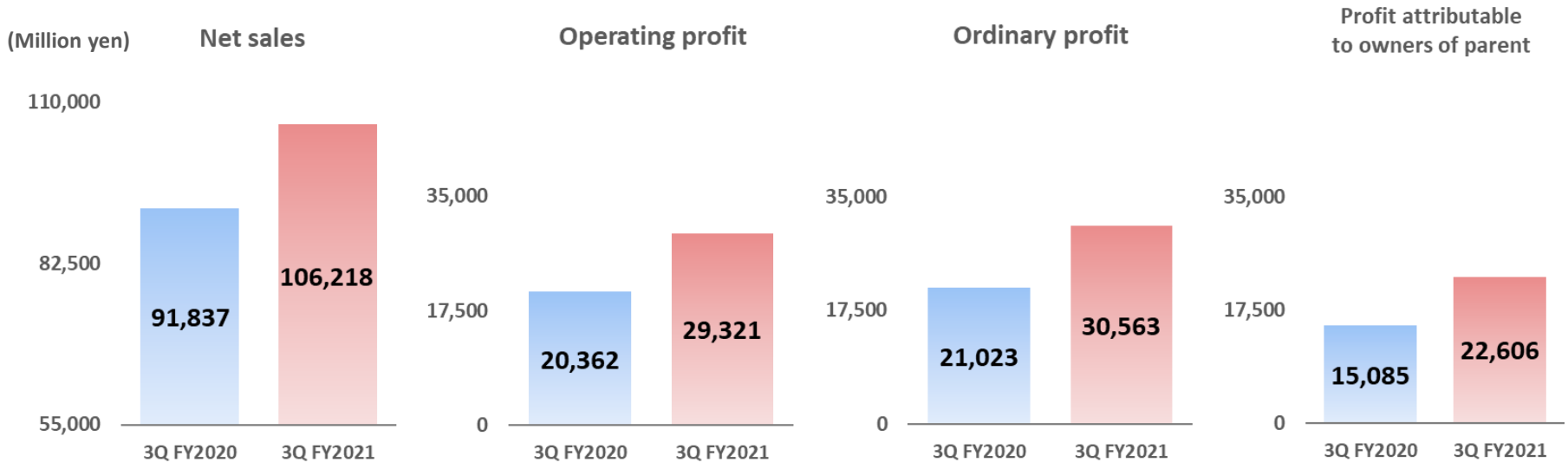
Outline of Consolidated Financial Results for the 3rd Quarter Ended December 31, 2021

February 10, 2022
NIPPON SHINYAKU CO., LTD.

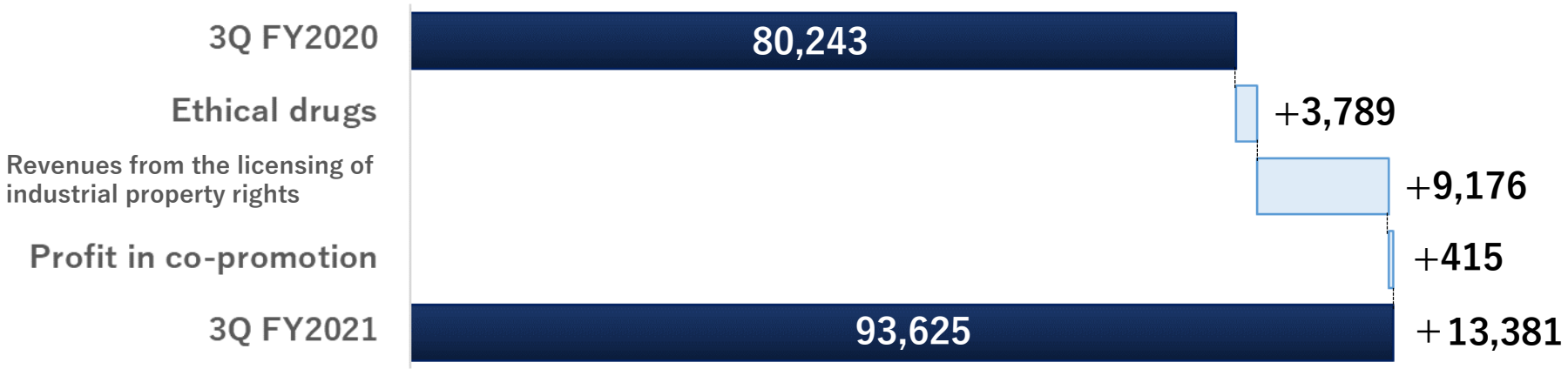
NIPPON SHINYAKU CO., LTD.

3Q FY2021 Summary

- Net sales : 106,218 million yen (+15.7%)
- Operating profit : 29,321 million yen (+44.0%)
- Ordinary profit : 30,563 million yen (+45.4%)
- Profit attributable to owners of parent : 22,606 million yen (+49.9%)



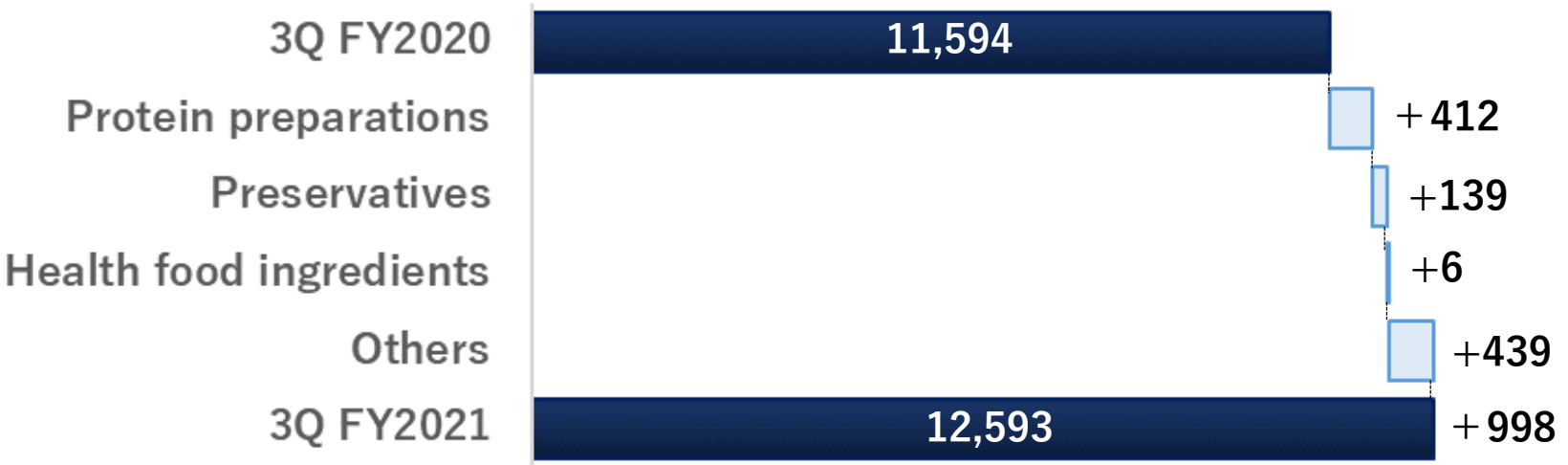
Segmental Review - Pharmaceuticals -



(Million yen)	3Q FY2020		3Q FY2021		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	56,230	70.1%	60,020	64.1%	+3,789	+6.7%
Revenues from the licensing of industrial property rights	17,637	22.0%	26,814	28.6%	+9,176	+52.0%
Profit in co-promotion	6,375	7.9%	6,791	7.3%	+415	+6.5%
Net sales	80,243	100.0%	93,625	100.0%	+13,381	+16.7%

Net sales increased by 16.7% through growth of ethical drugs such as “Vidaza”, “Uptravi”, ”Viltepso”, and revenues from the licensing of industrial property rights which contains of royalty revenue from Uptravi’s overseas sales and gain on sales from the priority review voucher.

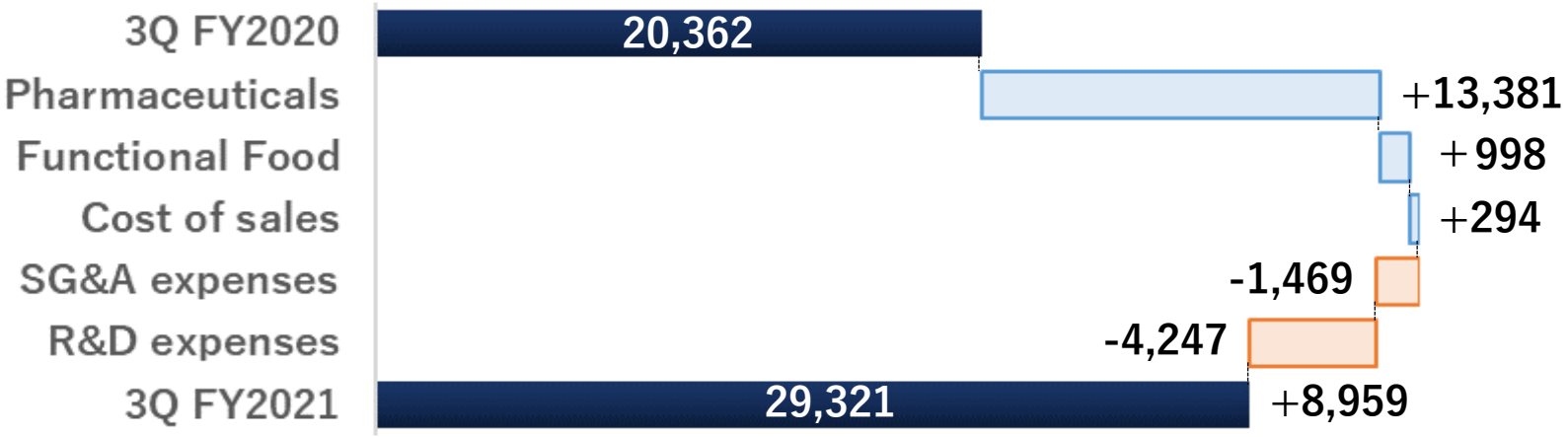
Segmental Review - Functional Food -



(Million yen)	3Q FY2020		3Q FY2021		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	7,745	66.8%	8,158	64.8%	+412	+5.3%
Preservatives	2,008	17.3%	2,147	17.1%	+139	+6.9%
Health food ingredients	774	6.7%	781	6.2%	+6	+0.9%
Others	1,066	9.2%	1,506	11.9%	+439	+41.2%
Net sales	11,594	100.0%	12,593	100.0%	+998	+8.6%

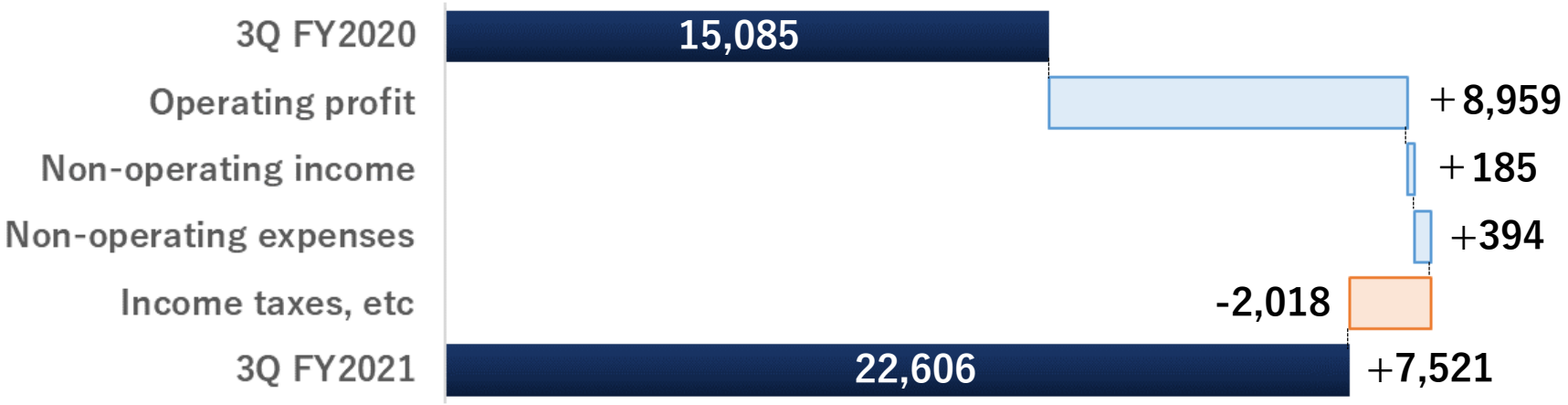
Net sales increased by 8.6% through sales from functional food products such as protein preparations, preservatives, etc.

Operating profit



(Million yen)	3Q FY2020		3Q FY2021		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	**91,837**	**100.0%**	**106,218**	**100.0%**	**+14,380**	**+15.7%**
(Pharmaceuticals)	(80,243)	(87.4%)	(93,625)	(88.1%)	(+13,381)	(+16.7%)
(Functional Food)	(11,594)	(12.6%)	(12,593)	(11.9%)	(+998)	(+8.6%)
Operating expenses	**71,475**	**77.8%**	**76,897**	**72.4%**	**+5,421**	**+7.6%**
Cost of sales	**38,146**	**41.5%**	**37,851**	**35.6%**	**-294**	**-0.8%**
SG&A expenses	**21,869**	**23.8%**	**23,338**	**22.0%**	**+1,469**	**+6.7%**
R&D expenses	**11,459**	**12.5%**	**15,706**	**14.8%**	**+4,247**	**+37.1%**
Operating profit	**20,362**	**22.2%**	**29,321**	**27.6%**	**+8,959**	**+44.0%**

Profit attributable to owners of parent



(Million yen)	3Q FY2020 Results	3Q FY2021 Results	YoY Change Amt	YoY Change %
Operating profit	20,362	29,321	+8,959	+44.0%
Non-operating income	1,599	1,785	+185	+11.6%
Non-operating expenses	938	543	-394	-42.1%
Ordinary profit	21,023	30,563	+9,539	+45.4%
Income taxes, etc	5,938	7,956	+2,018	+34.0%
Profit attributable to owners of parent	15,085	22,606	+7,521	+49.9%

Business Forecast for FY2021

(Million yen)	FY2020		FY2021		
	3Q Results	FY Results	3Q Results	Progress for FY	FY Forecasts
Net sales	**91,837**	**121,885**	**106,218**	**78.7%**	**135,000**
(Pharmaceuticals)	(80,243)	(106,478)	(93,625)	(78.5%)	(119,300)
(Functional Food)	(11,594)	(15,406)	(12,593)	(80.2%)	(15,700)
Operating profit	**20,362**	**26,134**	**29,321**	**104.7%**	**28,000**
Ordinary profit	**21,023**	**26,760**	**30,563**	**107.2%**	**28,500**
Profit attributable to owners of parent	**15,085**	**20,702**	**22,606**	**107.7%**	**21,000**

Sales of pharmaceuticals and functional food, and each profit have shown strong progress.

R&D Pipeline

NIPPON SHINYAKU CO., LTD.

R&D Pipeline (Domestic) ①

Code No. (Generic name) <Origin>	Application type	Indications	Preparation for development	Preparation for PI	PI	PII	PIII	NDA	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 (fenfluramine hydrochloride) <in-license>	NME	Dravet syndrome							
ZX008 (fenfluramine hydrochloride) <in-license>	NME	Lennox-Gastaut syndrome							

■ : Changes from 2nd Quarter 2021

R&D Pipeline (Domestic) ②

Code No. (Generic name) <Origin>	Application type	Indications	Preparation for development	Preparation for PI	PI	PII	PIII	NDA	Launch
NS-304 (selexipag) <in-house>	New indication	Arteriosclerosis obliterans							
	New dose	Pediatric pulmonary arterial hypertension							
NS-580 <in-house>	NME	Endometriosis							
NS-87 (daunorubicin / cytarabine) <in-license>	New combination	Secondary acute myeloid leukemia							
NS-229 <in-house>	NME	Inflammatory diseases							
NS-917 (radgocitabine) <in-license>	NME	Relapsed/refractory acute myeloid leukemia							
NS-401 (tagraxofusp) <in-license>	NME	Blastic plasmacytoid dendritic cell neoplasm							

R&D Pipeline (Overseas)

Code No. (Generic name) <Origin>	Application type	Indications	PI	Preparation for P II	PII	Preparation for PIII	PIII	Launch
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy					PIII in progress	
CAP-1002 <partnership>	NME	Duchenne muscular dystrophy						
NS-018 (ilginatinib) <in-house>	NME	Myelofibrosis						

■ : Changes from 2nd Quarter 2021

Reference Materials

NIPPON SHINYAKU CO., LTD.

Consolidated Balance Sheet

(Million yen)	End of FY2020	End of 3Q FY2021	YoY Change Amt
Assets	197,028	204,795	+7,766
Current assets	139,090	148,535	+9,444
Non-current assets	57,937	56,259	-1,677
Total assets	197,028	204,795	+7,766

	End of FY2020	End of 3Q FY2021	YoY Change Amt
Liabilities	34,485	27,555	-6,929
Current liabilities	31,514	24,508	-7,005
Non-current liabilities	2,970	3,046	+75
Net assets	162,543	177,240	+14,696
Total liabilities and net assets	197,028	204,795	+7,766

＝Assets＝

Notes and accounts receivable	＋9,027
Inventories	+2,105
Investments and other assets	-2,553

＝Liabilities and Net assets＝

Income taxes payable	-3,780
Provision for bonuses	-1,615
Retained earnings	+15,804

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

Development Phase	・Japan : Launch ・USA : Launch ・China : NDA filing ・Global : PIII in progress
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: NDA filing
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 (fenfluramine hydrochloride)
- Treatment for rare intractable epilepsy -

Development Phase	Japan: NDA filing　(Dravet syndrome) Japan: PIII　(Lennox-Gastaut syndrome)
Origin	[Mar. 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 based on combination therapy

CAP-1002
- Treatment for Duchenne muscular dystrophy -

Development Phase	USA : Preparation for PIII
Origin	[Jan. 2022] Commercial rights from: Capricor Therapeutics, Inc.
Development	Capricor Therapeutics, Inc.
Mechanism of action	Exosomes released from cardiosphere-derived cells
Indication	Duchenne muscular dystrophy
Dosage form	Injection
Feature	・Exosomes released from this drug are expected to reduce oxidative stress, inflammation, fibrosis, and increase cell energy and myocyte generation, resulting in improvement of motor and cardiac functions ・Its broad applicability makes it suitable for patients regardless of the type of genetic mutation

NS-304 (selexipag)

-Treatment for pulmonary hypertension, arteriosclerosis obliterans-

Development Phase	Japan: PIIb（ASO） Japan: PII （Pediatric PAH）
Origin	Nippon Shinyaku
Development	・Nippon Shinyaku（ASO） ・Co-development: Janssen Pharmaceutical K.K.（Pediatric PAH）
Mechanism of action	Selective IP receptor agonist
Indication	・Arteriosclerosis obliterans (ASO) ・Pediatric pulmonary arterial hypertension (Pediatric PAH)
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-018 (ilginatinib)
- Treatment for myelofibrosis -

Development Phase	USA: Preparation for PII
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

NS-87 (daunorubicin / cytarabine)
- Treatment for secondary acute myeloid leukemia -

Development Phase	Japan: PI/II
Origin	[Mar. 2017] Licensed-in from: Jazz Pharmaceuticals plc
Development	Nippon Shinyaku
Mechanism of action	Liposomal combination of daunorubicin and cytarabine
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-229
- Treatment for inflammatory diseases -

Development Phase	Japan: PI
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	JAK1 inhibitor
Indication	Inflammatory diseases (to be determined)
Dosage form	Oral agent
Feature	・Potent and highly selective JAK1 inhibitor ・High efficacy and good safety profiles are expected in the treatment for inflammatory diseases

NS-917 (radgocitabine)

- Treatment for relapsed or refractory acute myeloid leukemia -

Development Phase	Japan: Preparation for PI
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

NS-401 (tagraxofusp)

- Treatment for blastic plasmacytoid dendritic cell neoplasm -

Development Phase	Japan: Preparation for clinical development
Origin	[Mar. 2021] Licensed-in from: The Menarini Group
Development	Nippon Shinyaku
Mechanism of action	Induction apoptosis of cells by inhibiting protein synthesis by specifically targeting cancer cells expressing CD123
Indication	Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
Dosage form	Injection
Feature	・Composed of diphtheria toxin (DT) fusion protein and recombinant human IL-3 ・Novel targeted therapy directed to CD123 on tumor cells ・IL-3 binds to CD123-expressing tumor cells and delivers the cytotoxic diphtheria toxin to the cells, resulting in the blockage of protein synthesis in the cell and causing cell death in CD123-expressing cells

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