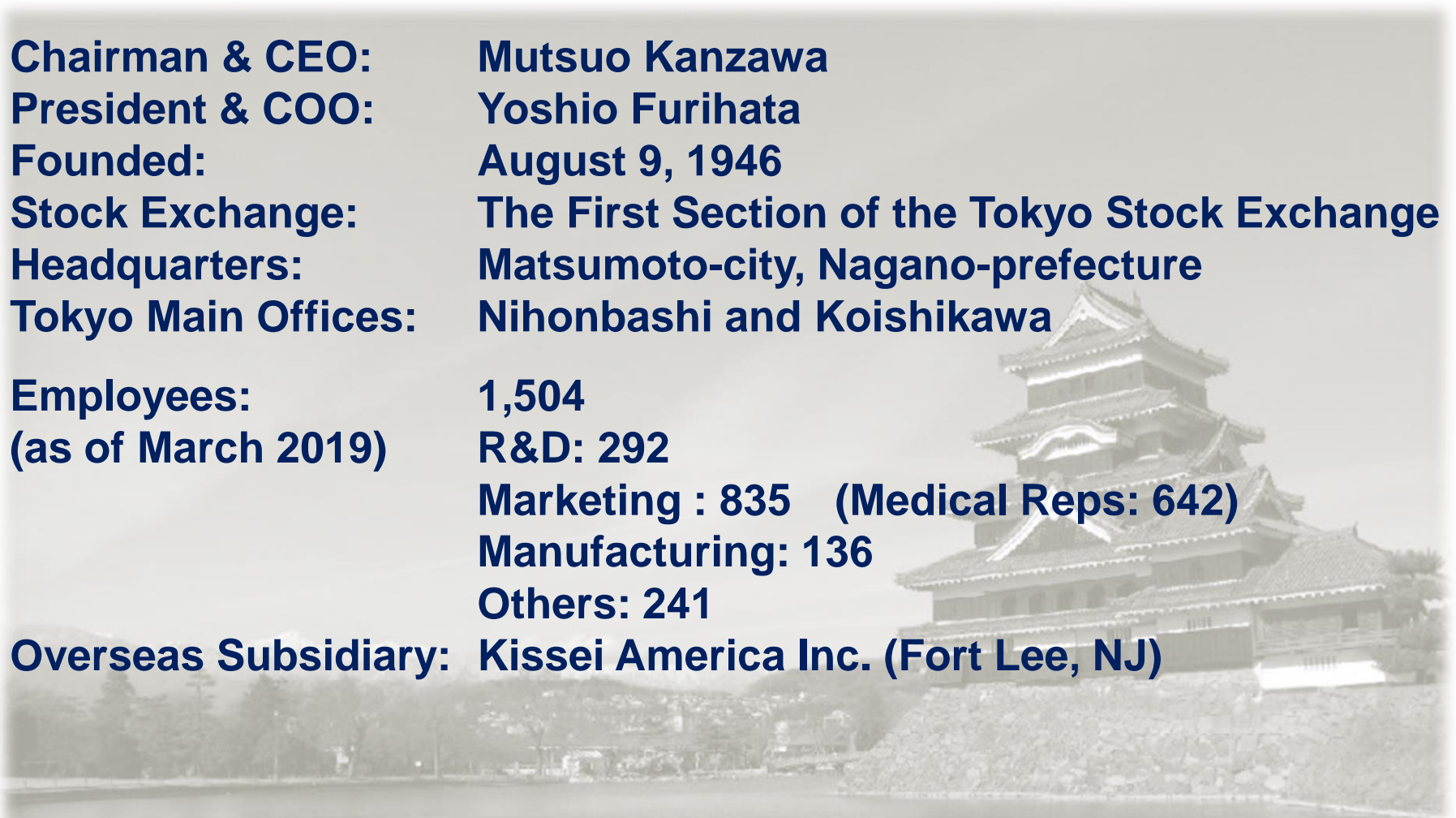


KISSEI's Company Profile

Updated in February 2020

 KISSEI PHARMACEUTICAL CO., LTD.

Corporate Profile



Chairman & CEO:	Mutsuo Kanzawa
President & COO:	Yoshio Furihata
Founded:	August 9, 1946
Stock Exchange:	The First Section of the Tokyo Stock Exchange
Headquarters:	Matsumoto-city, Nagano-prefecture
Tokyo Main Offices:	Nihonbashi and Koishikawa
Employees:	1,504
(as of March 2019)	R&D: 292
	Marketing : 835 (Medical Reps: 642)
	Manufacturing: 136
	Others: 241
Overseas Subsidiary:	Kissei America Inc. (Fort Lee, NJ)

KISSEI's Product Launch History

In-licensed

2019 **DARBEPOETIN α BS**, renal anemia

2018 **BEOVA®**, overactive bladder

2017 **RECTABUL®**, ulcerative colitis

2015 **P-TOL®**, hyperphosphatemia

2014 **SAVENE®**, anthracycline extravasation

2010 **EPOETIN α BS**, renal anemia

2005 **SALAGEN®**, xerostomia

2000 **ZOLADEX®**, endometriosis

1999 **RIZMON® TG**, glaucoma

1991 **BEZATOL®**, hyperlipidemia

1986 **UTEMERIN®**, premature labor

1982 **RIZABEN®**, allergic diseases

1961 **GASCON®**, anti-gas agent

1946 Founded

2011 **GLUBES®**, type 2 diabetes

2006 **URIEF®**, benign prostatic hyperplasia

2004 **GLUFAST®**, type 2 diabetes

1995 **RIZABEN® EYE DROPS**, allergic conjunctivitis

1992 **DOMENAN®**, bronchial asthma

1988 **XANBON®**, cerebral circulation

In-house

Operational Organization

◆ Sales Force: 10 Sales Branches ★
50 Offices

Headquarters



Matsumoto Plant



Shiojiri Plant



Matsumoto Area

- ◆ Headquarters
- ◆ Laboratories (3)
 - Central Research Labs.
 - Toxicological Labs.
 - Pharmaceutical Labs.
- ◆ Manufacturing Site (2)
 - Matsumoto and Shiojiri

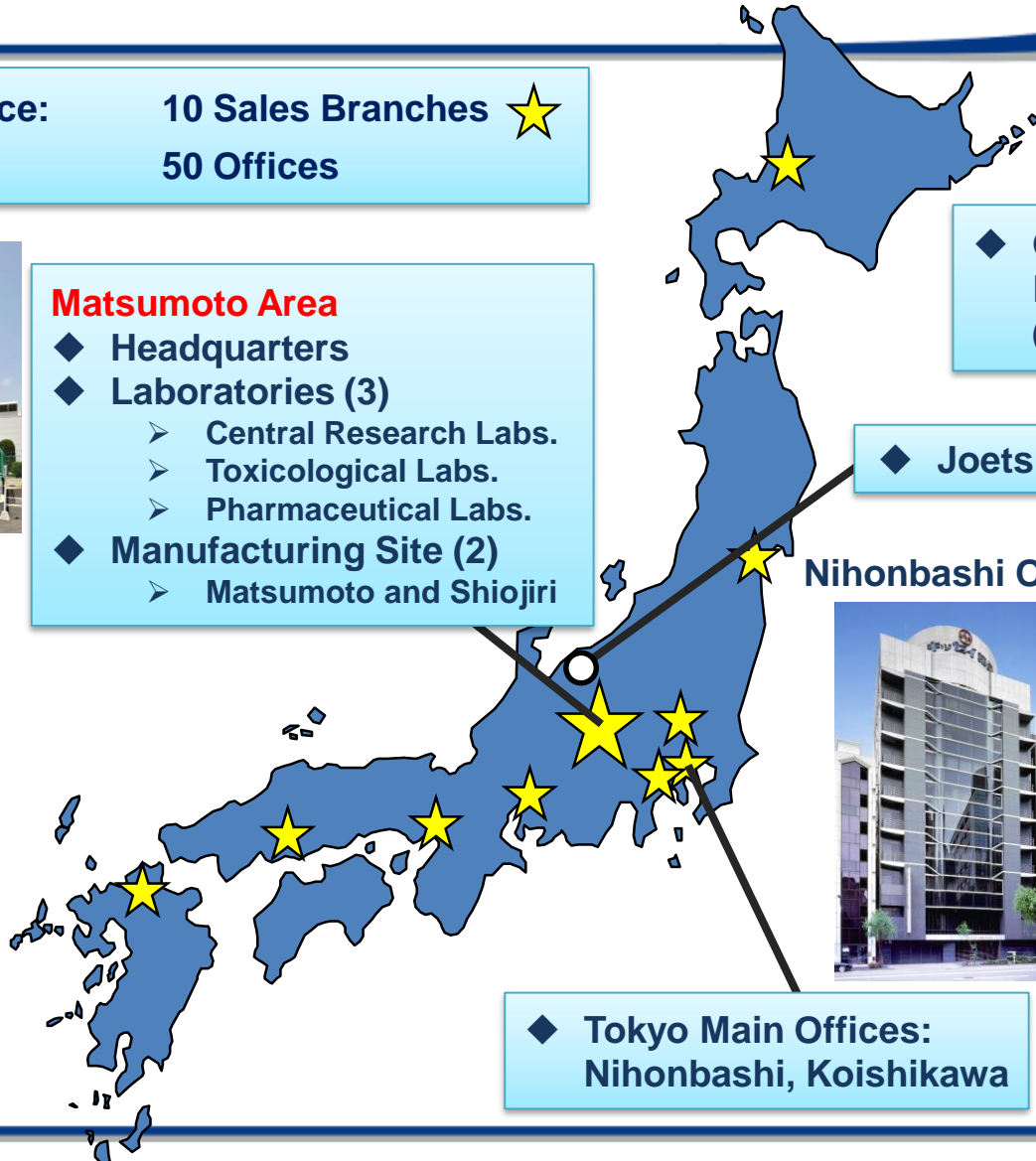
◆ Oversea Subsidiary:
Kissei America Inc.
(Fort Lee, NJ)

◆ Joetsu Chemical Laboratory

Nihonbashi Office Koishikawa Office



◆ Tokyo Main Offices:
Nihonbashi, Koishikawa



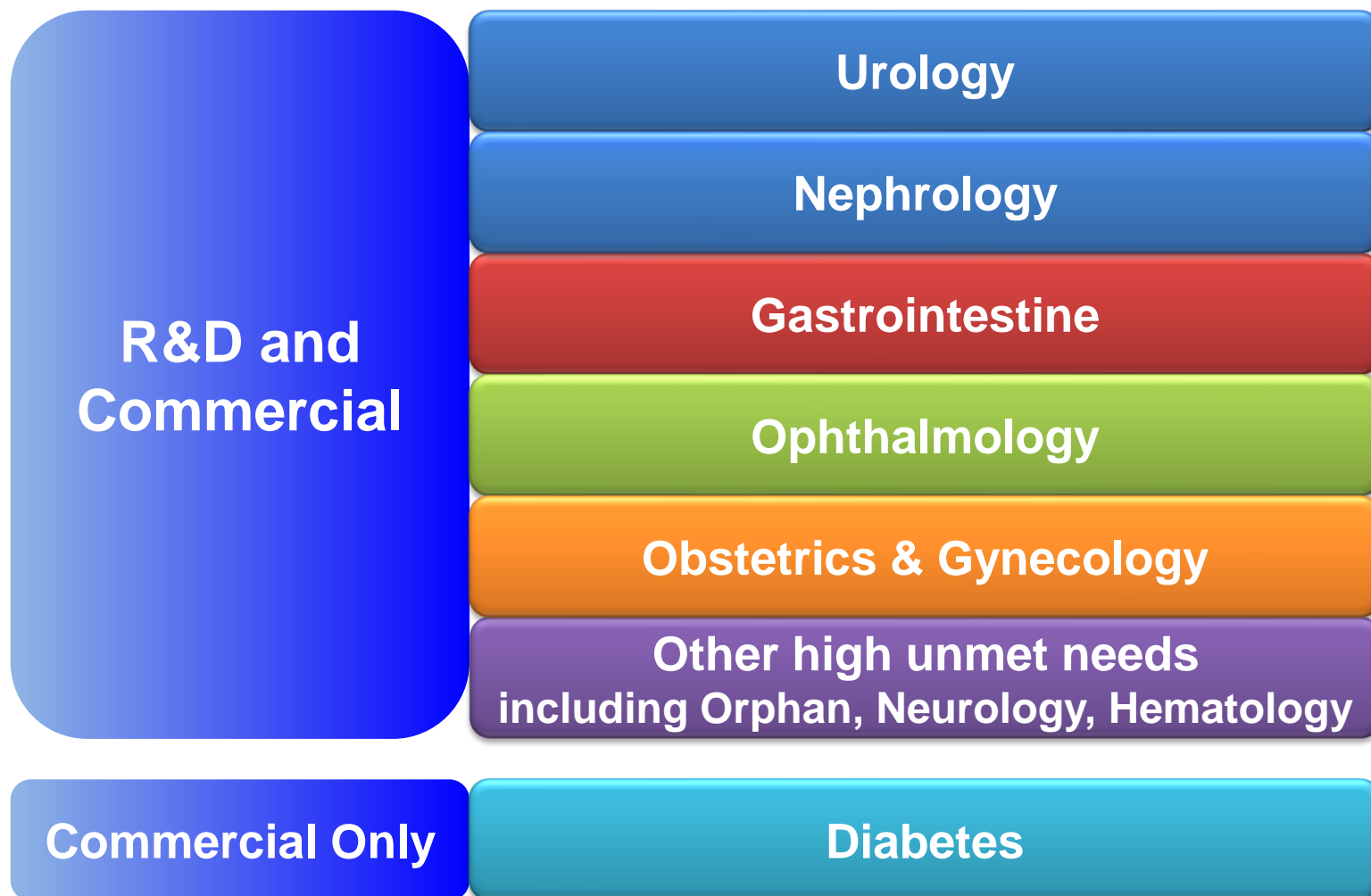
Location of Kissei's Laboratories



Kissei's Organization



Kissei's Areas of Strategic In-Licensing Focus



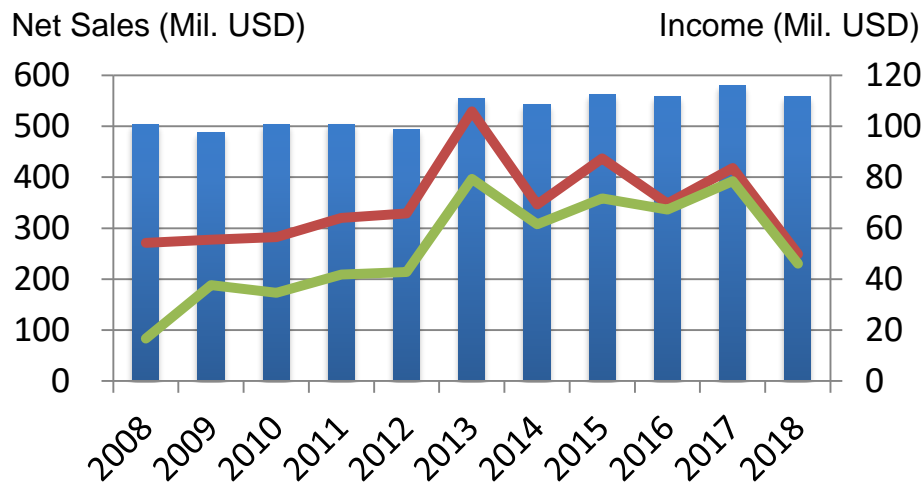
Financial Highlights in FY2018

(April 2018 to March 2019; Non-consolidated)

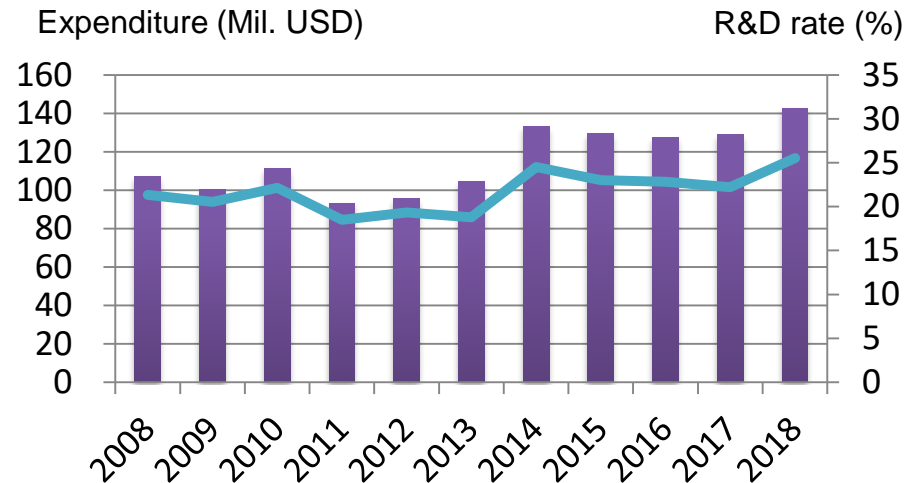
FY2018	Mil. JPY	Mil. USD
Net Sales	61,520	559.3
Operating Income	5,487	49.9
Net Income	5,064	46.0
R&D Expenditure*	15,711	142.8
% on Net Sales	25.5 %	

*consolidated

■ Net Sales ■ Operating Income ▲ Net Income



■ R&D Expenditure ■ R&D rate (% on Net Sales)



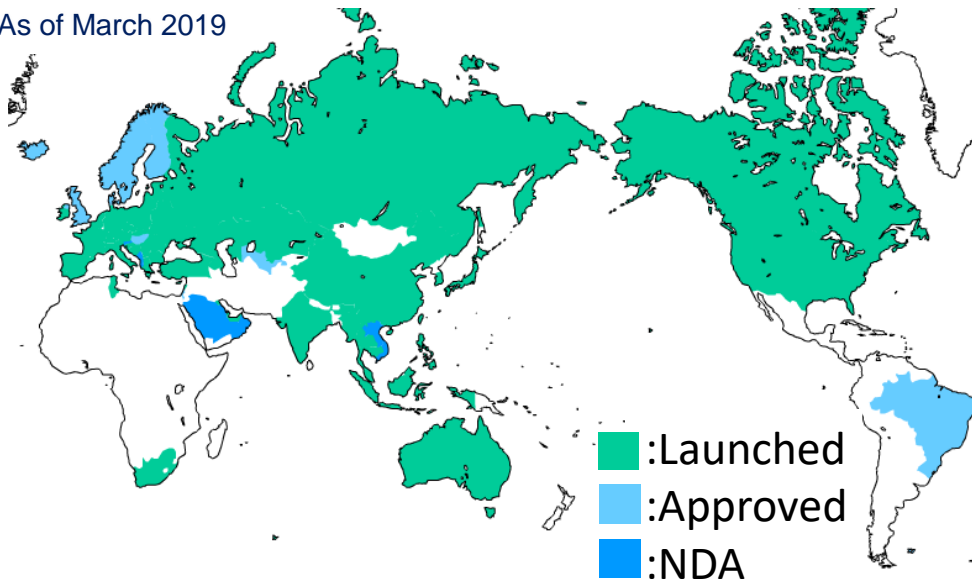
Fiscal year ends March 31 of each year. @:¥110/\$

Global Product (Urology)

- **URIEF® (Silodosin) in-house**

- MoA: Selective α 1A adrenoceptor antagonist
 - Dysuria associated with benign prostatic hyperplasia (2006)
 - Additional dosage form: Orally disintegrating tablet (2016)
- Co-marketing with Daiichi-Sankyo Co., Ltd. in Japan
 - Daiichi Sankyo Espha Co., Ltd. launched authorized generic (2019)
- Launched in over 50 countries

As of March 2019



Silodosin Partners

Licensee	Territory	Brand name
Allergan	US, Canada & Latin America	RAPAFLO®
Recordati	Europe & Middle East, Australia	UROREC®, SILODYX®, SILOSIN®
JW Pharma	Korea	THRUPAS®
Synmosa	Taiwan	URIEF®
Daiichi-Sankyo	China	URIEF®
Eisai	ASEAN & India	URIEF®

NEW Product (Urology)

- **BEOVA[®] (Vibegron) in-licensed**
 - MoA: β_3 -adrenergic receptor agonist
 - Overactive bladder (2018)
 - Dosage form: Tablet
 - Sublicensed from Kyorin Pharmaceutical Co., Ltd. 【Originator : MSD】
 - Co-development and co-marketing with Kyorin Pharmaceutical Co., Ltd.
 - Urovant Sciences Ltd. is developing in US and Europe for OAB.



NEW Product (Renal · Dialysis)

- **P-TOL[®] (Sucrofferic Oxyhydroxide) in-licensed**
 - MoA: Phosphate binder in gastrointestinal tract
 - Hyperphosphatemia in dialysis patients (2015)
 - Dosage form: Chewable tablet
 - Additional dosage form: Granules (2018)
 - Licensed from Vifor Fresenius Medical Care Renal Pharma Ltd.
 - Known as Velphoro[®] in Europe and US

Chewable tablet



The donut shape to be chewed easily and to avoid suffocation.

Granules



Micro-tablet-type granules(Φ2.3 mm), not to be stuck in dentures.



Development Pipeline 1

Therapeutic Field	Product Code Generic Name	Phase	MoA/ Indication	Originator/ Partner	Available Territory
Urology	PRX-302	JP Pre-IND	Genetically engineered Proaerolysin/ Benign Prostatic Hyperplasia, Prostate Cancer	Sophiris/ Kissei	-
	KSP-0576	JP Preclinical	Transient receptor potential cation channel subfamily M member 8 (TRPM8) antagonist/ Overactive bladder	Kissei	Global
Renal/ Dialysis	MR13A9	JP PII	Kappa opioid receptor agonist/ Uremic pruritus in dialysis	Cara/ Maruishi-Kissei	-
	Avacopan	JP PIII	Inhibitor of the complement C5a receptor/ ANCA-associated vasculitis	ChemoCentryx/ VFMCRP/Kissei	-
Metabolism	Remogliflozin	US,EU PIIb (India NEW Launched)	SGLT2 inhibitor/ Type 2 diabetes	Kissei/ Avolynt (Global), Glenmark (India)	Global (except India)
		US PII/III/IV in Prep	SGLT2 inhibitor/ NASH		
	KUX-1151 & KUX Back-Up	US PI JP PIIa (KUX-1151)	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
		US,EU PIII	Oral GnRH antagonist/ Uterine fibroid	Kissei/ ObsEva (Global)	
		US,EU PIII NEW	Oral GnRH antagonist/ Endometriosis		

Development Pipeline 2

Therapeutic Field	Product Code Generic Name	Phase	MoA/ Indication	Originator/ Partner	Available Territory
Ophthalmology	KCE-210	JP Preclinical	IgE trapping Fc-fusion protein/ Allergic Conjunctival Diseases	Kissei	Global
GI	AJM300 Carotegrast Methyl	JP PIII	Oral α 4 integrin antagonist/ Ulcerative colitis	EA/ EA-Kissei	-
	KWA-0711 Mizagliflozin	JP PII	SGLT1 inhibitor/ Chronic constipation	Kissei	Global
Neurology	KPS-0373 Rovatinetrol	JP PIII	Thyrotropin-releasing hormone analogue/ Spinocerebellar degeneration	Shionogi/ Kissei	-
	KDT-3594	JP PII	Dopamine agonist/ Parkinson's disease	Kissei	Global
	KCZ-1279	JP Preclinical	Oral CGRP receptor antagonist/ Migraine prophylaxis	Kissei	Global
Others	Fostamatinib	JP PIII NEW US Launch EU Approved	Spleen associated tyrosine kinase inhibitor/ Immune Thrombocytopenia	Rigel/ Kissei	China Korea Taiwan
	Bedradorine	US,EU PII	Selective β_2 adrenoceptor agonist/ Acute exacerbation of asthma	Kissei/ MediciNova	-
		US PI	Selective β_2 adrenoceptor agonist/ COPD		
	KNV-0969	JP Preclinical	Neurokinin 1 receptor antagonist/ Chronic pruritus	Kissei	Global

Seeking Partners

Therapeutic Field	Product Code Generic Name	Phase	MoA/ Indication	Originator/ Development	Available Territory
Urology	KSP-0576	JP Preclinical	Transient receptor potential cation channel subfamily M member 8 (TRPM8) antagonist/ Overactive bladder	Kissei	Global
Metabolism	Remogliflozin	US,EU PIIb (India Launched)	SGLT2 inhibitor/ Type 2 diabetes	Kissei/ Avolynt (Global), Glenmark (India)	Global (except India)
		US PII/III/IV in Prep	SGLT2 inhibitor/ NASH		
	KUX-1151 & KUX Back-Up	US PI JP PIIa (KUX-1151)	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
		US,EU PIII	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	Dopamine agonist/ Parkinson's disease	Kissei	Global
	KCZ-1279	JP Preclinical	Oral CGRP receptor antagonist/ Migraine prophylaxis	Kissei	Global
Others	Fostamatinib	JP PIII US Launch EU Approved	Spleen associated tyrosine kinase inhibitor/ Immune Thrombocytopenia	Rigel/ Kissei	China Korea Taiwan
	KNV-0969	JP Preclinical	Neurokinin 1 receptor antagonist/ Chronic pruritus	Kissei	Global

Kissei Partners

Partners of in-house products



Partners of in-licensed products



Partners of other products





Thank you for your attention.

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<Fax> +81-(0)3-3279-2541
<Web> https://www.kissei.co.jp/e_contents/**

Kissei License & Alliance Organization

Dr. K. Akiyama, *Senior Director*

Business Development

Mr. T. Shimizu, *Assistant Director*

Licensing

Ms. M. Okumura, *Manager*
Mr. T. Terayama, *Assistant Manager*
Ms. Y. Itakura, *Section Leader*
Mr. Y. Todoroki

Alliance Management & Global Marketing

Mr. H. Ishibashi, *Manager*
Mr. M. Tomae, *Deputy Manager*
Mr. N. Shiina, *Section Leader*
Ms. S. Furihata

Dr. Y. Takehana, *Managing Director*

Corporate Development

Mr. K. Nakata, *Director*

Strategic Alliance

Dr. M. Hiratochi, *Director*
Mr. T. Yamato, *Director*
Mr. Y. Shimizu, *Director*
Dr. O. Nakanishi, *Assistant Manager*

Kissei America Inc.

Mr. Y. Kato, *President*
Ms. M. Morikawa, *Manager*

Proportions of Sales by Therapeutic Areas in FY2018

Sales to Partners & Royalty

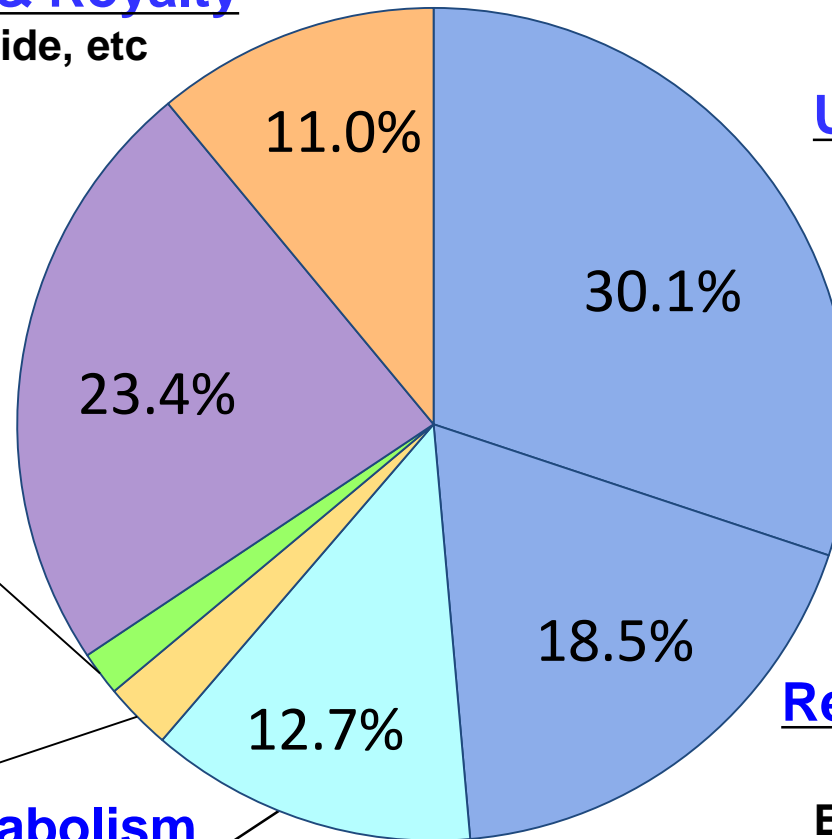
Silodosin, Mitiglinide, etc

Others

SALAGEN®
RIZABEN®
XANBON®
DOMENAN®, etc

Urology

URIEF®
BEOVA®



Ophthalmology

RIZABEN® EYE DROP 1.7%
RYSMON® TG

Ob/Gyn

UTEMERIN® 2.6%
ZOLADEX®

Metabolism

GLUFAST®
GLUBES®
BEZATOL®

Renal/Dialysis

P-TOL®
EPOETIN α BS
FRAGMIN®
FULSTAN®

Net Sales of Kissei's Main Products

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

FY2017

FY2018

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

Brand name	Mil. JPY	Mil. JPY	Mil. USD	Indication
◆ URIEF®	17,235	17,810	161.9	Benign prostatic hyperplasia
◆ EPOETIN α BS	6,093	6,015	54.7	Renal anemia
◆ P-TOL®	4,274	4,801	43.6	Hyperphosphatemia
◆ GLUBES®	4,477	4,428	40.3	Type II diabetes
◆ BEZATOL®	2,564	1,709	15.5	Hyperlipidemia
◆ GLUFAST®	2,762	1,678	15.3	Type II diabetes
◆ SALAGEN®	1,561	1,617	14.7	Xerostomia
◆ BEOVA® NEW		706	6.4	Overactive bladder
◆ RECTABUL®	228	663	6.0	Ulcerative colitis

Global Product (Metabolism)

- **GLUFAST® (Mitiglinide) in-house**
 - MoA: Rapid-acting insulin secretagogue
 - Type II diabetes
 - Monotherapy (2004)
 - α -GI combination use (2007)
 - TZD combination use (2009)
 - BG / DPP-4i combination use (2013)
 - Additional dosage form: Orally disintegrating tablet (2016)
 - Co-marketing with Takeda Pharmaceutical Co., Ltd.
 - Launched in Asian countries

Mitiglinide Partners

Licensee	Territory
JW Pharma	Korea
Orient EuroPharma	Hong Kong & Taiwan
Eisai	China & ASEAN



NEW Product (GI)

- **RECTABUL® (Budesonide Rectal Foam) in-licensed**
 - MoA: Glucocorticoid activity
 - Ulcerative colitis (2017)
 - Dosage form: Rectal foam
 - Sublicensed from EA Pharma Co., Ltd. 【Originator : Dr. Falk Pharma】
 - Co-marketing with EA Pharma Co., Ltd.
 - Known as Budenofalk® /Ulceris® rectal foam in Europe and US



Products 1

Therapeutic Field	Brand Name Generic name	Sales (Mil. US\$)	MoA/ Indication	Licensors
Urology	URIEF® Silodosin	161.9	Selective α 1A adrenoceptor antagonist/ Benign prostatic hyperplasia (2006)	In-house
	BEOVA® Vibegron	6.4	Selective β 3 adrenoceptor agonist/ Overactive bladder (2018)	MSD/ Kyorin-Kissei
	MINIRIN MELT® NEW Desmopressin Acetate	-	Vasopressin receptor agonist/ Nocturia due to nocturnal polyuria (2019)	Ferring (Co-Promotion)
Renal/ Dialysis	EPOETIN α Biosimilar	54.7	Recombinant human erythropoietin/ Renal anemia on dialysis (2010)	JCR
	DARBEPOETIN α Biosimilar NEW	-	Long-acting ESA/ Renal anemia (2019)	JCR
	P-TOL® Sucrofferic Oxyhydroxide	43.6	Phosphate binder in gastrointestinal tract/ Hyperphosphatemia in dialysis patients (2015)	VFMCRP
	FULSTAN® Falecalcitriol	3.8	Active vitamin D3/ Secondary hyperparathyroidism (2001)	Sumitomo Dainippon
	FRAGMIN® Dalteparin	1.3	Anticoagulant (low molecular weight heparin)/ Hemodialysis (1992) Disseminated intravascular coagulation (DIC) (1994)	Kabi Vitrum (Pfizer)
Metabolism	GLUBES® Mitiglinide + Voglibose	40.3	Mitiglinide & Voglibose combination product/ Type II diabetes (2011)	In-house
	BEZATOL® Bezafibrate	15.5	PPAR agonist/ Hyperlipidemia (1991)	Roche
	GLUFAST® Mitiglinide	15.3	Rapid-acting insulin secretagogue/ Type II diabetes (2004)	In-house
	MARIZEV® NEW Omarigliptin	-	DPP4 inhibitor/ Type 2 diabetes (2015)	MSD*

*Transfer of distribution operation from April 2020.

Products 2

Therapeutic Field	Brand Name Generic name	Sales (Mil. US\$)	MoA/ Indication	Licensors
Ob/Gyn	UTEMERIN® Ritodrine	10.4	β2 adrenoceptor agonist/ Premature labor (1986)	Solvay (Mylan)
	ZOLADEX® Goserelin	4.2	GnRH agonist/ Endometriosis (2000)	AstraZeneca
Ophthalmology	RIZABEN® EYE DROPS Tranilast	7.6	Inhibition of chemical mediators release from mast cells/ Allergic conjunctivitis (1995)	In-house
	RYSMON® TG Timolol	2.0	β adrenoceptor antagonist/ Glaucoma (1999), Ocular hypertension (1999)	Wakamoto
GI	RECTABUL® Budesonide	6.0	Budesonide rectal foam/ Ulcerative colitis (2017)	Dr. Falk/ EA-Kissei
Others	SALAGEN® Pilocarpine	14.7	Muscarinic receptor (M3) agonist/ Xerostomia (dry mouth) Radiation therapy (head and neck cancer) (2005) Sjögren syndrome (2007) Additional dosage form: Granule form (2014)	MGI (Eisai)
	XANBON® Ozagrel Na	3.7	Inhibition of thromboxane A2 synthetase/ Vasospasm after subarachnoid hemorrhage surgery (1988) Acute cerebral thrombosis (1992)	In-house
	RIZABEN® Tranilast	3.3	Inhibition of chemical mediators release from mast cells Inhibition of synthesis of collagen in fibroblasts/ Bronchial asthma (1982) Allergic rhinitis (1985) Atopic dermatitis (1985) Keloid, Hypertrophic scar (1993)	In-house
	DOMENAN® Ozagrel HCl	0.8	Inhibition of thromboxane A2 synthetase Bronchial asthma (1992)	In-house
	SAVENE® Dexrazoxane	0.7	Catalytic inhibitor of topoisomerase II/ Antidote for anthracycline extravasation (2014)	Clinigen