

# KISSEI Company Profile

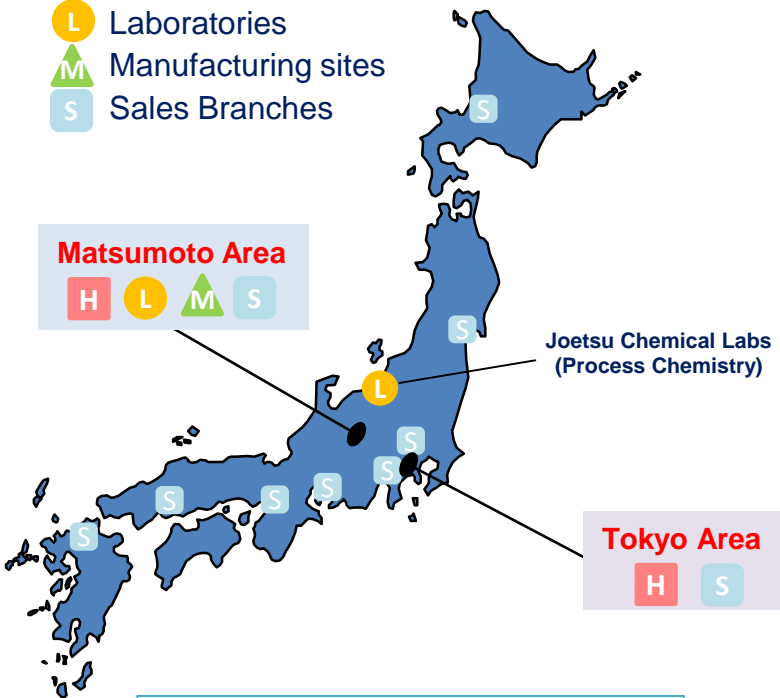
 KISSEI PHARMACEUTICAL CO., LTD.

# Corporate Profile

<b>Chairman &amp; CEO:</b>	<b>Mutsuo Kanzawa</b>
<b>President &amp; COO:</b>	<b>Yoshio Furihata</b>
<b>Founded:</b>	<b>August 9, 1946</b>
<b>Stock Exchange:</b>	<b>The 1st Section of the Tokyo Stock Exchange</b>
<b>Employees:</b> <b>(as of March 2020)</b>	<b>1,479</b>
	<b>R&amp;D: 294</b>
	<b>Medical Reps: 611</b>
	<b>Manufacturing: 137</b>
<b>Overseas Subsidiary:</b>	<b>Kissei America Inc. (Fort Lee, NJ)</b>

# Business Sites

- H Headquarters
- L Laboratories
- M Manufacturing sites
- S Sales Branches



◆ Sales Force: 10 Sales Branches  
 50 Offices  
 611 MRs

## Matsumoto Area

Headquarters



## Matsumoto Plants

(Pharmaceutical)



## Shiojiri Plants

(Packaging)



## Central Research Labs

(Drug discovery, Pharmacology / Pharmacokinetics)



## Safety Research Labs

(Toxicology)



## Pharmaceutical Labs

(Formulation)



## Tokyo Area

Nihonbashi Head Office (Business development, Marketing)



## Koishikawa Head Office

(Clinical development, Regulatory Affairs)



## Overseas

Kissei America Inc. (Fort Lee, New Jersey)



# Location of Kissei's Laboratories in Azumino



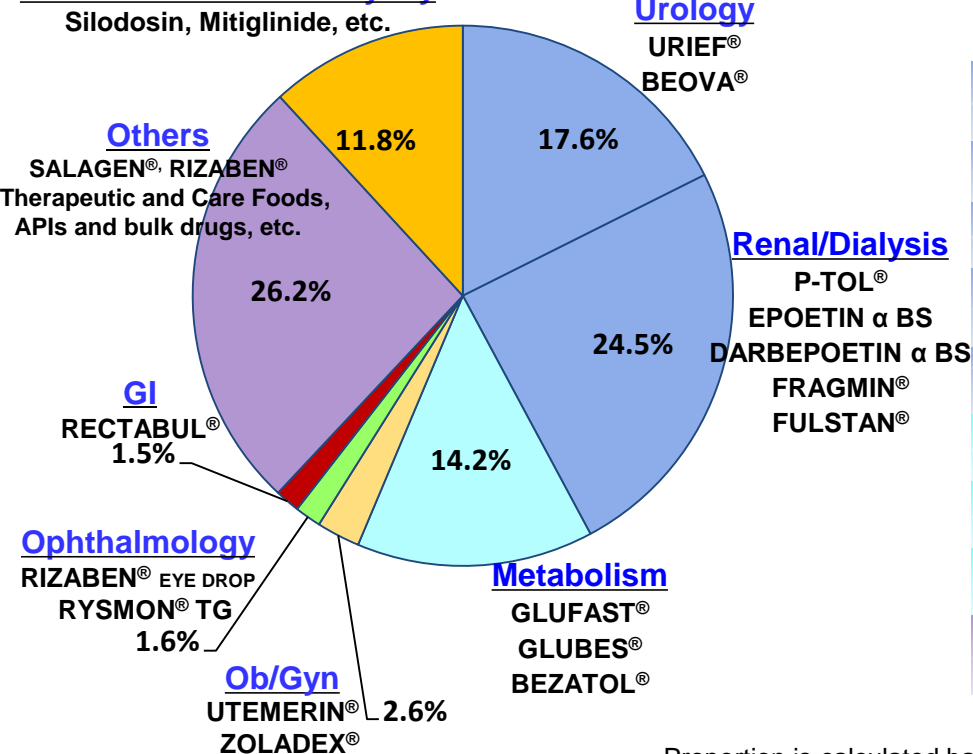
**Mt. Jonen  
Northern Alps  
(Japanese Alps)**

**Safety Research  
Laboratories**

**Central Research Laboratories  
& Pharmaceutical Laboratories**

# Sales by Therapeutic Areas & Main Products

## Sales to Partners & Royalty



Brand name of main products	FY2018	FY2019		Indication
	Mil. JPY	Mil. JPY	Mil. USD	
◆ URIEF®	17,810	5,857	53.2	Benign prostatic hyperplasia
◆ BEOVA® <b>[NEW]</b>	706	3,185	29.0	Overactive bladder
◆ P-TOL®	4,801	5,752	52.3	Hyperphosphatemia
◆ EPOETIN α BS	6,015	5,520	50.2	Renal anemia
◆ DARBEPOETIN α BS <b>[NEW]</b>		812	7.4	Renal anemia
◆ GLUBES®	4,428	4,501	40.9	Type II diabetes
◆ BEZATOL®	1,709	1,364	12.4	Hyperlipidemia
◆ GLUFAST®	1,678	1,406	12.8	Type II diabetes
◆ SALAGEN®	1,617	1,604	14.6	Xerostomia

◆ : In-house product  
◆ : In-licensed product

# Financial Highlights (Consolidated)

	FY2019		FY2024 (Target in mid-term management plan)	
	Mil. JPY	Mil. USD	Mil. JPY	Mil. USD
<b>Net Sales</b>	<b>63,234</b>	<b>574.9</b>	<b>87,000</b>	<b>790.9</b>
<b>Operating Income</b>	<b>1,857</b>	<b>16.9</b>	<b>9,000</b>	<b>81.8</b>
<b>Net Income</b>	<b>2,817</b>	<b>25.6</b>		
<b>R&amp;D Expenditure</b>	<b>10,767</b>	<b>97.9</b>	<b>13,000</b>	<b>118.2</b>
<b>% on Net Sales</b>	<b>17.0 %</b>		<b>14.9 %</b>	

Fiscal year ends March 31 of each year. @:¥110/\$

Although profits were squeezed reflecting on patent expiration of major product, we restarted to re-growth toward 2024 in the mid-term management plan.

# Kissei's Areas of Strategic In-Licensing Focus



R&D and Commercial

Urology &  
Renal • Dialysis

Orphan & Other  
high unmet needs

Gastro-  
intestine

Ophthal-  
mology

Obstetrics &  
Gynecology

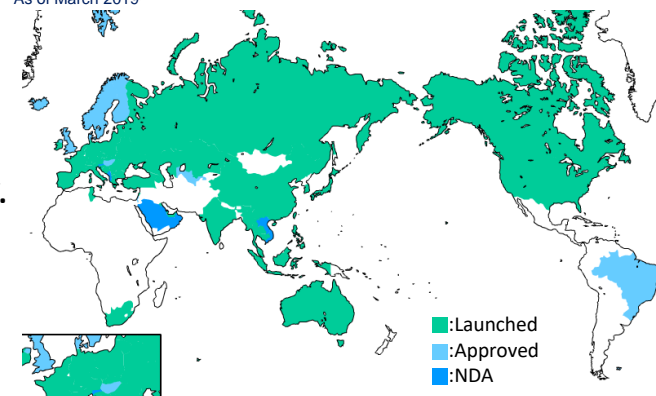
Commercial  
Stage Only

Diabetes &  
Metabolism

# Kissei in Urology

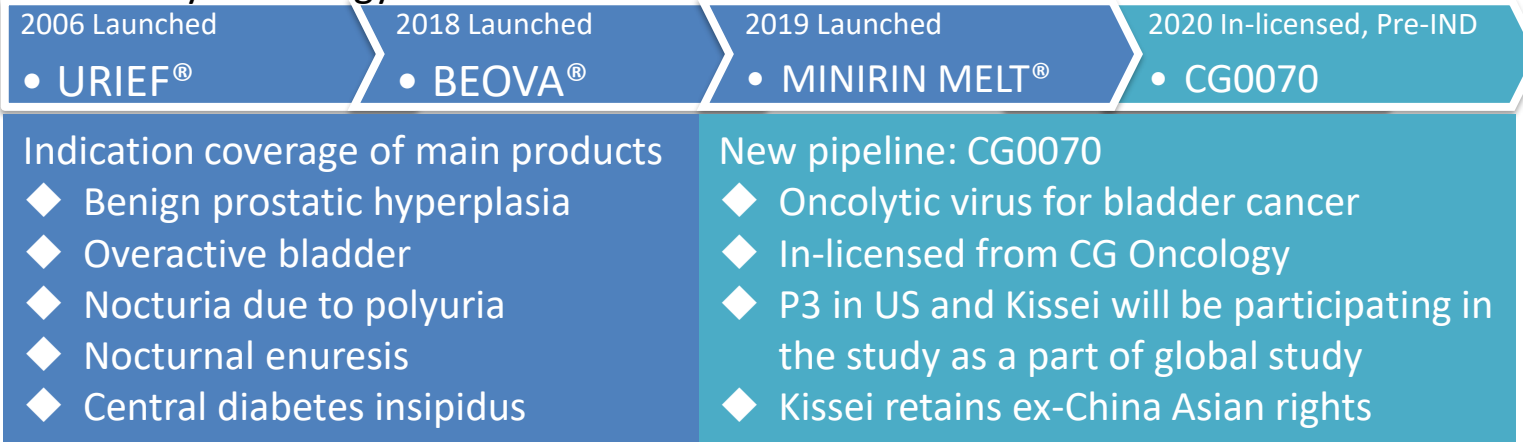
1. Known as originator of URIF® (Silodosin).
2. Commits to urology field through 30-year activities.\*
3. Has strong relationship with urologists and physicians in urology.
4. Has broad coverage of products for urologic indications.

As of March 2019



Silodosin has been launched in over 50 countries.

## The history of Urology Field



\*Originally, Kissei launched a OAB treatment drug, Terodiline in 1989.



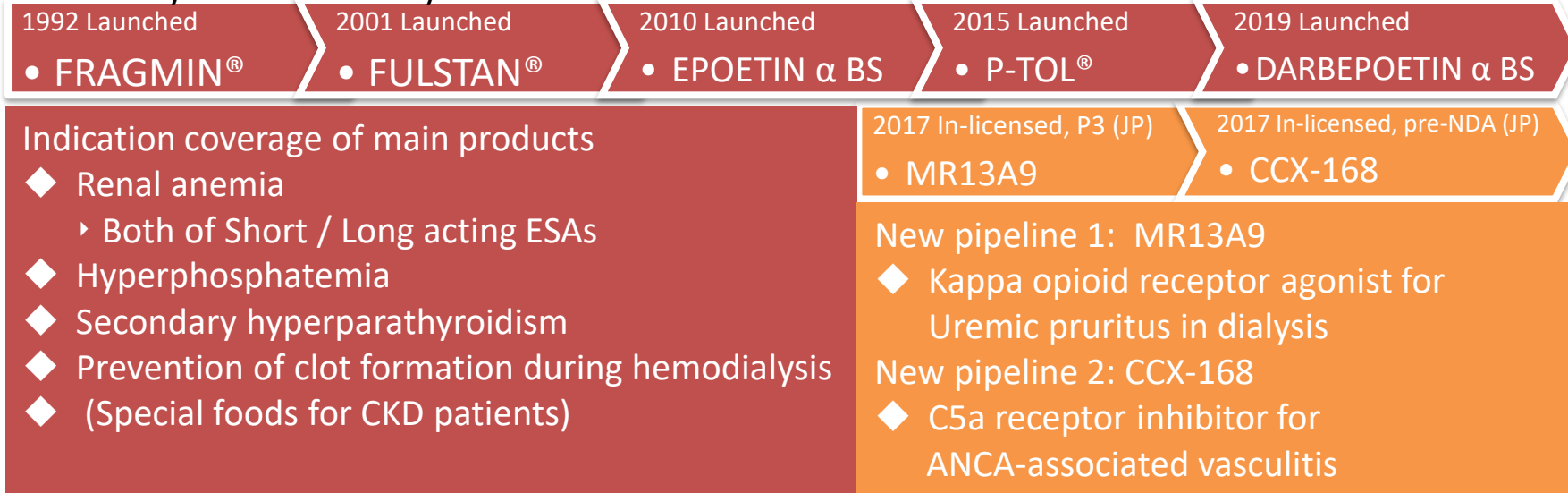
# Kissei in Renal & Dialysis

1. Has strong connection with physicians from early 1990s.
2. Covers almost all dialysis facilities in Japan.
3. First Japanese domestic company to successfully launch BS in Japan\*<sup>1</sup>
4. No.1 Supplier of special foods for CKD patients in Japan. \*<sup>2</sup>



Major Therapeutic &amp; Care Foods

## The history of Renal & Dialysis Field



\*1 We succeeded in EPO BS business, following Sandoz's launch of Somatostatin BS.

\*2 According to the survey conducted by third party in 2015.

# Kissei in Rare Diseases & Unmet Needs Area



1. Focuses on rare diseases in mid-term management plan.
2. Has many development expertise in the rare disease filed.
3. Developing promising candidates in late clinical stages.

## P3 stage pipelines in Japan

◆ In-house / ◆ In-licensed

◆ KPS-0373 / Rovatirelin	◆ CCX-168 / Avacopan (pre-NDA)
◆ Spinocerebellar degeneration	◆ ANCA-associated vasculitis
◆ R788 / Fostamatinib	◆ AJM300 / Carotegrast Methyl (pre-NDA)
◆ Immune thrombocytopenia	◆ Ulcerative colitis

## P2 stage pipelines in Japan

◆ KLH-2109 / Linzagolix	◆ KDT-3594
<ul style="list-style-type: none"> <li>◆ Indications: Uterine fibroid(UF), Endometriosis(EM)</li> <li>◆ Oral GnRH antagonist</li> <li>◆ ObsEva has been developing in US/EU.</li> <li>UF : MAA submitted in EU and ready to NDA in US.</li> <li>EM: Conducting P3 studies in US/EU</li> <li>➤ Kissei in Ob/Gyn area : We have over 20 years history of contribution to Women's Health through Kanzawa Medical Research Foundation.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Indication: Parkinson's disease</li> <li>◆ Best in class dopamine receptor agonist</li> <li>◆ Affamed has the right in China, Hong Kong, Macau, Taiwan &amp; Southeast Asian countries*</li> <li>➤ Kissei in CNS area : We once launched Cabaser® for Parkinson's disease with peak sales about 100 m\$, and has good expertise in CNS field.</li> </ul>

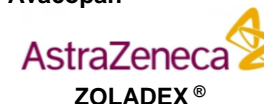
\*Southeast Asian countries : Singapore, Malaysia, Thailand, Indonesia, Vietnam, and Philippines.

# Kissei Partners

## Partners of in-house products



## Partners of in-licensed / other alliance products



# Seeking Partners

Therapeutic Field	Product Code Generic Name	Phase	MoA/ Indication	Originator/ Development	Available Territory
Urology	CG0070 <b>[NEW]</b>	US PIII JP Pre-IND	Oncolytic viral therapy/ Bladder cancer	CG Oncology	Asia (ex-China)
	KSP-0576	JP Preclinical	Transient receptor potential cation channel subfamily M member 8 (TRPM8) antagonist/ Overactive bladder	Kissei	Global
Metabolism	KGT-1681 Remogliflozin	US,EU PIIb (India Launched)	SGLT2 inhibitor/ Type 2 diabetes	Kissei/ Avolynt (Global), Glenmark (India)	Global (ex-India)
		US PII/III/IV in Prep	SGLT2 inhibitor/ NASH		
	KUX-1151	US PI JP PIIa	Inhibition of Xanthine Oxidase and URAT1/ Hyperuricemia, gout	Kissei	Global
Ob/Gyn	KLH-2109 Linzagolix	JP PII	Oral GnRH antagonist/ Endometriosis, Uterine fibroid	Kissei	Asia (Kissei), ex-Asia (ObsEva)
		US pre-NDA EU MAA <b>[NEW]</b>	Oral GnRH antagonist/ Uterine fibroid	Kissei/ ObsEva (Global)	
		US,EU PIII	Oral GnRH antagonist/ Endometriosis		
Ophthalmology	KCE-210	JP Preclinical	IgE trapping Fc-fusion protein/ Allergic Conjunctival Diseases	Kissei	Global
GI	KWA-0711 Mizagliflozin	JP PII	SGLT1 inhibitor/ Chronic constipation	Kissei	Global
Neurology	KDT-3594	JP PII CN Pre-IND <b>[NEW]</b>	Dopamine agonist/ Parkinson's disease	Kissei/ Affamed	Global (ex-China & Southeast Asia)
	KCZ-1279	JP Preclinical	Oral CGRP receptor antagonist/ Migraine prophylaxis	Kissei	Global
Others	R788 Fostamatinib	JP PIII US Launched EU Launched <b>[NEW]</b>	Spleen associated tyrosine kinase inhibitor/ Immune Thrombocytopenia	Rigel/ Kissei	China Korea Taiwan
	KNV-0969	JP Preclinical	Neurokinin 1 receptor antagonist/ Chronic pruritus	Kissei	Global <sup>12</sup>



# Thank you for your attention.

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