

2019 Second quarter financial results briefing

November 28, 2019

 **ASKA Pharmaceutical Co., Ltd.**

Stock ticker number : 4514

2019 1H Consolidated Financial Summary

ASKA Pharmaceutical Co., Ltd.

Atsushi Maruo,

Senior Managing Director

Income statement (consolidated)

Millions of yen	FY2018 Apr. 2018-Sep. 2018	FY2019 Apr. 2019-Sep. 2019	Increase (decrease)	YoY
amount of sales	23,477	26,582	3,105	13.2%
Cost of sales	14,030	14,492	462	3.3%
Gross profit	9,446	12,089	2,643	28.0%
Selling, general and administrative expenses	8,486	11,343	2,857	33.7%
Operating profit	960	746	△ 213	△22.3%
Ordinary profit	1,078	869	△ 208	△19.3%
Attributable to parent company shareholders Net sales	743	577	△ 166	△22.4%

Sales by business (consolidated)

Millions of yen	FY2018 Apr. 2018- Sep. 2018	FY2019 Apr. 2019- Sep. 2019	Composition ratio	Increase and decrease	YoY
Ethical drugs	20,906	24,177	90.9%	3,270	15.6%
Veterinary medicine	2,462	2,319	8.7%	△ 143	△ 5.8%
Other	108	86	0.4%	△ 21	△20.1%
Total	23,477	26,582	100.0%	3,105	13.2%

Main product sales

		Millions of yen					
Areas	Products	FY2018 Apr. 2018-Sep. 2018	FY2019 Apr. 2019-Sep. 2019		FY2019		
		Results	Results	YoY (%)	Plan	YoY (%)	
INTERNAL MEDICINE	※1, ※2 CANDESARTANS	6,077	6,878	113.2%	13,600	116.0%	
	THYRADIN	3,010	3,433	114.0%	6,982	126.4%	
	RIFXIMA	1,178	1,845	156.6%	3,893	132.6%	
	※1 AMLODIPINE	703	790	112.3%	1,525	111.1%	
	LIPDIL	1,117	777	69.5%	1,208	35.6%	
	MERCAZOLE	599	700	116.8%	1,338	116.2%	
OBSTETRICS GYNECOLOGY	※1 FREWELL (2018.12~)	—	1,012	—	2,010	285.4%	
	RELUMINA (2019.3~)	—	865	—	1,981	—	
	ANGE	419	538	128.4%	1,000	111.7%	
	LUTEUM	196	246	125.2%	483	116.6%	
	NORLEVO	658	121	18.4%	664	52.8%	
UROLOGY	※1, ※3 LEUPRORELIN	2,076	2,472	119.1%	4,524	99.7%	
	※1 BICALUTAMIDE	622	692	111.3%	1,058	90.3%	
	PROSTAL	222	208	93.7%	395	87.9%	

※1 Generics

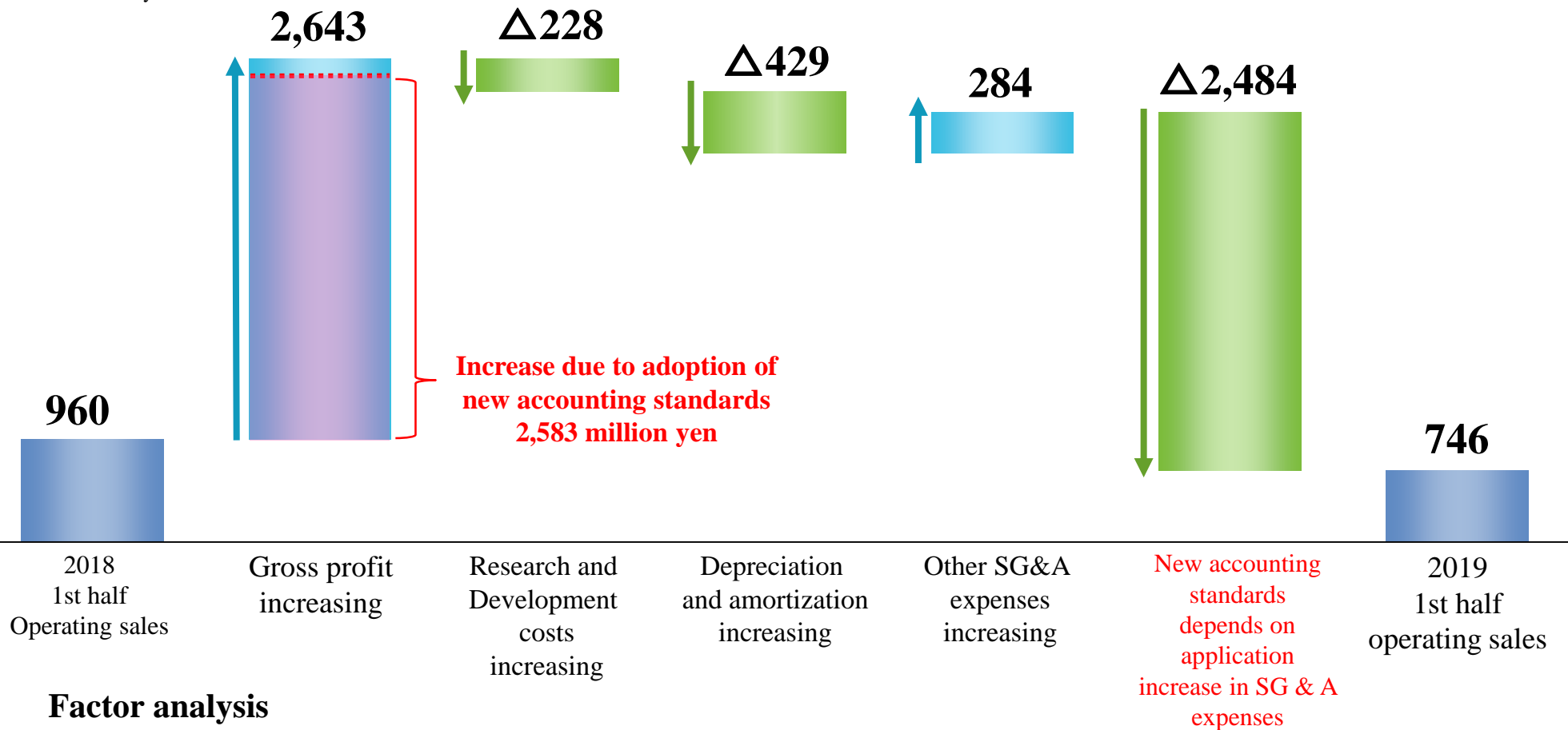
※2 Including compounding agents

※3 1.88mg formulation is only for obstetrics and gynecology, but combined with 3.75mg

Applying "Accounting Standards for Revenue Recognition" from Fiscal 2019

Analysis of change in operating sales (YoY)

Millions of yen



Factor analysis

- Gross profit increased, but operating sales decreased due to
 - (1) an increase in depreciation expenses due to the commencement of amortization of sales rights,
 - (2) an increase in R & D expenses due to progress in the development stage, etc.

Consolidated Balance Sheet

End of Fiscal 2018

Millions of yen

Current assets 37,829	Current liabilities 18,002
Property, plant and equipment 13,573	Long-term liabilities 20,735
Intangible fixed assets 15,332	Net assets 43,456
Investments and other assets 15,458	

Total assets 82,194 million yen

End of Fiscal 2019

Millions of yen

Current assets 38,951 (+1,122)	Current liabilities 20,381 (+2,379)
Property, plant and equipment 14,036 (+462)	Long-term liabilities 20,247 (△488)
Intangible fixed assets 14,373 (△958)	Net assets 42,137 (△1,318)
Investments and other assets 15,404 (△54)	

Total assets 82,766 million yen
(+572)

■ Asset section

Cash and Deposits △3,690
Notes and accounts receivable 4,112
Inventory 963
Tangible fixed assets 462
Intangible fixed assets △958
Other △316

■ Liabilities and net assets

Notes payable and accounts payable △1,399
Debt 3,425
retained earnings △942
Other △511

FY2019 forecast(Consolidated)

Millions of yen	FY2018 result	FY2019 forecast	From the previous year increase (decrease)	From the previous year rate of changes
Net sales	46,706	53,000	6,294	13.5
Operating sales	1,782	2,000	218	12.2
Ordinary sales	1,980	2,100	120	6.1
Profit attributable to owners of parent net sales	1,744	1,000	△744	△42.7

Factor

- Sales are expected to increase due to the impact of the adoption of the “Revenue Recognition Accounting Standard” and the expansion of sales of new products in the obstetrics and gynecology field such as “RELUMINA” and “RIFXIMA”.
- Operating profit and ordinary profit are expected to increase as sales increase. On the other hand, net income attributable to owners of the parent is expected to decrease as extraordinary losses are expected due to the transfer of the research institute.

2019 1st Half Summary Fiscal Year Interim Report

ASKA Pharmaceutical Co., Ltd.

Takashi Yamaguchi,
president of director

Today's content

- Summary of Fiscal 2019
- Action on the second half of fiscal 2019
 - **Obstetrics and gynecology**
 - **Rifxima**
 - **Thyroid**
 - **Shonan iPark**
 - **Overseas operation**
 - **Development pipeline**
 - **Joint R&D**
 - **ASKA PLAN 2020**

Summary of the first half of fiscal 2019

Main achievements in the second half of 2019

Market penetration of new obstetrics and gynecology products



Launched on October 4, 2018 from Nobel Pharma Corporation
 Treatment for dysmenorrhea
JEMINA® Tablets **Co-promotion**



Launched on December 14, 2018
 Treatment for dysmenorrhea
FREWELL® Combination Tablet LD/ULD "Aska" **Authorized generics**



Launched on March 1, 2019
 GnRH antagonist
RELUMINA® Tablets 40mg **Introduced from Takeda Pharmaceutical Co., Ltd.**

- Increase RIFXIMA's market share
 - Ongoing awareness activities for thyroid disease
 - Development pipeline progress (Ulipristal acetate, etc.)
 - Concluded joint research agreement (RaQualia Pharma Inc.)
- } Posted on page 27.

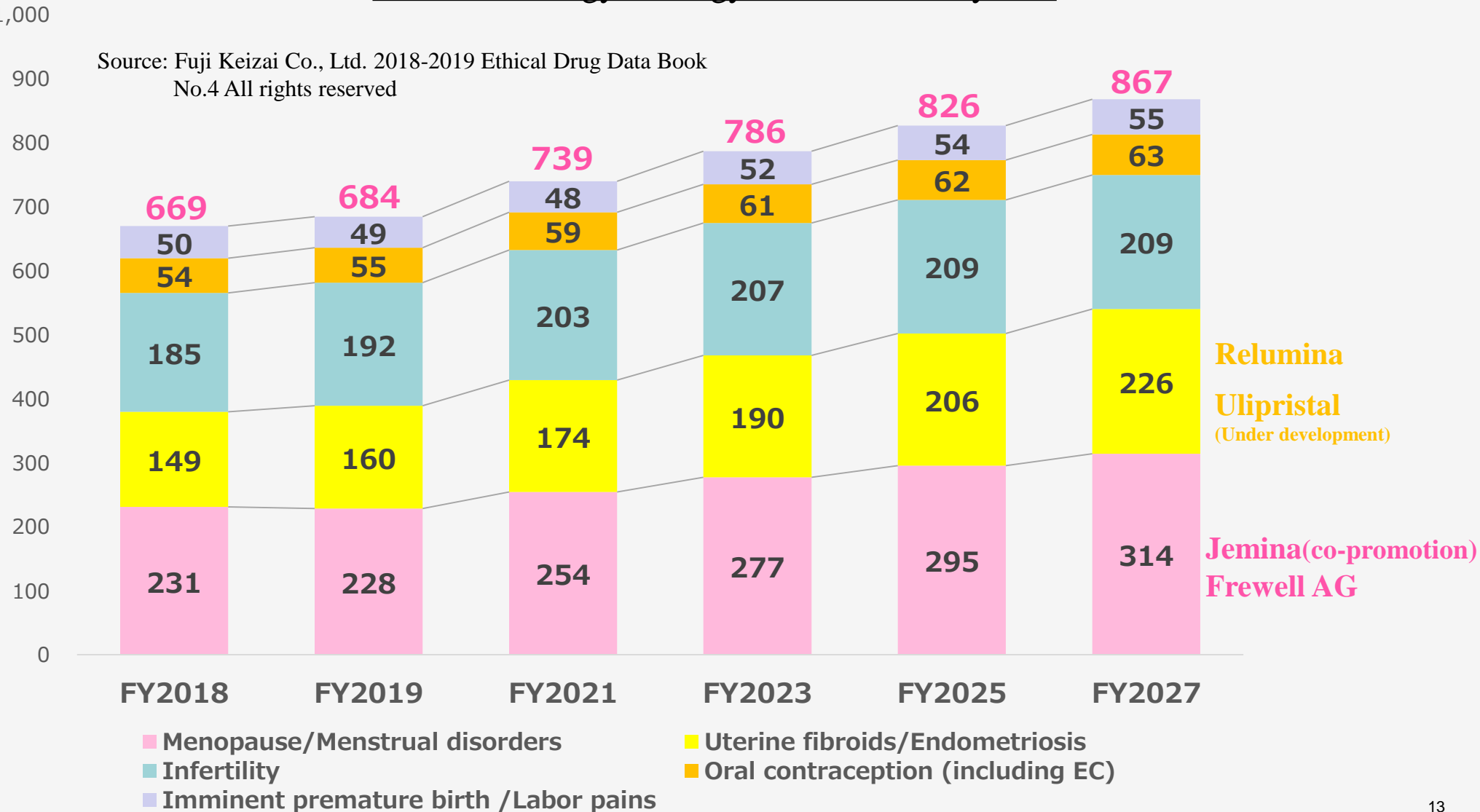
Action on the second half of fiscal 2019

Obstetrics and gynecology market

(hundred millions of yen)

Obstetrics and gynecology market trends by area

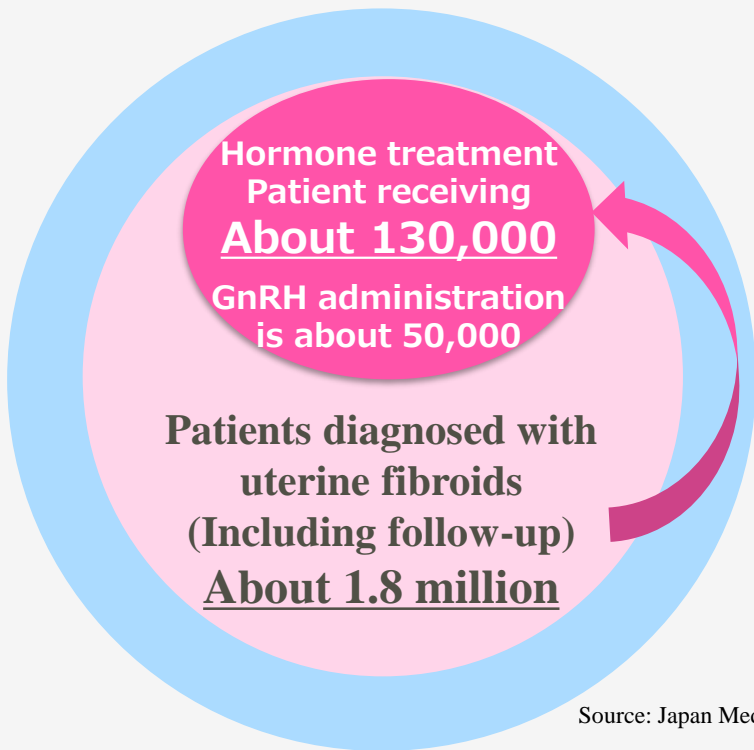
Source: Fuji Keizai Co., Ltd. 2018-2019 Ethical Drug Data Book
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Uterine fibroids / endometriosis therapeutic agent



Uterine Fibroids market



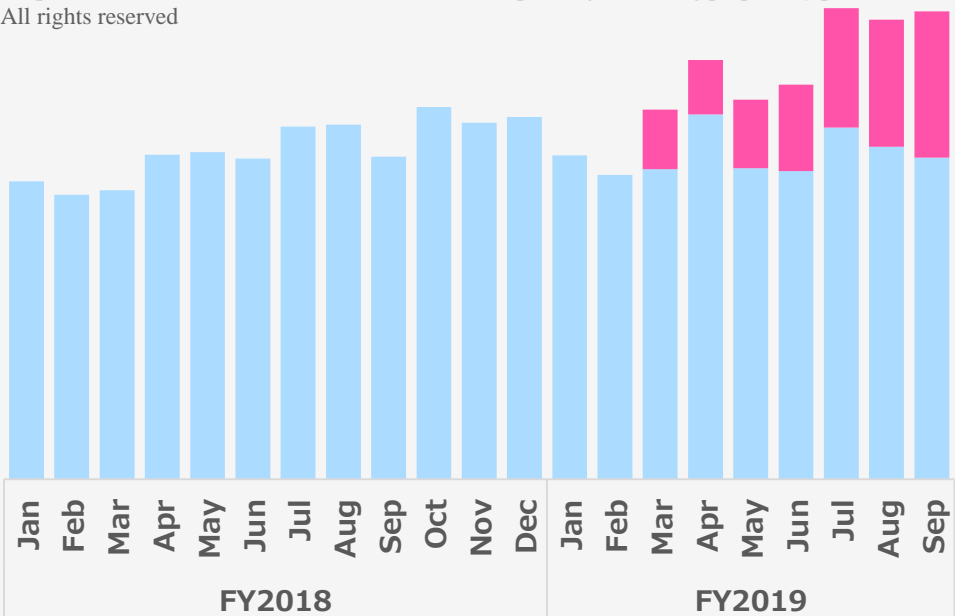
Source: Japan Medical Data Center

Uterine fibroids-estimated number of cases

* Estimated from quantity

■ Leuprorelin 1.88 ■ Relumina

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 JPM In-house estimate based on January 2018 to September 2019
 "Leuprorelin 1.88 total" is the combined value of multiple drugs including proprietary products
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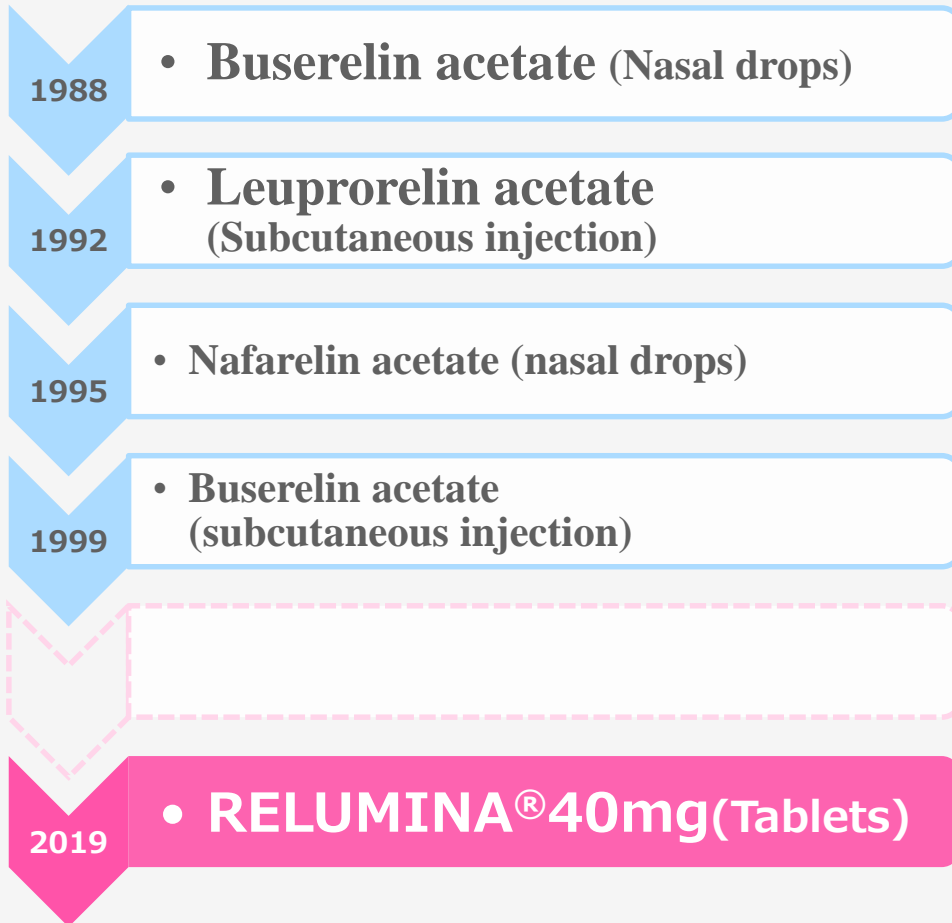


March 2019 release
 GnRH antagonist
RELUMINA® Tablet 40mg

**No change in Leuprorelin acetate
Presumed to be from another treatment**



Year of launch of uterine fibroids treatment



Uterine fibroids treatment for the first time in 20 years

Out of 81 university hospitals nationwide
78 university hospitals adopted
 ※ As of November 2019

- <Evaluation from the medical field>
- New pharmacological action
 - There was no existing drug
 - Frequency of side effects
 - Administration route, dosage form, etc.

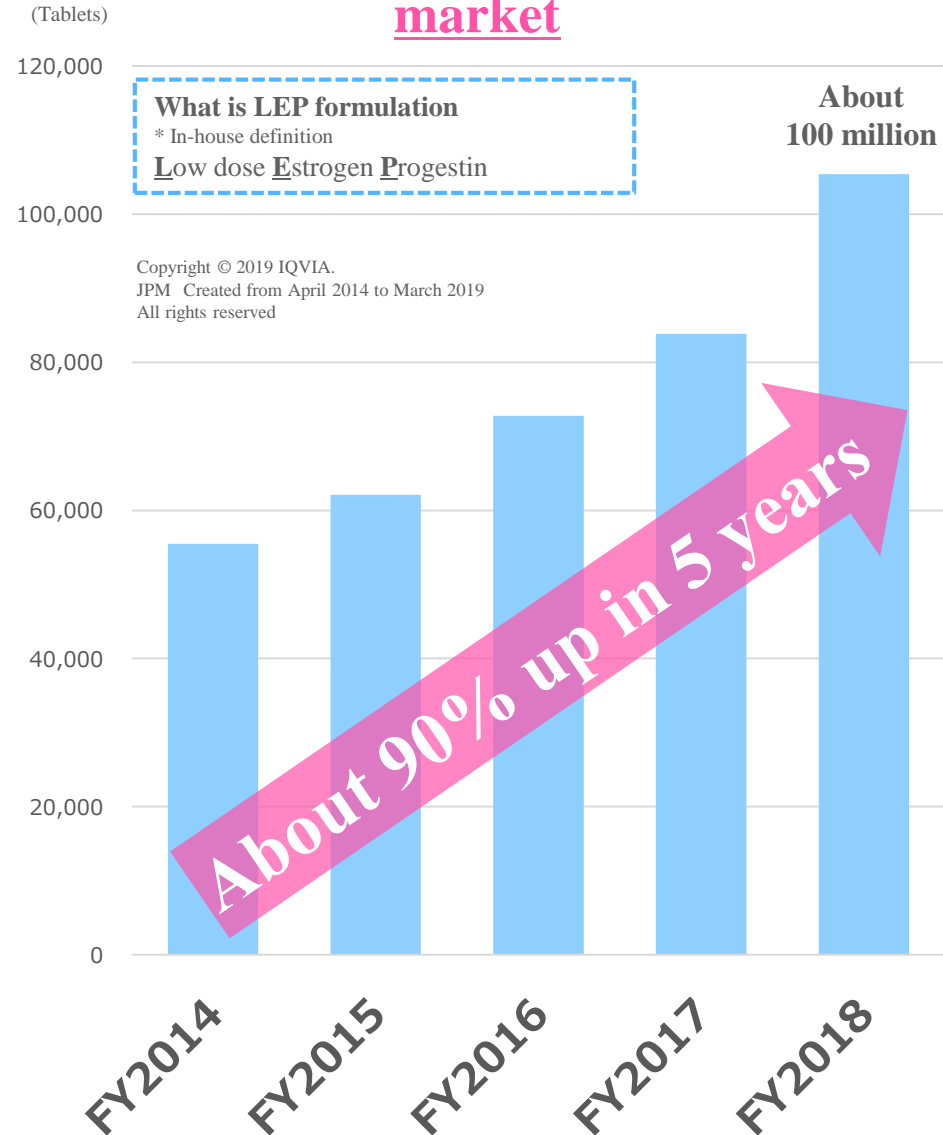
~2020 March~
Achieving further market penetration by removing prescription days limit

Menopause treatment

menstrual disorder treatment

LEP formulation (JEMINA / FREWELL)

Expanding LEP formulation market



Launched on October, 2018 by Nobel Pharma
Treatment for dysmenorrhea

JEMINA® Tablets

Co-promotion

<2019 Sep>
Release of prescription days limit

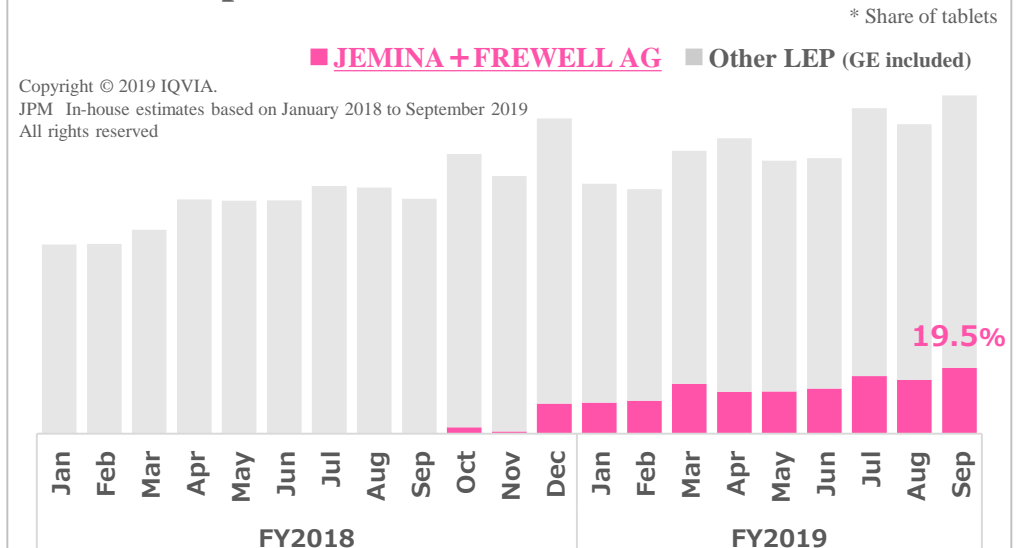


Launched on December, 2018
Treatment for dysmenorrhea

FREWELL® Tablets LD/ULD"ASKA"

Authorized generic

Our presence in LEP formulation market



**Imminent preterm birth treatment
Labor pains promoting agent**

Succession from Toa Biopharma Co., Ltd. (February 1, 2020)



Uterine contraction inhibitor

Magsent® Injection 100mL

Magsent® Injection Syringe 40mL

Common name : Magnesium sulfate hydrate / glucose

<Effects>

- **Suppression of uterine contractions**
in imminent preterm birth
- **Suppression and treatment of eclampsia**
in Pregnancy-induced hypertension



Inhibition and treatment of eclampsia

MAGNESOL®

Common name : Magnesium sulfate hydrate / glucose

<Effects>

- **Suppression and treatment of eclampsia**
in Pregnancy-induced hypertension

**Succession
From
February, 2020**

Enhance obstetrics lineup

Expand obstetrics and gynecology lineup

Succession from February, 2020

- Uterine contraction inhibitor 「Magsent」
- Inhibition and treatment of eclampsia 「Magnesol」

In development

- Ulipristal (Uterine Fibroids)
- Relumina (Endometriosis)



Launched March 2019
GnRH antagonist
RELUMINA® Tablets 40mg



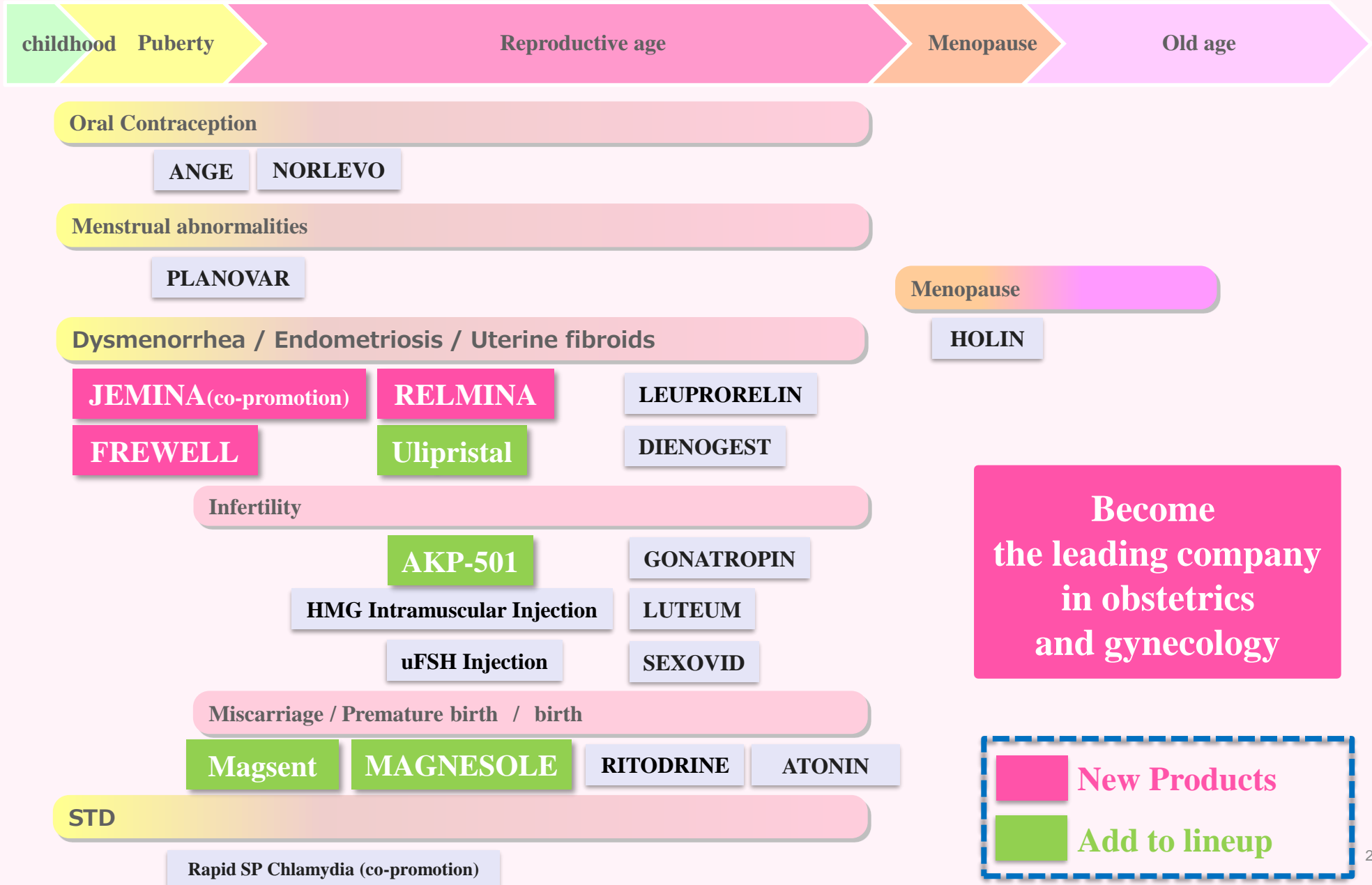
Launched December 2018
Treatment for Dysmenorrhea
Authorized Generic
FREWELL® Tablets LD/ULD “ASKA”



Launched on October, 2018 from Nobel Pharma Corporation
Treatment for dysmenorrhea
JEMINA® Tablets *co-promotion

Enhance presence

Obstetrics and gynecology products by life stage



Become the leading company in obstetrics and gynecology

New Products
 Add to lineup

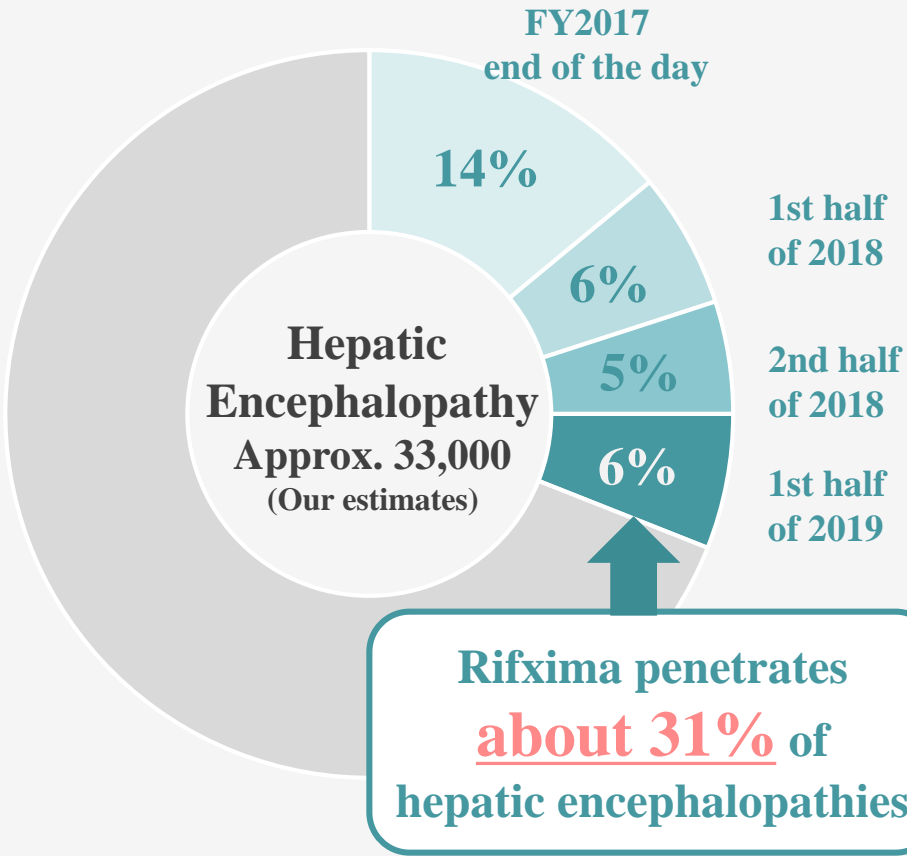


To the key drug of hepatic encephalopathy

- 1 Switching from existing antibiotics**

 - ❑ Subject to all usage results survey
 - ❑ Distribution management products
- 2 Combination with existing treatments**

 - ❑ Release of restrictions on the number of prescriptions
 - ❑ Unregistering all usage grade survey
- 3 Positioning of central drugs**
- 4 Achieve further market penetration**

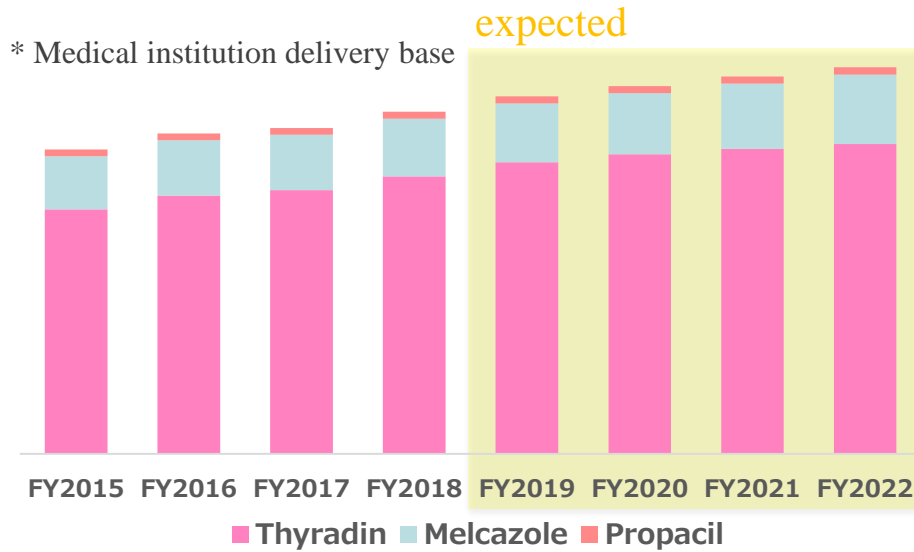


Aim for “1st line” for treatment of HE

Action on thyroid area

~Towards the 100th anniversary of the birth of THYRADIN in 2022~

Sales trends for thyroid products



Disease awareness



<New establishment> Member site for medical professionals

A site where you can download and request materials required for medication instruction. It is intended to be used for daily medical treatment and explanation / education of diseases.

* Compatible with **thyroid, hepatic encephalopathy, obstetrics and gynecology**

Under application

- **AKP-015 (Levothyroxine sodium injection)**
- **MERCAZOLE Half dosage (Standard addition)**

Formulations
that meet medical needs

Relocation to Shonan iPark

Purpose

Strengthen drug discovery functions by accelerating open innovation

Present situation

- In June 2019, the Advanced Drug Discovery Research Department relocated and started research activities at Shonan iPark. Promoting collaboration with Shonan iPark tenants.
- Preparing for complete relocation from Kawasaki laboratory by April 2020.

Expected effect

- A large number of researchers and organizations accumulate, and active exchange with industry, academia and government and diverse researchers
- Efficiently promote advanced drug discovery research using the latest equipment and technologies
- Collaboration with tenant companies such as drug discovery support ventures and bio-ventures from academia

Foreign Operation

NeoASKA Pharma Private Limited On track for operation in April 2020




Photo: Jawaharlal Nehru Pharma City website



Development pipeline

R & D status (as of November 2019)

 Changes from last time

Development number (generic name) / area / effect	PhI	PhII	PhIII	Appl	Approved
AKP-015 (Levothyroxine sodium) Myxoedematous coma/ hypothyroidism			(PhII, PhIII not required)	Under application	
CDB-2914 (Ulipristal) Uterine Fibroid				Preparing application	
TAK-385 (Relugolix) Endometriosis				PhIII Ongoing	
AKP-501 (Foliotropin gamma) Infertility		PhI termination			
L-105 (Rifaximin) Hepatic encephalopathy (Children)				Starting PhII/III	
L-105 (Rifaximin) Crohn's disease			PhI termination		
AKP-009 Benign prostatic hyperplasia		Preparing PhII			

Ulipristal

Phase II

At the 64th Annual Meeting of Japan Society for reproductive medicine,
CDB-2914 (Ulipristal) Phase 2 study results announced

* November 8, 2019

選択的プロゲステロン受容体調節剤
「ウリプリスタル酢酸エステル」の
子宮筋腫患者に対する有効性及び安全性の検討

第2相用量設定試験

岩佐 武¹、苛原 稔¹、前嶋 康弘²、新保 宣宏²、水沼 英樹³

¹徳島大学、²あすか製薬株式会社、³福島県立医科大学

Phase III

Phase IIIa now complete

Summary of Phase 3 comparative study results

Compared to leuprorelin acetate in patients with uterine fibroids, non-inferiority to leuprorelin was shown for amenorrhea rate. Uripriстал was shorter in the period to reach amenorrhea, and early symptom improvement was observed. No major safety concerns were identified in this study

Application scheduled for December 2019

Joint R & D

RaQualia Pharma Inc. (7/1 press release)

- Joint research on drug discovery research targeting **specific ion channels** *
- Disease areas and indications are not disclosed.



* Ion channel is a general term for membrane proteins that transmit ions into and out of cells. It plays an important role in transmitting information in sensory and motor nerves and regulating the release of neurotransmitters in various tissues.

Promote joint R & D with ventures

ASKA PLAN 2020

Medium-term management plan “ASKA PLAN 2020”

Consolidated	FY2016	FY2017	FY2018	FY2019	FY2020	Next management plan
	Results	Results	Results	Results	Plan	
Net sales (billion)	48.5	48.9	46.7	53.0	70.0	70.0
Operating income margin	3.7%	5.8%	3.8%	3.8%	10.0%	10.0%
ROE	7.8%	5.8%	4.1%	2.3%	8.0%	8.0%

- It is difficult to achieve the plan set forth in “ASKA PLAN 2020” within the period.

Drastic reform of the drug price system, changes in the GE market, etc.

- The materials to achieve 70 billion yen are being prepared.

Already released: Relumina (Uterine fibroids), Frewell, Rifxima

Under development: Ulipristal, Relumina (Endometriosis)

- Aim for achievement during the next medium-term plan

Net sales: ¥ 70 billion Operating profit ratio: 10% ROE: 8%

The next mid-term plan is being formulated. It will be announced around autumn 2020.

ASKA Pharmaceutical Group

ASKA Pharmaceutical Co., Ltd.



Ethical drug business



ASKA Pharmaceutical Medical Co., Ltd.



Inspection and Healthcare Business

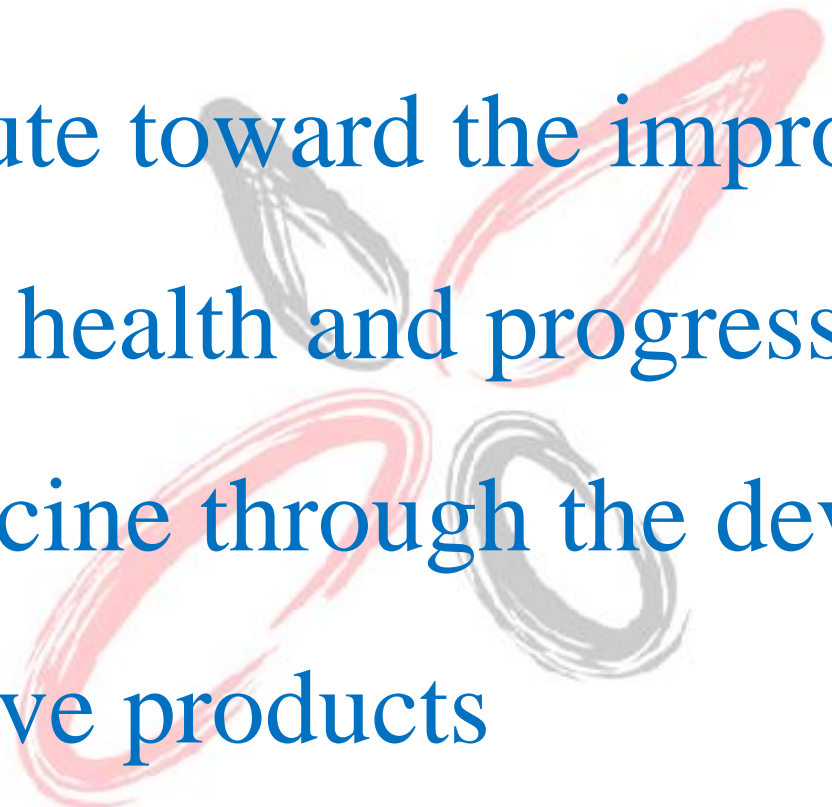


ASKA Animal Health Co., Ltd.



Feed and Pharmaceutical Business for Animal





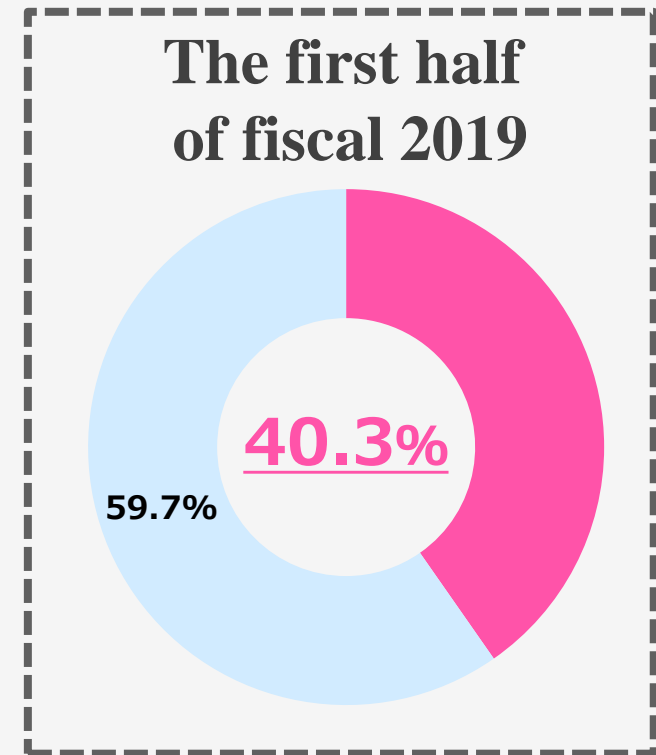
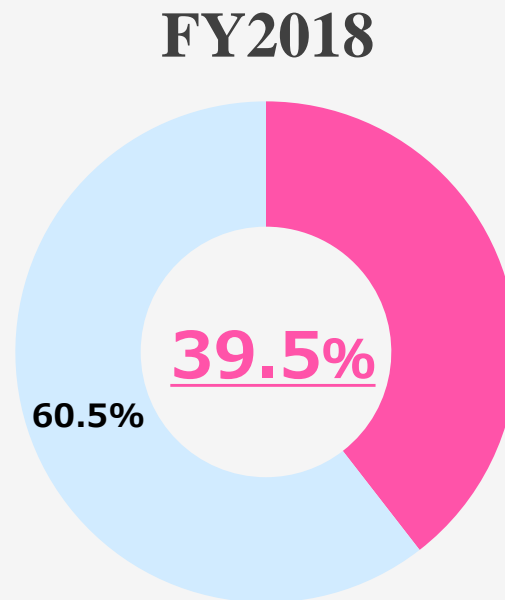
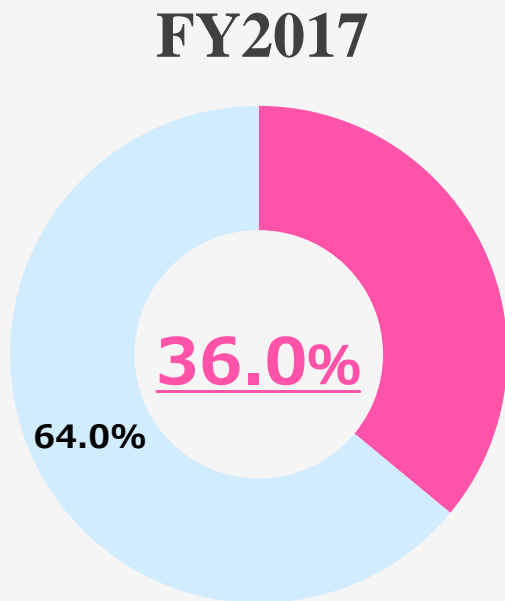
Contribute toward the improvement of
people's health and progress
in medicine through the development of
innovative products

あすか製薬株式会社

ASKA Pharmaceutical Co., Ltd.

Reference: Sales composition of ethical drugs

■ Branded
■ Generics



Increase the rate of branded drugs

Reference: Capital investment, Depreciation, R & D expenses

Capital investment

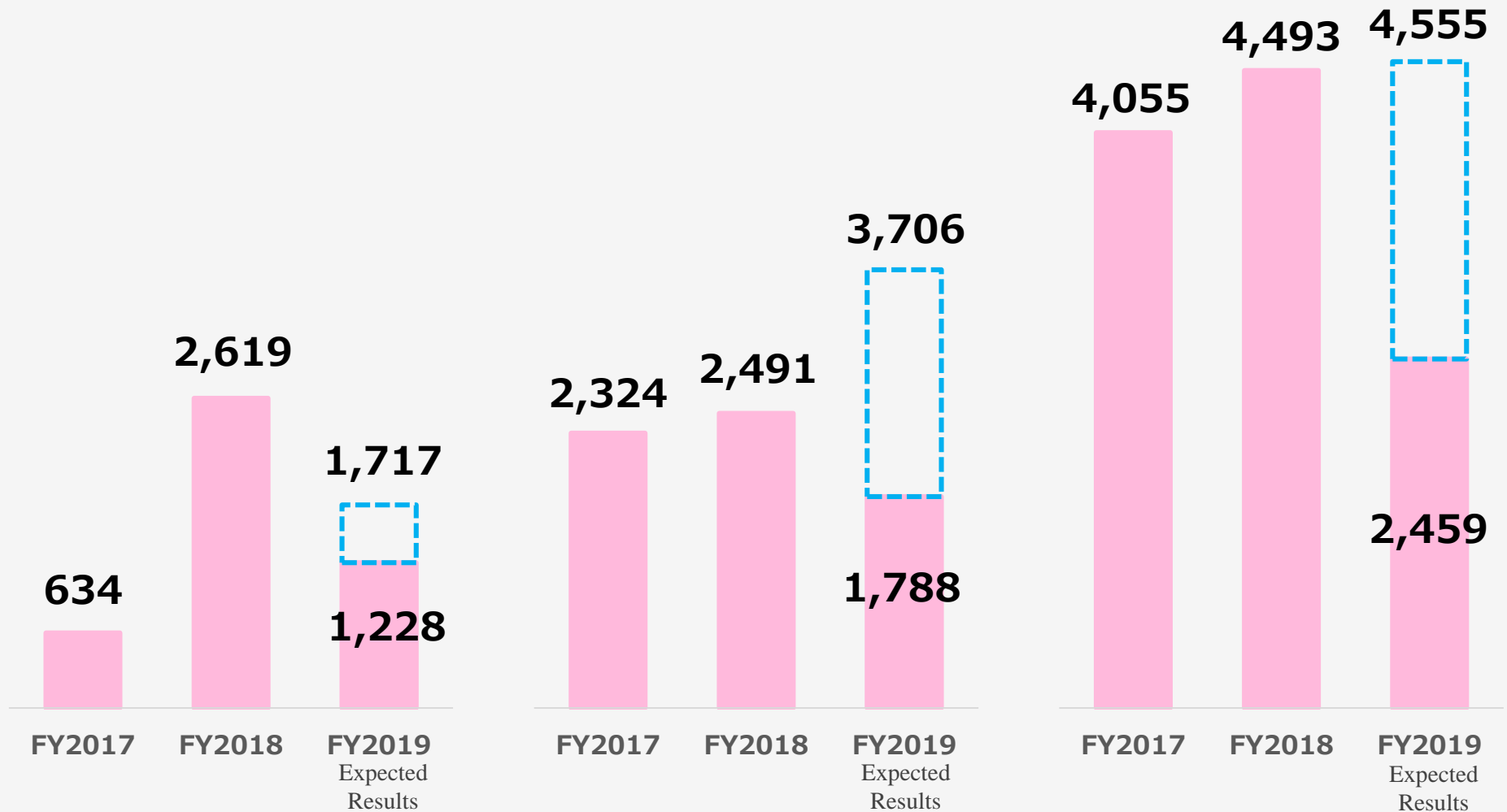
Millions of yen

Depreciation

Millions of yen

R&D expenses

Millions of yen



Reference : Accounting Standards for Revenue Recognition

1. Summery

- On March 30, 2018, the Corporate Accounting Standards Committee released the “Accounting Standards for Revenue Recognition” (“This Standard”). This standard was enacted and will be enforced from FY2021 (early adoption from FY2018 onward).
- Previously, under Japanese accounting standards, there was no comprehensive accounting standard for revenue recognition. Instead, sales were recorded on the basis of "delivery of goods" and "receipt of cash equivalents." However, this standard has been issued and will be applied in order to conform with the International Financial Reporting Standards (IFRS).
 - Revenue is recognized when not only “ownership” and “possession” but also “significant risks” are transferred to the customer.
 - In agency transactions (brokerage, etc.), only commissions are net sales after offsetting net sales against purchases.
 - Rebates are deducted from sales rather than recorded as SG&A expenses.
- We are able to compare sales with those of other companies by changing the timing of recording sales. We also introduced ERP in fiscal 2018, and the environment for applying this standard is in place, so we have reached early adoption.

Reference : Accounting Standards for Revenue Recognition

2. Effect of this standard on us

- Previously, sales were recorded when products were shipped to Takeda Pharmaceutical.
- Therefore, the timing of recording sales of our company after the adoption of this standard is the time when the product is handed over to the dealer. Under this standard, our sales are recorded when Takeda delivers the product to them.

- The contents regarding future forecast in this material are known, un-known risks, uncertain due to information based on our assumption and forecasts by press release at the time that we presented.
- Actual results and development forecasts may differ materially from these forecasts due to various factors.
- This information includes information on pharmaceuticals (including those under development), but the content of this information is not intended for advertising or medical advice.

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