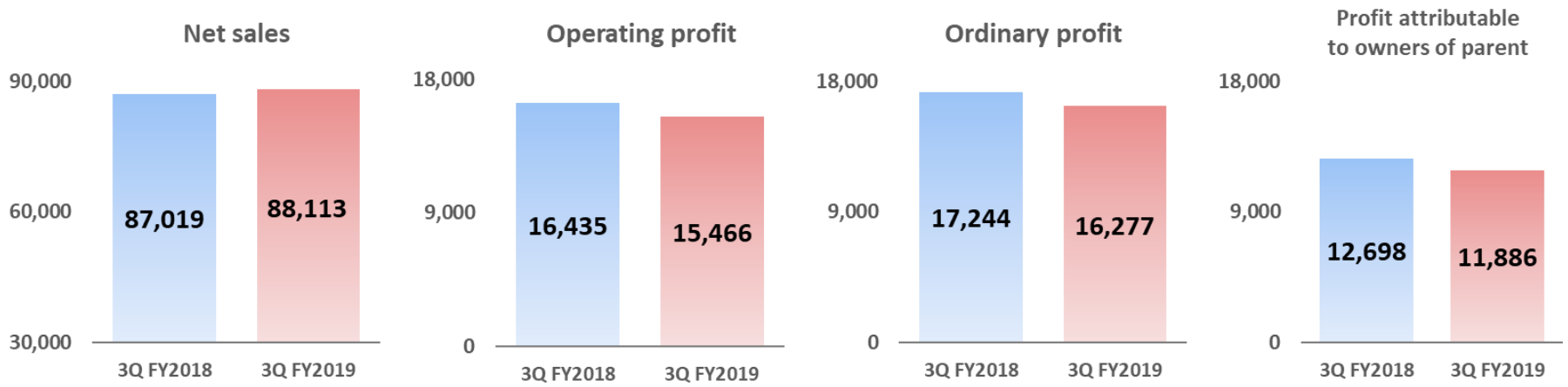
Outline of Consolidated Financial Results for the 3rd Quarter Ended December 31, 2019

February 5, 2020
NIPPON SHINYAKU CO., LTD.

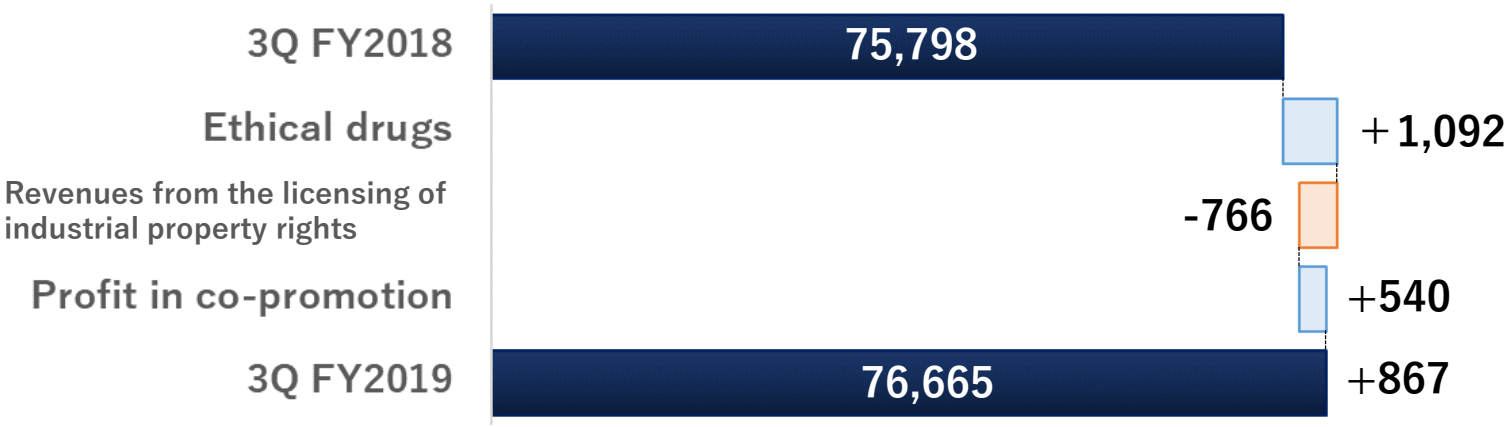
3Q FY2019 Summary

- **Net sales** : 88,113 million yen (+1.3%)
- **Operating profit** : 15,466 million yen (-5.9%)
- **Ordinary profit** : 16,277 million yen (-5.6%)
- **Profit attributable to owners of parent** : 11,886 million yen (-6.4%)

(Million yen)



Segmental Review - Pharmaceuticals -

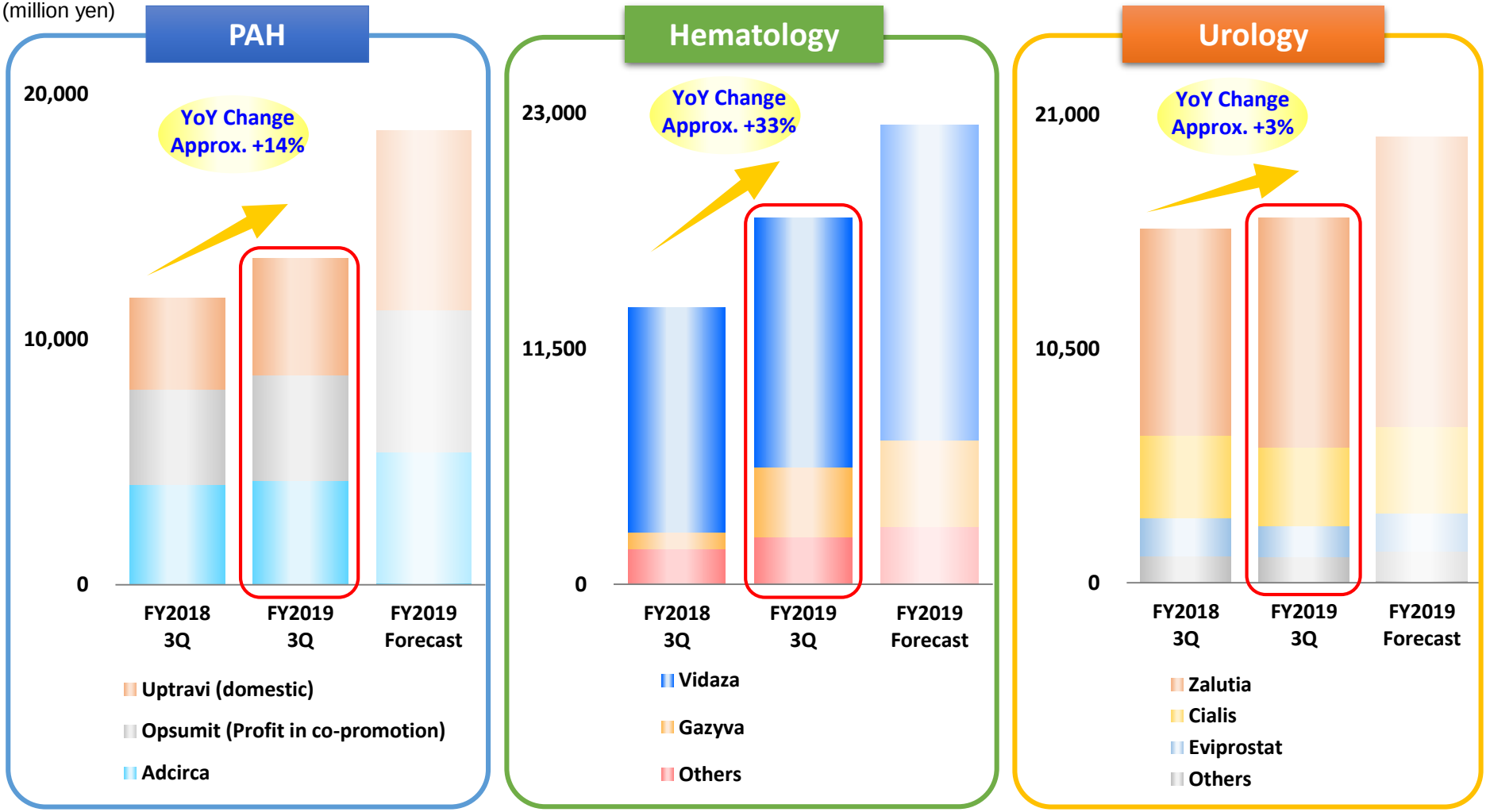


(Million yen)	3Q FY2018		3Q FY2019		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	59,936	79.1%	61,029	79.6%	+1,092	+1.8%
Revenues from the licensing of industrial property rights	11,963	15.8%	11,197	14.6%	-766	-6.4%
Profit in co-promotion	3,898	5.1%	4,438	5.8%	+540	+13.9%
Net sales	75,798	100.0%	76,665	100.0%	+867	+1.1%

Although revenues from the licensing of industrial property rights decreased due to the absence of milestone revenue from Uptravi, net sales increased by 1.1% through growth of new products and profit in co-promotion.

Three Main Fields of Focus

(million yen)



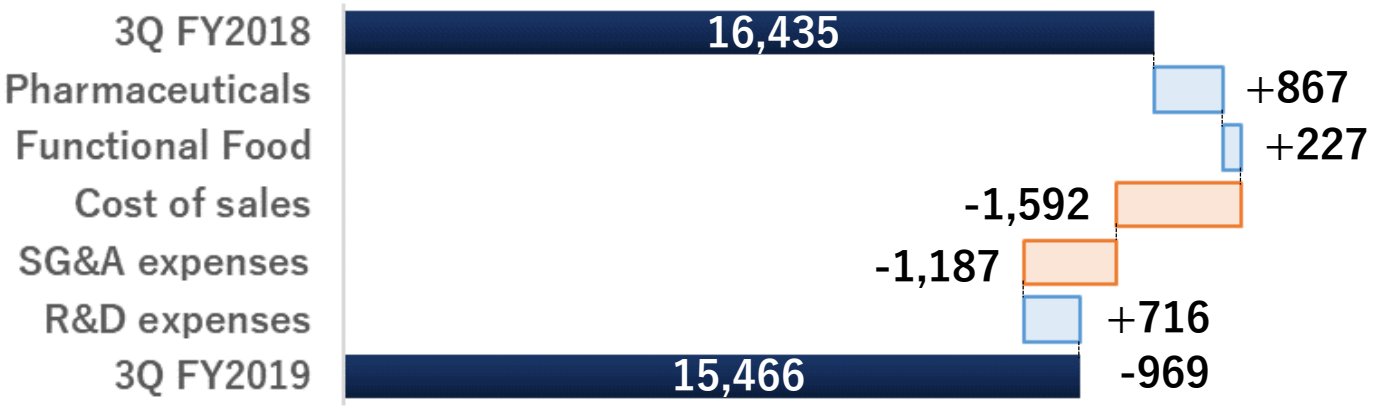
Sales in the focus fields increased over the same period of the previous year, and have smoothly progressed toward FY forecasts.

Segmental Review - Functional Food -

(Million yen)	3Q FY2018		3Q FY2019		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	7,439	66.3%	7,550	65.9%	+110	+1.5%
Preservatives	1,814	16.2%	1,884	16.5%	+70	+3.9%
Health food ingredients	855	7.6%	850	7.4%	-5	-0.6%
Others	1,112	9.9%	1,164	10.2%	+51	+4.6%
Net sales	11,221	100.0%	11,448	100.0%	+227	+2.0%

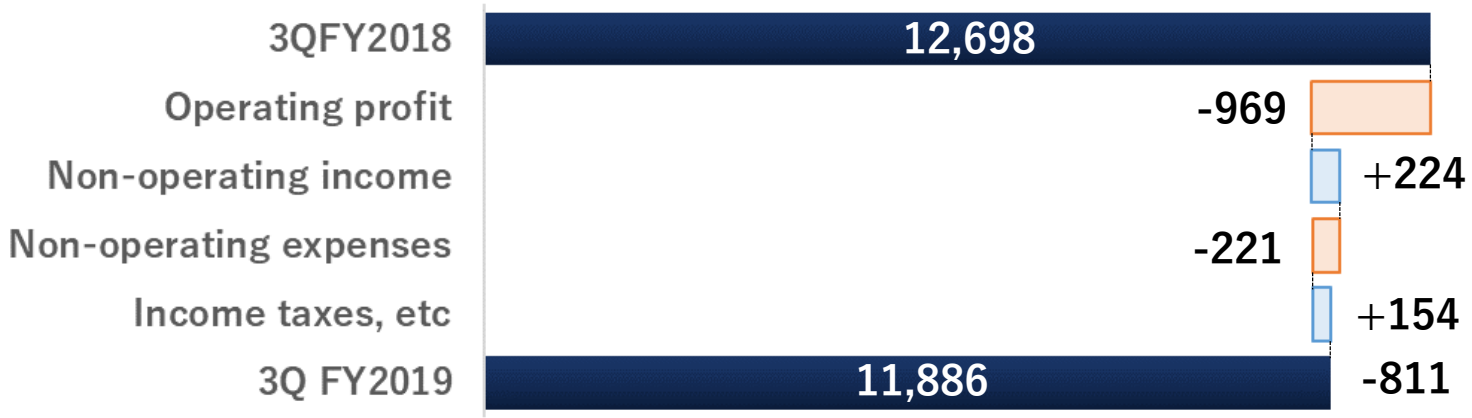
Net sales increased by 2.0% through growth of protein preparations and preservatives.

Operating profit



(Million yen)	3Q FY2018		3Q FY2019		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	**87,019**	**100.0%**	**88,113**	**100.0%**	**+1,094**	**+1.3%**
(Pharmaceuticals)	(75,798)	(87.1%)	(76,665)	(87.0%)	(+867)	(+1.1%)
(Functional Food)	(11,221)	(12.9%)	(11,448)	(13.0%)	(+227)	(+2.0%)
Operating expenses	**70,584**	**81.1%**	**72,647**	**82.4%**	**+2,063**	**+2.9%**
Cost of sales	**39,091**	**44.9%**	**40,683**	**46.2%**	**+1,592**	**+4.1%**
SG&A expenses	**19,765**	**22.7%**	**20,952**	**23.7%**	**+1,187**	**+6.0%**
R&D expenses	**11,727**	**13.5%**	**11,011**	**12.5%**	**-716**	**-6.1%**
Operating profit	**16,435**	**18.9%**	**15,466**	**17.6%**	**-969**	**-5.9%**

Profit attributable to owners of parent



(Million yen)	3Q FY2018 Results	3Q FY2019 Results	YoY Change Amt	YoY Change %
Operating profit	16,435	15,466	-969	-5.9%
Non-operating income	1,208	1,433	+224	+18.6%
Non-operating expenses	399	621	+221	+55.5%
Ordinary profit	17,244	16,277	-966	-5.6%
Income taxes, etc	4,546	4,391	-154	-3.4%
Profit attributable to owners of parent	12,698	11,886	-811	-6.4%

Business Forecast for FY2019

(Million yen)	FY2018		FY2019		
	3Q Results	FY Results	3Q Results	Progress for FY	FY Forecasts
Net sales	**87,019**	**114,716**	**88,113**	**76.0%**	**116,000**
(Pharmaceuticals)	(75,798)	(100,223)	(76,665)	(75.8%)	(101,100)
(Functional Food)	(11,221)	(14,492)	(11,448)	(76.8%)	(14,900)
Operating profit	**16,435**	**20,644**	**15,466**	**73.6%**	**21,000**
Ordinary profit	**17,244**	**21,540**	**16,277**	**74.0%**	**22,000**
Profit attributable to owners of parent	**12,698**	**16,302**	**11,886**	**72.0%**	**16,500**

We look for operating profit, ordinary profit and profit attributable to owners of parent to increase year on year.

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	NDA filing
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy				Preparation for PIII	
NS-73 (defibrotide) <in-license>	New indication	Sinusoidal obstruction syndrome (prevention)					
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					

R&D Compounds (Overseas)

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

Reference Materials

NIPPON SHINYAKU CO., LTD.

Consolidated Balance Sheet

(Million yen)	End of FY2018	End of 3Q FY2019	YoY Change Amt
Assets	168,763	172,719	+3,956
Current assets	110,720	116,707	+5,986
Non-current assets	58,042	56,012	-2,030
Total Asset	168,763	172,719	+3,956

	End of FY2018	End of 3Q FY2019	YoY Change Amt
Liabilities	33,572	30,914	-2,658
Current liabilities	25,406	23,807	-1,599
Non-current liabilities	8,165	7,106	-1,059
Net assets	135,190	141,805	+6,615
Total liabilities and net assets	168,763	172,719	+3,956

＝Assets＝

Cash and deposits	-2,902
Notes and accounts receivable	+2,684
Inventories	+5,619
Investment securities	-961
Deferred tax assets	-1,340

＝Liabilities and Net assets＝

Notes and accounts payable	+3,984
Accounts payable	-1,722
Income taxes payable	-3,126
Retained earnings	+6,228

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

Development Phase	・Japan: NDA filing ・USA　: NDA filing ・Preparation for 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-73 (defibrotide)
- Prevention of hepatic sinusoidal obstruction syndrome -

Development Phase	Japan : PIII (prevention)
Origin	[Mar. 2017] Licensed-in from : Jazz Pharmaceuticals
Development	Co-development in Japan : Jazz Pharmaceuticals
Mechanism of action	Protective action on vascular endothelium, normalization of the coagulation/fibrinolysis balance
Indication	Sinusoidal obstruction syndrome (SOS)
Dosage form	Injection
Feature	・SOS is a life-threatening complication which develops in patients following HSCT, and in severe cases, leading to death at high rates. ・NS-73 is the only drug for the treatment of SOS (EU/US guideline). It has been launched in various countries. ・NS-73 is the only drug for the prevention of SOS.

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	・[Apr. 2008] Licensed-out to (outside Japan): Actelion Pharmaceuticals Ltd. (Switzerland) ・Co-development in Japan: Actelion Pharmaceuticals Japan Ltd. (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 cytrabine 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)	・NDA filing in China
・Algorithm (Lebanon)	・Launch in Lebanon (Jan. 2012)

NS-018
- 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	・Highly selective for active form of JAK2 ・Possibly best-in-class treatment for myelofibrosis

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