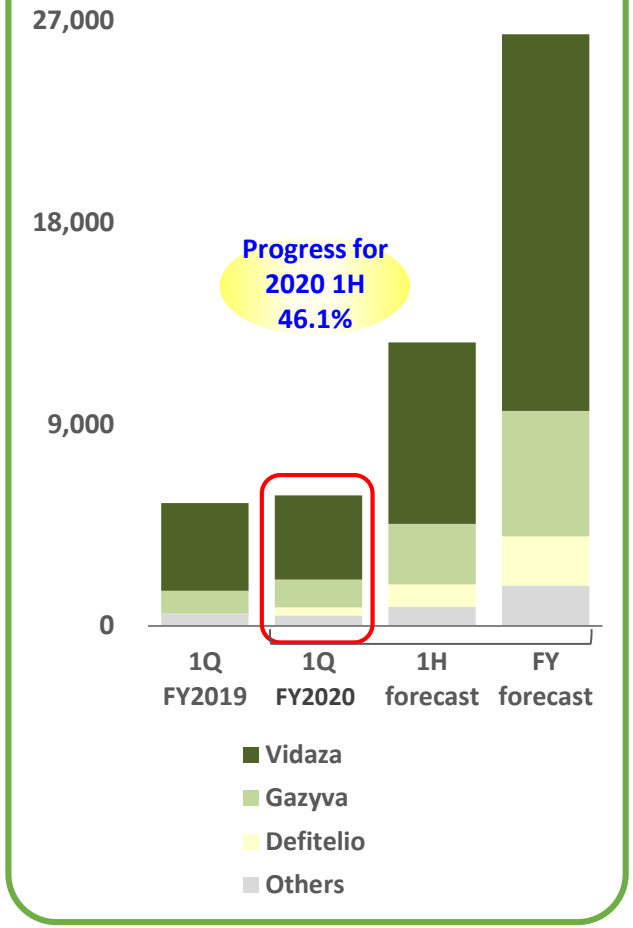
Three Main Fields of Focus

(million yen)

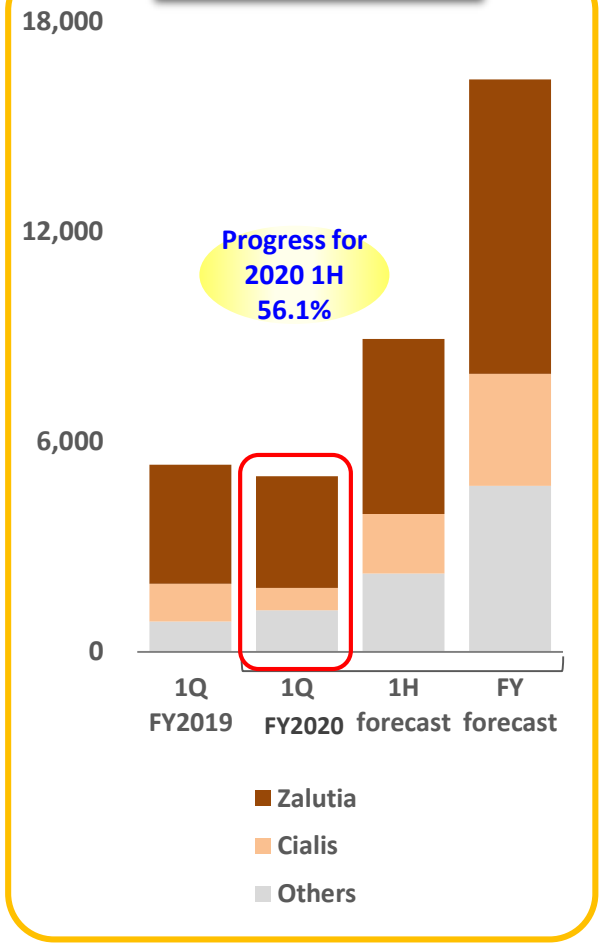
PAH



Hematology



Urology

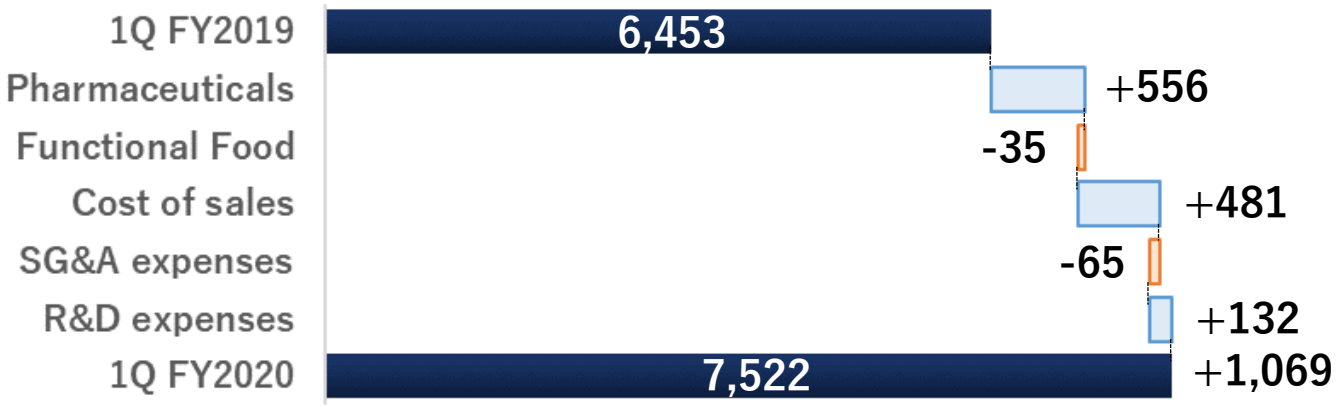


Sales in the focus fields have smoothly progressed toward 1H forecasts.

Segmental Review - Functional Food -

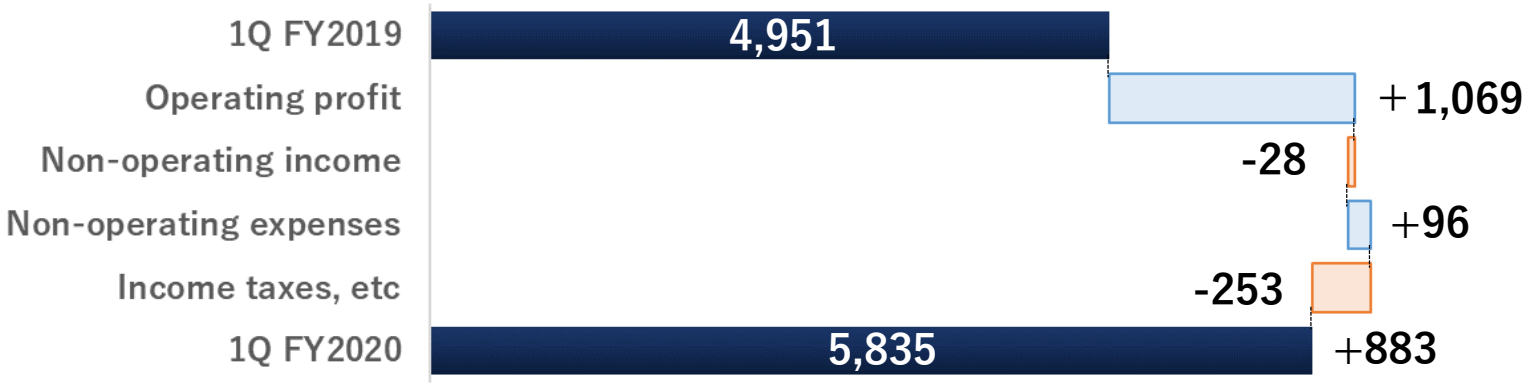
(Million yen)	1Q FY2019		1Q FY2020		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	2,491	66.6%	2,477	66.9%	-13	-0.6%
Preservatives	570	15.3%	610	16.5%	+40	+7.0%
Health food ingredients	277	7.4%	250	6.8%	-26	-9.5%
Others	400	10.7%	364	9.8%	-35	-8.8%
Net sales	3,739	100.0%	3,703	100.0%	-35	-0.9%

Operating profit



(Million yen)	1Q FY2019		1Q FY2020		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	**29,391**	**100.0%**	**29,913**	**100.0%**	**+521**	**+1.8%**
(Pharmaceuticals)	(25,652)	(87.3%)	(26,209)	(87.6%)	(+556)	(+2.2%)
(Functional Food)	(3,739)	(12.7%)	(3,703)	(12.4%)	(-35)	(-0.9%)
Operating expenses	**22,938**	**78.0%**	**22,390**	**74.9%**	**-548**	**-2.4%**
Cost of sales	**13,300**	**45.3%**	**12,818**	**42.9%**	**-481**	**-3.6%**
SG&A expenses	**6,668**	**22.6%**	**6,734**	**22.5%**	**+65**	**+1.0%**
R&D expenses	**2,969**	**10.1%**	**2,836**	**9.5%**	**-132**	**-4.5%**
Operating profit	**6,453**	**22.0%**	**7,522**	**25.1%**	**+1,069**	**+16.6%**

Profit attributable to owners of parent



(Million yen)	1Q FY2019 Results	1Q FY2020 Results	YoY Change Amt	YoY Change %
Operating profit	6,453	7,522	+1,069	+16.6%
Non-operating income	455	427	-28	-6.3%
Non-operating expenses	323	226	-96	-29.9%
Ordinary profit	6,585	7,723	+1,137	+17.3%
Income taxes, etc	1,634	1,887	+253	+15.5%
Profit attributable to owners of parent	4,951	5,835	+883	+17.9%

Business Forecast for FY2020

(Million yen)	FY2019		FY2020			
	1Q Results	FY Results	1Q Results	Progress for 1H	1H Forecasts	FY Forecasts
Net sales	**29,391**	**116,637**	**29,913**	**50.3%**	**59,500**	**126,000**
(Pharmaceuticals)	(25,652)	(101,643)	(26,209)	(50.3%)	(52,100)	(110,700)
(Functional Food)	(3,739)	(14,994)	(3,703)	(50.1%)	(7,400)	(15,300)
Operating profit	**6,453**	**21,668**	**7,522**	**75.2%**	**10,000**	**25,000**
Ordinary profit	**6,585**	**22,442**	**7,723**	**75.7%**	**10,200**	**25,500**
Profit attributable to owners of parent	**4,951**	**16,866**	**5,835**	**81.0%**	**7,200**	**19,000**

Sales of pharmaceuticals and functional food, and each profit have progressed toward achievement of 1H, FY forecasts.

Status of Product Pipeline

NIPPON SHINYAKU CO., LTD.

R&D Compounds (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Preparation for development	PI	PII	PIII	Launch
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy				PIII in progress	
NS-32 (ferric derisomaltose) <in-license>	NME	Iron deficiency anemia					
ZX008 <in-license>	NME	Dravet syndrome Lennox-Gastaut syndrome					
NS-304 (selexipag) <in-house>	New indication	Chronic thromboembolic pulmonary hypertension					
		Arteriosclerosis obliterans					
		Lumbar spinal stenosis					
NS-580 <in-house>	NME	Endometriosis					
NS-17 (azacitidine) <in-license>	New indication	Acute myeloid leukemia					
NS-87 <in-license>	New combination	Secondary acute myeloid leukemia					
NS-917 <in-license>	NME	Relapsed/refractory acute myeloid leukemia					

: changes from the Fiscal Year Ended March 31, 2020

R&D Compounds (Overseas)

Code No. (Generic name) <Origin>	Application type	Indications	Preparation for development	PI	PII	PIII	NDA filing
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy				PIII in progress	
NS-304 (selexipag) <in-house>	New indication	Chronic thromboembolic pulmonary hypertension					
NS-018 (ilginatinib) <in-house>	NME	Myelofibrosis					

Reference Materials

NIPPON SHINYAKU CO., LTD.

Consolidated Balance Sheet

(Million yen)	End of FY2019	End of 1Q FY2020	Change Amt		End of FY2019	End of 1Q FY2020	Change Amt
Assets	175,017	178,391	+3,374	Liabilities	29,256	28,627	-628
Current assets	121,925	123,986	+2,061	Current liabilities	24,965	24,696	-268
Fixed assets	53,091	54,404	+1,313	Long-term liabilities	4,290	3,930	-360
				Net assets	145,760	149,763	+4,002
Total Asset	175,017	178,391	+3,374	Total liabilities and net assets	175,017	178,391	+3,374

＝Assets＝

Cash and deposits	-971
Inventories	+2,048
Investment and other assets	+1,419

＝Liabilities and Net assets＝

Notes and accounts payable	-2,885
Net defined benefit liability	-350
Accounts payable	+585
Provision for bonuses	+1,489
Retained earnings	+2,958

NS-065/NCNP-01 (viltolarsen)
- Treatment for Duchenne muscular dystrophy -

Development Phase	・Japan: Launch ・USA　: NDA filing ・global PIII
Origin	Co-development: National Center of Neurology and Psychiatry
Development	Nippon Shinyaku
Mechanism of action	Exon 53 Skipping
Indication	Duchenne muscular dystrophy
Dosage form	Injection
Feature	・Improvement in symptoms and prevention of the disease progression by recovery of dystrophin protein expression ・Morpholino based oligonucleotide with possible high safety profile and maximized activity

NS-32 (ferric derisomaltose)
- Treatment for iron deficiency anemia -

Development Phase	Japan: PIII
Origin	[Dec. 2016] Licensed-in from: Pharmacosmos A/S
Development	Nippon Shinyaku
Mechanism of action	Iron
Indication	Iron deficiency anemia
Dosage form	IV bolus injection or IV drip infusion
Feature	・Can be administered in high doses allowing full iron correction in the majority of patients ・Good safety profile with no dose dependent ADRs ・Minimal potential toxicity from release of labile iron due to tight iron binding in a matrix structure of interchanging isomaltoside and iron ・No profound hypophosphatemia

ZX008
- Treatment for rare intractable epilepsy -

Development Phase	Japan: PIII
Origin	[March. 2019] Commercial rights from: Zogenix, Inc.
Development	Zogenix, inc
Mechanism of action	Serotonin agonist
Indication	Dravet syndrome and Lennox-Gastaut syndrome
Dosage form	Oral liquid agent
Feature	・Effective for Dravet syndrome and Lennox-Gastaut syndrome patients refractory to existing treatment options ・ZX008 can be used in combination with other drugs, as standard of care for intractable epilepsy is based on combination therapy.

NS-304 (selexipag)

- Treatment for pulmonary hypertension, arteriosclerosis obliterans, lumbar spinal stenosis -

Development Phase	<CTEPH> Japan: PIII Overseas: PIII <ASO> Japan: PIIb <LSS> Japan: PIIa
Origin	Nippon Shinyaku
Development	・Co-development in Japan: Janssen Pharmaceutical K.K. (CTEPH) ・Overseas: Johnson & Johnson (CTEPH) ・Nippon Shinyaku (ASO) ・Nippon Shinyaku (LSS)
Mechanism of action	Selective IP receptor agonist
Indication	・Chronic thromboembolic pulmonary hypertension (CTEPH) ・Arteriosclerosis obliterans (ASO) ・Lumbar spinal stenosis (LSS)
Dosage form	Tablet
Feature	Long-acting oral drug

NS-580
- Treatment for endometriosis -

Development Phase	Japan: PIIa
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	Inhibition of membrane-associated prostaglandin E synthase-1
Indication	Endometriosis
Dosage form	Oral agent
Feature	Treatment for endometriosis without hormonal effect and with possible analgesic potency

NS-17 (azacitidine)
- Treatment for acute myeloid leukemia -

Development Phase	Japan: PII
Origin	[Oct. 2006] Licensed-in from: Celgene Corporation
Development	Nippon Shinyaku
Mechanism of action	Inhibition of DNA methylation, Cytotoxic effects
Indication	Acute myeloid leukemia
Dosage form	Injection
Feature	・Standard Treatment for acute myeloid leukemia that ineligible for intensive chemotherapy ・Improvement for life prognosis

NS-87
- Treatment for secondary acute myeloid leukemia -

Development Phase	Japan: PI/II
Origin	[Mar. 2017] Licensed-in from: Jazz Pharmaceuticals
Development	Nippon Shinyaku
Mechanism of action	Liposomal combination of cytarabine and daunorubicin
Indication	Secondary acute myeloid leukemia (secondary AML)
Dosage form	Injection
Feature	・NS-87 is the first therapy for the treatment of secondary AML in Japan ・The enhancement of antitumor activity and reducing adverse events are expected by NS-87 accumulated in bone marrow.

NS-917
- Treatment for relapsed or refractory acute myeloid leukemia -

Development Phase	Japan: Preparation for Clinical Development
Origin	[Mar. 2017] Licensed-in from: Delta-Fly Pharma, Inc.
Development	Nippon Shinyaku
Mechanism of action	DNA strand-break by incorporating itself into DNA
Indication	Relapsed or refractory (r/r) acute myeloid leukemia (AML)
Dosage form	Injection
Feature	・Significant anti-leukemic activity with unique mechanism of action from other nucleoside analogs at low dose continuous infusion ・Tolerable safety profile available to elderly patients with r/r AML

Prulifloxacin
- Quinolone antibacterial -

Japan

Licensee	Development phase
・Meiji Seika Pharma Co., Ltd.	・Launch (Dec. 2002) / Sword® Tablets

Overseas

Licensee	Development phase
・Angelini (Italy)	・Approval (Sep. 2004) ・Launch in Italy (Nov. 2004) ・Approval in European countries (Apr. 2005)
・Lee's Pharmaceutical Holdings Ltd. (Hong Kong)	・Launch in Hong Kong (Nov. 2012) ・Approval in China (Jun. 2020)
・Algorithm (Lebanon)	・Launch in Lebanon (Jan. 2012)

NS-018 (ilginatinib)
- Treatment for myelofibrosis -

Development Phase	Overseas (USA): PI/II
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	JAK2 inhibitor
Indication	Myelofibrosis
Dosage form	Tablet
Feature	・Potent and highly selective JAK2 inhibitor ・High efficacy and safety are expected for myelofibrosis (MF) patients with low platelet count, for whom QOL improvement can't be obtained because no treatment is available

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