

**Financial Results
for the 1st Quarter of
Fiscal Year 2021**



SEIKAGAKU CORPORATION

(TSE:4548)

Contents

■ 1Q Results	P3	■ Research and Development	P10
● Net Sales	P3-6	● SI-6603 (Lumbar disc herniation)	P11
● Income	P7	● SI-613 (Osteoarthritis/Enthesopathy)	P12
● JOYCLU	P8	● SI-722 (Interstitial cystitis and bladder pain syndrome)	P13
● Trend in R&D Expenses	P9	● SI-449 (Adhesion Barrier)	P14
		■ Dividend of Surplus and Acquisition of Treasury Stocks	P15
		■ Appendix	P16

< Cautionary Notes >

This material contains forward-looking statements regarding future management strategies or performance forecasts. These statements are based on judgments derived from information that is currently available to Seikagaku and are subject to risk and uncertainty. Actual results and developments may differ significantly from these forward-looking statements due to various factors.

Information about pharmaceutical products or medical devices (including products currently in development) included in this material is not intended to constitute an advertisement or medical advice.

Overview for 1Q of FY 2021

(Millions of Yen)	1Q FY2021 Results	Year-on-Year		(Reference) FY2021 Full Year Forecasts	
		Change	% of Change	FY 2021 Forecasts	Degree of Progress
Net sales	11,784	+4,918	+71.6%	32,200	36.6%
Operating Income	4,446	+4,050	+1,022.2%	4,550	97.7%
Ordinary Income	4,613	+4,002	+655.8%	4,650	99.2%
Net Income	3,652	+3,122	+589.3%	3,650	100.1%
R&D Expenses (excluding royalty income)	1,936 (23.5%)	+320 (-0.3pt)	+19.8%	7,900 (28.3%)	24.5%
Average Exchange Rate (1US\$)	109.49円	+1.87円			

	1Q FY2021 Results	1Q FY2020 Results	(Reference) FY2021 Forecasts
Net Income per Share	¥64.73	¥9.39	¥64.83* ²
SKK EBITDA * ¹	4,672million yen	557million yen	5,750million yen

* 1 SKK EBITDA : A profit indicator that adds depreciation to operating income
* 2 Including the impact of the acquisition of treasury stock in July 2021

Net sales by Business Segment (1Q of FY2021)

(Millions of Yen)	1Q FY2021 Results	Year-on-Year	% of Change
Net sales	11,784	+4,918	+71.6%
Pharmaceuticals	9,707	+4,685	+93.3%
Domestic Pharmaceuticals	3,847	+342	+9.8%
Overseas Pharmaceuticals	1,589	+459	+40.6%
Bulk Products /CDMO	720	+425	+144.0%
Royalty Income	3,550	+3,459	+3,818.3%
LAL Business	2,076	+232	+12.6%
(Overseas sales)	3,894	+1,192	+44.1%

* Foreign exchange impact on overall net sales : approx. -20million yen

Domestic Pharmaceuticals

▶ ARTZ (Joint-function improving agent)

- Market recovery from the impact of COVID-19 (+8.9%)
- Higher deliveries to medical institutions (+12.2%)
Market share up as well (+1.9 pt)
- Seikagaku sales down due to NHI drug price reductions and a decline in shipments from a high level in 1Q FY2020

▶ JOYCLU (Joint-function improving agent)

- May 19, 2021 launch
- Information provision efforts to ensure appropriate use

▶ OPEGAN series (Ophthalmic viscoelastic devices)

- Market recovery from the impact of COVID-19 (+13.6%)
- Higher deliveries to medical institutions (+14.4%)
- Seikagaku sales down due to NHI drug price reductions and a decline in shipments from a high level in 1Q FY2020

▶ MucoUp

(Submucosal injection agent for endoscopic surgery)

- Seikagaku sales up slightly due to shipment timing

▶ HERNICORE (Treatment for lumbar disc herniation)

- Steady increase in deliveries to medical institutions
- Seikagaku sales down due to shipment timing

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* Foreign exchange impact on overall net sales : approx. -20million yen

Overseas Pharmaceuticals

*Foreign exchange impact on Overseas Pharmaceuticals: approx. +30 million yen

► Gel-One in the U.S. (Single injection)

- Market nearly recovered from the impact of COVID-19
- Local sales volume up substantially, rebounding from the substantial impact of COVID-19 in 1Q FY2020 (approx. +60%)
- Seikagaku sales up as well



Gel-One:
Intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis

► SUPARTZ FX in the U.S. (Multiple injection)

- Continuation of the trend toward preference for products that require a low number of injections
- Local sales volume and Seikagaku sales up

► ARTZ in China (Multiple injection)

- Outpatient services nationwide returned to near normal
- Local sales volume up, reflecting aggressive sales promotion activities
- Seikagaku sales up, due in part to earlier-than-planned shipments

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* Foreign exchange impact on overall net sales : approx. -20million yen

Bulk Products / CDMO

- Sales up due to the addition of sales from contract development and manufacturing at Dalton Chemical Laboratories, despite lower sales of bulk products

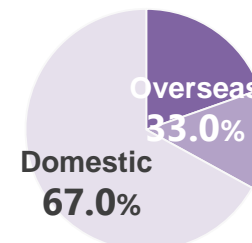
Royalty Income

- Huge increase
- * Royalty income reclassified from non-operating income to net sales beginning in FY2021

LAL Business

- *Foreign exchange impact on LAL Business: approx. -50million yen
- Sales up on growth in sales of Bacterial Endotoxin Testing (BET), contract services and Clinical Diagnostic (Fungitell) reagents

Overseas Sales Ratio



Year-on-Year
-6.4pt

Income for 1Q of FY2021 (Year-on-Year)

(Millions of Yen)	1Q FY2021 Results	Year-on-Year	% of Change
Net sales	11,784	+4,918	+71.6%
Cost of Sales (excluding royalty income)	3,716 (45.1%)	+230 (-6.4pt)	+6.6%
SGA expenses	3,621	+637	+21.4%
R&D Expenses (excluding royalty income)	1,936 (23.5%)	+320 (-0.3pt)	+19.8%
Operating Income (to Net sales ratio)	4,446 (37.7%)	+4,050 (+31.9pt)	+1,022.2%
Ordinary Income	4,613	+4,002	+655.8%
Net Income	3,652	+3,122	+589.3%
Depreciation	225	+63	+39.5%

Operating Income

Cost of sales ratio (-6.4pt)

- Decrease attributable to change in the sales mix

SGA Expenses (+637)

- Increase in R&D expenses due to progress in additional clinical study of SI-6603 in the U.S. (+320)

Ordinary Income

Non-operating Income / Expenses (-47)

- Decrease in dividend income (-66)

Net Income

Income Taxes (+880)

- Higher income taxes due to the profit increase

Safety Information on Joint Function Improving Agent JOYCLU

Blue Letter (rapid safety information) issued June 1 Prompt provision of information to alert healthcare professionals

Dear Healthcare Professionals Letter of Rapid Safety Communication (Blue Letter)

issued on June 1 in response to multiple reports of anaphylaxis occurring in patients following administration of JOYCLU



- To ensure patient safety by promptly alerting healthcare professionals of the situation to enable the provision of appropriate treatment and measures
- Addition of a WARNING section to the drug package insert and revision of the IMPORTANT PRECAUTIONS section



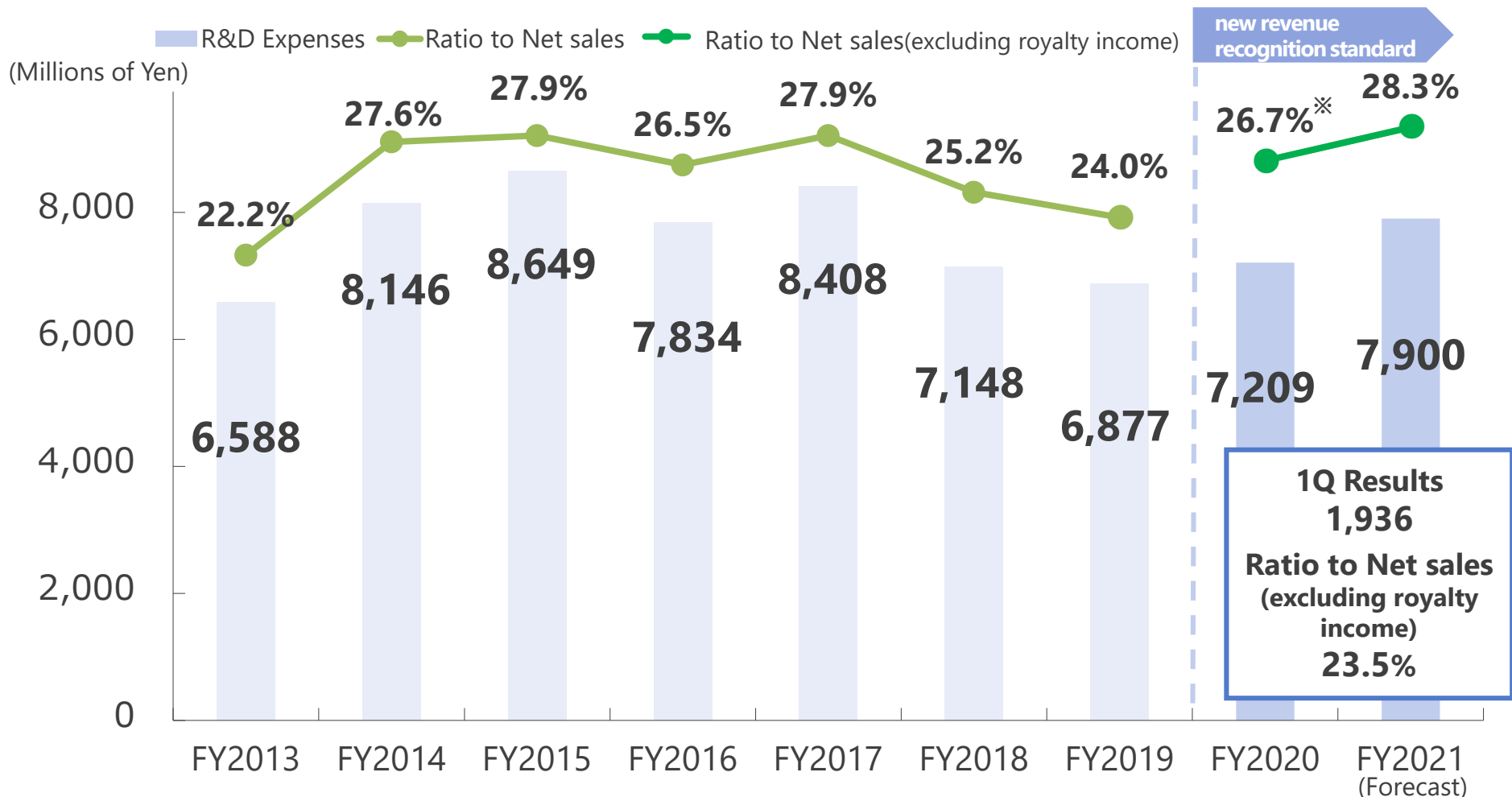
Seikagaku will continue efforts to proactively gather side effects information on the basis of collaboration with sales partner Ono Pharmaceutical Co., Ltd. and strive to provide safety and effectiveness information to promote the appropriate use of JOYCLU.

Information included in the package insert at the time of NDA approval

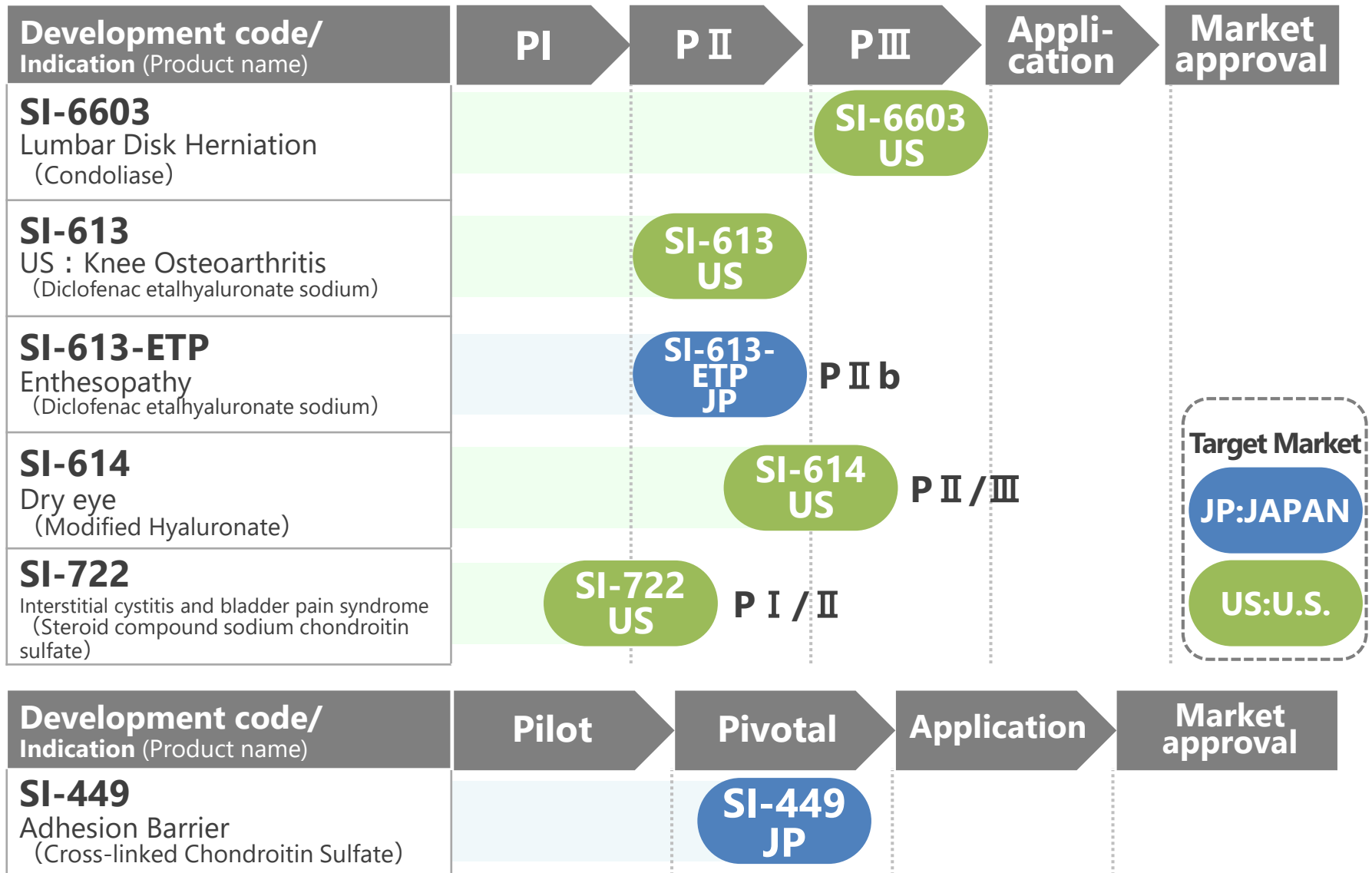
- Important Side Effects: Shock, anaphylaxis (0.4%)
- Contraindications: Patients with a previous history of hypersensitivity to diclofenac sodium and sodium hyaluronate (the ingredients of JOYCLU)

Trend in R&D Expenses

**Continuing to focus on drug discovery specializing in Glycoscience
Undertaking improvement in R&D efficiency**



Pipeline List (Research and Development themes)



SI-613 (Osteoarthritis)

A marketing alliance agreement for China and South Korea concluded with Eisai Considering future's policy in China and South Korea

SI-613 (osteoarthritis of the knee) U.S.

- ▶ Analysis of Phase II clinical study results is complete
Proceeding with partner selection in parallel with examination of Phase III study

SI-613 (osteoarthritis of the knee) China

- ▶ Agreement with Eisai on a co-development and marketing alliance in China,
in April 2020
Proceeding with preparation of a clinical development plan

SI-613 (osteoarthritis of the knee) South Korea

- ▶ Agreement with Eisai for a market alliance in South Korea in September 2020
Considering an NDA approach using clinical study data and approval details
from Japan

<SI-613 summary>

Dev. code : SI-613 Generic name : Diclofenac etalhyaluronate sodium

Indication : Osteoarthritis/Enthesopathy

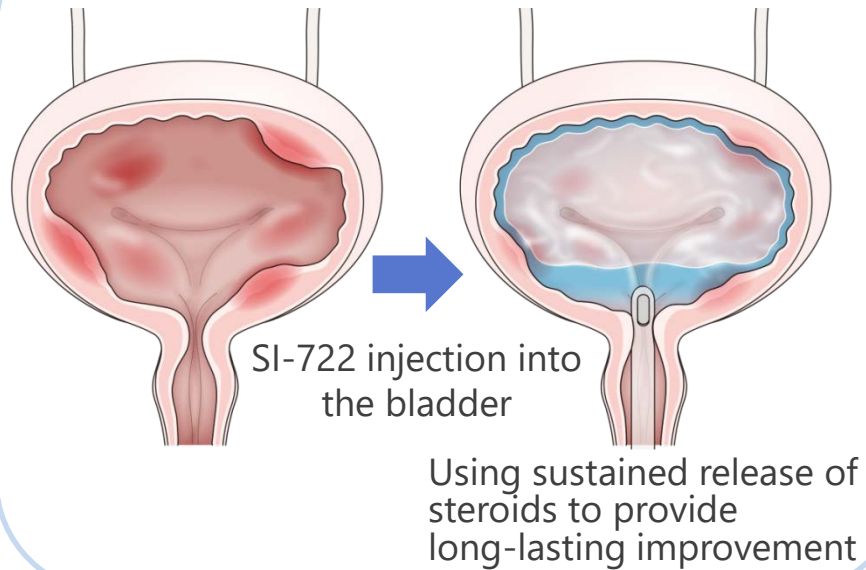
Method of use : Injection into joint cavity

Estimated patients : 24 million (U.S.) / 47 million (China) / 3.7 million (South Korea) (Seikagaku estimates)

SI-722 (Interstitial cystitis and bladder pain syndrome)

**Subject enrollment for PI/PII studies in the U.S. completed
Analysis of study results to proceed**

SI-722 Administration image



Development status

- ▶ U.S. Phase I/II / Starting November 2019
- Subject enrollment complete in January 2021
- ⇒ Tolerability confirmed (a primary objective)
- Will consider the next-phase study

Promising features

- ▶ Designed for sustained release by bonding steroids to chondroitin sulfate
- ▶ Anti-inflammatory effects of steroids under sustained release should provide sustainable relief of frequent urination and bladder pain

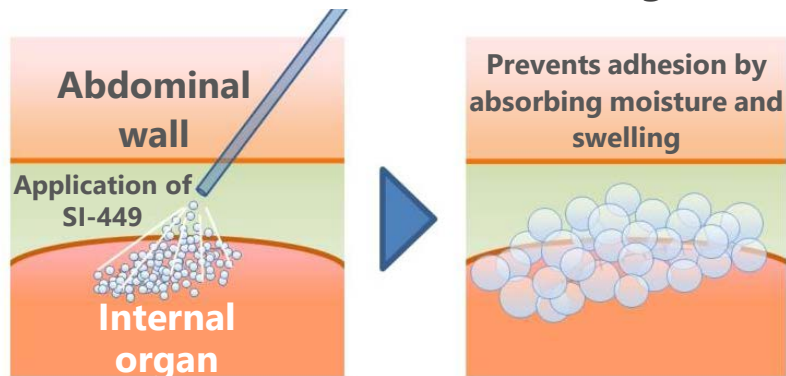
<SI-722 summary>

Dev. Code : SI-722 Generic name : Steroid conjugated with chondroitin sulfate
 Indication : Interstitial cystitis and bladder pain syndrome
 Method of use : Injection into the bladder
 Estimated U.S. patients : 1.3 million (Seikagaku estimates)

SI-449 (Adhesion Barrier / Medical Device)

Pivotal study started in May 2020 Delays caused by effects from COVID-19

SI-449 Administration image



Development status

- ▶ **Japan pivotal study / Starting May 2020**
 - **Evaluated for effectiveness, safety, and usability**
 - ⇒ Plans delayed by restrictions on visits to facilities due to COVID-19 infection effects
 - ⇒ Treatment countermeasures in progress under a remote set-up
- ▶ Proceed with development with a view to global development; Start of U.S. pilot study under review

Promising features

- ▶ Leveraging pulverized characteristics to respond to healthcare needs through the spreading use of laproscopic surgery

<SI-449 summary>

Dev. Code : SI-449 Generic name : Cross-linked chondroitin sulfate
 Product name : Adhesion barrier
 Method of use : Intra-abdominal application (powdered formulation)
 Adhesion barrier market : Japan: ¥14 billion, Global: ¥100 billion (Seikagaku estimates)

Dividend of Surplus and Acquisition of Treasury Stocks

Dividend from Retained Earnings (Commemorative Dividend, Special Dividend) Acquisition of Treasury Stocks

FY2020

Year-end dividend : Ordinary dividend ¥10 + **JOYCUL approval commemorative dividend ¥4**
Total ¥14 per share
→Annual dividend : ¥24 per share, including the interim dividend of ¥10 per share

FY2021

Ordinary dividend ¥20 + **JOYCUL launch special dividend ¥10**
→Annual dividend : ¥30 per share, including the interim dividend of ¥15 per share

	FY2017	FY2018	FY2019	FY2020	FY2021 (Forecast)
Net Income per share	¥69.30	¥39.76	¥-192.15	¥75.54	¥64.83 ^{※3}
Annual Total Dividend	¥26.00	¥26.00	¥26.00	¥24.00 ^{※1}	¥30.00 ^{※2}
Dividend Payout Ratio	37.5%	65.4%	—	31.8%	46.3%

※1 including a JOYCUL approval commemorative dividend ¥4

※2 including a JOYCUL launch special dividend ¥10

※3 Including in the impact of the acquisition of treasury stock in July 2021

Acquisition of Treasury

Total number of shares to be acquired : 200,000shares (maximum)

Total amount of acquisition cost : ¥221,596,300 (maximum)

Acquisition period : July 1, 2021 to July 16, 2021

Appendix

Change in Accounting Standards

(Application of new revenue recognition standard, change in accounting classification of royalty income)

Change in accounting standards beginning from the first quarter of the fiscal year ending March 31, 2022

1. Application of a new revenue recognition standard

- Implementation of Accounting Standard for Revenue Recognition and its implementation guidance
- Reclassification of sales commissions paid to sales partners from SGA expenses to a sales deduction

2. Change in accounting classification of royalty income

- Revision of the sales and income recognition method to coincide with application of the new revenue recognition standard
- Royalty income, previously recognized as non-operating income, to be reclassified as net sales

	FY2020	FY2021
Net sales	<ul style="list-style-type: none"> • Pharmaceuticals • LAL Business 	<ul style="list-style-type: none"> • Pharmaceuticals + Royalty Income △ Sales Commissions • LAL Business
SGA Expenses	+ Sales Commissions	
Operating Income		
Non-operating Income / Expenses	+ Royalty Income	
Ordinary Income		

The diagram illustrates the changes in accounting standards between FY2020 and FY2021. In FY2020, Net sales included Pharmaceuticals and LAL Business. SGA Expenses included Sales Commissions. Non-operating Income / Expenses included Royalty Income. In FY2021, Net sales now includes Pharmaceuticals, LAL Business, and Royalty Income. Sales Commissions are now shown as a deduction (△) from Net sales. The reclassification of Royalty Income from non-operating income to net sales is indicated by a blue arrow, and the reclassification of Sales Commissions from SGA Expenses to net sales is indicated by an orange arrow.

Overview of Forecasts in FY2021

(Millions of Yen)	FY2021 Forecasts	FY2020 Results *		
		Results	Change	% of Change
Net sales	32,200	27,734	+4,465	+16.1%
Operating Income	4,550	2,248	+2,301	+102.3%
Ordinary Income	4,650	3,024	+1,625	+53.7%
Net Income	3,650	4,262	-612	-14.4%
R&D Expenses (Ratio to net sales excluding royalty income)	7,900 (28.3%)	7,209 (26.7%)	+690 (+1.6pt)	+9.6%
Average Exchange Rate (1US\$)	¥105.00	¥106.06		

	FY2021 Forecasts	FY2020 * 1
Net Income per share	¥64.83 ^{*2}	¥75.54
Dividend per share	¥30.00	¥24.00
Dividend Payout ratio	46.4%	31.8%

Exchange Rate Sensitivity (Impact of a change of ¥1 against the US\$)	
Net sales	Approx. ¥150 million
Operating income	Approx. ¥60 million

* 1 It's corrected retrospectively in the new revenue recognition standard
 * 2 Including the impact of the acquisition of treasury stock in July 2021

Forecasts (Net sales) in FY2021

(Millions of Yen)	FY2021 Forecasts	Year-on-Year *	
		Change	% of Change
Net sales	32,200	+4,465	+16.1%
Pharmaceuticals	25,150	+4,356	+21.0%
Domestic Pharmaceuticals	11,600	+147	+1.3%
Overseas Pharmaceuticals	6,900	+123	+1.8%
Bulk Products /CDMO	2,350	+503	+27.3%
Royalty income	4,300	+3,581	+498.8%
LAL Business	7,050	+108	+1.6%
(Overseas sales)	14,500	+856	+6.3%

Foreign exchange impact on overall net sales : approx. -50million yen

* It's corrected retrospectively in the new revenue recognition standard

Net sales

- Forecast of higher sales from an increase in royalty income, the launch of the new product JOYCLU, and higher sales for bulk products/contract development and manufacturing, despite the negative impact of NHI price reductions

* Foreign exchange impact on overall net sales : approx. -50million yen

Pharmaceuticals

Domestic Pharmaceuticals :

Sales at prior-year level, with the launch of JOYCLU offsetting the negative impact of NHI drug price reductions

Overseas Pharmaceuticals :

Sales increase from higher local sales volumes of Gel-One and ARTZ in China

Bulk Products/CDMO :

Sales increase from contract development and manufacturing (Dalton)

Royalty income :

Projected increase in royalty income

LAL Business

- Projected increase in royalty income

Forecasts (Income) in FY2021

(Millions of Yen)	FY2021 Forecasts	Year-on-Year *	
		Change	% of Change
Net sales	32,200	+4,465	+16.1%
Operating Income (Ratio to net sales)	4,550 (16.3%)	+2,301 (+8.0pt)	+102.3%
Ordinary Income	4,650	+1,625	+53.7%
Net Income	3,650	-612	-14.4%
Cost of Sales ratio (excluding royalty income)	38.8% (44.8%)	-4.9pt (±0.0pt)	—
R&D Expenses	7,900	+690	+9.6%
R&D Expenses ratio (excluding royalty income)	24.5% (28.3%)	-1.5pt (+1.6pt)	—
Depreciation	1,150	+341	+42.2%

* It's corrected retrospectively in the new revenue recognition standard

Operating Income

SGA Expenses (approx. +1,700) :

- Increase in R&D expenses (+690)
- JOYCLU post-marketing surveillance, higher subsidiary expenses

Ordinary Income

Non-operating Income / Expenses :

- Projected increase in foreign exchange loss

Net Income

Income Taxes

- Recognition of deferred income taxes in connection with recognition of deferred tax assets in the prior-year period (-1,561)

Overview of JOYCLU

Manufacturing and marketing approval in Japan obtained in March 2021
For the indication of osteoarthritis (knee joint and hip joint)
May 19 NHI drug price listing and launch



Product name	JOYCLU® 30mg Intra-articular Injection
Generic name	diclofenac etalhyaluronate sodium
Indication	Osteoarthritis (knee joint and hip joint)
Dosage and administration	The usual adult dosage is 1 syringe per dose (30 mg of diclofenac etalhyaluronate sodium) injected intra-articularly every 4 weeks.

Overview of JOYCLU

Improvement of symptoms expected by administration once every 4 weeks First joint function improvement agent in Japan indicated for the treatment of osteoarthritis of the hip joint

features

- ▶ Hyaluronic acid and diclofenac chemically bound using a proprietary technology
- ▶ Diclofenac released by hydrolysis in the joint
- ▶ Improvement of symptoms of osteoarthritis (knee joint and hip joint) expected by administration once every four weeks
- ▶ First joint function improvement agent in Japan indicated for the treatment of osteoarthritis of the hip joint

Expected positioning

- ▶ **Establishment as a new base drug** in the treatment of osteoarthritis alongside existing hyaluronic acid formulations and NSAIDs

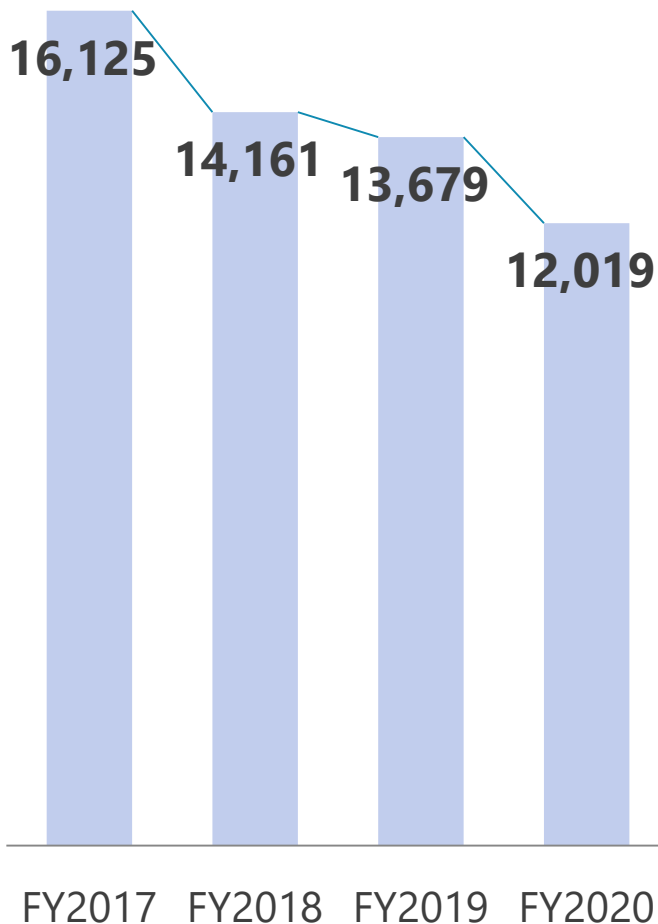
<Target Patients>

- ▷ People for whom existing hyaluronic acid formulations are insufficiently effective
- ▷ People who want to avoid NSAIDs, such as oral drugs or patches, in consideration of side effects
- ▷ People for whom frequent hospital visits are a hardship
- ▶ Provision of **a new treatment option for osteoarthritis of the hip joint**

Domestic Pharmaceuticals (Unit deliveries to medical institutions/Year-on-Year)

Domestic Pharmaceuticals Sales trend

(Millions of Yen)



FY2020 Results

-12.1%

(sales basis)

Sales down, reflecting the impact of NHI drug price reductions coupled with market contraction due to the impact of COVID-19

Joint-function improving agent (Unit deliveries to medical institutions) Market (-5.8%)

- Market contraction due to decrease in outpatients attributable to impact of COVID-19

ARTZ (-3.7%)

- Lower deliveries accompanying market contraction
- Market share increase due in part to the continuing effectiveness of measures to acquire new user facilities (61.2% / +1.3 pt)

Ophthalmic viscoelastic devices (Unit deliveries to medical institutions) Market (-13.2%)

- Decrease in the number of cataract surgeries attributable to spread of COVID-19

OPEGAN (-1.0%)

- Deliveries at the prior-year level thanks to an increase in new user facilities because of the impact of shipment adjustments for competing products
- Market share expansion (53.7% / +6.6 pt)

Treatment for lumbar disc herniation (Unit deliveries to medical institutions) HERNICORE

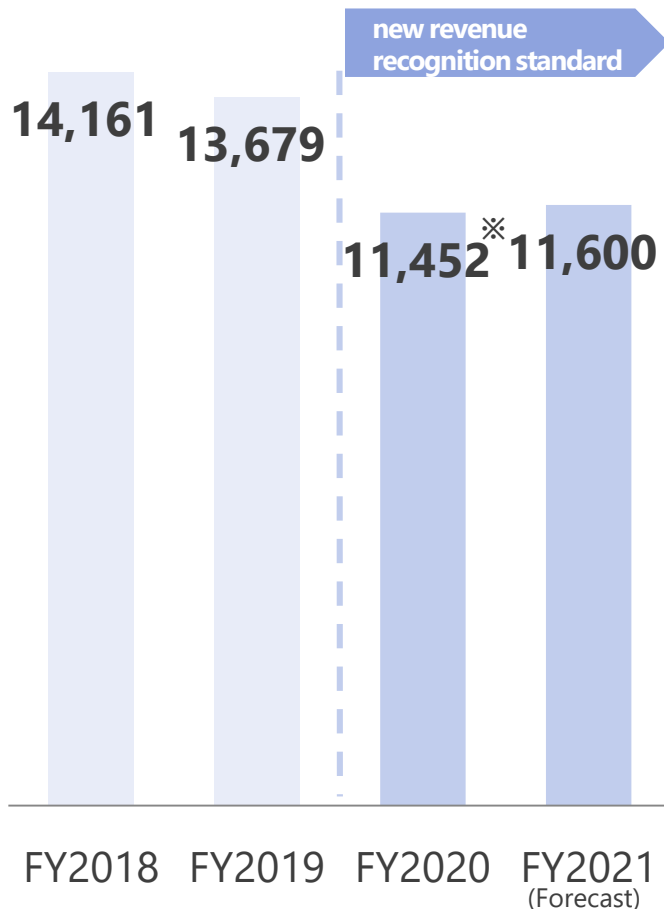
HERNICORE

- Deliveries at the prior-year level due to a decrease in outpatient services attributable to impact of COVID-19
- Steady increase in the number of new user institutions

Domestic Pharmaceuticals (FY2021 Forecast Year-on-Year / Unit deliveries to medical institutions)

Domestic Pharmaceuticals Sales trend

(Millions of Yen)



FY2021 Forecast

+1.3%
(sales basis)

Sales at prior-year level, with the launch of JOYCLU offsetting the negative impact of NHI drug price reductions

Joint-function improving agent (Unit deliveries to medical institutions)

Market

- Projected continuation of the downtrend in outpatient services

ARTZ

- Forecasting a year-on-year decrease due in part to continued impact of COVID-19

JOYCLU

- Aiming for early market penetration through appropriate information provision

Ophthalmic viscoelastic devices (Unit deliveries to medical institutions)

Market

- Number of surgeries expected to remain at the low prior-year level

OPEGAN

- Forecasting a decrease due to resumption of shipments of competing products

Treatment for lumbar disc herniation (Unit deliveries to medical institutions)

HERNICORE

- Deliveries at the prior-year level projected due to growth in the number of new user institutions, despite continuation of the downtrend in outpatient services

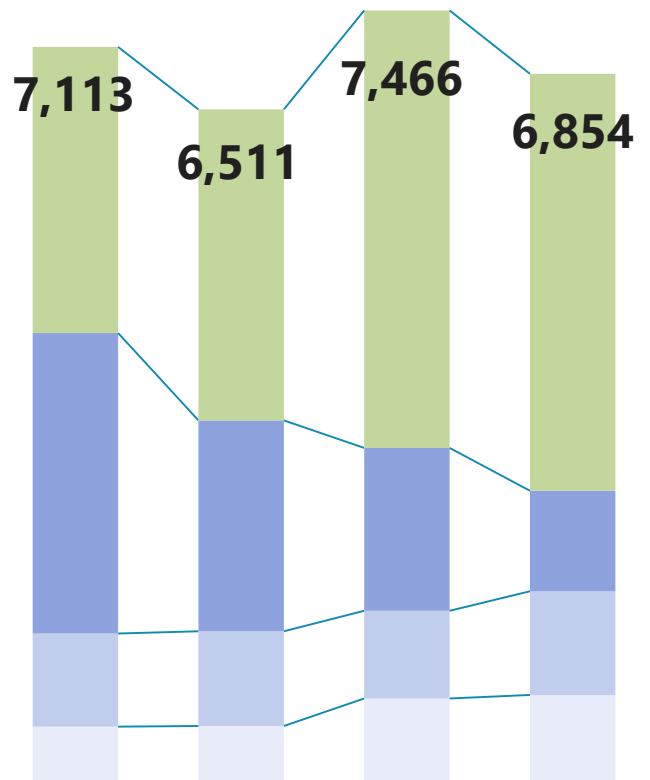


Overseas Pharmaceuticals 1/2 (FY2020 Results Year-on-Year / value basis)

Overseas Pharmaceuticals Sales trend

<Breakdown> (Millions of Yen)

■ Gel-One in the U.S.
 ■ SUPARTZ FX in U.S.
■ ARTZ in China
 ■ Others



FY2017 FY2018 FY2019 FY2020

FY2020 Results
-8.2%

Sales down, reflecting lower shipments attributable to the impact of COVID-19
Market trending toward recovery

* Foreign exchange impact: approx. - ¥100million

U.S.

● Market in the U.S.

- Sales on a recovery trend, reflecting easing of measures such as postponement of non-urgent and non-emergency medical procedures, despite sharp market contraction due to spread of COVID-19
- Continuation of the trend toward preference for products that require a low number of injections

● Sales in the U.S.

Gel-One : Increase attributable to effectiveness of measures to promote switching from competing products
(approx. +5% on a volume basis)

SUPARTZ FX : Decrease due to continuation of the trend favoring products that require a low number of injections

▶ Seikagaku exports

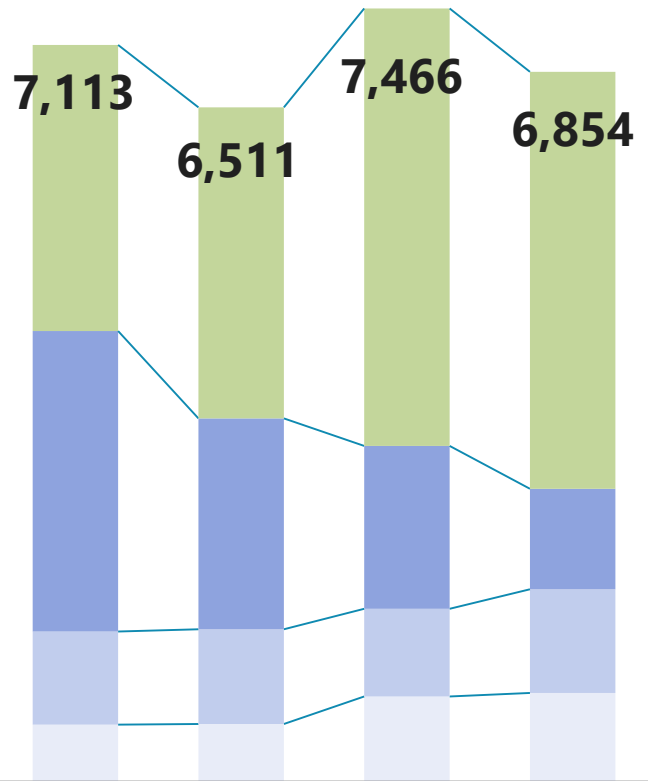
- Gel-One sales down due to the impact of lower shipments in 1Q
- SUPARTZ FX sales down on lower local sales

Overseas Pharmaceuticals 2/2 (FY2020 Results Year-on-Year / value basis)

Overseas Pharmaceuticals Sales trend

<Breakdown> (Millions of Yen)

■ Gel-One in the U.S.
 ■ SUPARTZ FX in U.S.
■ ARTZ in China
 ■ Others



FY2017 FY2018 FY2019 FY2020

FY2020 Results
-8.2%

Sales down, reflecting lower shipments attributable to the impact of COVID-19
Market trending toward recovery

* Foreign exchange impact: approx. - ¥100million

China, Other Regions

● Market in China

- Steady recovery from April 2020 onward following substantial impact from COVID-19 during January to March 2020
- Return to near normal, despite curbing of outpatient services in some regions

● Local sales of ARTZ in China

- Market recovery and higher local unit sales following a low level of sales in the previous year due to impact of COVID-19

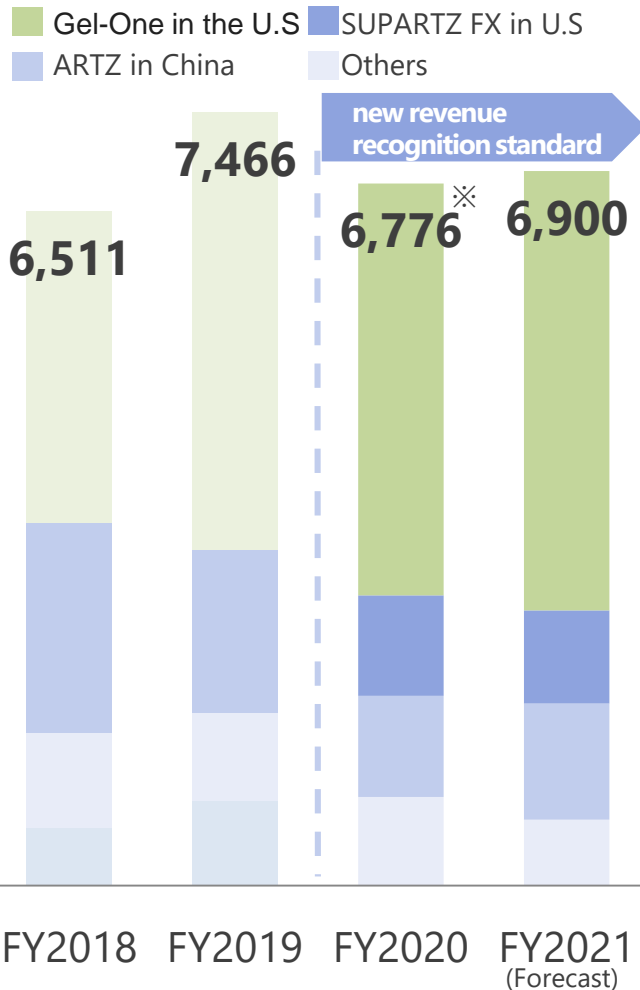
▶ Seikagaku exports

- Seikagaku sales to China up, reflecting recovery of local sales of ARTZ
- Seikagaku sales to Italy down, reflecting no improvement in the outpatient services situation in the market

Overseas Pharmaceuticals (FY2021 Forecast Year-on-Year / value basis)

Overseas Pharmaceuticals Sales trend

<Breakdown> (Millions of Yen)



FY2021 Forecast
+1.8%

The impact of COVID-19 expected to run its course, and sales projected to increase on higher volumes

U.S.

● Market in the U.S.

Projected market recovery trend, with impact of COVID-19 running its course

● Sales in the U.S.

Gel-One : Forecasting a local sales increase due to strengthening of sales promotion activities

SUPARTZ FX : Forecasting a decrease due to continuation of the trend favoring products that require a low number of injections

▶ Seikagaku exports

Gel-One exports projected to rise due to the local sales increase/
SUPARTZ FX exports projected to fall due to the local volume decrease

China, Other Regions

● Local sales of ARTZ in China

Forecasting a sales increase to result from maintenance of the current level of sales to large urban hospitals and opening up of the mid-size hospital market

▶ Seikagaku exports

ARTZ exports to China projected to rise due to a local sales increase
No recovery from the impact of COVID-19 in Italy expected, and exports projected to be at the prior-year level

* It's corrected retrospectively in the new revenue recognition standard

Sales of LAL Business (year-on-year / value basis)

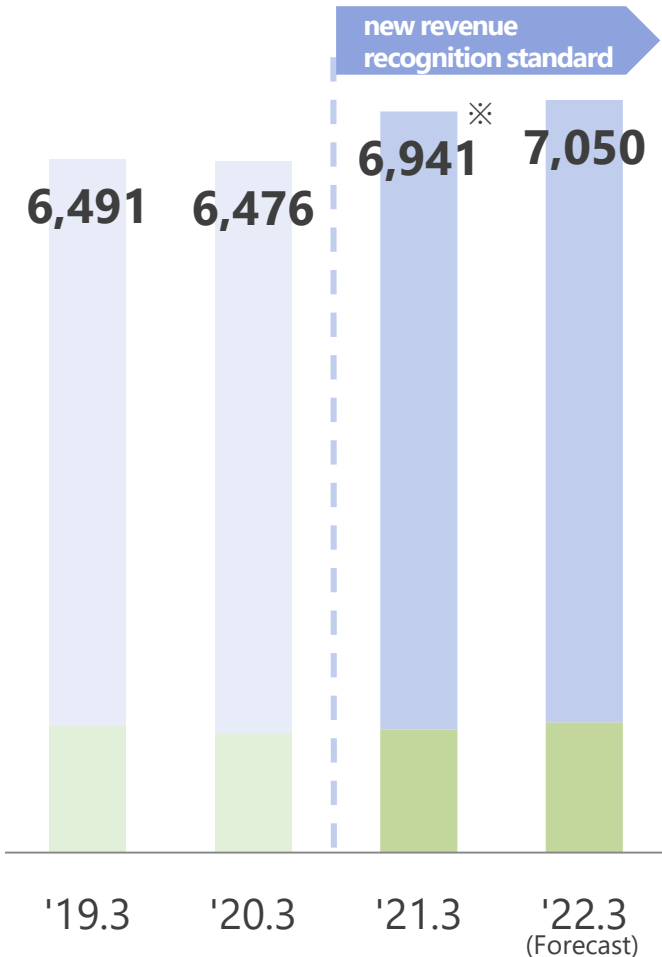
LAL Business Sales trend

<Breakdown>

■ Overseas ■ Domestic

(Millions of Yen)

new revenue recognition standard



FY2020 Results : +7.2% (Year-on-Year)

Overseas

* Foreign exchange impact: approx. - ¥150million

Growth in sales of Bacterial Endotoxin Testing (BET) and Clinical Diagnostic (Fungitell) reagents at overseas subsidiary ACC

Domestic

Slight sales increase on solid sales of reagents and other products

FY2021 Results : +1.6% (Year-on-Year)

Overseas

Launch of a recombinant LAL reagent
Projected increase due to strengthening of sales promotion activities

Domestic

Slight decrease projected because of a change in shipment timing due to the impact of COVID-19

LAL Business : The manufacturing and sales of Endotoxin detection reagents* used in the quality control of pharmaceuticals and medical devices

*Endotoxin detection reagents are reagents whose main ingredient is Limulus Amebocyte Lysate (LAL).



Recombinant LAL reagent 「PyroSmart NextGen™」

April 2021 launch at ACC

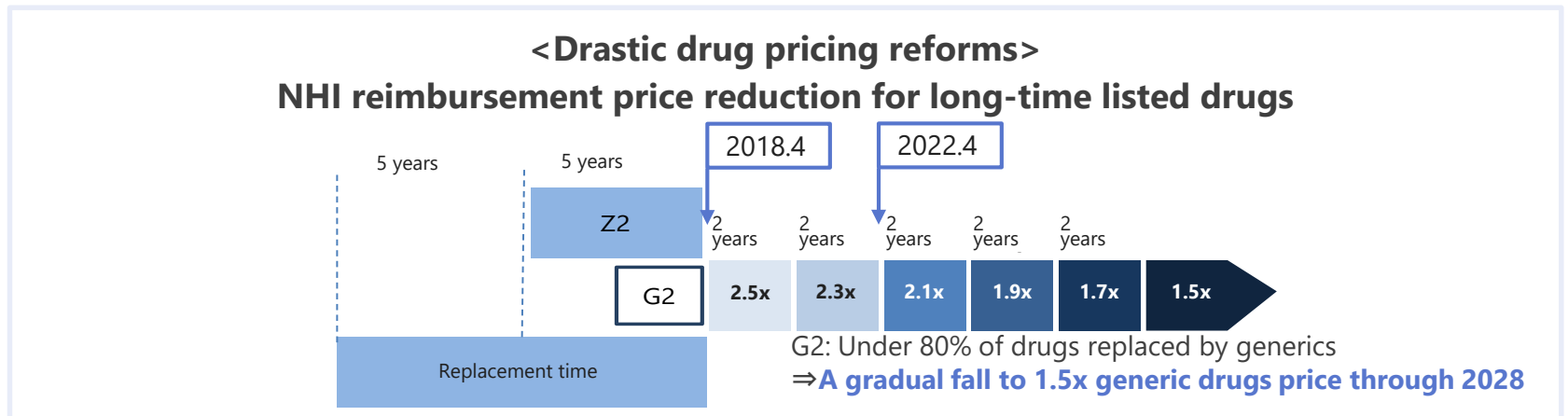
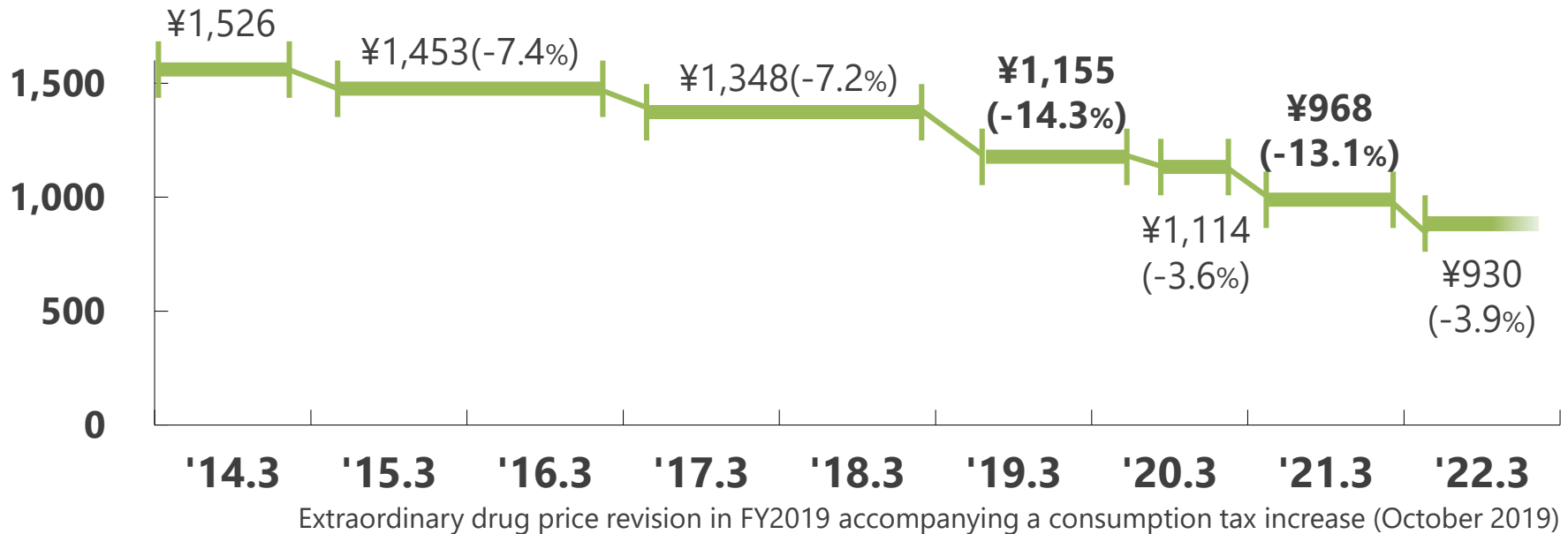
Product to be marketed globally, with a launch in Japan planned for May or later in 2021



Product Features

- ▶ Product manufactured using recombinant technology without using blood harvested from horseshoe crabs, a raw material used in traditional products
 - Ensures continuous product supply
- ▶ Ability to utilize the same test methods and instruments as naturally sourced products
 - Ensures consistency with endotoxin-testing reagents
 - A next-generation BET reagent designed to deliver highly reliable quantitation of endotoxins

Trend in NHI Reimbursement Price of ARTZ to Domestic



Trend in Deliveries of ARTZ / OPEGAN to Domestic Medical Institutions

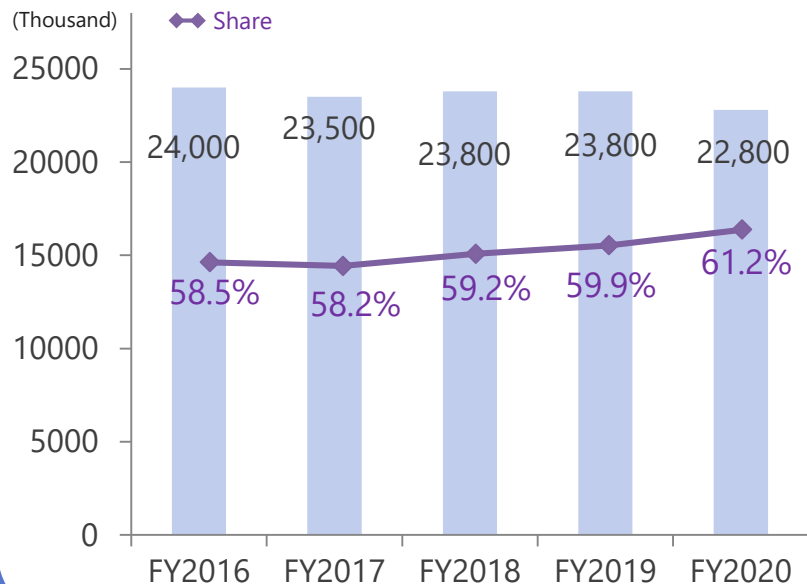
Joint-function improving agent

ARTZ



- The first HA joint function improving agent in the world
- Knee osteoarthritis (OA) pain relief
- Distributor: Kaken Pharmaceutical

Trend in unit deliveries to medical institutions



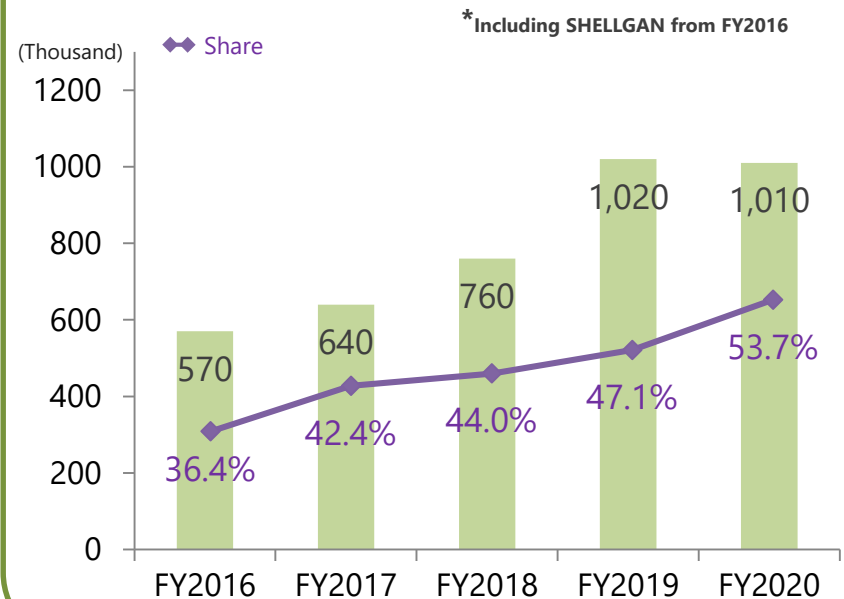
Ophthalmic viscoelastic devices

OPEGAN



- The first domestically HA formulation
- Used in cataract surgery to anterior chamber expansion
- Distributor: Santen Pharmaceutical

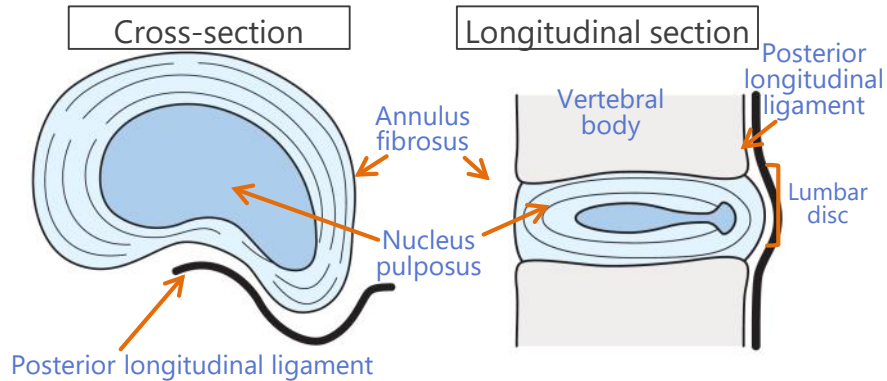
Trend in unit deliveries to medical institutions



Four types of lumbar disc herniation

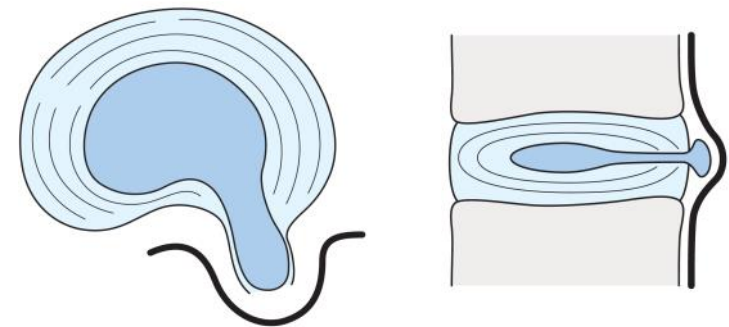
1. Protrusion

The hernia does not extend beyond the outermost layer of the annulus fibrosus



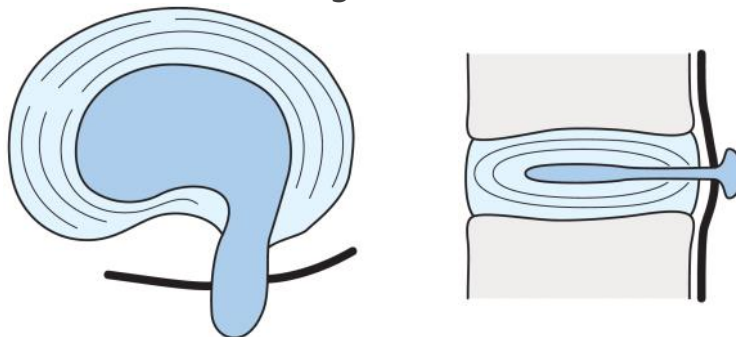
2. Subligamentous extrusion

Although the hernia extends beyond the outermost layer of the annulus fibrosus, it is covered by the posterior longitudinal ligament



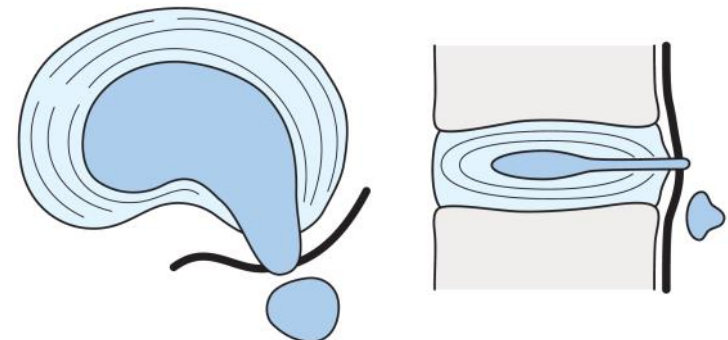
3. Transligamentous extrusion

The hernia perforates the posterior longitudinal ligament



4. Sequestration

The hernia migrates outside the dura mater



Post-marketing of HERNICORE in Japan

Promoting appropriate use and expanding opportunities for use; Firming up usage as new treatment options

- Coordinating with Kaken Pharmaceutical **engaging in information provision activities to ensure appropriate use and safety** through seminars with scientific societies and local workshops
- **Collecting pertinent information (post marketing surveillance)** with emphasis on safety information
- **Raising patients' recognition through awareness campaigns on the ailment**
- **Gradually expanding available physicians and facilities** through a review of requirements (expecting moderate growth)



Roll-out to scientific societies
Requirements review
Adding facilities, etc.

• November 2019
 Non-fulltime work facilities of supervisory physicians of the JSSR

• April 2019
 Physicians of the Neurospinal Society of Japan *²

• August 2018
 Physicians of the Japanese Society for Spine Surgery and Related Research (JSSR) *¹

Physician requirements

- ※1 ① Supervisory physicians or certified physicians of the Japanese Society for Spine Surgery and Related Research (JSSR) or who are supervised under the JSSR, or who participated in the this clinical study
 ② Physicians having experience with performing intradiscal puncture or at least 50 surgeries for lumbar disc herniation
- ※2 ① Supervisory physicians or certified physicians of the Neurospinal Society of Japan
 ② Physicians having experience with performing intradiscal puncture or at least 50 surgeries for lumbar disc herniation

Physician and Facilities Requirements for HERNICORE Use

Setting of physician and facility requirements for HERNICORE use to promote appropriate use and ensure safety

[Physician requirements]

[Japanese Society for Spine Surgery and Related Research]

: Physicians under the following conditions (as of April 2019)

1. Supervisory physicians or certified physicians of the Japanese Society for Spine Surgery and Related Research (JSSR) or who are supervised under the JSSR, or who participated in this clinical study
2. Physicians having experience with performing intradiscal puncture or at least 50 surgeries for lumbar disc herniation

[Neurospinal Society of Japan] : Physicians under the following conditions (as of April 2019)

1. Supervisory physicians or certified physicians of the Neurospinal Society of Japan
2. Physicians having experience with performing intradiscal puncture or at least 50 surgeries for lumbar disc herniation

[Facility requirements] : Facilities under the following conditions

1. Facilities equipped with an X-ray fluoroscopic system (C-arm, etc.) capable of administering HERNICORE using clean technique
2. Facilities capable of treating shock and anaphylaxis
3. Facilities capable of performing urgent spine surgery or facilities that cooperate with facilities capable of performing spine surgery
4. Facilities with hospitalization equipment

※ Among those who meet the physician requirements, supervisory physicians in the JSSR may be used at non-fulltime work facilities that meet the facilities requirements (as of November 2019)

We plan to review these requirements with the consent of PMDA* approximately six months to one year after launching, following collection and careful examination of post-marketing safety information etc.

Ophthalmic viscoelastic devices SHELLGAN

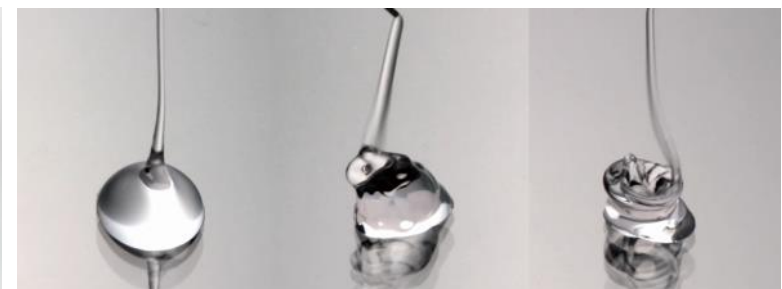


■ Product SHELLGAN Outline

- Suited to a surgical procedure that has become more pervasive in recent years
- Can be stored at room temperature
 - ▶ A product feature unavailable from competitors
- Strengthening of the OPEGAN family product line
 - ▶ Seven-product line up provides a wider range of options appropriate to symptoms and physician needs



The OPEGAN series, used mainly in cataract surgery



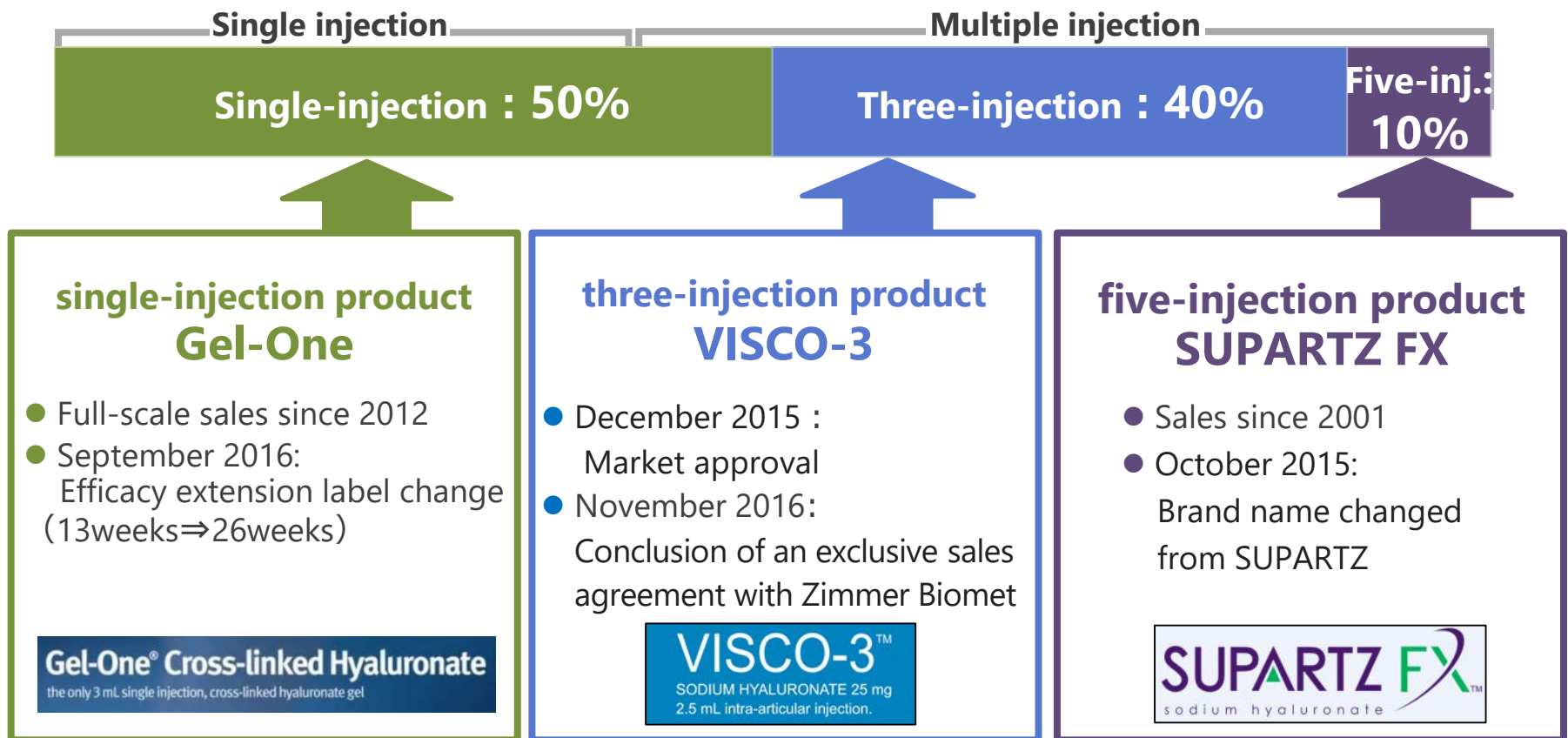
OPEGAN Sodium Hyaluronate 0.85 Ophthalmic Viscoelastic Preparation 1% 「SEIKAGAKU」 **SHELLGAN**

The OPEGAN family viscoelasticity comparison

Market Situation of Hyaluronic Acid Products in the U.S.

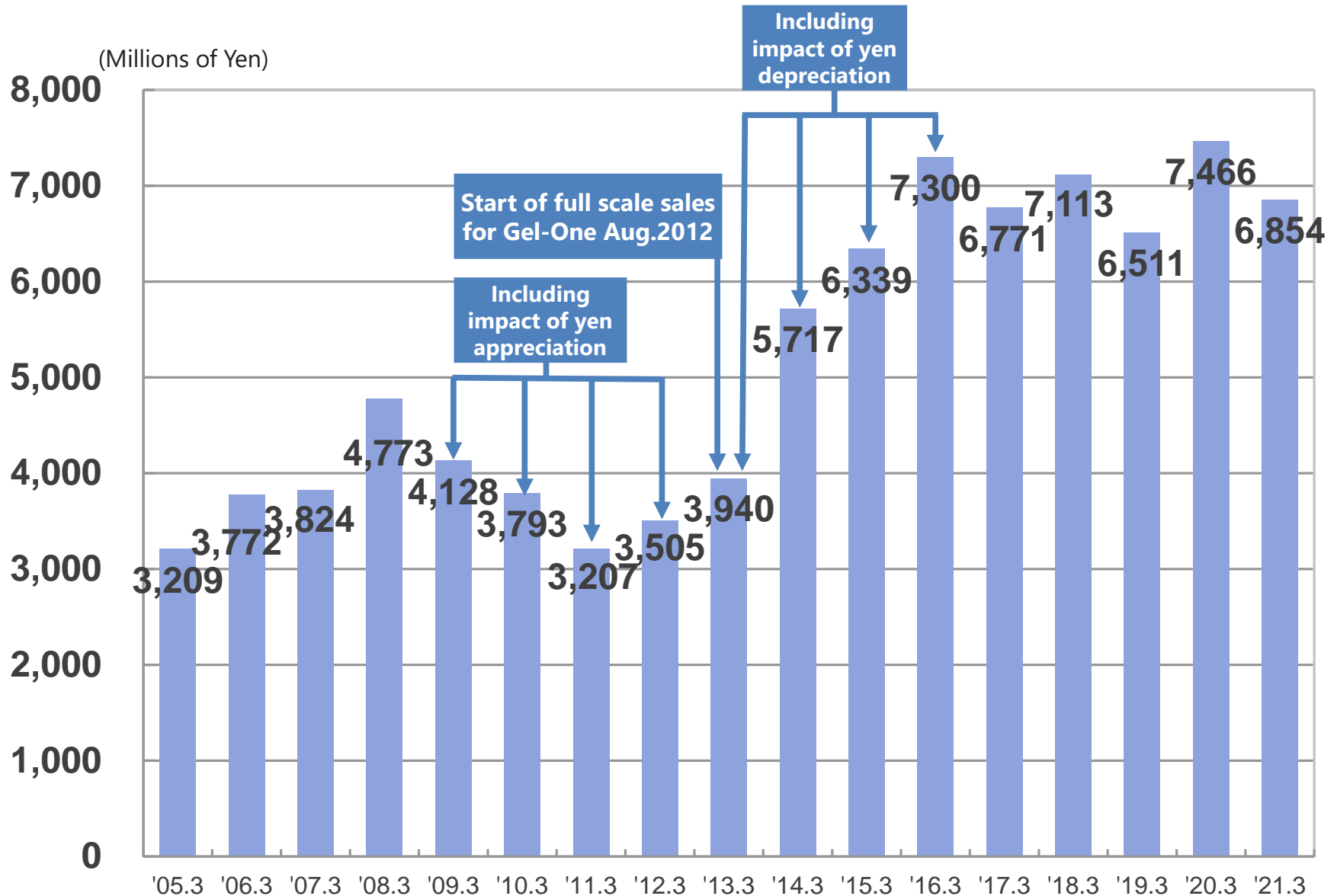
Market size of US\$800 mil. in 2020 (-15.0% year-on-year)

■ **U.S. market share by number of injections** (Value basis, including competitors)



*Figures for 2019, Seikagaku estimates

Trend in Overseas Sales of Hyaluronic Acid Products



The LAL Business

What is the LAL business?

The manufacturing and sale of reagents used in the quality control of pharmaceuticals, medical devices, biopharmaceuticals, and in water quality control in dialysis at hospitals

- * Endotoxin detection reagents are reagents whose main ingredient is Limulus Amebocyte Lysate (LAL).
- * Endotoxins are substances derived from bacteria. Since they cause fever even in minute amounts, testing for endotoxin contamination in pharmaceuticals is regulatorily required by certain jurisdictions

► **Size of the global market: Approx. ¥25.0 billion**
(Seikagaku estimate, including required equipments)

Associates of Cape Cod, Inc. (ACC)

- U.S. subsidiary of Seikagaku (established in 1974, acquired by Seikagaku in 1997)
- Developed the world's first endotoxin detection reagent and obtained FDA approval in 1977
- A sales network spanning over 80 countries
- Strong revenue growth in recent years

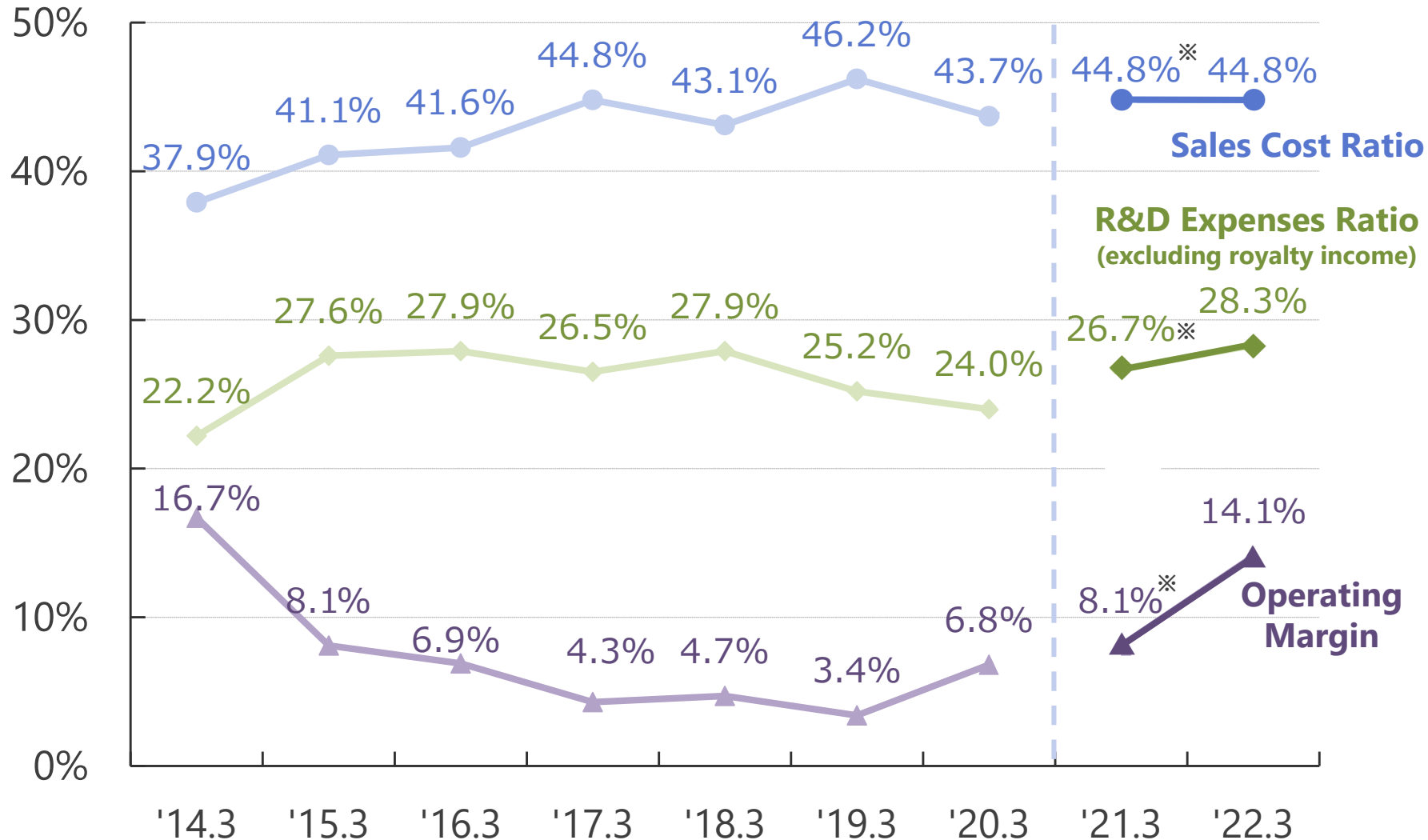


Endotoxin detection reagents
(for quality control of pharmaceuticals and medical devices)



PYROCHROME®

Trend in Financial Index

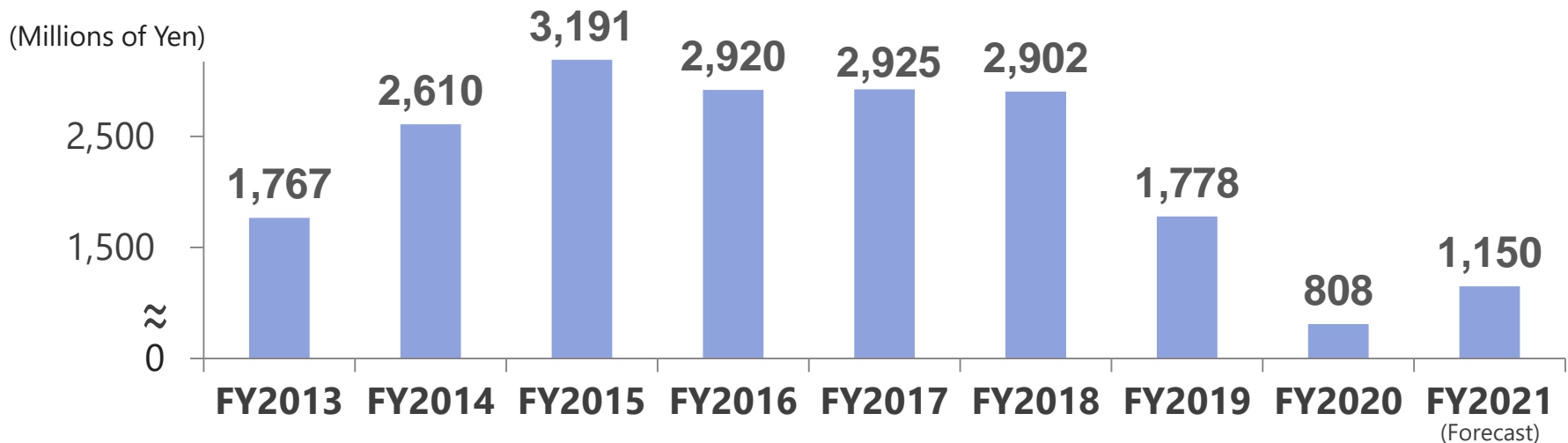


* It's corrected retrospectively in the new revenue recognition standard

Trends in Depreciation & Capital Investments

Impairment loss taken in FY2019 Depreciation will trend toward ¥1.0 billion

■ Trend in Depreciation

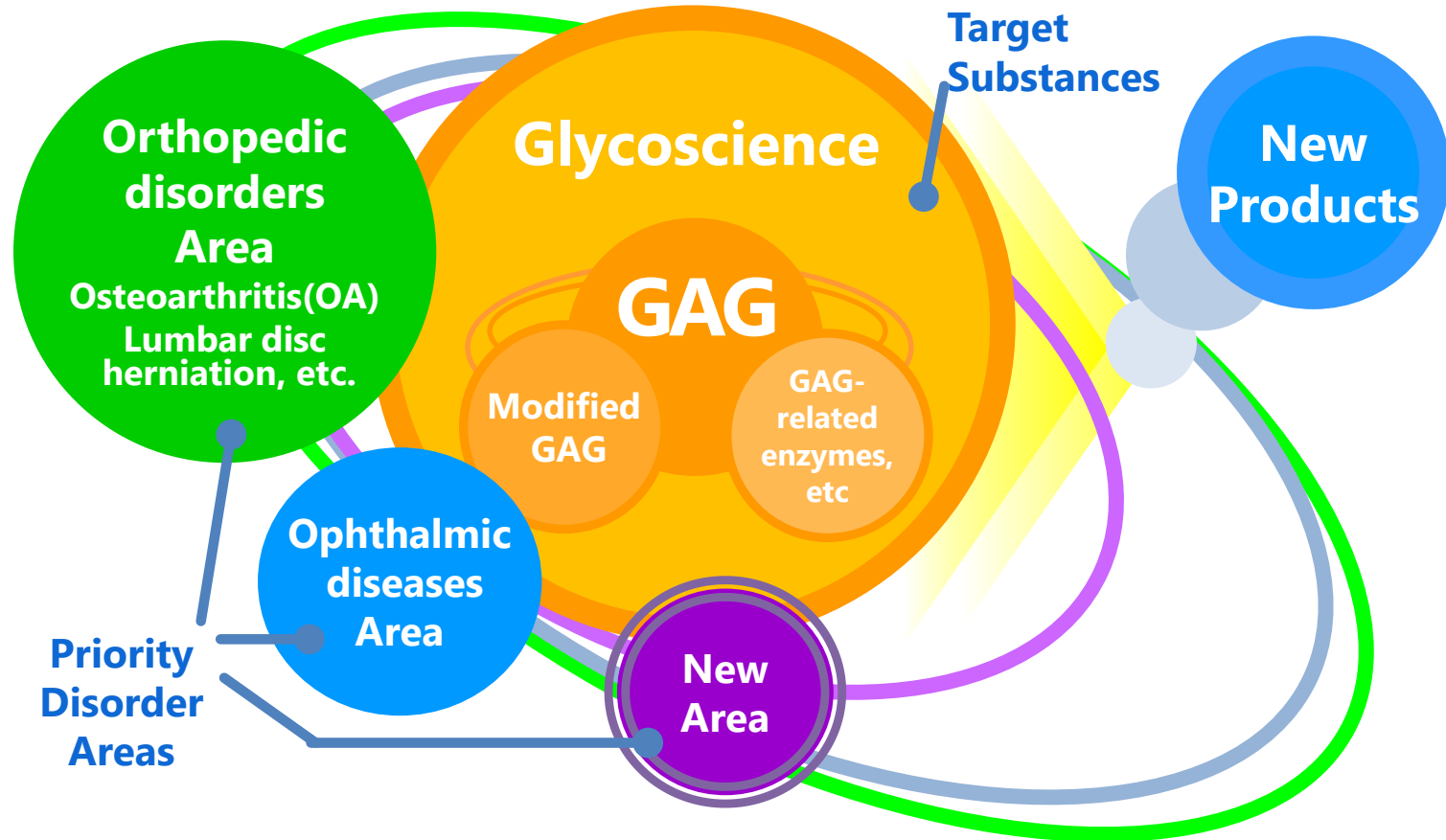


■ Trend in Capital Investments (Millions of Yen)

FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021 (Forecast)
7,222	2,095	1,975	1,173	1,591	1,310	2,109	2,127	3,000

Basic Policy on Research and Development

Continue Our R&D policy to make the most of our technology and knowledge



GAG: Glycosaminoglycans (One of the constituents of complex carbohydrates)

Strengthening and Making Use of The Company's Own GAG-related Core Technology

Accelerating R&D by leveraging our innovative drug discovery technology

1. Developing drugs through modification, processing, and bioactivity

- GAG **photo-cross-linking and chemical-cross-linking**
- **Physio-chemical functions** including viscoelasticity and retention
- Bioactive substances (degrading enzymes)

Gel-One
HERNICORE
SI-449

2. Applying drug delivery systems (DDS)

- **Support and delivery of** active pharmaceutical ingredients
- Expanding the lineup of supportable and deliverable drugs (low molecular→medium molecular→cells)
- DDS technology highly adaptable to general use (establishing drug discovery techniques)

SI-613
SI-722

GAG

New Drugs

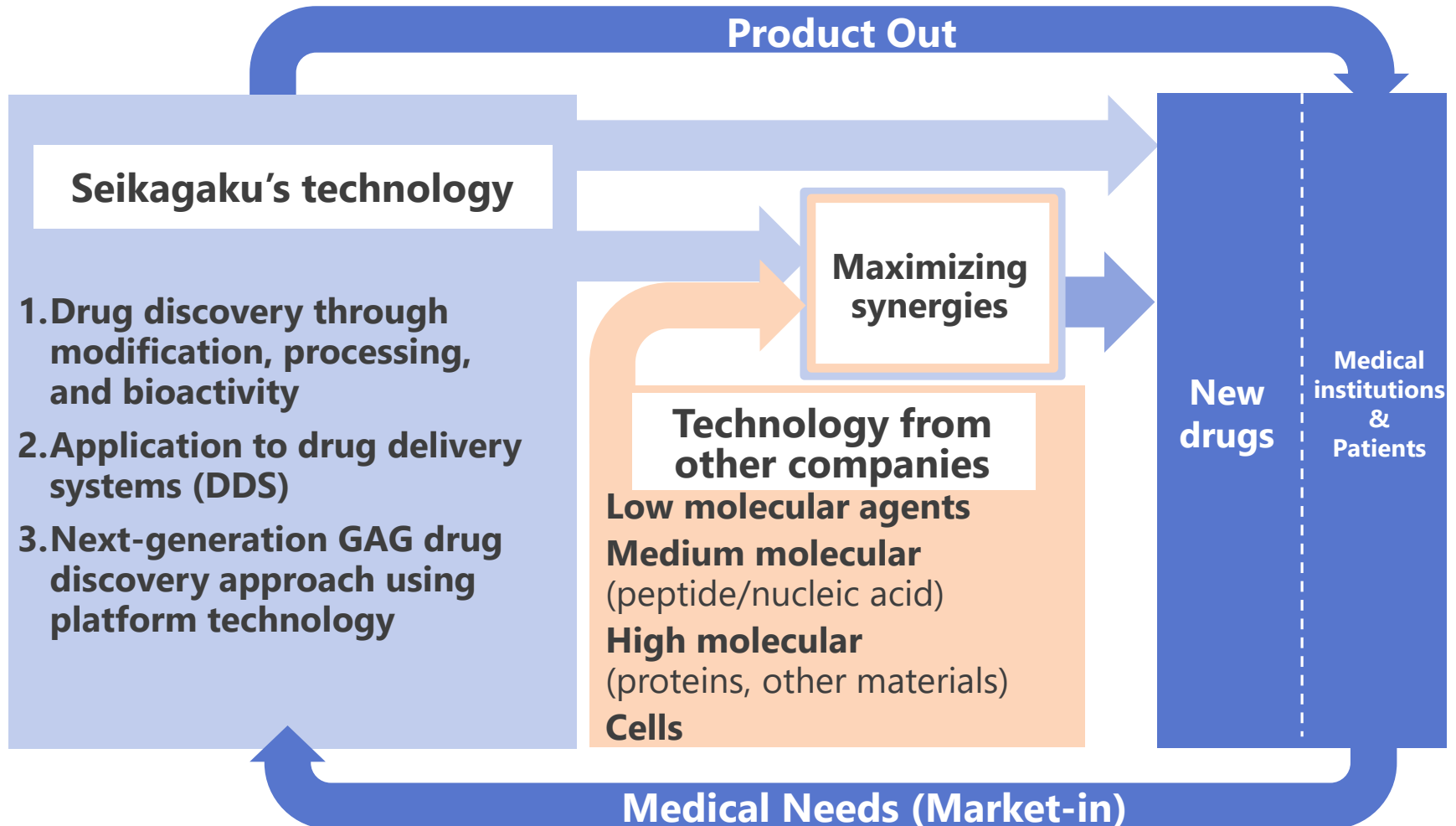
3. Next-generation GAG drug discovery approach using platform technology

- Conversion from natural GAG **to fermented GAG**
- Expanding the field of sugar chain drug discovery Applying to glycobiology

SI-613
SI-614

Accelerating Innovative Drug Discovery Using The Open Innovation Strategy

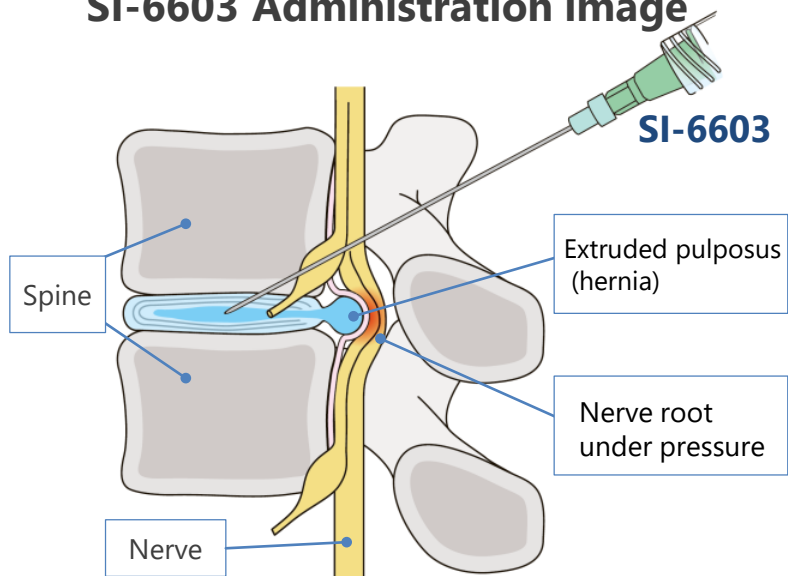
Speeding up and augmenting the number of projects through a drug discovery approach using Open Innovation



SI-6603 (Treatment for Lumbar Disc Herniation)

Single injection expected to relieve the pain of lumbar disc herniation by decreasing intradiscal pressure and then reducing the pressure on nerve root

SI-6603 Administration image



Expected Features

- ▶ Relieving symptoms by decreasing intradiscal pressure and reducing the pressure on the nerve root by single injection
- ▶ It can be administered without general anesthesia, and the administration can be less invasive for the patient compared to surgical technique because of direct intradiscal injection

<SI-6603 summary>

Dev. Code : SI-6603 Generic name : Condoliase

Indication : Lumbar disc herniation

Method of use : Injection into lumbar disc (under X-ray observation)

Estimated U.S. patients : New patients with lumbar disc herniation: 3 to 5 million per year
(Seikagaku estimates)

Result for SI-6603 Phase III Clinical Study in the U.S.

Significant improvement in the primary endpoint was demonstrated in Phase III study of Japan but Phase III study in the U.S. did not meet its primary endpoint of pain improvement

Pharmacological effect (Objective indicator)

- Statistically significant decrease in the intervertebral disc and herniation volume assessed with MRI: **Confirmed pharmacological effect of SI-6603**

Evaluation of safety

- No major concern such as adverse reactions was observed: **Confirmed safety of SI-6603**

Improvement at alleviation of leg pain (Subjective indicator)

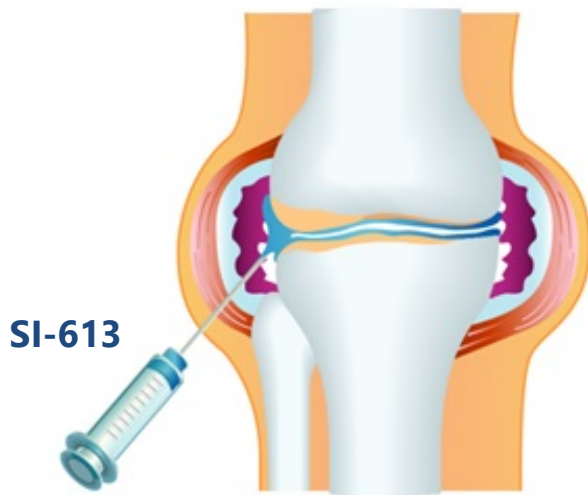
- Statistically significant improvement of leg pain at 13 weeks by VAS was not demonstrated
- ▶ ① There is a guideline for diagnostic and pathology of lumbar disc herniation in Japan, however there is no widely used guideline in the U.S. Therefore, there is possibility that some patients out of Japanese guideline were included in the clinical trial in the U.S.
- ② There is possibility that some factors such as complications biased assessment of leg pain

Increasing the certainty of success for the additional study by reflecting the knowledge and perception obtained from result of the study

SI-613 (Treatment of Osteoarthritis/Enthesopathy)

Aiming for rapid and sustained improvement of pain and other clinical manifestations associated with osteoarthritis and Enthesopathy

SI-613 Administration image



Expected Features

- ▶ **Hyaluronic acid and diclofenac (an anti-inflammatory drug) are bound in a formulation designed for gradual release of diclofenac over a fixed period of time**
Sustained improvement of clinical manifestations, including pain, for 28 days from the day after administration shown in a clinical trial of osteoarthritis patients
- ▶ **The first pharmaceutical suitable for treatment of osteoarthritis in the hip joint using a hyaluronic acid formulation**
- ▶ **Directly administered to the affected area as an injectable treatment, resulting in low systemic exposure to diclofenac**
Low risk of systemic side effects

<SI-613 summary>

Dev. code : SI-613 Generic name : Diclofenac Etalhyaluronate Sodium

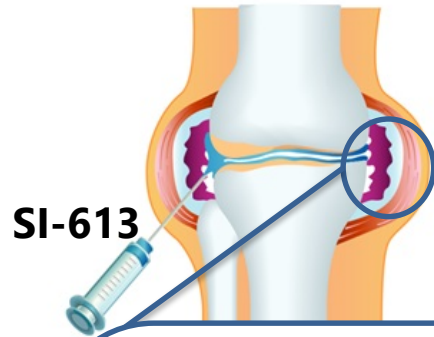
Indication : Osteoarthritis/Enthesopathy

Method of use : Injection into joint cavity

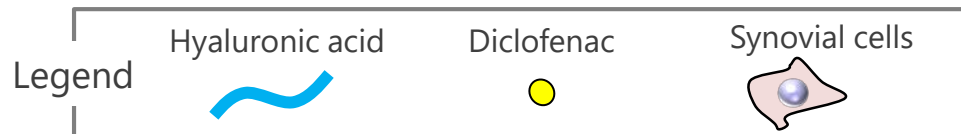
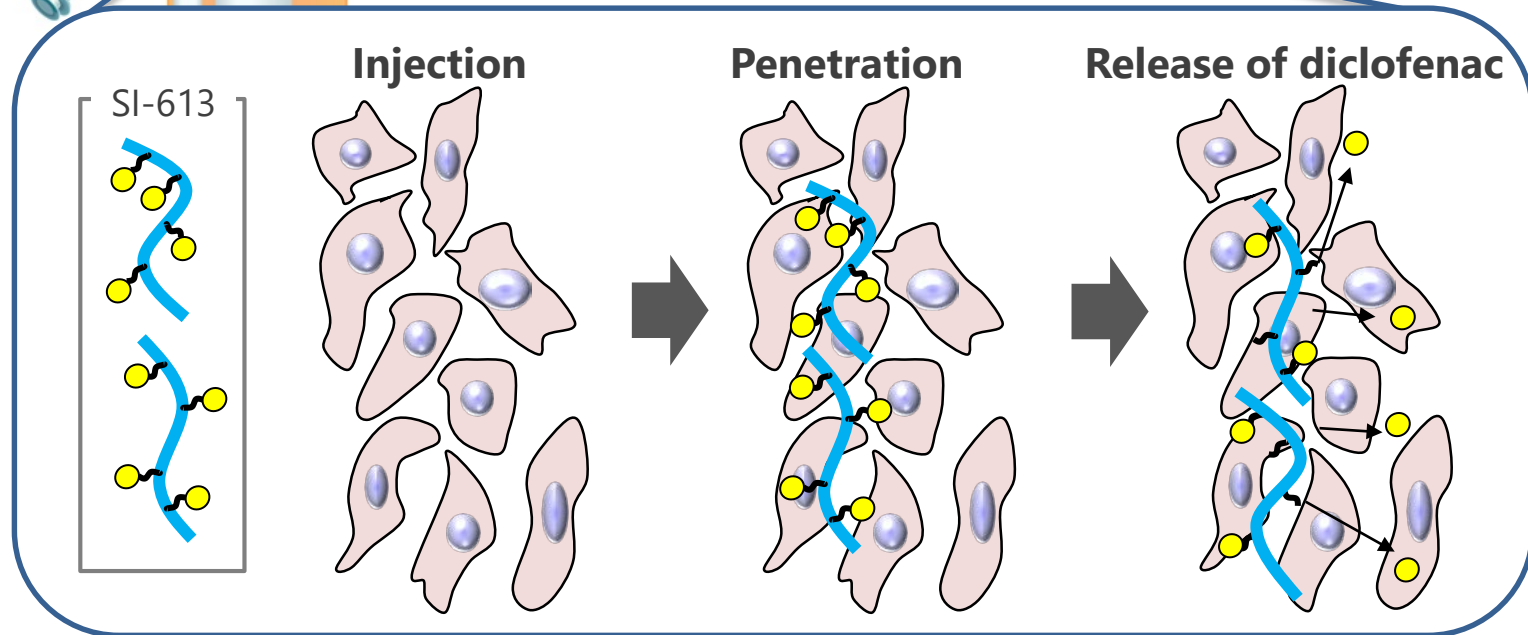
Estimated patients : 24 million (U.S.) / 47 million (China) / 3.7 million (South Korea)

(Seikagaku estimates)

Sustained Release of Diclofenac in SI-613

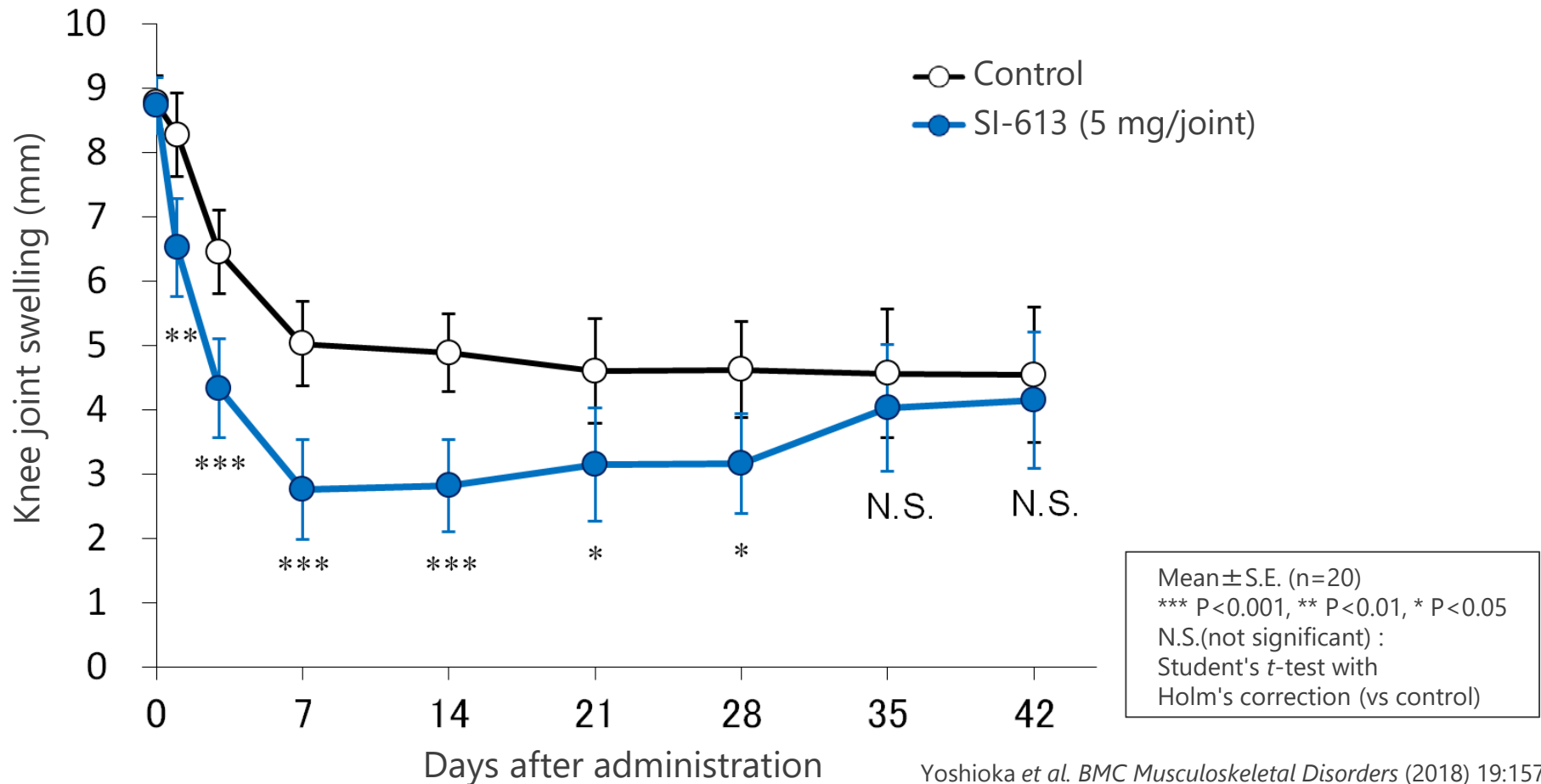


SI-613 (substance name: Diclofenac Etalhyaluronate Sodium) is thought to penetrate the synovial membrane (connective tissue within the articular capsule) and gradually release diclofenac



Results of Non-clinical Study for SI-613

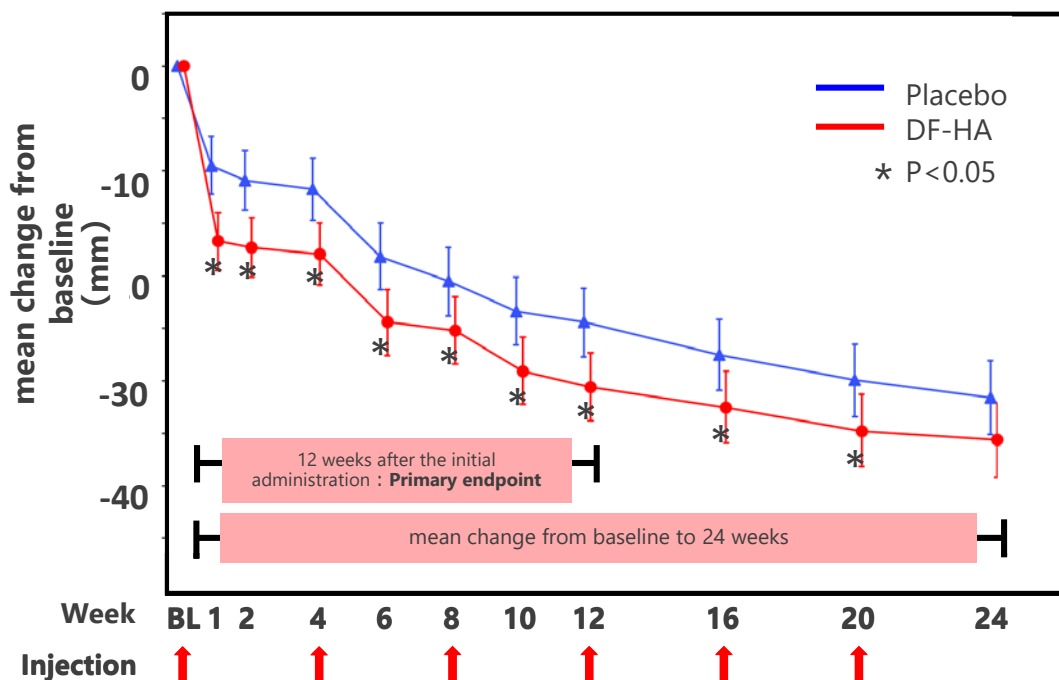
Results of non-clinical study : Anti-inflammatory effect of SI-613 on antigen-induced arthritis in rabbits



Yoshioka et al. *BMC Musculoskeletal Disorders* (2018) 19:157
<https://doi.org/10.1186/s12891-018-2077-8>

SI-613 (Treatment of Osteoarthritis)

On the WOMAC A (pain) score, the primary endpoint, a statistically significant difference is recognized between the placebo group



	Placebo (n=220)	DF-HA (n=218*)
mean change from baseline to 12 weeks : Primary endpoint		
mean change from baseline	-17.1 [-19.8, -14.4]	-23.2 [-25.9, -20.4]
difference	-6.1 [-9.4, -2.8]	
P value	<0.001	
mean change from baseline to 24 weeks		
mean change from baseline	-20.8 [-23.6, -18.0]	-26.4 [-29.2, -23.6]
difference	-5.6 [-9.1, -2.2]	
P value	0.001	

least square mean [The 95% confidence interval]

Mixed model for repeated measures analysis

*FAS : Except for two cases with no effectiveness results after administration

※ DF-HA : Diclofenac Etalhyaluronate Sodium (SI-613)

Source : The 93rd Annual Meeting of the Japanese Orthopaedic Association

The phase III study of Diclofenac etalhyaluronate (ONO-5704/SI-613) in osteoarthritis of the knee

SI-613 (Treatment of Osteoarthritis/Enthesopathy)

Academic conference presentation of the results of a phase III study in Japan of SI-613 in patients with knee osteoarthritis

Outline of Conference Presentation

The results of a phase III study in Japan of SI-613 in patients with knee osteoarthritis were presented at the 93rd Annual Meeting of the Japanese Orthopaedic Association, an online meeting held from June 11 to August 31, 2020.

Abstract Number: 3-12-15

The phase III study of Diclofenac Etalhyaluronate Sodium(ONO-5704/SI-613) in osteoarthritis of the knee

Conducted as a randomized, double-blind, placebo-controlled, parallel-group comparative study in 440 patients with knee osteoarthritis to evaluate efficacy and safety

Primary endpoint: WOMAC pain score

Statistically significant difference found versus the placebo group in difference in mean change in WOMAC score from baseline to 12 weeks after initial administration

Main Secondary endpoints: WOMAC stiffness score and physical function score

Statistically significant difference found versus the placebo group in difference in mean change in WOMAC scores from baseline to 12 weeks after initial administration

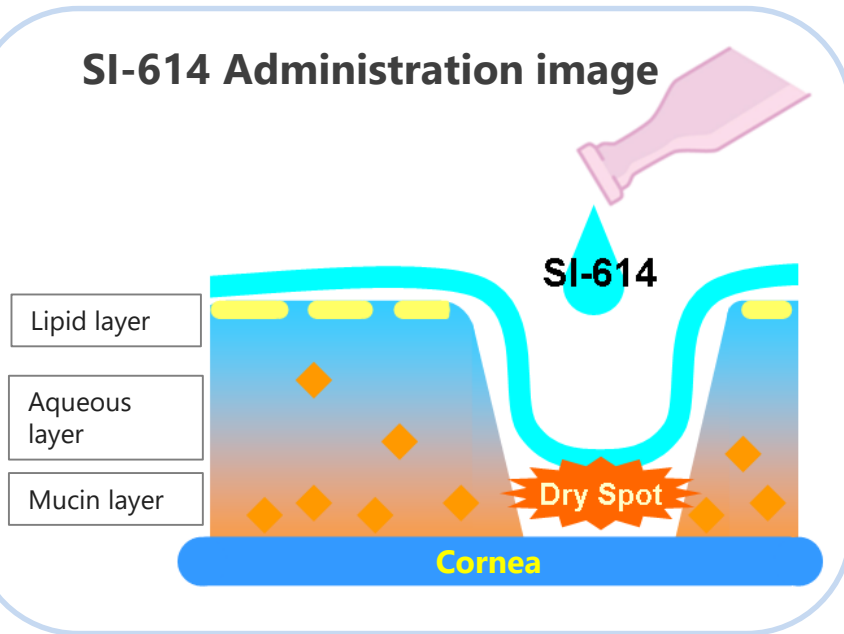
Safety evaluation:

No difference in frequency of adverse events and no clinically evident problems found

SI-614 (Dry Eye)

Aimed at improvement of symptoms of dry eye by protecting the ocular surface and promoting corneal epithelial wound healing

SI-614 Administration image



Development status

▶ U.S. : P II/III

- January 2015: Phase II/III clinical study completed
- Plan to conduct a PIII study after a sales partner has been decided

infection Promising features

- ▶ SI-614 Improves symptoms of dry eye by protecting the ocular surface and promoting corneal epithelial wound healing
- ▶ Dry Eye is a multifactorial disease, and Seikagaku aims to provide a treatment option based on a new mechanism unavailable from existing products

<SI-614 summary>

Dev. Code : SI-614

Generic name : Modified Hyaluronate

Product name : Dry eye

Formulation : Ophthalmic solution

Estimated U.S. patients : 4.9 million (Seikagaku estimates)

Clinical Study Information

Development code/ Indication	Develop- ment Location	Clinical Study Title (Study ID)	Target Enroll- ment	Estimated Period	Primary End Point (Primary Follow-up period)
SI-6603 Lumbar Disk Herniation	U.S.	Phase III additional study (NCT03607838)	320	May. 2018 – Nov. 2022	Leg pain (13 weeks)
SI-613-ETP Enthesopathy	Japan	Late-stage Phase II clinical study (JapicCTI-173758)	240	Oct. 2017 – Oct. 2018	Pain in motion (4 weeks)
SI-613 Knee Osteoarthritis	U.S.	Phase II clinical study (NCT03209362)	80	Oct. 2017 – Nov. 2018	WOMAC(Knee pain) (12 weeks)
SI-614 Dry eye	U.S.	Phase II / III clinical study (NCT02205840)	240	Jul. 2014 – Nov. 2014	Corneal staining score, Symptom score (28 days)
SI-722 Interstitial cystitis and bladder pain syndrome	U.S.	Phase I / II clinical study (NCT04208087)	32	Mar. 2020 – Jan. 2021	Maximum observed plasma concentration
SI-449 Adhesion Barrier	Japan	Pivotal study (JapicCTI-205343)	130	Jun. 2020 – Dec. 2022	efficacy

Note: The table shows data registered (or planned to be registered) on clinical trial information websites. The information is updated from time to time. Refer to the websites for details and the latest information. (The websites can be accessed from the trial ID links.)

- Japan Pharmaceutical Information Center(JAPIC) http://www.clinicaltrials.jp/user/cteSearch_e.jsp
- University hospital Medical Information Network (UMIN) Center <http://www.umin.ac.jp/ctr/index.htm>
- ClinicalTrials.gov <https://clinicaltrials.gov/ct2/search>

Note: Actual enrollments or trial periods may differ from targets and plans due to various factors.

Contract Status by R&D Theme

Planned receipt of milestone royalties in accordance with future progress in development and marketing

Development Code Indication	Development Location	Sales Partner	Total Amount of Milestone Royalties (of which, in upfront payment)
SI-6603 Lumbar Disk Herniation	U.S.	Ferring Pharmaceuticals (Switzerland)	Max. US \$95 million (US \$5 million)
SI-613 Japan: Osteoarthritis U.S. : Knee Osteoarthritis	Japan	Ono Pharmaceutical Co., Ltd.	Max. ¥12.0 billion (¥2.0 billion)
	U.S.	Searching	—
	China	Eisai Co., Ltd.	—
	Korea	Eisai Co., Ltd.	—
SI-613-ETP Enthesopathy	Japan	Ono Pharmaceutical Co., Ltd.	*included in the above
SI-614 Dry eye	U.S.	Searching	—
SI-722 Interstitial cystitis	U.S.	—	—
SI-449 Adhesion Barrier	Japan	—	—

Outline of Acquisition

Dalton, a Canadian CDMO, becomes a subsidiary Acquiring a pharmaceuticals manufacturing base compliant with US/Canadian GMP

Outline of acquisition

- Name : Dalton Chemical Laboratories, Inc.
- Acquisition cost : Up to CAD 41 million
- Acquisition method : Acquired all issued shares

Dalton Chemical Laboratories, Inc.

- Location : Toronto, Ontario Province, Canada
- Established : 1986
- Business description :
Contract manufacturing services (CDMO*), including the manufacturing of chemosynthesis products and active pharmaceutical ingredients (API) and API process development for pharmaceutical companies
- Employee number : 132 (2021.3)

* CDMO : Contract Development and Manufacturing Organization

A business that supplies comprehensive services in drug development and manufacturing to pharmaceutical companies, including contract drug manufacturing, pharmaceutical formulation planning at the development stage, manufacturing of investigational drugs, and optimization of manufacturing conditions.



Exterior of the Dalton offices

Synergistic effects of making Dalton a subsidiary

Accelerating new drug discovery and advancing production optimization and efficiency

Seikagaku

Specialized in new drug development & manufacturing

- Glycoscience R&D ability
- Final formulation technology and know-how in pharmaceuticals and medical devices

Dalton

Technology prowess related to CDMO

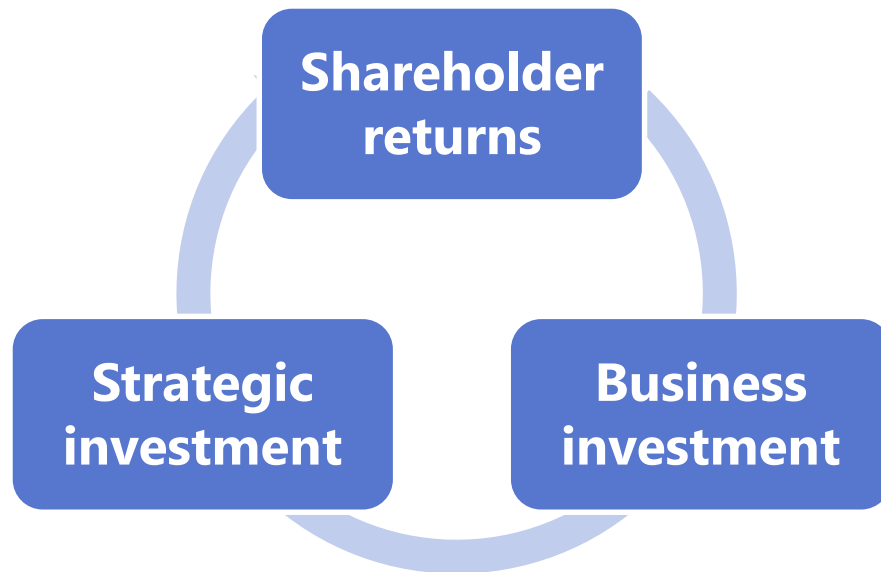
- Advanced technical skills in chemosynthesis
- Know-how in investigational drug manufacturing and process development
- Overseas GMP-certified

Synergies between the two companies

- **Seikagaku**
 - Accelerating drug discovery (applying Dalton technology)
 - In-house development of chemosynthesis products used in R&D, etc.
 - Production optimization and efficiency improvements
- **Dalton**
 - Business expansion by contracting from Seikagaku
 - Developing a final formulation business

Basic policy on profit distributions

Investing for sustainable profit growth and raising corporate value, implement business performance-linked dividends



Shareholder returns

- Aiming for a 50% dividend payout after considering business profits etc.
- Examining the purchase of company treasury stock when appropriate

Business investment

Investing efficiently in R&D and production facilities etc. for creating new value

Strategic investment

Carrying out initiatives for strategic investments with prospects for future growth and synergy effects

* Dividend plan: FY2019-¥26, FY2020 & 2021-based on dividend policy described here

Seikagaku's vision

Our vision

A company that is valued by the world through its innovative drug discovery

Core values (motto)

Creativity, Fairness, Dreams and Passion

Creed

We create safe and useful products for human well-being with basic research based on glycoscience.

Guidelines for Our Activities

- We create a corporate environment of mutual trust and communication using individual abilities.
- We create innovative and useful products through in-depth cooperation between industrial and academic circles.
- We assure the highest quality and safety of our products.
- We enhance interaction with society by establishing genuine trust. Through these efforts, Seikagaku will strive to become a sound and socially responsible company that protects the natural environment and improves quality of life.

Mission statement

"Glycoscience for human well-being"

Corporate slogan of the new mid-term management plan

"Innovative Thinking"
Creating value based on innovative thinking

Special Profile

1

Specialization in Glycoscience

- Niche field, market not big enough for the major pharmaceutical companies to penetrate
- Focusing on this field more than **70 years**

2

State-of-the-art technology related to GAG

- Drug discovery expertise using **modified-GAG, GAG-related enzymes**, etc.
- **Extraction, Purification, Fermentation**, etc. technology to manufacture GAG related products

3

Unique business model

- Concentration on **R&D** and **manufacturing**
- R&D staff comprising **one-third** of our total employees
- Allocation of **25% to 30%** of net sales to R&D investment

GAG: Glycosaminoglycans (One of the constituents of complex carbohydrates)

Our Business Segment

Pharmaceutical Business 74.9%

Ophthalmic Surgical Aids



Bulk Products



Domestic
Pharmaceuticals
→ 43.4%

Joint Function
Improving Agents



Bulk Products/
CDMO
→ 6.7%

Overseas
Pharmaceuticals
→ 24.8%



Endotoxin-detecting
reagents
(used mainly for quality control
of pharmaceuticals and medical
devices)



LAL Business 25.1%

Net Sales
27,662million
(FY2020 Results)

Main Hyaluronic Acid (HA) Products

ARTZ[®] Joint function improving agent by multiple injections

- The first HA joint function improving agent in the world
- Main distributors:
 - Kaken Pharmaceutical (Japan): ARTZ
 - Bioventus (U.S.): SUPARTZ FX
 - Kunming Baker Norton Pharmaceutical (China): ARTZ



Gel-One[®] Intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis

- Requires only 3ml to be as effective as multiple injections
- Full-scale sales since August 2012
- Distributor: Zimmer (U.S.)



■ Cautionary Notes

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