

Financial Results for the 1st Quarter of Fiscal Year 2020

(April 1, 2020 – June 30, 2020)



SEIKAGAKU CORPORATION

(TSE:4548)

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< 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 FY2020

(Millions of Yen)	1Q FY2020 Results	Year-on-Year	
		Change	% of Change
Net sales	6,972	-676	-8.8%
Operating Income	305	-658	-68.3%
Ordinary Income	610	-641	-51.2%
Net Income	529	-450	-46.0%
R&D Expenses (Ratio to net sales)	1,615 (23.2%)	+326 (+6.4pt)	+25.4%
Average Exchange Rate (1US\$)	¥107.62	¥-2.28	

	1Q FY2020 Results	1Q FY2019 Results
Net Income per Share	¥9.39	¥17.38
SKK EBITDA*	557million yen	1,692million yen

* SKK EBITDA : A profit indicator that adds depreciation and royalty income to operating income

Net sales by Business Segment (1Q of FY2020)

(Millions of Yen)	1Q FY2020 Results	Year-on-Year	% of Change
Net sales	6,972	-676	-8.8%
Pharmaceuticals	5,128	-808	-13.6%
Domestic Pharmaceuticals	3,694	+4	+0.1%
Overseas Pharmaceuticals	1,138	-817	-41.8%
Bulk Products	295	+4	+1.7%
LAL Business	1,844	+131	+7.7%
(Overseas sales)	2,710	-654	-19.5%

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

Domestic Pharmaceuticals

▶ ARTZ (Joint-function improving agent)

- Market share up (+0.6%), but deliveries to medical institutions down (-10.9%) on overall market contraction (-11.9%), reflecting a decrease in outpatient services due to the impact of the COVID-19 infection
- Although shipments were up, Seikagaku sales down due to NHI drug price decreases

▶ OPEGAN series (Ophthalmic viscoelastic devices)

- Despite market contraction (-13.1%), reflecting less surgeries due to the impact of the COVID-19 infection, deliveries to medical institutions up (+1.0%) due to the impact of shipment adjustments for competing products
- Seikagaku sales up, with higher shipments compensating for NHI drug price decreases

▶ MucoUp

(Submucosal injection agent for endoscopic surgery)

- Seikagaku sales down due to a sales offensive for a competing product and a decrease in the number of endoscopic surgeries

▶ HERNICORE

(Treatment for lumbar disc herniation)

- Deliveries to medical institutions and Seikagaku sales increased due to steady growth in the number of new user facilities, despite the impact of a decrease in outpatient services

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

Overseas Pharmaceuticals

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

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

- Local sales volume down (approx. -15.0%) due to the lockdown of urban areas and postponement of non-urgent and non-emergency medical procedures accompanying the spread of the COVID-19 infection
- Seikagaku sales down, reflecting the decrease in local sales volume
- Local sales on a recovery trend since mid-May

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

- Local sales volume down sharply due to a continuing trend in the U.S. market toward preference for products that require a low number of injections, coupled with the impact of the COVID-19 infection
- Seikagaku sales also down, reflecting the decrease in local sales volume

► ARTZ in China (Multiple injection)

- Despite early resumption of economic activity in China compared to other countries, local sales volume and the Company's sales of ARTZ decreased, reflecting the impact of continued curtailment of outpatient services in some areas even after April

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(Overseas sales)	2,710	-654	-19.5%

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

Bulk Products

The Company's sales were at the prior-year level, despite intensification of competition for hyaluronic acid

*Bulk Products : High-purity, high-quality hyaluronic acid and chondroitin sulfate for pharmaceuticals

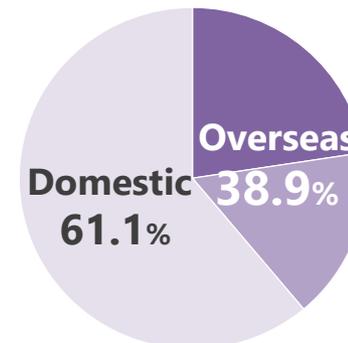
LAL Business

*Foreign exchange impact on LAL Business: approx. -20million yen

- Seikagaku sales up on growth in overseas sales of Bacterial Endotoxin Testing (BET) and Clinical Diagnostic (Fungitell) reagents
- Impact of the COVID-19 infection limited at this time

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

Overseas Sales Ratio



Year-on-Year:
-5.1pt

Income for 1Q of FY2020 (Year-on-Year)

(Millions of Yen)	1Q FY2020 Results	Year-on-Year	% of Change
Net sales	6,972	-676	-8.8%
Cost of Sales (Cost of Sales ratio)	3,485 (50.0%)	-110 (+3.0pt)	-3.1%
SGA expenses	3,180	+92	+3.0%
R&D Expenses (to Net sales ratio)	1,615 (23.2%)	+326 (+6.4pt)	+25.4%
Operating Income (to Net sales ratio)	305 (4.4%)	-658 (-8.2pt)	-68.3%
Ordinary Income	610	-641	-51.2%
Net Income	529	-450	-46.0%
Depreciation	161	-567	-77.9%

Operating Income

Cost of Sales Ratio (+3.0pt) :

- Increase reflecting NHI drug price reductions in Japan, despite a substantial decrease in depreciation

* Impairment loss on property, plant and equipment related to the pharmaceuticals business recognized in FY2019

SGA Expenses (+92) :

- Increase in R&D expenses partly attributable to costs related to measures to promote subject enrollment for an additional clinical study underway in the U.S. for SI-6603 (+326)
- Decrease in operating expenses (-170)

Net Income

Non-operating Income / Expenses (+17) :

- Decrease in gain on sale of investment securities (-191)
- Increase in royalty income (+90)
- Decrease in foreign exchange losses (+90)

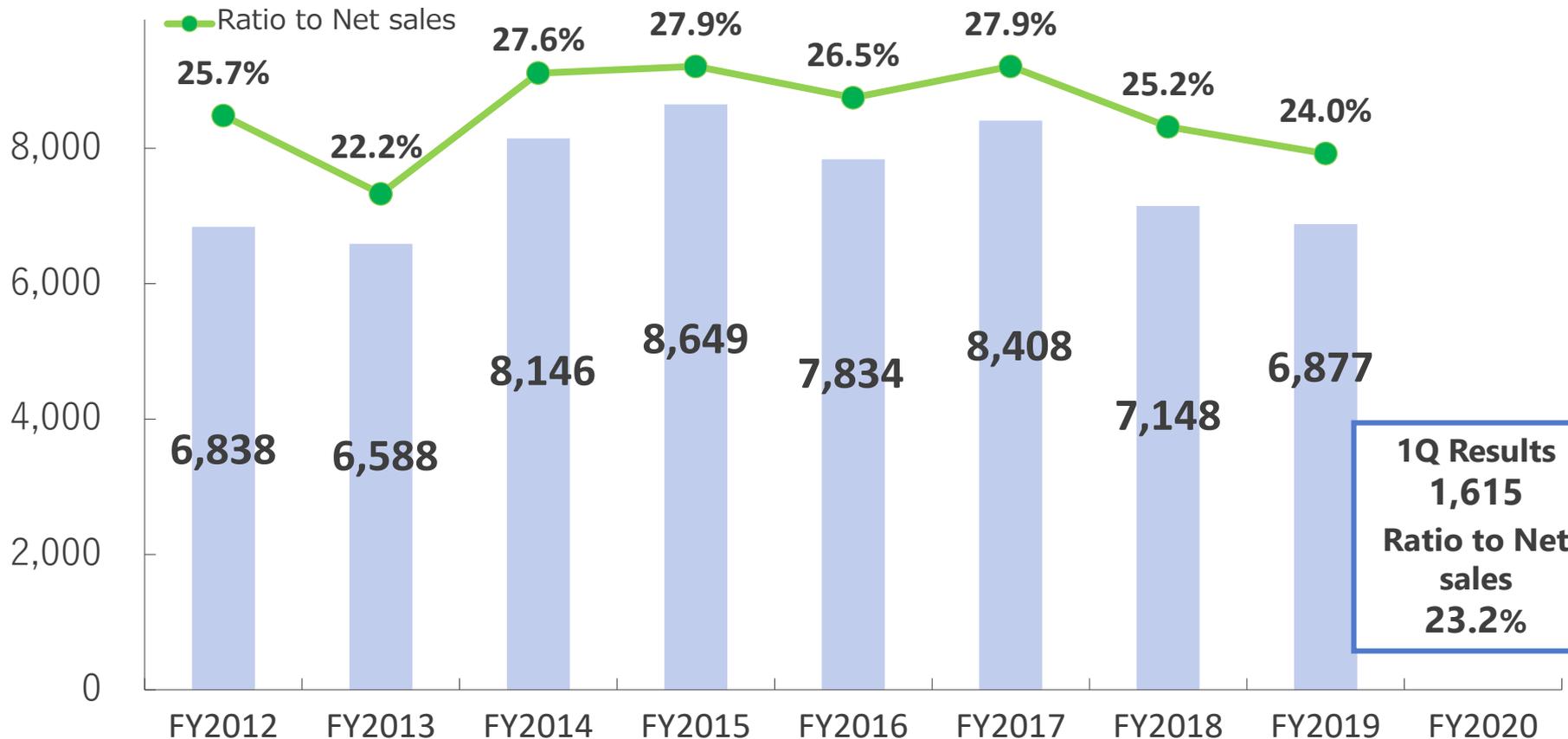
Trend in R&D Expenses

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

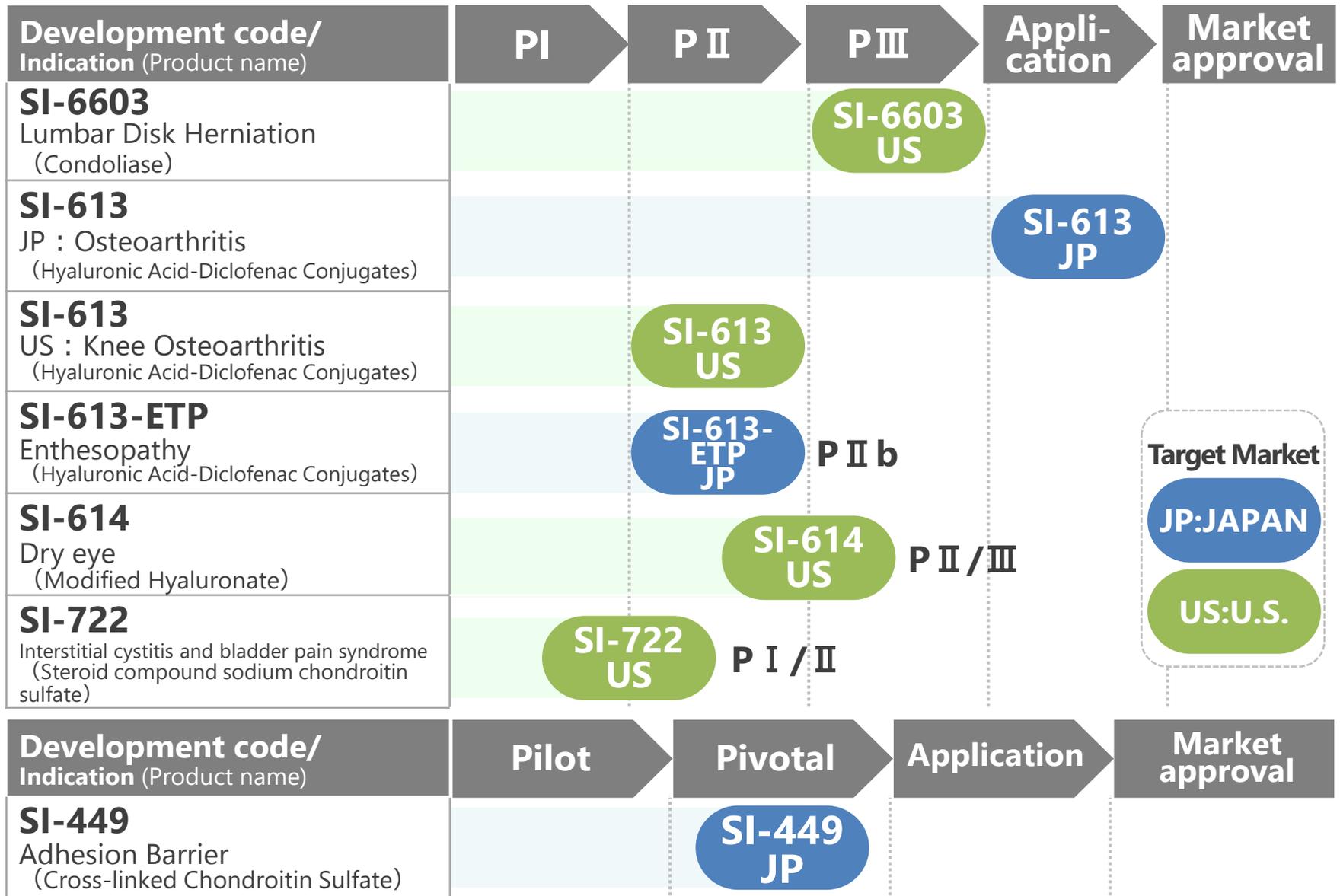
(Millions of Yen)

R&D Expenses

Ratio to Net sales



Pipeline List (Research and Development themes)



SI-6603 (Treatment for Lumbar Disc Herniation)

Although a delay in the progress of the study due to the impact of the spread of COVID-19 is anticipated, implementing measures to promote subject enrollment

Development status

▶ **Additional Phase III study in the U.S.** Initiated February 2018.

Extending enrollment by two years, aiming for November 2022 completion

⇒ **Delay of approx. six months anticipated due to the spread of COVID-19**
(as of June 2020)

- **Impacted by discontinuation of the study at some medical institutions and subjects postponing hospital visits**
- **Possibility of a further delay if a lockdown is ordered in a state where many trial sites are located**

⇒ **Proceeding with the study while placing the highest priority on the situation at medical institutions and prevention of infection of patients and medical personnel**

Measures to promote enrollment

- Increase number of subjects
 - Advertising suited to treatment facility requirements
 - Strengthen coordination with medical institutions and increase patient introductions
 - Relax enrollment standards
- Increase trial facilities
 - Link-up with support vendors specializing in facility selection to increase number of facilities

SI-613 (Treatment of Osteoarthritis/Enthesopathy)

Responding to NDA review in Japan (osteoarthritis) Entered into an agreement with Eisai for co-development and a marketing alliance in China

SI-613 (osteoarthritis) Japan

- ▶ **Submitted a new drug application (“NDA”) for manufacturing and marketing approval in Japan, for the treatment of osteoarthritis in January 2020**

NDA based on the results of the following three Phase III clinical studies conducted in Japan

1) **Knee confirmatory study :**

Demonstrated statistically significant improvement in a primary endpoint compared with a placebo

2) **Study for four sites (four joint sites: shoulder, elbow, hip, and ankle):**

Met a primary endpoint in patients with osteoarthritis of the hip joint and ankle joint

3) **Long-term administration study:**

No major safety concerns identified in any osteoarthritis patients

- ▶ **Results of a Phase III clinical study in patients with knee osteoarthritis presented at the 93rd Annual Meeting of The Japanese Orthopaedic Association (held online from June 11 to August 31, 2020)**

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-ETP (enthesopathy) Japan

- ▶ Analysis of Phase IIb clinical study results is complete
Next action is under consideration with Ono Pharmaceutical

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 (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

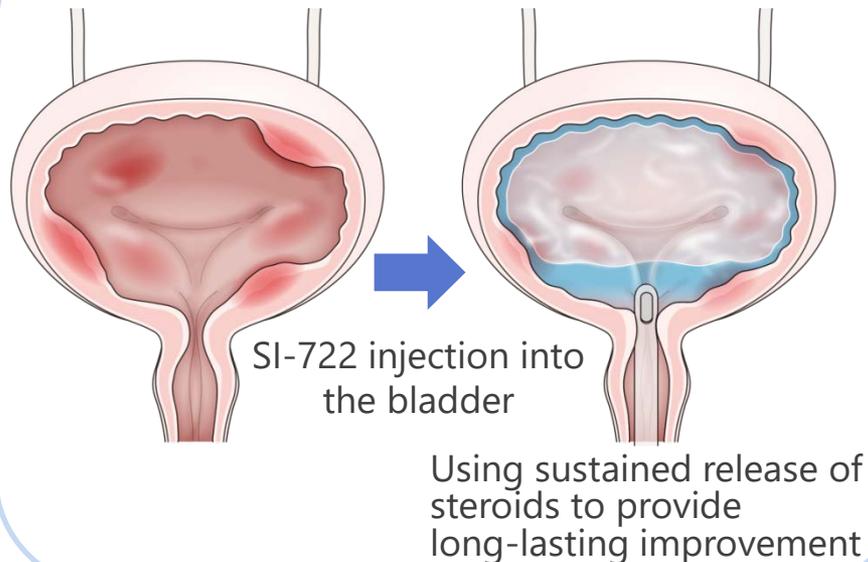
Safety evaluation:

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

SI-722 (Treatment of Interstitial cystitis and bladder pain syndrome)

Although a delay of approx. four months is expected due to the impact of the spread of COVID-19, the operational status of trial sites is recovering

SI-722 Administration image



Development status

- ▶ **U.S. Phase I/II / Starting November 2019**
 - **Started subject administration in March 2020**
- ⇒ **Delay of approx. four months expected (as of June 2020)**
Further adverse impact on subject enrollment anticipated if another lockdown is ordered in a state where trial sites are located
- ⇒ **Proceeding with the trials while placing the highest priority on prevention of infection**

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

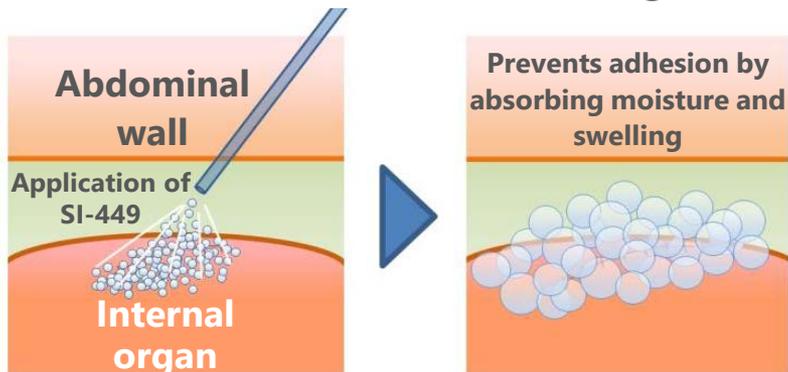
<SI-722 summary>

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)

Confirming useful effects in pilot study Starting pivotal study in May 2020

SI-449 Administration image



Development status

- ▶ Japan pivotal study / Starting May 2020
 - Evaluated for effectiveness, safety, and usability
 - **Proceeding with preparations for the start of subject enrollment while placing the highest priority on preventing COVID-19 infection**
- ▶ 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: ¥13 billion, Global: ¥100 billion (Seikagaku estimates)

Basic Policy on Profit Distribution

Investing for substantial profit growth and raising corporate value, implementing business performance-linked dividends

Shareholder returns

- Setting a basic policy on linking dividends to financial performance
FY2020 & 2021 : in consideration of business profits, it aims for a dividend payout ratio of 50%
- 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

	FY2015	FY2016	FY2017	FY2018	FY2019
Net Income per share	¥45.39	¥31.55	¥69.30	¥39.76	¥-192.15
Annual Total Dividend	¥26.00	¥31.00 [※]	¥26.00	¥26.00	¥26.00
Dividend Payout Ratio	57.3%	98.3%	37.5%	65.4%	—

Appendix

Response to the COVID-19 Infections

Measures to prioritize assurance of safety for employees and related parties

Production

- ▶ Establishing minimum operations to ensure production continuity at the Kurihama and Takahagi plants to bear complete responsibility for stable supply
- ▶ Ensuring sufficient inventories of raw materials, other materials, and hygienic materials; request made for standing purchasing arrangements
- ▶ Securing appropriate product inventories given the market trends
- ▶ Production continuity at overseas subsidiary

R&D

- ▶ In Japan and the US, clinical trials at some medical institutions were interrupted and subjects have missed their clinic visits, creating delays in the trials' progress.
- ▶ Infection prevention for patients and medical personnel in clinical trials are considered sufficient, and trials are being conducted to the extent possible according to the wishes of the trial facilities
- ▶ Once the spread of infection settles down, attention will focus on recruitment of subjects, and the test plan will be re-evaluated

Seikagaku's actions

- ▶ Launch an emergency headquarters for the response, develop infection control measures for employees and their families; for business continuity, build out a system in which essential work can be executed
- ▶ Supply masks and other PPE to medical facilities

Forecasts for Fiscal 2020

Fiscal 2020 financial forecasts

Continuing to carefully examine the impact of COVID-19 infection on financial results, and will promptly make an announcement once it becomes possible to disclose the earning forecast

Business impacted by COVID-19 infection novel coronavirus

Pharmaceutical Business

Domestic pharmaceuticals

- ▶ Forecasting a decline in deliveries to medical institutions due to curtailment of outpatient services and recommendations to delay surgeries

Overseas pharmaceuticals

- ▶ Forecasting a decrease in local sales because of guidance to postpone non-urgent medical procedures

LAL Business

- ▶ No significant impact has emerged at this time, but if voluntary restraint on economic activity is prolonged, then business may be affected

R&D

- ▶ Delays in progress of clinical studies may affect the timing of recognition of R&D expenses

Other Assumptions

- ▶ NHI drug price reduction (from April 2020) ARTZ -13.1%, OPEGAN -1.7%
- ▶ Financial results of Dalton, now a consolidated subsidiary, to be reflected in the Pharmaceutical Business segment

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

ARTZ (Joint-function improving agent)

● FY2019 Results

- Market share increases as successful measures to acquire new user facilities see success
- Market shrinks and deliveries to medical institutions undergo a sales slump as applications expand for externally and internally administered medicines and COVID-19 infection exerts an impact

growth rate : -0.7%
 Market growth rate : -1.8%
 Market share : 59.9%
 (+0.7pt)

▶ FY2020 Measures

- Continuing to aim for share expansion due to switching from competing products

OPEGAN (Ophthalmic viscoelastic devices) ※including SHELLGAN

● FY2019 Results

- Aggressively furnishing product feature information
- Taking share from competing products and shipment interruptions for other companies' products leads to a temporary increase in deliveries to medical institutions

growth rate : +21.4%
 Market growth rate : +13.4%
 Market share : 47.1%
 (+3.1pt)

▶ FY2020 Measures

- Strengthening measures to induce switching from competing products and aiming to maintain accounts acquired in fiscal 2019

HERNICORE (Treatment for lumbar disc herniation)

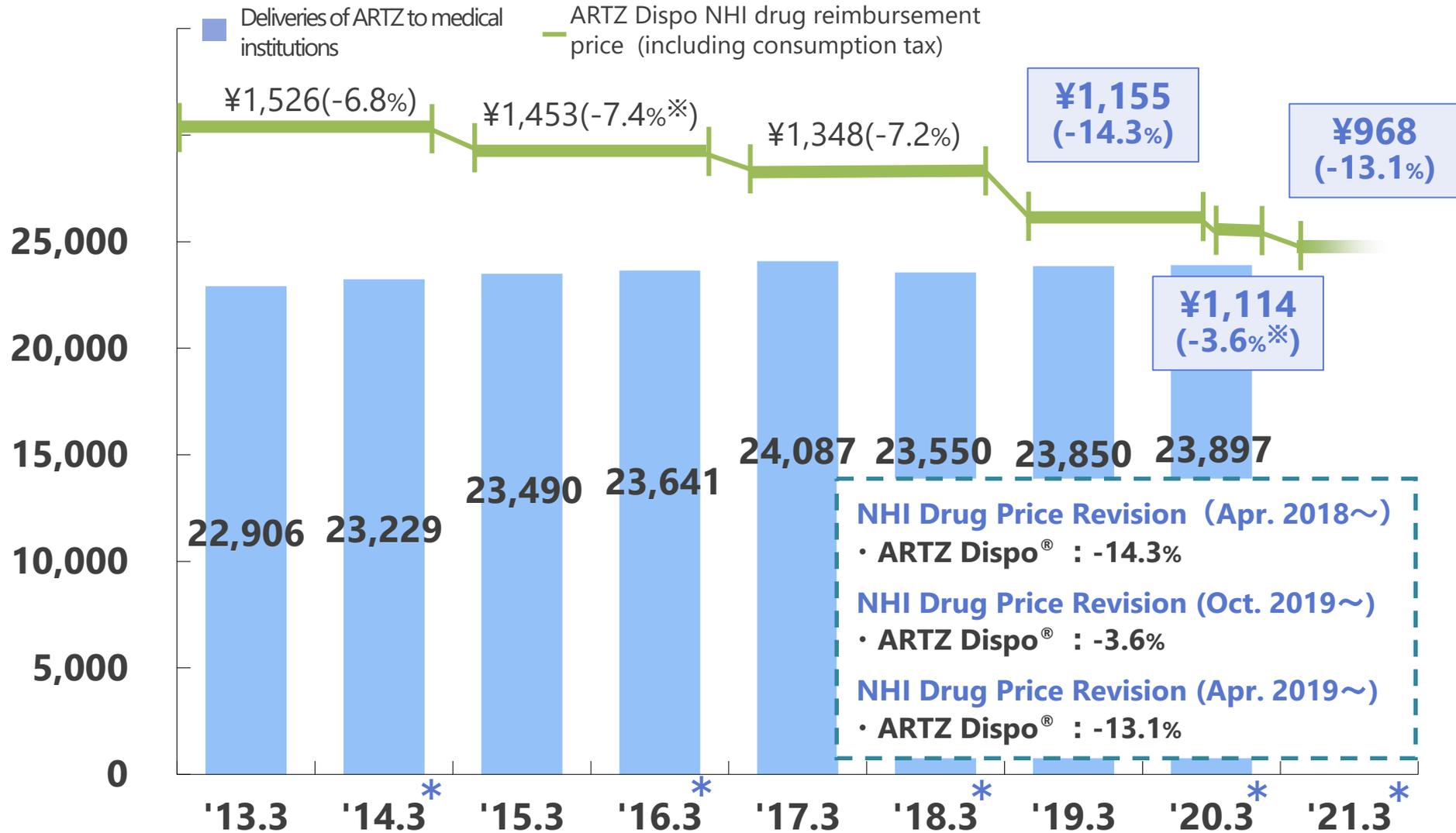
● FY2019 Results

- Market penetration proceeding steadily as deliveries to medical institutions increase
- Since November 2019, emergency facilities have been available through without full-time supervisory physicians at the JSSR

▶ FY2020 Measures

- Promoting proper use and appropriately implementing the compiling of safety information

Trend in NHI Reimbursement Price and Trend in Deliveries of ARTZ to Domestic Medical Institutions



NHI Drug Price Revision (Apr. 2018~)
 • ARTZ Dispo® : -14.3%

NHI Drug Price Revision (Oct. 2019~)
 • ARTZ Dispo® : -3.6%

NHI Drug Price Revision (Apr. 2019~)
 • ARTZ Dispo® : -13.1%

* NHI drug price reduction

Extraordinary drug price revision in FY2019 accompanying a

consumption tax increase (October 2019) ※ excluding the impact of consumption tax hike

Trend in Deliveries of ARTZ / OPEGAN to Domestic Medical Institutions

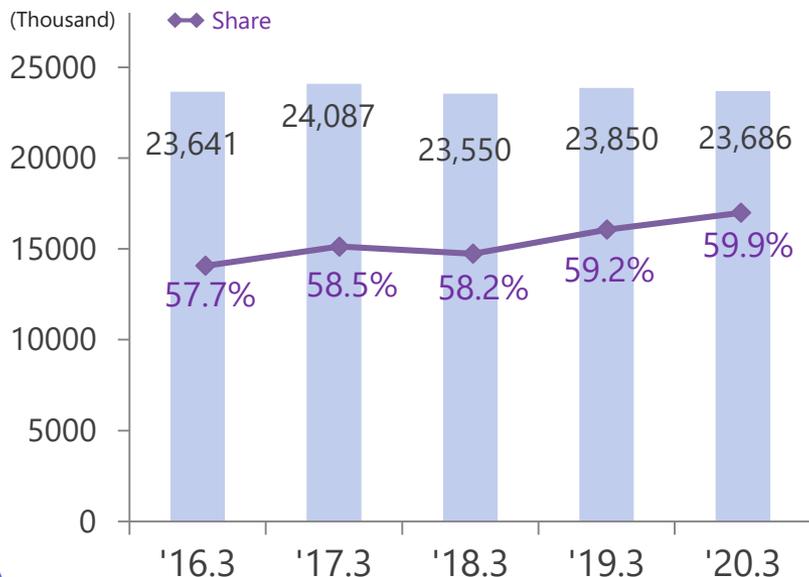
Joint-function improving agent

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



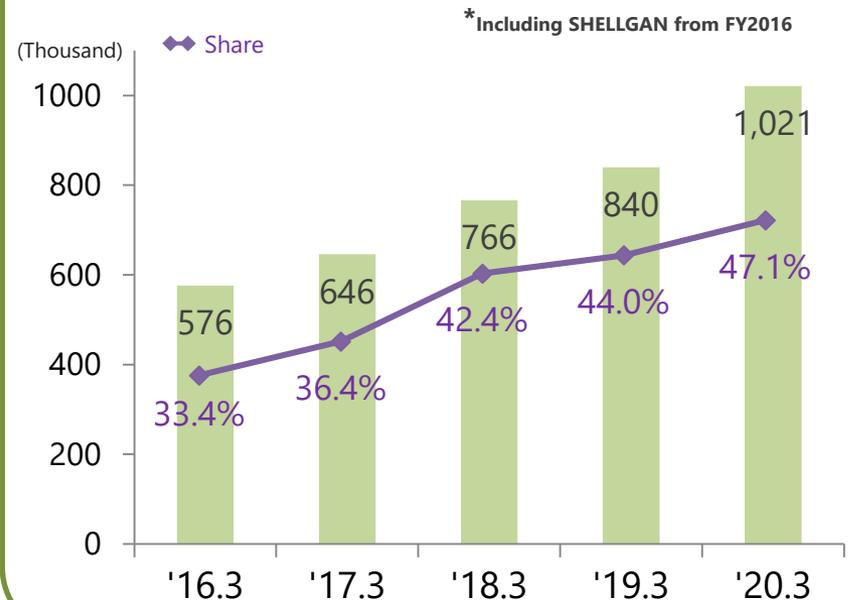
Ophthalmic viscoelastic devices

OPEGAN



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

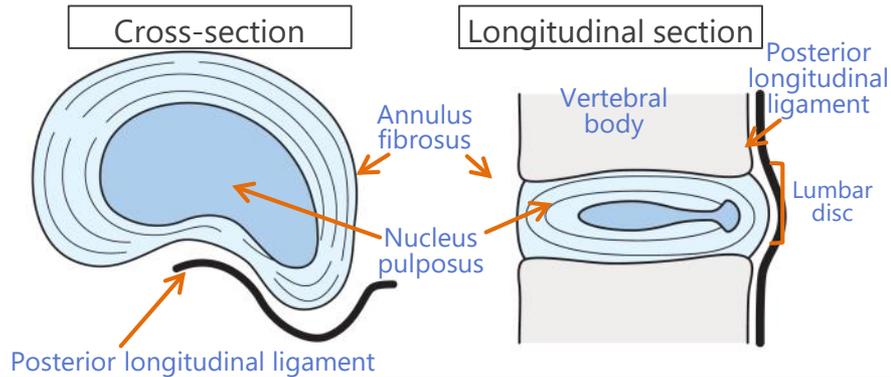
Trend in unit deliveries to medical institutions



Four types of lumbar disc herniation

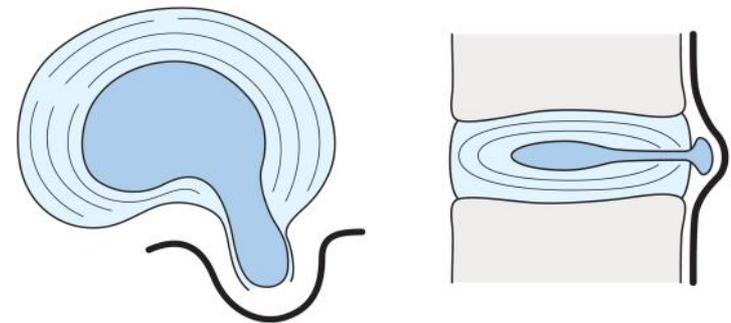
1. Protrusion

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



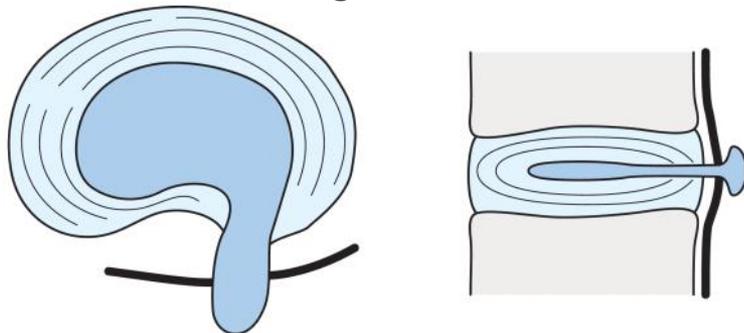
2. Subligamentous extrusion

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



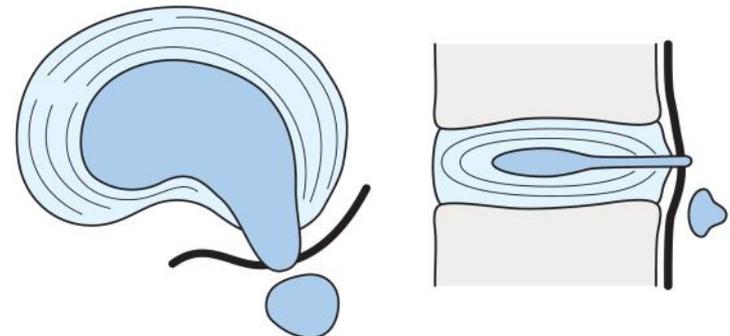
3. Transligamentous extrusion

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 series 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 OPEGAN HI SHELLGAN

The OPEGAN series viscoelasticity comparison

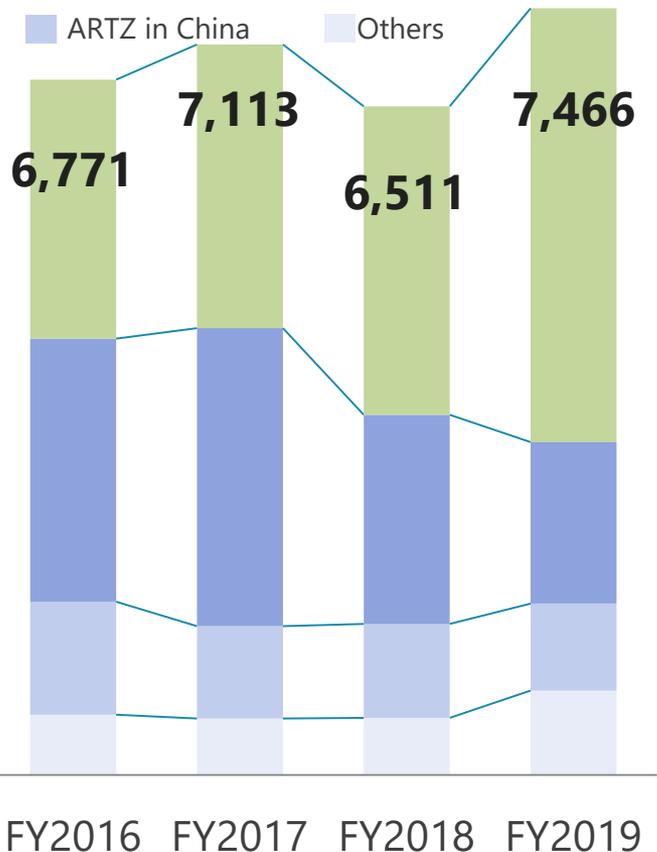
Overseas Pharmaceuticals (FY2019 Results Year-on-Year / value basis)

Overseas Pharmaceuticals Sales trend

(Millions of Yen)

<Breakdown>

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



FY2019 Results
+14.7%

Gel-One is trending firm
China ARTZ declining due to impact
of COVID-19 infection

U.S.

● Sales in the U.S.

Gel-One : Increase due to qualification for preferential reimbursement status with multiple insurers, and the sales partner to promote switching from competing products (+30% volume-based)

SUPARTZ FX : Decline as trends continue towards selection of products requiring few injections (-20% volume-based)

▶ Seikagaku exports

An increase as SUPARTZ FX declines due to local sales drop and inventory adjustments, but major growth at Gel-One compensates

▶ FY2020 Measures

Gel-One : Grow local sales through enhanced access to targeted physicians and qualifying for preferred reimbursement status with multiple insurers

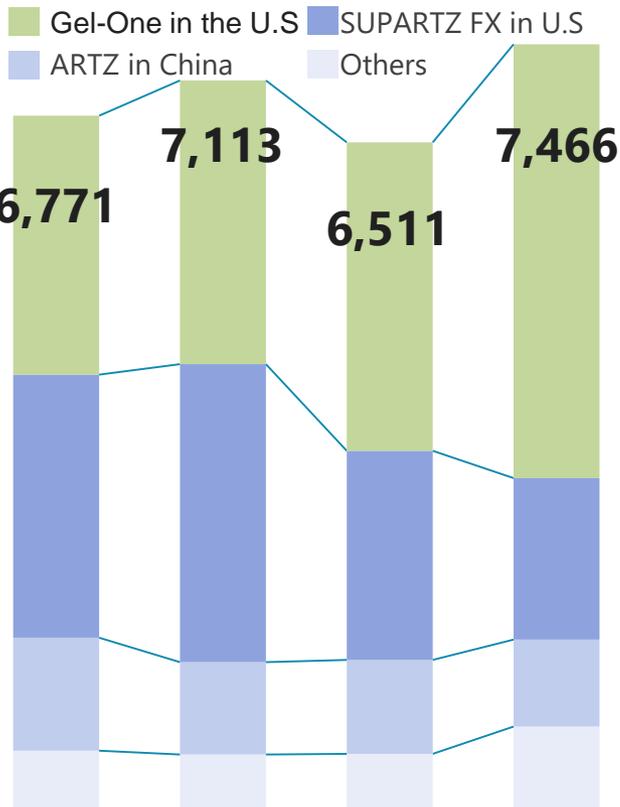
SUPARTZ FX : Differentiate from other 5-injection products, patient awareness campaigns, direct-to-consumer ads, strengthen tie-ups with patient groups, other activities to shrink declines

Overseas Pharmaceuticals (FY2019 Results Year-on-Year / value basis)

Overseas Pharmaceuticals Sales trend

(Millions of Yen)

<Breakdown>



FY2016 FY2017 FY2018 FY2019

FY2019 Results
+14.7%

Gel-One is trending firm
China ARTZ declining due to impact
of COVID-19 infection

China, Other Regions

Local sales of ARTZ in China

Sales decline due to control on clinic visits due to the expanding COVID-19 infection

(-17% volume-based)

Seikagaku exports

An increase due to growth for Taiwan and Italy, despite lower shipments of China ARTZ

FY2020 Measures

Maintain sales to large hospitals in major cities and continue to develop in peripheral cities and for mid-size clinics and hospitals

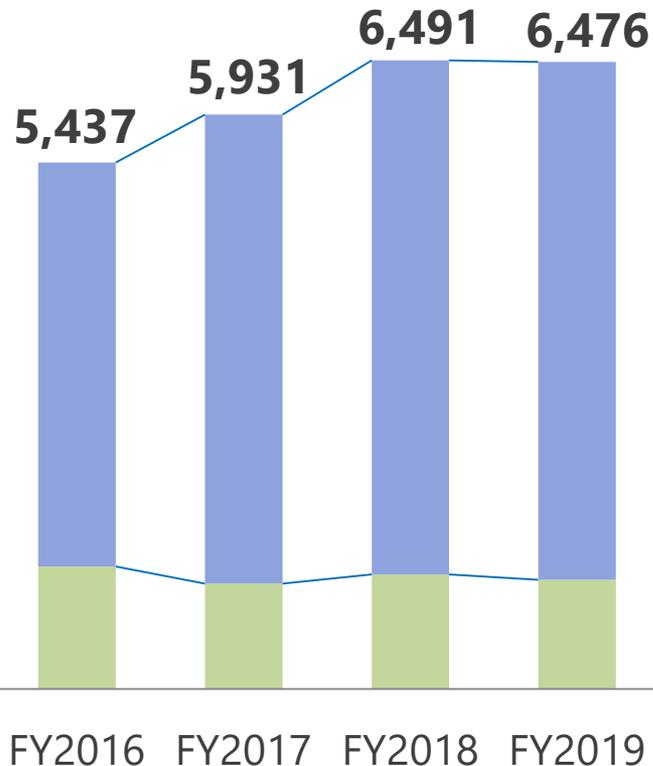
Sales of LAL Business (year-on-year / value basis)

LAL Business Sales trend

(Millions of Yen)

<Breakdown>

■ Overseas ■ Domestic



FY2019 Results : - 0.2% (Year-on-Year)

* Foreign exchange impact: approx. - ¥70million

Overseas

Sales are up for sales of Bacterial Endotoxin Testing (BET) and Clinical Diagnostic (Fungitell) reagents due to enhanced sales activities at overseas subsidiary ACC

Domestic

Sales down due to snapback from large previous-year reagent sales and impact of selling-period adjustments

FY2020 Measures

At ACC, planning to expand product lineup with an aim for developing new markets

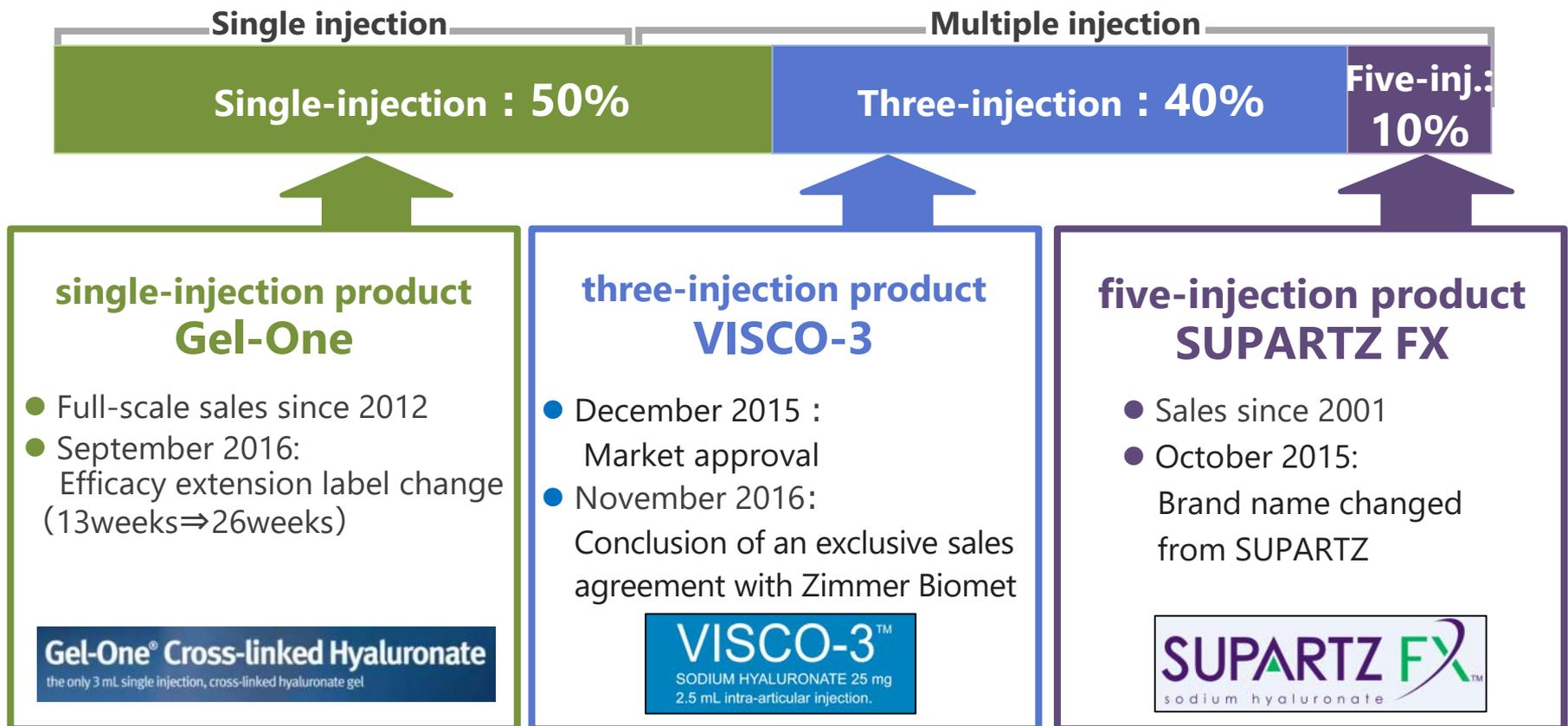
LAL Business : The manufacturing and sales of Endotoxin detection reagents* used in the quality control of pharmaceuticals and medical devices

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

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

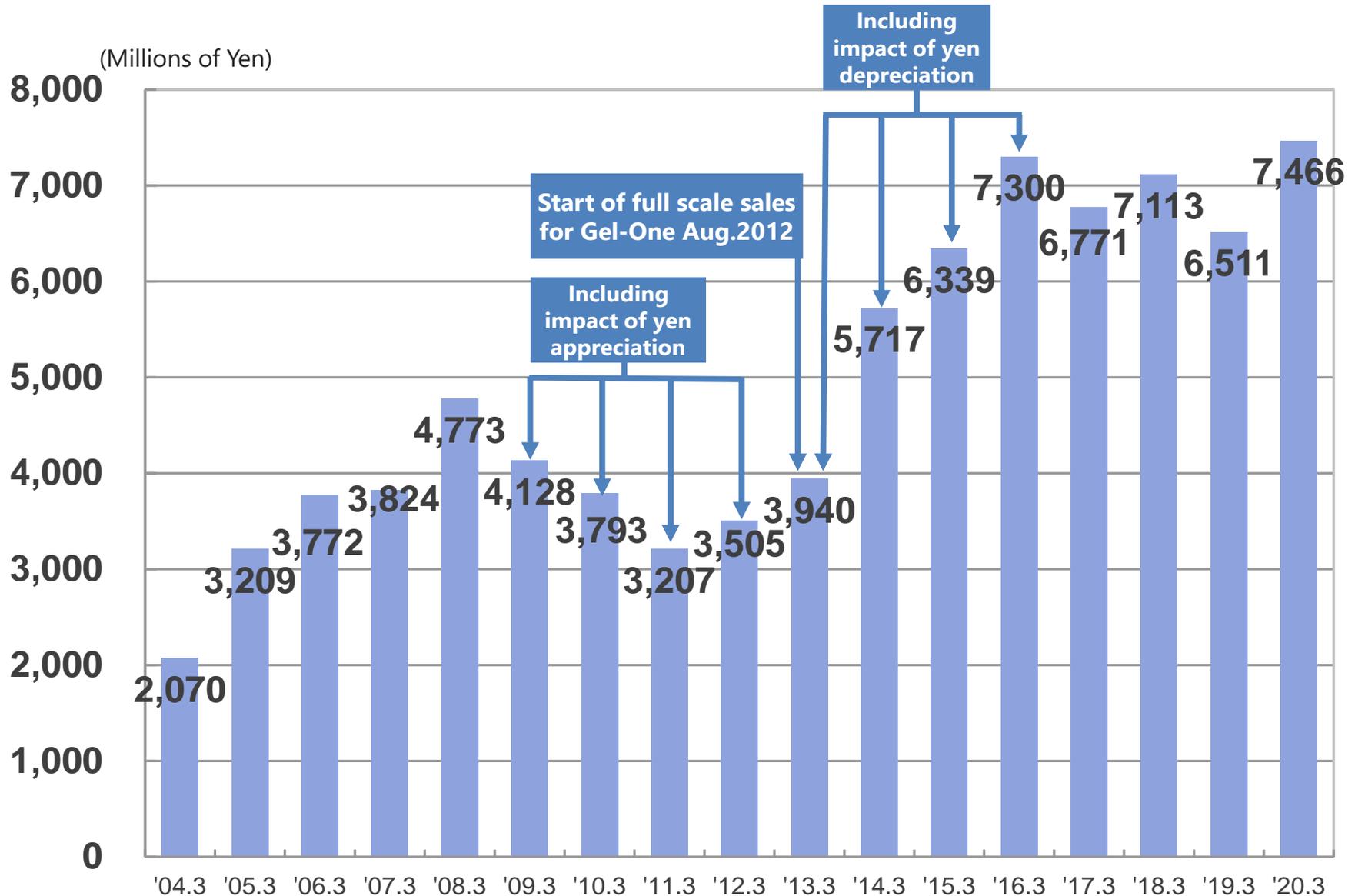
Market size of US\$1,000 mil. in 2019 (-6.5% year-on-year)

■ **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)



Exterior of the ACC offices



PYROCHROME®

Progress Against the Mid-Term Management Plan in Fiscal 2019

I . Accelerating new drug discovery to become the pillar of new profits

- ▶ SI-613 (osteoarthritis): Submitted a new drug application for manufacturing and marketing approval (Jan 2020)
- ▶ SI-722: US Phase I/II clinical study started (Nov 2019)
- ▶ SI-449 pivotal study begins (May 2020)
- ▶ Enhancing R&D system to respond quickly to changing environments

II . Solidifying the profit foundation through market expansion of new products

- ▶ SI-613: Concluded an agreement for a co-development and marketing alliance in China with Eisai (April 2020)
- ▶ HERNICORE: Use in Japan at facilities without full-time supervisory physicians accredited by the JSSR became possible (Nov 2019)

III . Productivity improvement reforms

- ▶ Dalton added as a subsidiary (March 2020)
- ▶ implementing a cost review as a result of a cost reduction project



**Solidifying our foundation in order to lay out a path for revived growth
Initiating various measures towards accelerated expansion and
early realization**

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 : 117

* 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

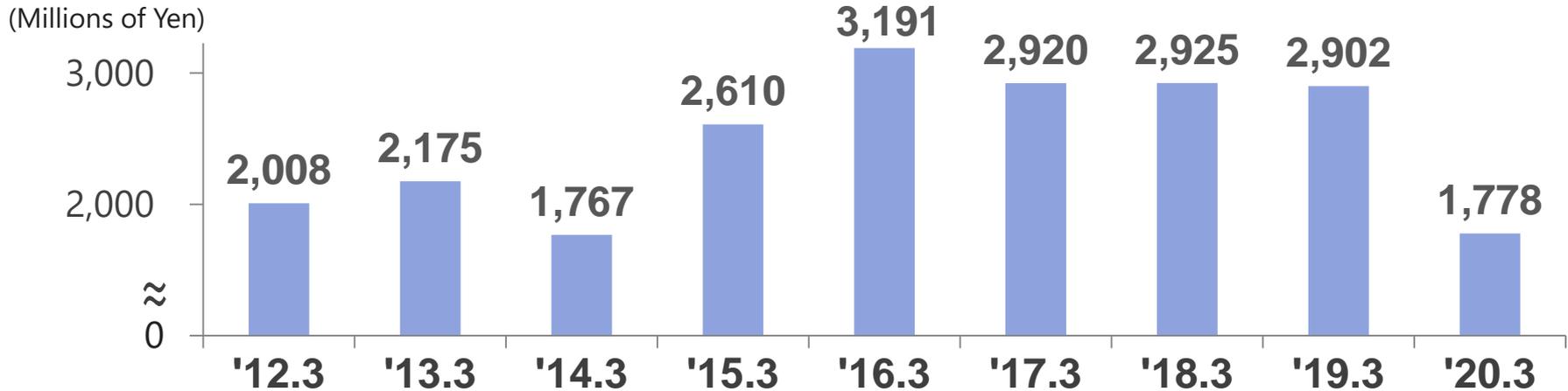
Synergies between the two companies

- **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

Trends in Depreciation & Capital Investments

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

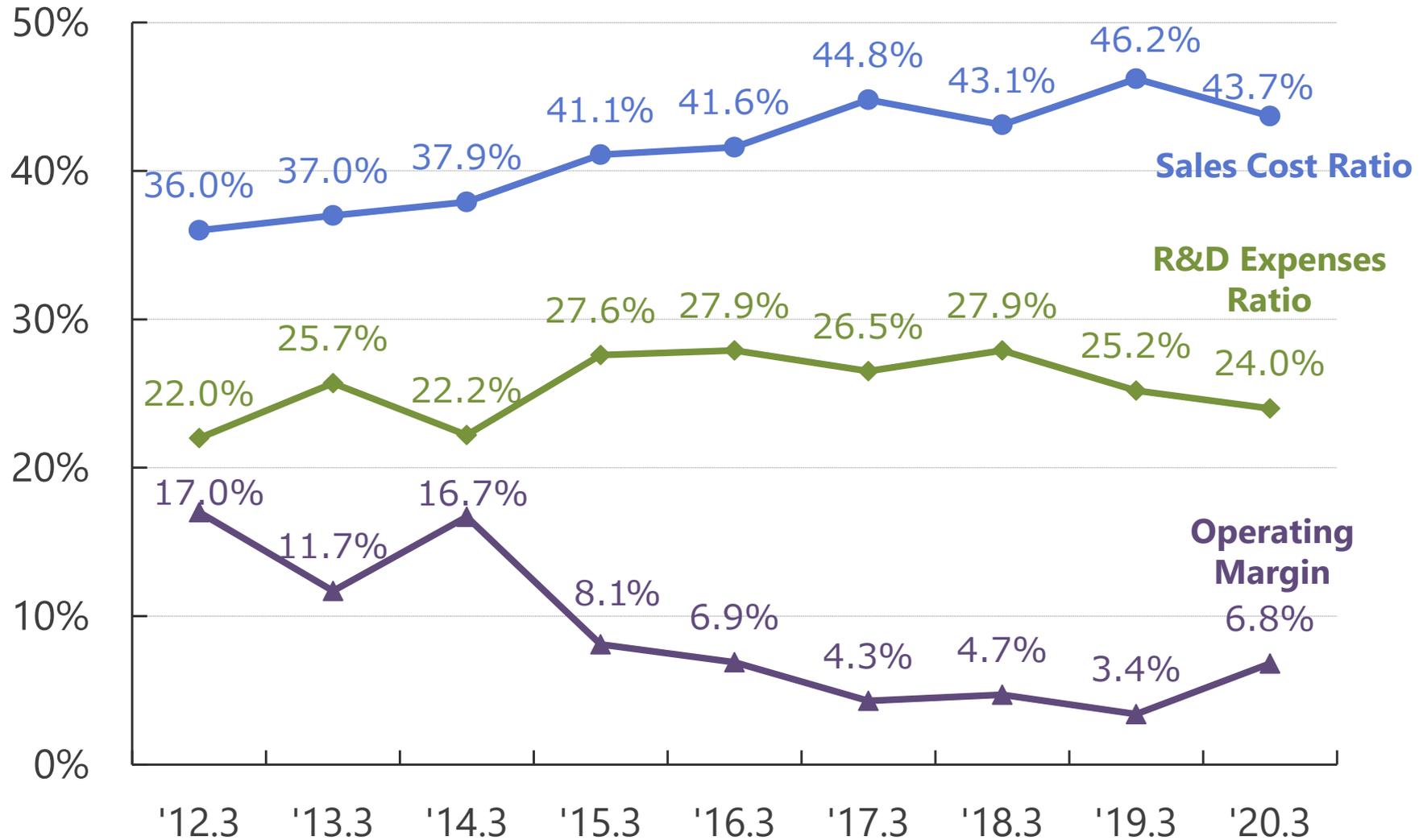
■ Trend in Depreciation



■ Trend in Capital Investments (Millions of Yen)

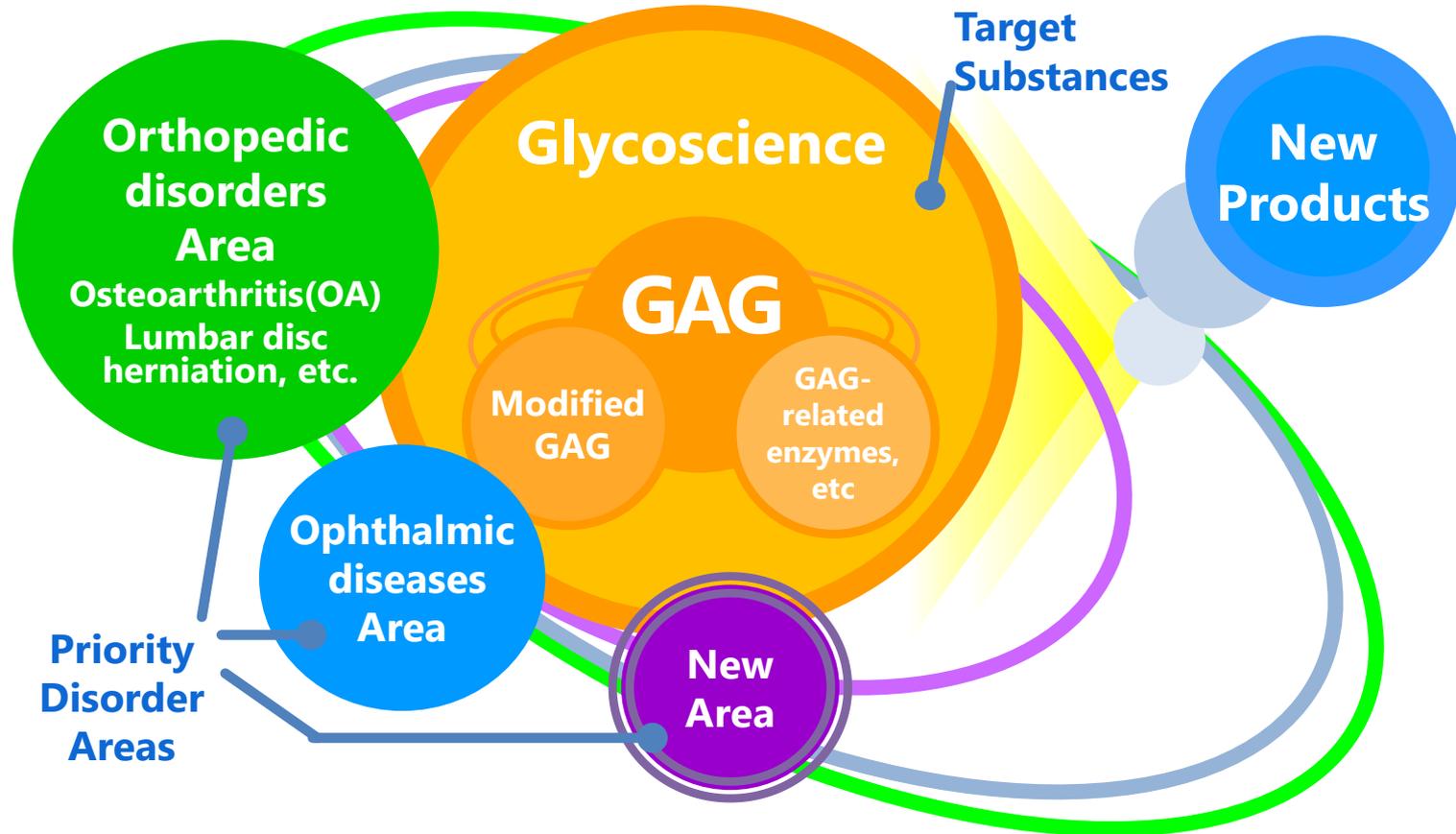
'12.3	'13.3	'14.3	'15.3	'16.3	'17.3	'18.3	'19.3	'20.3
5,718	9,164	7,222	2,095	1,975	1,173	1,591	1,310	2,109

Trend in Financial Index



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

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

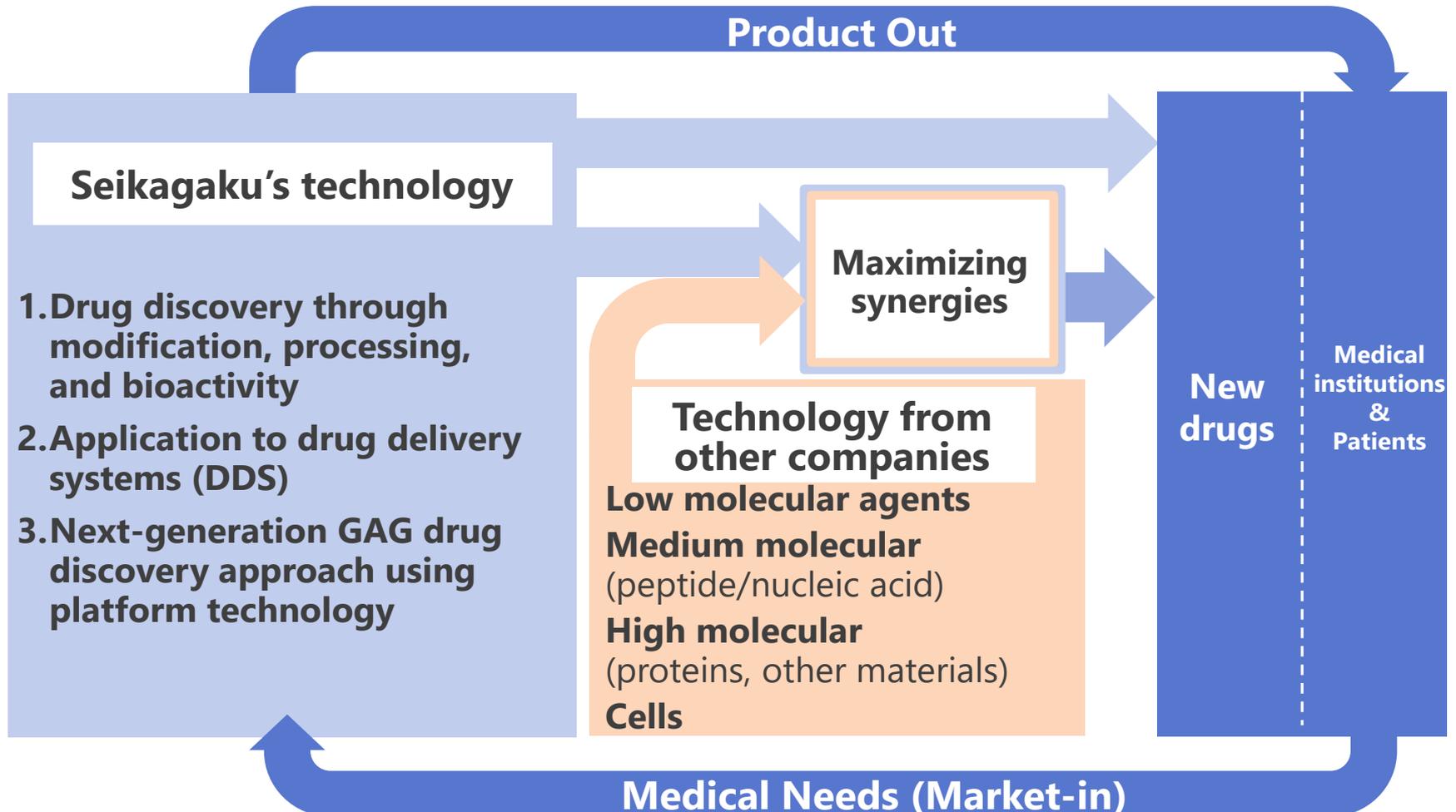
- Conversion from natural GAG **to fermented GAG**
- Expanding the field of sugar chain drug discovery Applying to glycobiology

**SI-613
SI-614**

New Drugs

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



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)

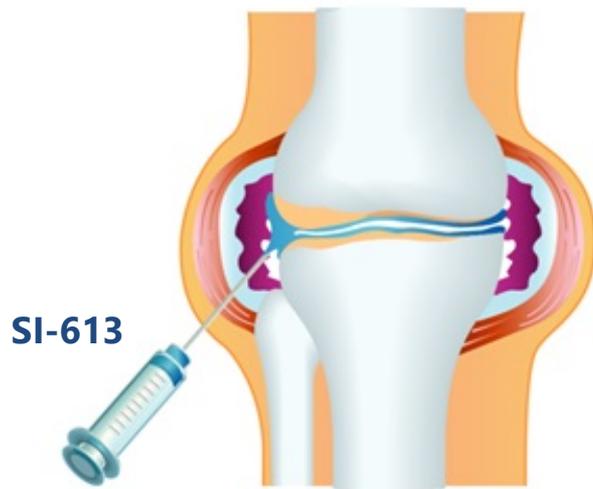
- Statistically significant improvement of leg pain at 13 weeks by VAS was not demonstrated
- ▶ ① There is a guideline for diagnostic and pathology of lumbar disc herniation in Japan, however there is no widely used guideline in the U.S. Therefore, there is possibility that some patients out of Japanese 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 at prompt and sustained relief of the pain and inflammation associated with osteoarthritis or Enthesopathy

SI-613 Administration image



Expected Features

- ▶ Hyaluronic acid and diclofenac (an anti-inflammatory agent) are chemically bound by the drug delivery system
SI-613 is designed for sustained release* of diclofenac

Prompt and sustained relief of pain and inflammation

- ▶ Since SI-613 is directly injected into the affected area as an injectable treatment, systemic exposure to diclofenac is low

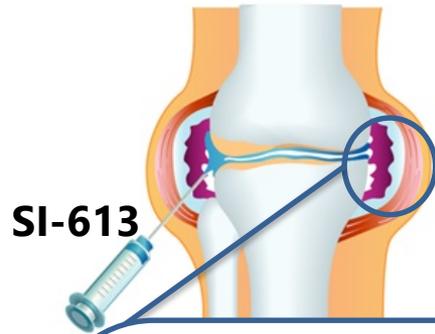
Low risk of systemic side effects

* Sustained release: Gradual release of active ingredients to achieve a sustained therapeutic effect

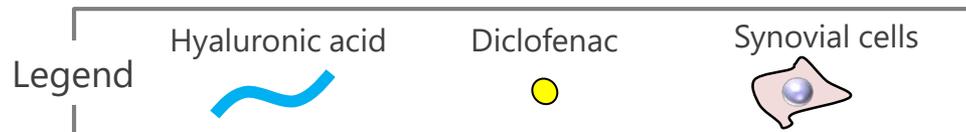
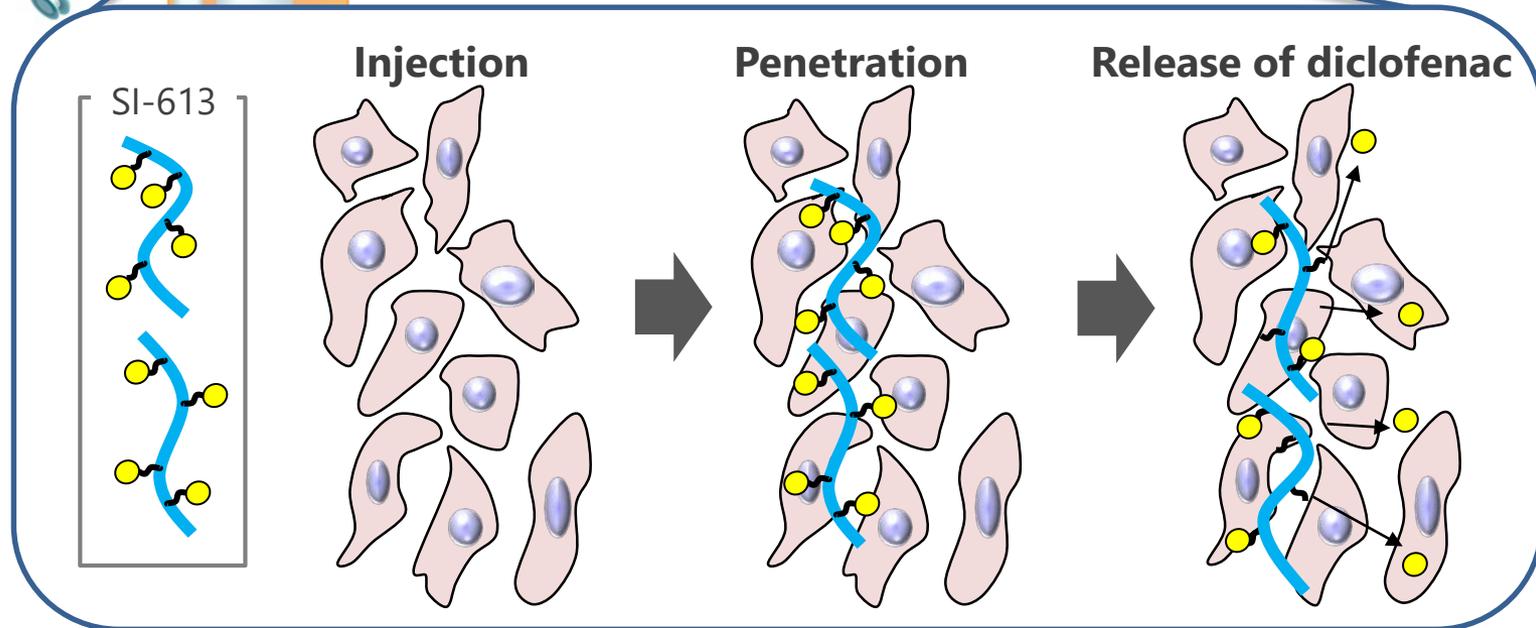
<SI-613 summary>

Dev. code : SI-613 Generic name : Hyaluronic Acid-Diclofenac Conjugates
 Indication : Osteoarthritis/Enthesopathy
 Method of use : Injection into joint cavity
 Estimated patients : 7.8 million (Seikagaku estimates)

Sustained Release of Diclofenac in SI-613

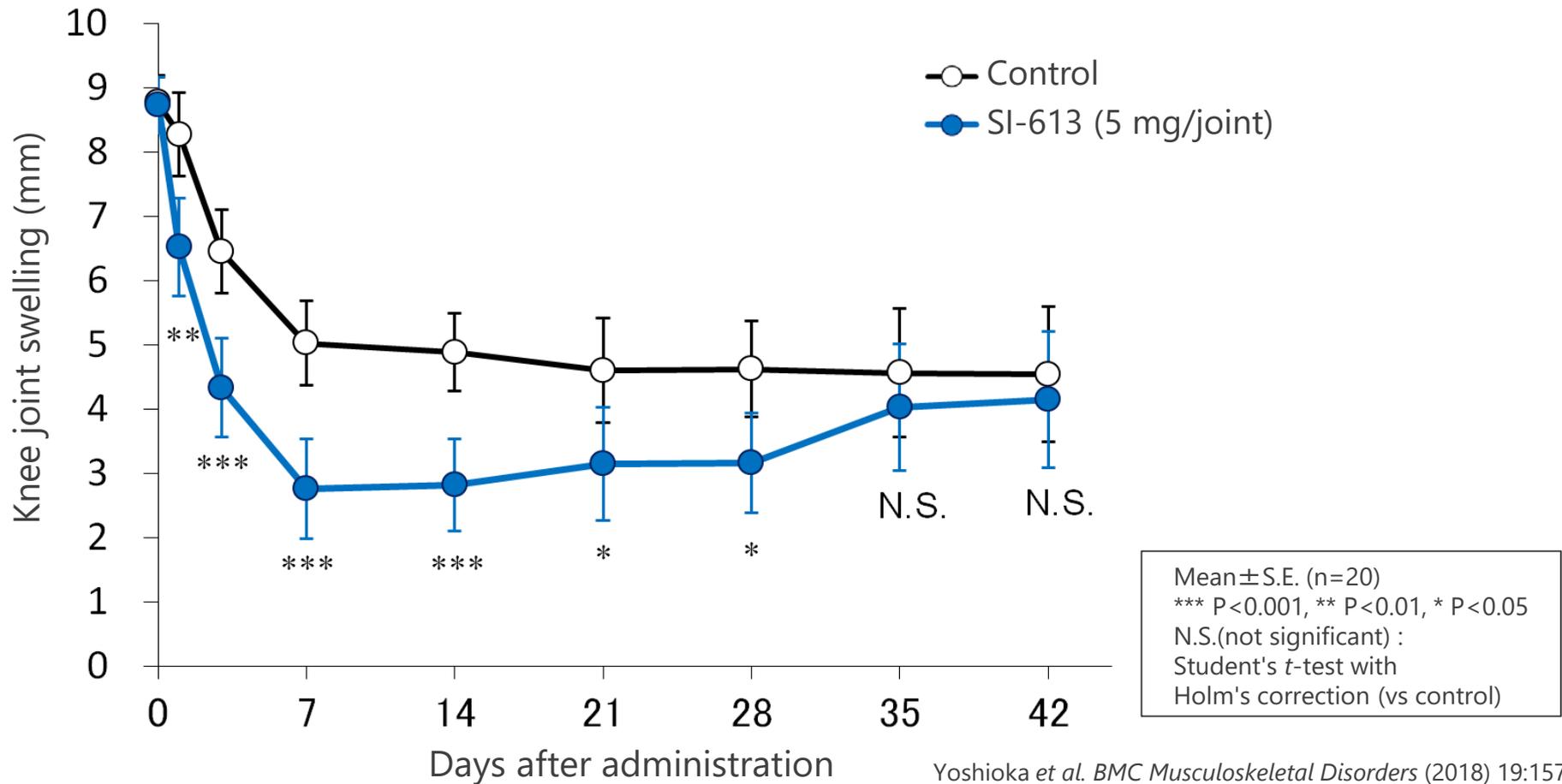


SI-613 (substance name: hyaluronic acid-diclofenac conjugate) is thought to penetrate the synovial membrane (connective tissue within the articular capsule) and gradually release diclofenac



Results of Non-clinical Study for SI-613

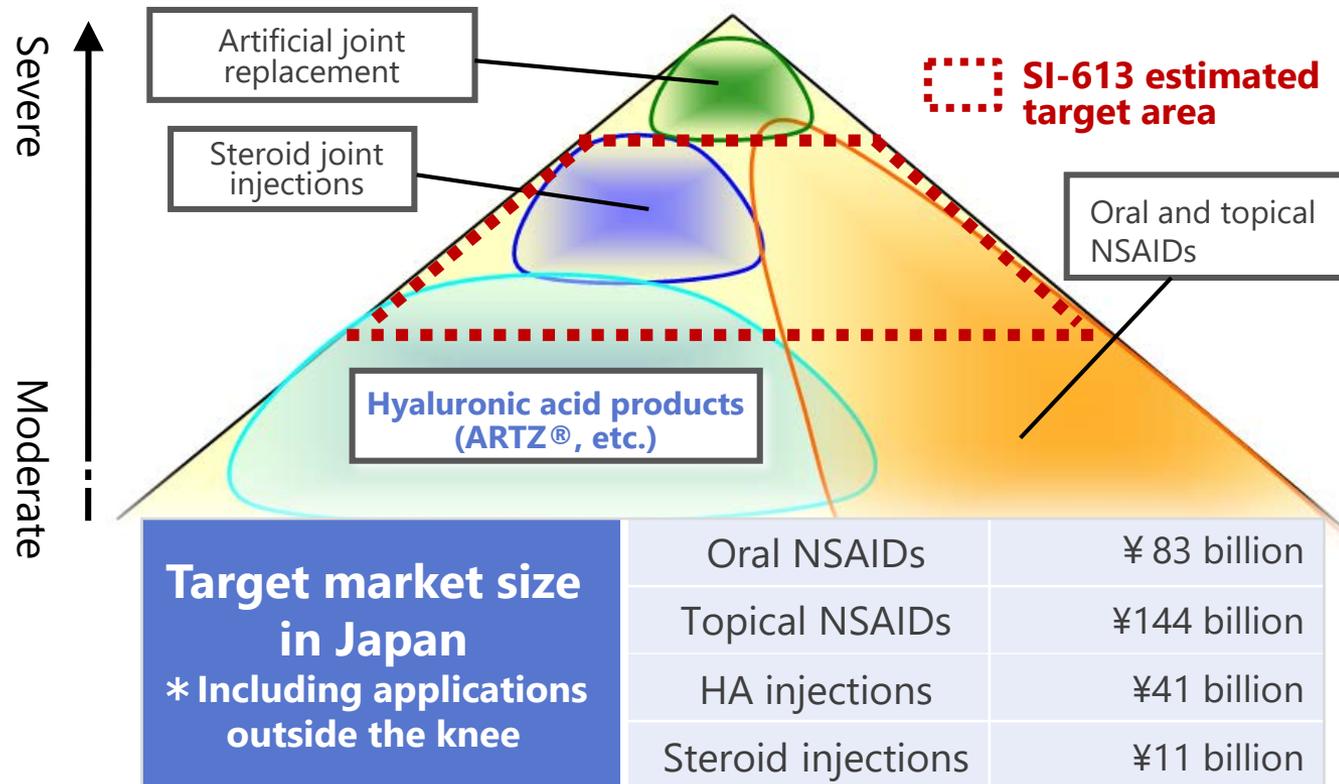
Results of non-clinical study : Anti-inflammatory effect of SI-613 on antigen-induced arthritis in rabbits



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

SI-613 Estimated Target Patients

Quickly fostering approval and launching
as a new core product

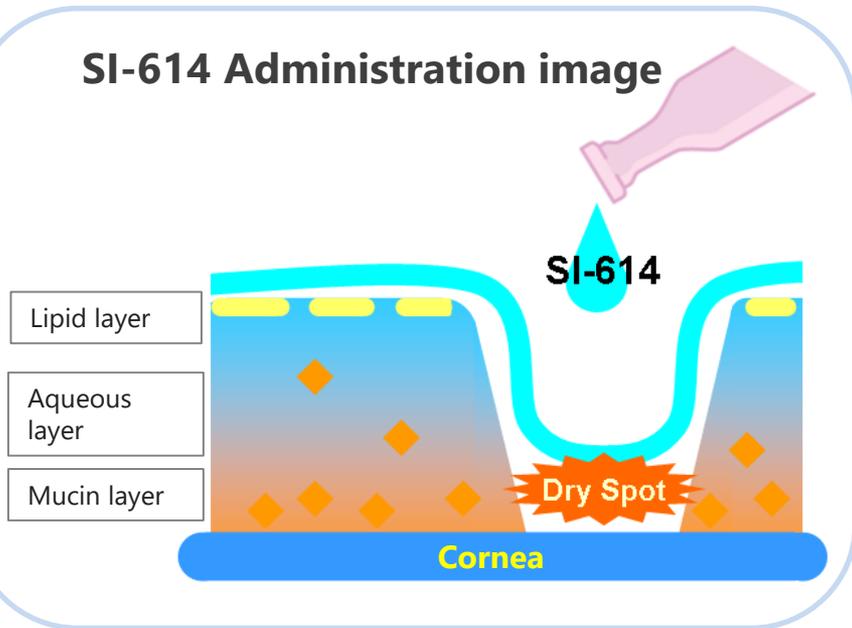


*Numbers in this slide are estimated by Seikagaku, as of March 31, 2019

SI-614 (Treatment of 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

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	Development 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 Osteoarthritis	Japan	Phase III Knee confirmatory study (JapicCTI-173537)	440	Feb. 2017 – Jan. 2019	WOMAC(Knee pain) (12 weeks)
		Phase III study for four sites (JapicCTI-173678)	280	Aug. 2017 – Jun. 2019	Daily pain diary (12 weeks)
		Long-term administration study(JapicCTI-183855)	160	Feb. 2018 – Sep. 2019	Safety (52 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	Dec. 2019 – Jun. 2020	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	—
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	—	—

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 77.4%

Ophthalmic Surgical Aids



Bulk Products



Domestic
Pharmaceuticals
→ 47.8%

Joint Function
Improving Agents



Overseas
Pharmaceuticals
→ 26.1%



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



Net Sales
28,642 million
(FY2019 Results)

Bulk Products
→ 3.6%

LAL Business 22.6%

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

This material contains forward-looking statements regarding future management strategies or performance forecasts. These descriptions 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 descriptions due to various factors. Information about pharmaceutical products or medical devices (including products currently in development) contained in this material is not intended to constitute an advertisement or medical advice.



<https://www.ehiza.jp/>



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