

Financial Results
for the 2nd Quarter of Fiscal Year 2019
(April 1, 2019 – September 30, 2019)



SEIKAGAKU CORPORATION

(TSE:4548)

Overview for 2Q of FY2019

(Millions of Yen)	2Q FY2019 Results	Year-on-Year		(Reference) FY2019 Full Year Forecasts	
		Change	% of Change	FY 2019 Forecasts	Degree of Progress
Net sales	15,555	+1,299	+9.1%	28,600	54.4%
Operating Income	2,150	+1,186	+123.1%	1,350	159.3%
Ordinary Income	2,471	-3	-0.2%	3,750	65.9%
Extraordinary loss	-12,304	-12,304	—	-13,550	—
Net Income	-10,766	-12,679	—	-11,000	—
R&D Expenses (Ratio to net sales)	3,007 (19.3%)	-279 (-3.8pt)	-8.5%	7,000 (24.5%)	43.0%
Average Exchange Rate (1US\$)	¥108.63	¥-1.64		2Q forecast ¥105.00	
		2Q FY2019 Results	2Q FY2018 Results	(Reference) FY2019 Forecasts	
Net Income per Share		¥-190.86	¥33.85	¥-194.99	

Net sales by Business Segment (2Q of FY2019)

(Millions of Yen)	2Q FY2019 Results	Year-on-Year	% of Change
Net sales	15,555	+1,299	+9.1%
Pharmaceuticals	12,236	+1,297	+11.9%
Domestic Pharmaceuticals	7,260	+286	+4.1%
Overseas Pharmaceuticals	4,439	+1,010	+29.5%
Bulk Products	535	-0	-0.0%
LAL Business	3,319	+2	+0.1%
(Overseas sales)	7,216	+991	+15.9%

* Foreign exchange impact on overall net sales : approx. -35million yen

Domestic Pharmaceuticals

▶ ARTZ (Joint-function improving agent)

- Sales up as shipments are concentrated through Q2



ARTZ :
Joint function improving agent with hyaluronic acid as its active pharmaceutical ingredient

▶ OPEGAN series (Ophthalmic viscoelastic devices)

- Sales rise on steady performance of SHELLGAN

▶ MucoUp

(Submucosal injection agent for endoscopic surgery)

- Sales decline due to impact from introduction of a competing products

▶ HERNICORE

(Treatment for lumbar disc herniation)

- Deliveries to medical institutions show steady increase; Seikagaku sales also up
- Ongoing efforts towards phased rollout



HERNICORE:
Japan's first treatment for lumbar disc herniation launched in August 2018

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海外医薬品

*Foreign exchange impact on Overseas Pharmaceuticals: approx. -70 million yen

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

- Large sales increase due to acquiring preferred reimbursement status from multiple insurance companies, successful measures to switch from competing products



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

▶ **SUPARTZ FX in the U.S.** (Multiple injection)

- Continues to be selected among products with small no. of administrations
- Seikagaku sales rise despite declining local sales volume, as shipments increase after being moved forward

▶ **ARTZ in China** (Multiple injection)

- Seikagaku sales decline despite increasing local sales volume due to foreign exchange impact

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Bulk Products

At prior-year level as hyaluronic acid increased, but chondroitin sulfate declined

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

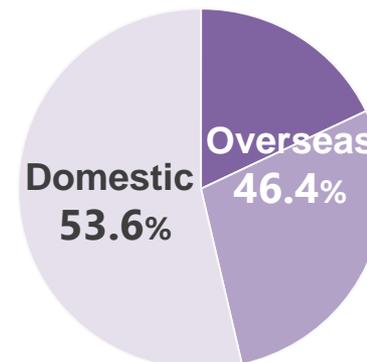
LAL Business

*Foreign exchange impact on LAL Business: approx. +35 million yen

At prior-year level as strong overseas sales compensate for a domestic decline

* LAL business: Manufacturing and sale of endotoxin-detecting reagents used in quality control for pharmaceuticals and medical equipment

Overseas Sales Ratio



Year-on-Year
+2.7pt

Income for 2Q of FY2019 (Year-on-Year)

(Millions of Yen)	2Q FY2019 Results	Year-on-Year	% of Change
Net sales	15,555	+1,299	+9.1%
Cost of Sales (Cost of Sales ratio)	6,780 (43.6%)	+262 (-2.1pt)	+4.0%
SGA expenses	6,624	-149	-2.2%
R&D Expenses (to Net sales ratio)	3,007 (19.3%)	-279 (-3.8pt)	-8.5%
Operating Income (to Net sales ratio)	2,150 (13.8%)	+1,186 (+7.0pt)	+123.1%
Ordinary Income	2,471	-3	-0.2%
Extraordinary loss	-12,304	-12,304	—
Net Income	-10,766	-12,679	—
Depreciation	1,452	+5	+0.4%

Operating Income

Cost of Sales Ratio (-2.1pt) :

- An improvement due to impact of greater production of Gel-One and ARTZ

SGA Expenses (-149) :

- R&D expense declines (-279)

Net Income

Non-operating Income / Expenses (-1,190) :

- Decrease in gain on sales of investment securities (-569)
- No royalty income included in results (-508)
- Foreign exchange valuation reduced (-171)

Extraordinary loss (-12,304) :

- Impairment loss taken on property, plant and equipment in the pharmaceutical business in conjunction with lower profitability*

*Large NHI drug price reductions as a result of fundamental reform of drug pricing in Japan, volume sales of joint function improving agents below projections at time of investment

Revised Forecasts in FY2019

(Millions of Yen)	FY2019 Revised Forecasts	Initial Forecasts		FY2018 Results		(Reference) Degree of 2Q Progress
		Change	% of Change	Change	% of Change	
Net sales	28,600	+350	+1.2%	+215	+0.8%	54.4%
Operating Income	1,350	+950	+237.5%	+372	+38.1%	159.3%
Ordinary Income	3,750	+1,450	+63.0%	+890	+31.2%	65.9%
Extraordinary loss	-13,550	-13,900	—	-13,550	—	—
Net Income	-11,000	-13,000	—	-13,244	—	—
R&D Expenses (Ratio to net sales)	7,000 (24.5%)	+200 (+0.4pt)	+2.9%	-148 (-0.7pt)	-2.1%	43.0%
Average Exchange Rate (1US\$)	<small>2Q forecast</small> ¥105.00	—		—		

	FY2019 Revised Forecasts	FY2019 Initial Forecasts	FY2018 Results
Net Income per share	¥-194.99	¥35.46	¥39.76
Dividend per share	¥26.00	¥26.00	¥26.00
Dividend Payout ratio	—	73.3%	65.4%

Exchange Rate Sensitivity (Impact of a change of ¥1 against the US\$)	
Net sales (2Q only)	Approx. ¥50 million
Operating income (2Q only)	Approx. ¥15 million

Revised Net Sales in FY2019 (Comparison with the initial forecast)

(Millions of Yen)	FY2019 Revised Forecasts	Initial Forecasts	
		Change	% of Change
Net sales	28,600	+350	+1.2%
-Pharmaceuticals	22,050	+450	+2.1%
-LAL Business	6,550	-100	-1.5%
Operating Income (Ratio to net sales)	1,350 (4.7%)	+950 (+3.3pt)	+237.5%
Ordinary Income	3,750	+1,450	+63.0%
Extraordinary loss	-13,550	-13,900	—
Net Income	-11,000	-13,000	—
Cost of Sales ratio	44.1%	-3.0pt	
R&D Expenses (Ratio to net sales)	7,000 (24.5%)	+200 (+0.4pt)	+2.9%
Depreciation	1,750	-1,200	-40.7%

Net sales

Pharmaceutical business increases led by Gel-One in the U.S.

* Total foreign exchange impact on net sales: +¥290 million

Operating Income

Raised forecast for operating income to reflect small depreciation expense in second half as a result of impairment loss

Cost of sales ratio:

Improved due to lower depreciation as a result of impairment loss

SGA Expenses (approx. +100) :

Engaged in enrolling subjects U.S. clinical study for SI-6603

Net Income

Net income forecast lowered substantially due to impairment loss

Non-operating income:

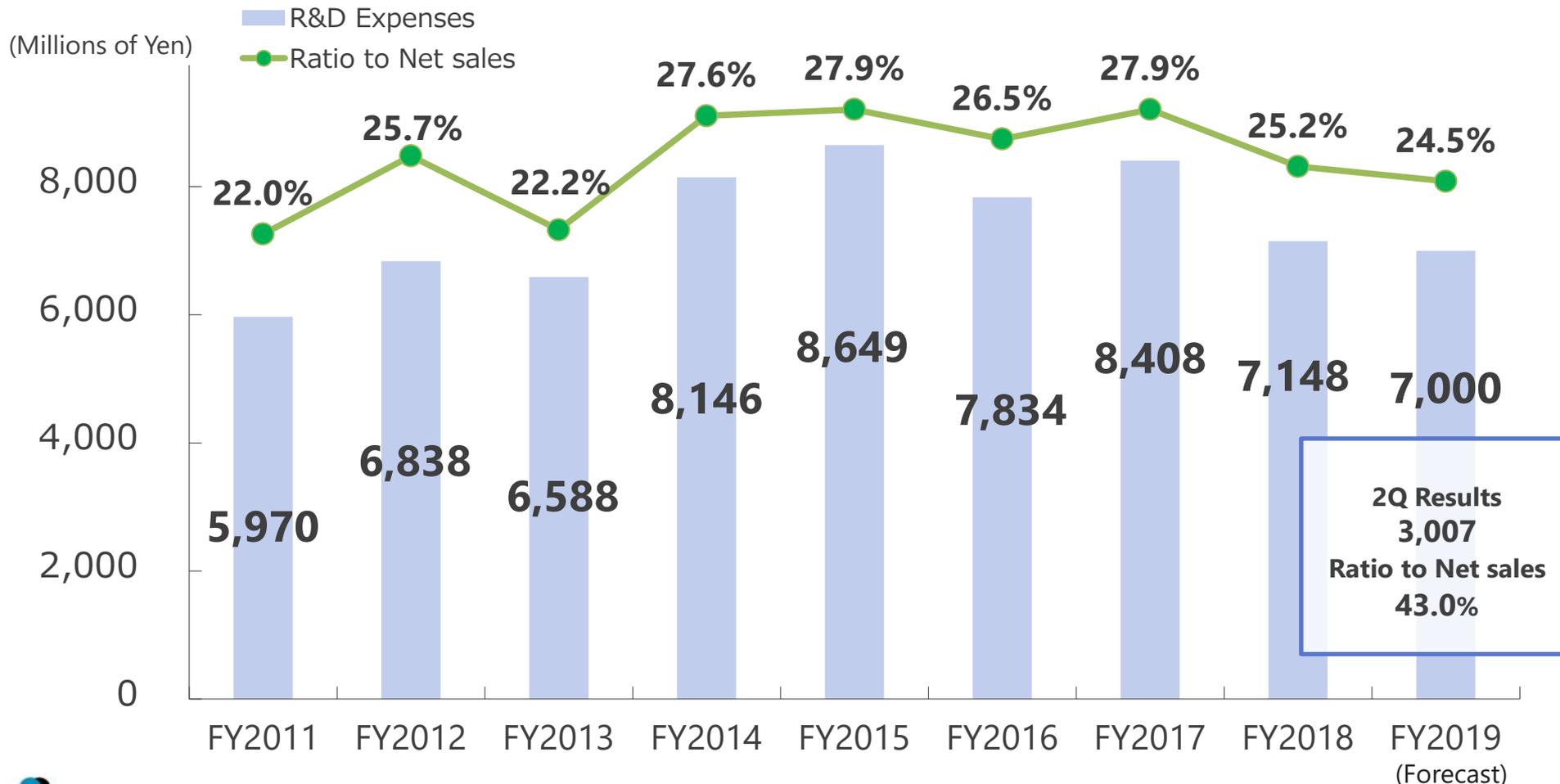
Forecasting higher royalty income

Extraordinary loss:

Impairment loss on property, plant and equipment (including more in 2Q)

Trend in R&D Expenses

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



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

ARTZ (Joint-function improving agent)

● 2Q FY2019 Results

- Slight increase against generally flat market as sales promotion
(growth rate : +0.4% / Market growth rate : +0.1% / Market share : 59.4% (+0.2pt))

▶ FY2019 Forecasts

- Maintaining volumes supported by sales promotion campaigns using reconstruction of evidence data
(growth rate : +0.2% / Market share : 60.0%)



OPEGAN (Ophthalmic viscoelastic devices) ※including SHELLGAN

● 2Q FY2019 Results

- SHELLGAN keeps up the overall good performance of OPEGAN series, whose share is also expanding

(growth rate : +11.5% / Market growth rate : +10.4% / Market share : 44.3% (+0.4pt))

▶ FY2019 Forecasts

- Raising our forecast from the initial one due to switching from competing products

(growth rate : +5.4% ⇒ +18.5% / Market share : 45.8% ⇒ 47.0%)



HERNICORE (Treatment for lumbar disc herniation)

● 2Q FY2019 Results

- Market penetration proceeding steadily as deliveries to medical institutions increase

▶ FY2019 Forecasts

- Seeking further market penetration through information provision activities to ensure appropriate use and safety.



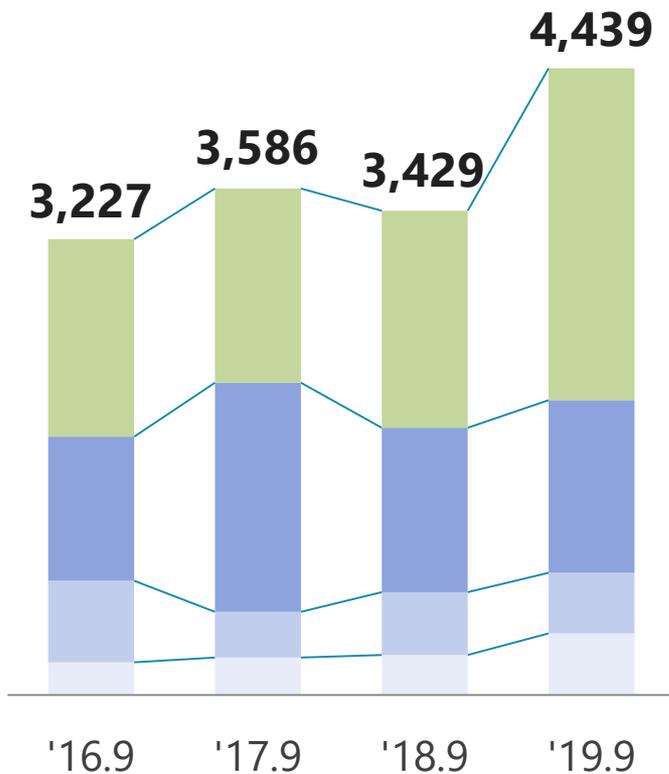
Overseas Pharmaceuticals (2Q FY2019 Results Year-on-Year / value basis)

Overseas Pharmaceuticals Sales trend

(Millions of Yen)

<Breakdown>

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



2Q FY2019 Results

+29.5%

Gel-One up considerably, SUPARTZ FX in the U.S. slightly increasing. ARTZ in China declines

U.S.

● Sales in the U.S.:

- Gel-One** : Increase due to acquiring preferred reimbursement status from multiple insurance companies and successful measures to switch from competing products
(+35% volume-based)
- SUPARTZ FX** : A downward effect from the continuing trend towards selection of products requiring fewer injections, including single- and three-injection
(-16% volume-based)
- Seikagaku exports** :
 Gel-One has a large increase with greater local sales volume; SUPARTZ FX up slightly owing to shipments being moved forward

China, Other Regions

● Local sales of ARTZ in China

Increasing due to successful sales expansion in cities and also surrounding areas
(+16% volume-based)

▶ Seikagaku exports :

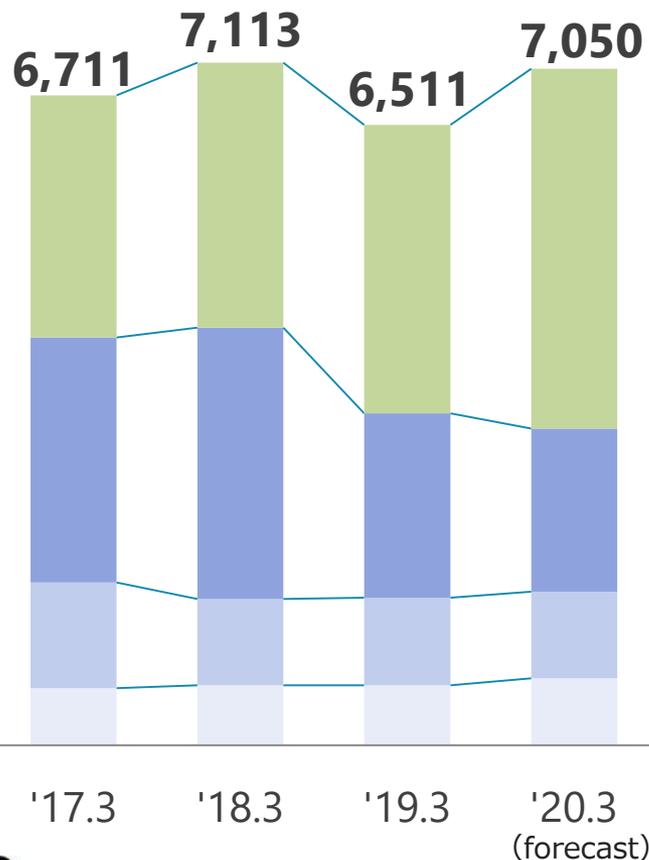
ARTZ in China declines due to shipment timing and foreign exchange effects
 HyLink in Italy having an effect, leading to increase

Overseas Pharmaceuticals (FY2019 Forecast 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



FY2019 Forecasts
+8.3%

Increase forecasted with increasing Gel-One that compensate for a decline in SUPARTZ FX

U.S.

● Sales in the U.S.:

- **Gel-One** : Lifting our growth forecast
(+4% ⇒ +30% volume-based)
 - **SUPARTZ FX** : Lowering forecast owing to harsher market conditions and struggling local sales
(-3% ⇒ -15%, volume-based)
- ▶ **Seikagaku exports** : Gel-One revised upward because of higher shipments tied to favorable local sales SUPARTZ revised downward because of unfavorable local sales

China, Other Regions

- **Local sales of ARTZ in China**
Trending as initially forecast (+7% , volume-based)
- ▶ **Seikagaku exports** :
Forecasted to be generally in line with initial forecast

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

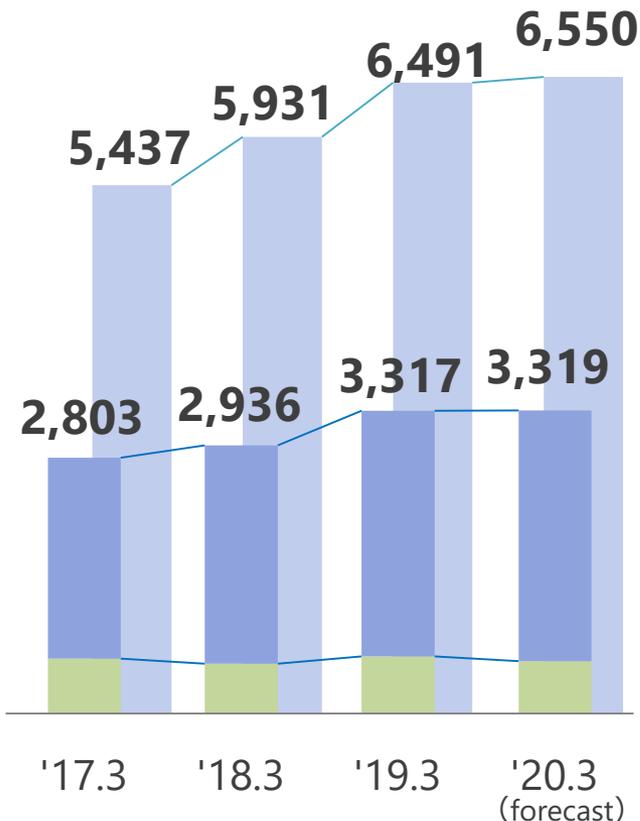
LAL Business Sales trend

(Millions of Yen)

■ Full year

<2Q Breakdown>

■ Overseas ■ Domestic



2Q FY2019 Results : +0.1% (Year-on-Year)

Overseas

* Foreign exchange impact: approx. -¥120million

Sales growing in bacterial Endotoxin Testing (BET) and Clinical Diagnostic (FungitellR) reagents (products used in diagnostics of fungal infections)

Domestic

A year-on-year decline in reaction to prior-period large volume sales of reagents and devices

FY2019 Forecasts : +0.9% (Year-on-Year)

Overseas

Increase forecasted due to enhanced sales activities by ACC

Domestic

Forecast is generally at prior-year level

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).

Mid-term Management Plan FY2019 to FY2021

Contents

- **Summary of Previous Mid-term Management Plan**
- **Overview of Medium-term Management Plan**
 - Business Environment
 - Our Vision
 - Mission Statement /
Corporate Slogan of the New Mid-term Business Plan
- **Important Measures**
 - I . Accelerating new drug discovery to become
the pillar of new profits
 - II . Solidifying the profit foundation through market
expansion of new products
 - III . Productivity improvement reforms
- **Numerical targets / Basic policy on profit distributions**
 - Numerical targets
 - Basic policy on profit distributions

Summary of Previous Mid-term Management Plan

▶ **Development of SI-6603, a treatment for lumbar disc herniation**

- Japan: Although it took time to obtain approval, successfully introduced in Japan (product name in Japan: HERNICORE)
- U.S.: Phase III clinical study did not meet its primary endpoint. Additional study now in progress

▶ **Development of the knee osteoarthritis market**

- Gel-One in the U.S.: U.S. local sales volumes increased, but the growth rate fell short of target
- Expansion into new markets: The single-injection product HyLink introduced in Italy
- ARTZ in Japan: Sales volume maintained, but sales declined sharply accompanying NHI drug price system reform
- SI-613: Substantial progress with clinical study in Japan. Agreement concluded with Ono Pharmaceutical and co-development in progress

▶ **Enhancement of the development pipeline**

- SI-449 added to the development pipeline and other themes progressing toward advancement to the clinical development stage

▶ **Initiatives in pursuit of an optimal production and quality control system**

- Strengthening of control systems: upgrading of manufacturing facilities, introduction of a new quality control system
- Product cost reduction: Implemented plant production efficiency improvement and cost reductions, achieving a certain level of results



Our response to the fall-off in profitability resulting from drastic reforms in the NHI drug pricing system and intensifying overseas competition is a critical issue

Overview of Medium-term Management Plan

Business Environment

Japan market

- Aging society & Growth in healthy longevity
- Pressure on healthcare financing
- Urging use of generic drugs
- Diversification of treatment options

U.S. OA market

- OA patients increasing (aging, etc.)
- More active seniors
- Some insurance companies suspend reimbursement
- Fiercer competition as new products enter market
- A broad range of treatment options

* OA: osteoarthritis

R&D

- Explosion in R&D costs and risks
- Depletion of seeds for drug discovery
- New treatment methods such as regenerative medicine appear
- Diversification of new drug modalities

<Drastic drug pricing reforms>

NHI reimbursement price reduction for long-time listed drugs



G2: Under 80% of drugs replaced by generics
 ⇒ **A gradual fall to 1.5x generic drugs price through 2028**

Our responses to the rapidly changing business environment must break through existing frameworks

Our Vision

Our vision

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

In pursuit of innovation

Applying glycoscience expertise to proprietary technology to have and realize the dreams and passions of innovative new drugs

Improvement of existing value

Based on fair and earnest business activities, continually providing products that are truly demanded for healthy and well-being of people around the the world

Acceleration of global market expansion

With our sights set upon the world, we cultivate new markets in R&D and products, leading to greatly enhanced profits

Mission Statement/Corporate Slogan of the New Mid-term Business Plan

Core values (motto)

Creativity, Fairness, Dreams and Passion

Mission statement

"Glycoscience for human well-being"

Corporate slogan of the new mid-term business plan

Innovative Thinking
Creating value based on innovative thinking

Important Measures

Our Three Important Measures

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

- Strengthening and making use of the Company's own GAG-related core technology related to GAGs
- Accelerating innovative drug discovery using the Open Innovation strategy
- Steady progress of the development pipeline with an eye towards global expansion

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

- Post-marketing of HERNICORE in Japan
- Accelerating multinational expansion of existing products and products in development
- Global expansion of endotoxin-detecting reagents that leverage genetic recombination technology

III . Productivity improvement reforms

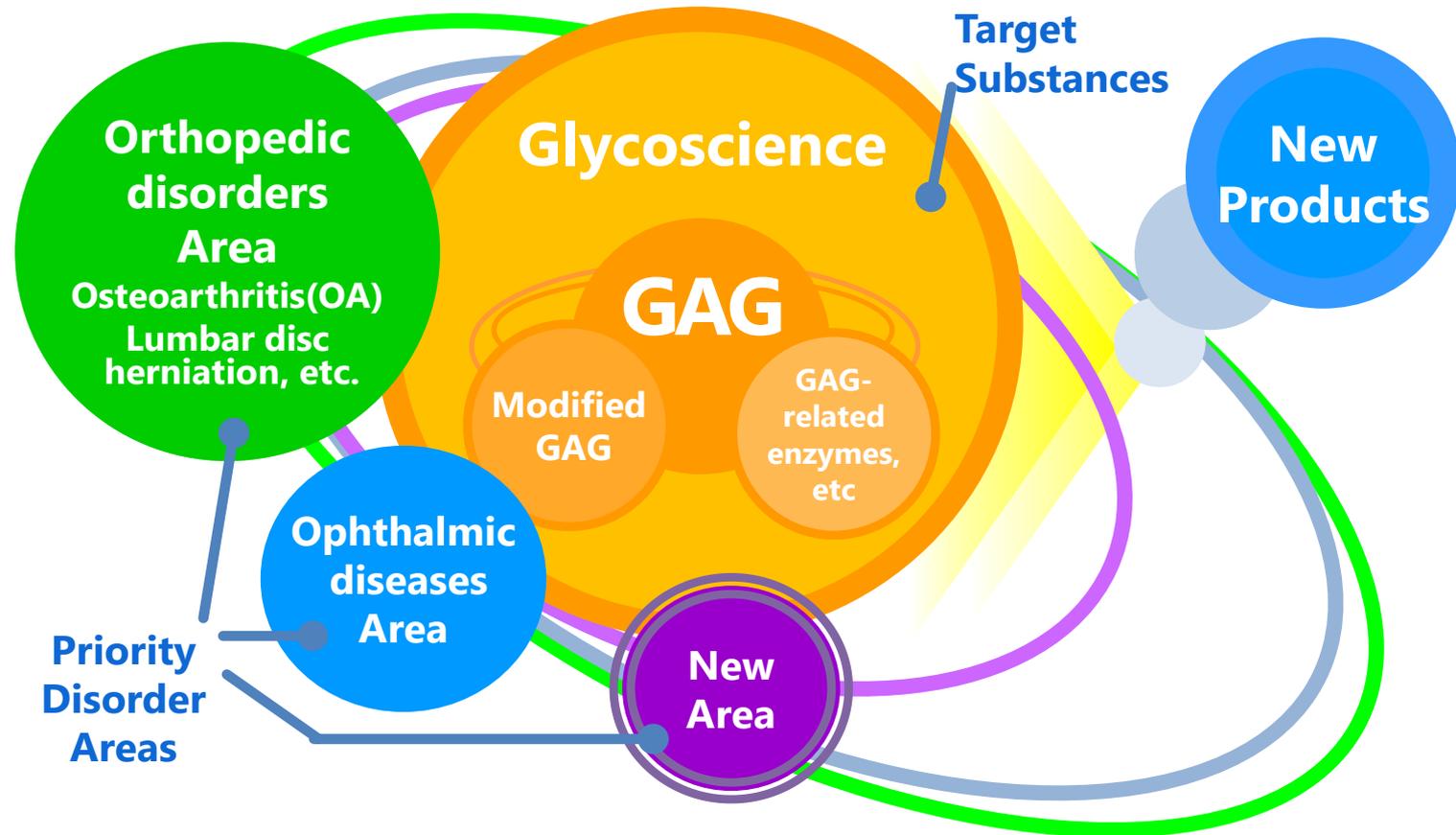
- Thorough cost reductions
- Diversifying the profit model
- Creating an organization for maximizing the value of resources

**A period to solidify our foundation
in order to lay out a path for revived growth**

I . Accelerating New Drug Discovery to Become the Pillar of New Profits

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

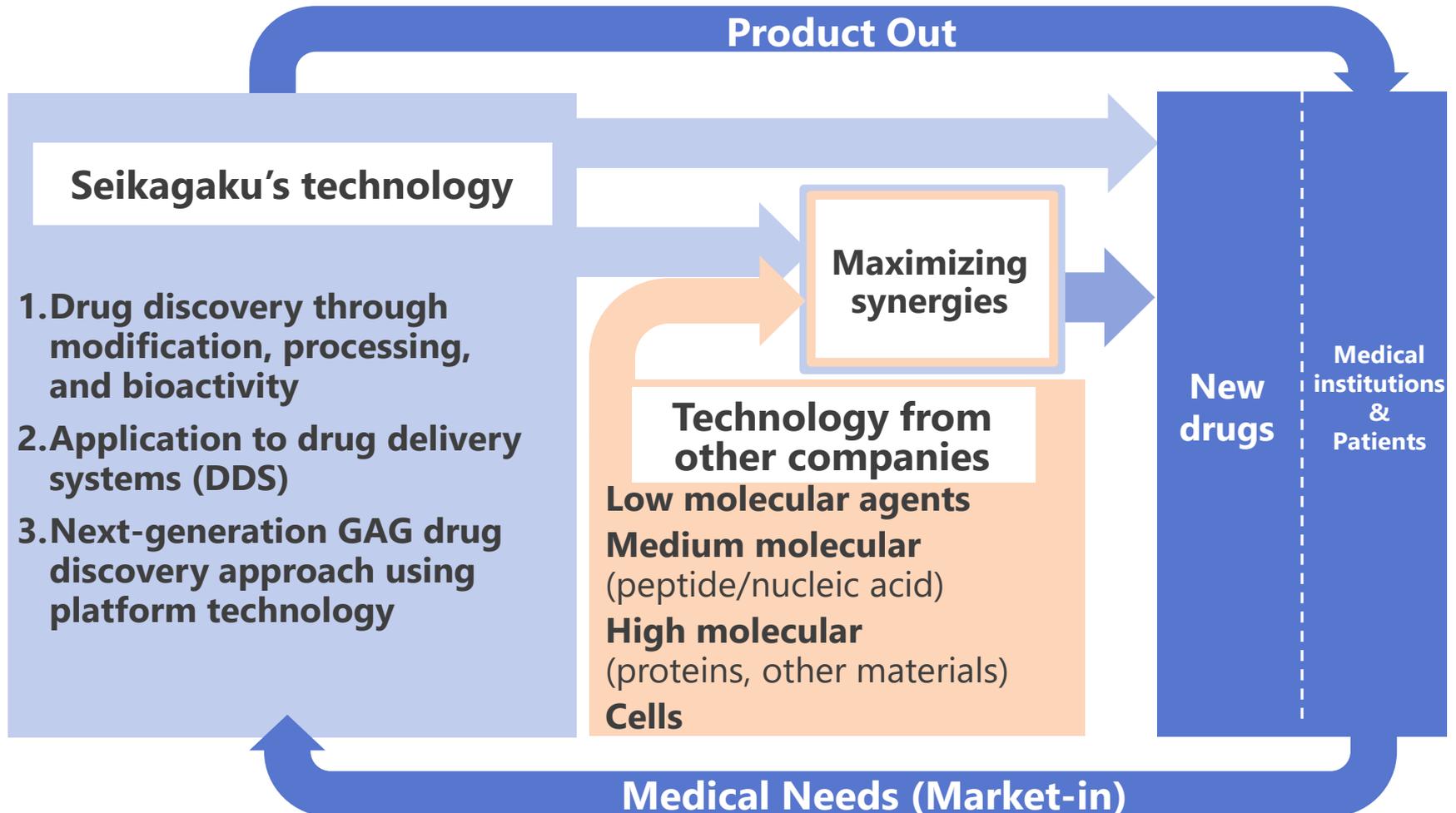
- Conversion from natural GAG **to fermented GAG**
- Expanding the field of sugar chain drug discovery Applying to glycobiology

SI-613
SI-614

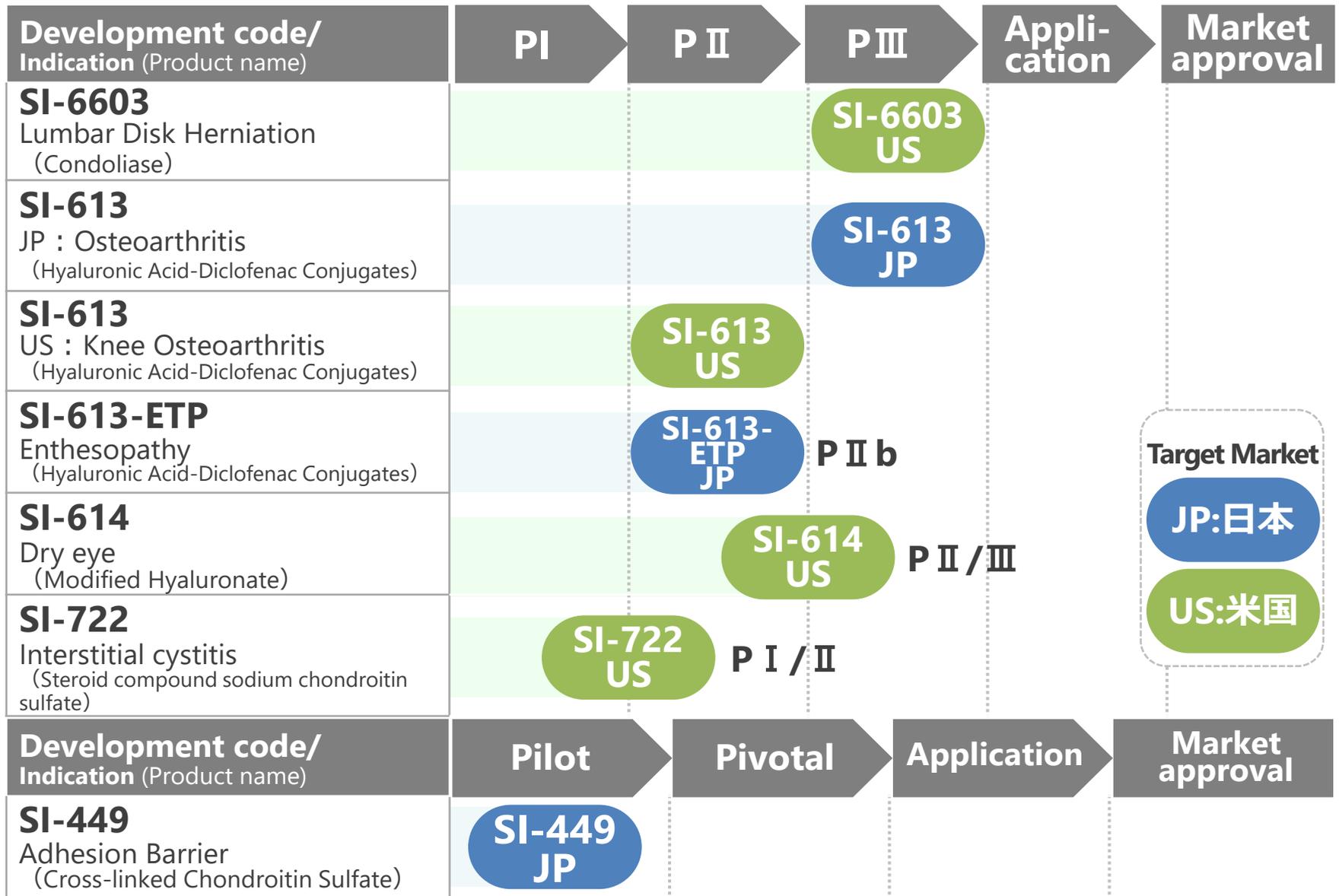
New Drugs

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



Pipeline List (Research and Development themes)



SI-613 ①

Aiming to file an application for a manufacturing and marketing approval in Japan in FY2019

SI-613 (osteoarthritis) Japan

- ▶ All Phase III clinical studies* are completed
 - **Aiming to file an application for a manufacturing and marketing approval in FY2019**
 - Targeted locations: Planning to apply for the knee joint in addition to some other joints

* (1)Knee confirmatory study (2)study for four sites (3)long-term administration study

SI-613-ETP (enthesopathy) Japan

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

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

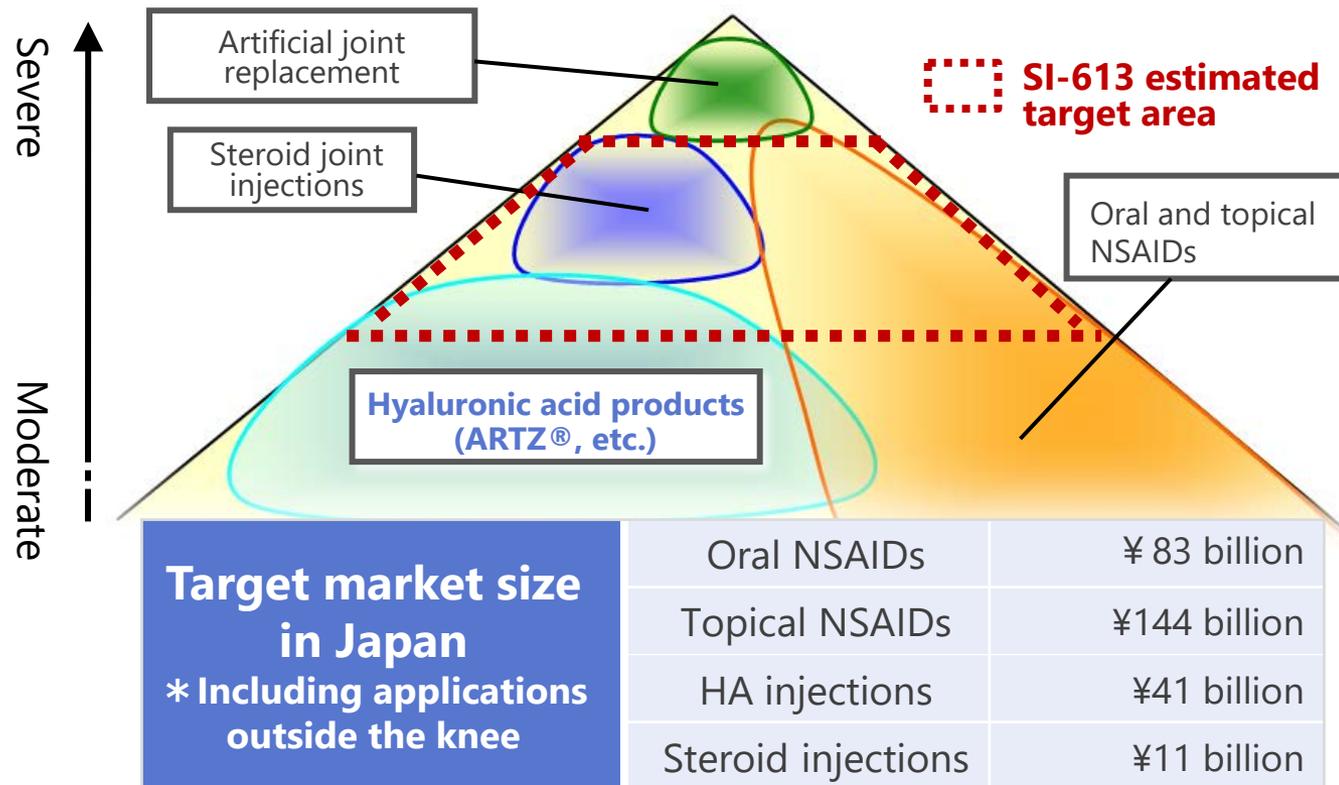
<SI-613 summary>

"Next-generation product for rapid and sustainable relief of inflammation associated with osteoarthritis"

Dev. code	: SI-613	Generic name	: Hyaluronic Acid-Diclofenac Conjugates
Indication	: Osteoarthritis	Method of use	: Injection into joint cavity

SI-613 ②

Quickly fostering approval and launching as a new core product, during the mid-term management plan

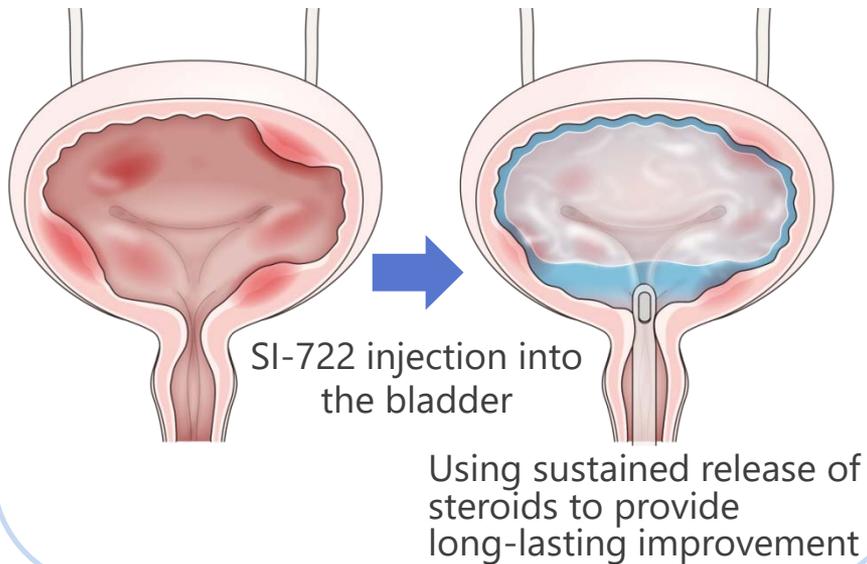


*Numbers in this slide are estimated by Seikagaku, as of March 31, 2019

SI-722

U.S. Phase I/II clinical study starting Aiming to step up to Phase IIa during the mid-term management plan period

SI-722 Administration image



Development status

▶ U.S. Phase I/II

- **Starting November 2019**

- Study completion expected during FY2020

* Phase I completed in June 2019

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
- ▶ Improving patient quality of life

<SI-722 summary>

Dev. Code : SI-722

Generic name : Steroid conjugated with chondroitin sulfate

Indication : Interstitial cystitis and bladder pain syndrome

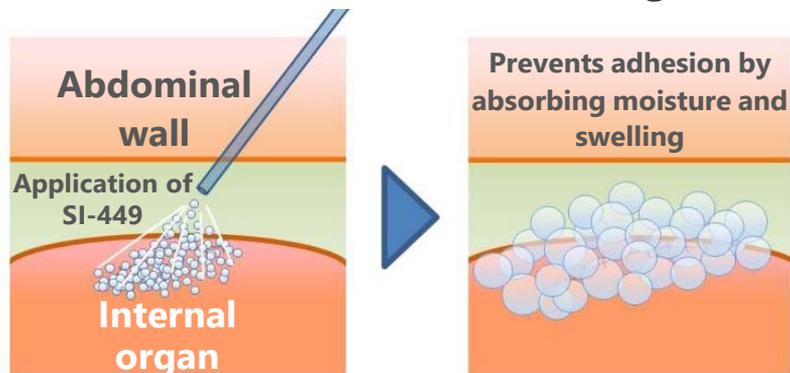
Method of use : Injection into the bladder

Estimated U.S. patient count : 1.3 million (Seikagaku estimates)

SI-449

Pilot study to completion during FY2019 Aiming to start pivotal study during mid-term management plan period

SI-449 Administration image



Development status

▶ Japan pilot study

- Starting May 2018
- Enrollment completed, follow-up observation ongoing
- **Aiming to start pivotal study during FY2020**

- ▶ Proceed with development with a view to global development; Start of U.S. pilot study under review

<SI-449 summary>

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

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)

II . Solidifying the Profit Foundation Through Market Expansion of New Products

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

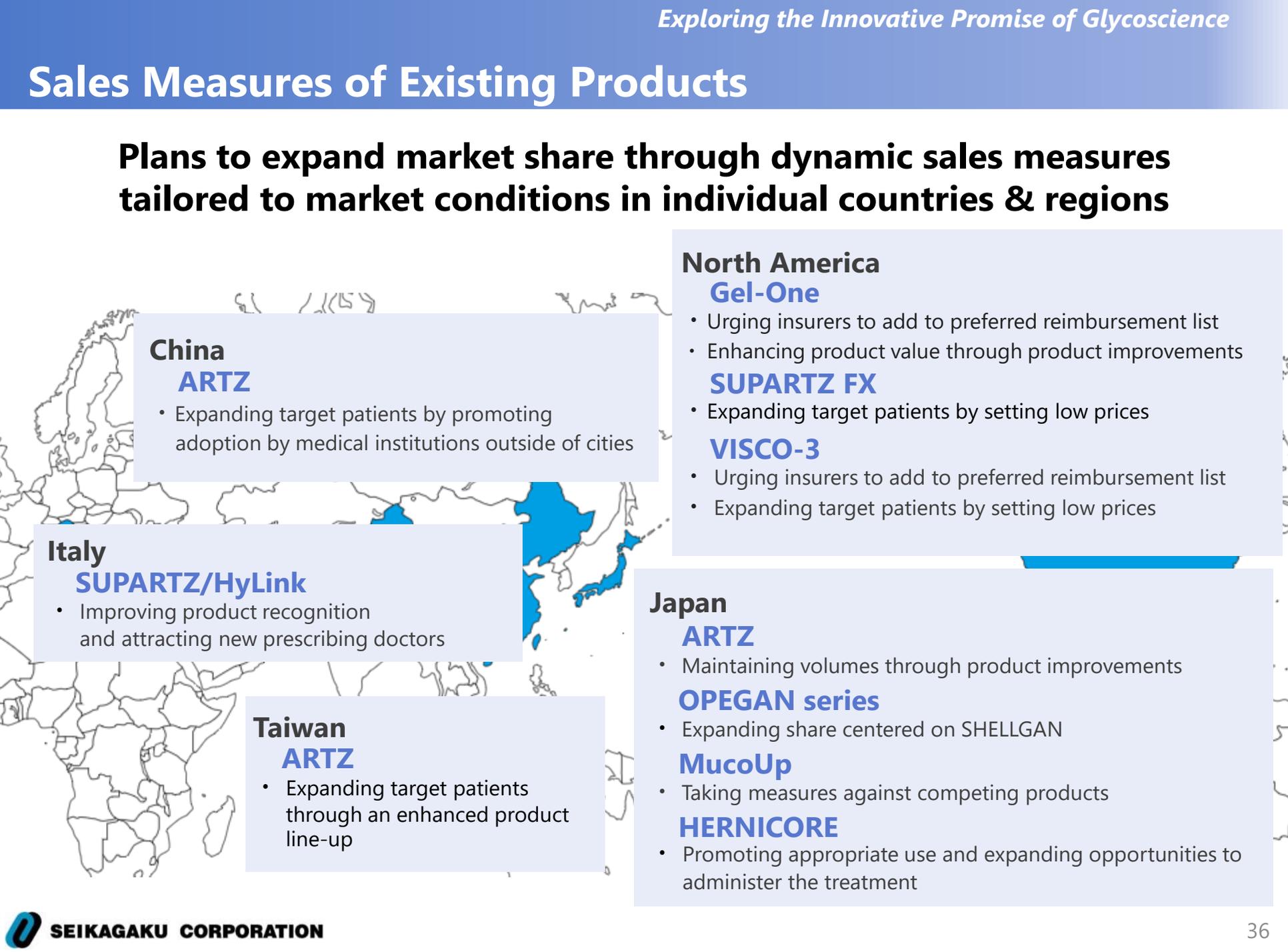
• August 2018
 Physicians of the Japanese Society for Spine Surgery and Related Research (JSSR) *1

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

Sales Measures of Existing Products

Plans to expand market share through dynamic sales measures tailored to market conditions in individual countries & regions



China

ARTZ

- Expanding target patients by promoting adoption by medical institutions outside of cities

Italy

SUPARTZ/HyLink

- Improving product recognition and attracting new prescribing doctors

Taiwan

ARTZ

- Expanding target patients through an enhanced product line-up

North America

Gel-One

- Urging insurers to add to preferred reimbursement list
- Enhancing product value through product improvements

SUPARTZ FX

- Expanding target patients by setting low prices

VISCO-3

- Urging insurers to add to preferred reimbursement list
- Expanding target patients by setting low prices

Japan

ARTZ

- Maintaining volumes through product improvements

OPEGAN series

- Expanding share centered on SHELLGAN

MucoUp

- Taking measures against competing products

HERNICORE

- Promoting appropriate use and expanding opportunities to administer the treatment

Accelerating Multinational Expansion of Existing Products and Products in Development



SI-613

SI-6603



- Setting sights on expansion regions based on current market surveys for rapid business expansion
- Promoting product improvement and application development to meet treatment needs in expansion regions



SI-614

SI-722



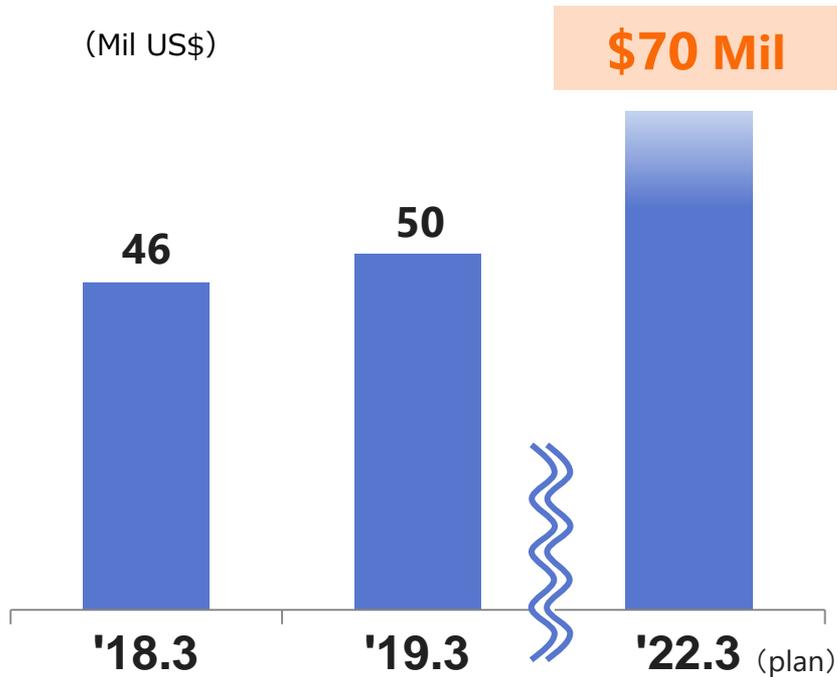
SI-449



Solidifying the profit foundation by expanding business in existing products and products in development

Global Expansion of Endotoxin-detecting Reagents that Leverage Genetic Recombination echnology

Worldwide roll-out led by ACC to expand LAL business



Sales for ACC (U.S. subsidiary)

* \$70 Mil. plan projected to be achieved one year later than initial plan

* ACC社 : Associates of Cape Cod, Inc., a Seikagaku wholly owned subsidiary

1. Global expansion of gene-recombinant endotoxin-detecting reagents

2. Using tie-ups with related companies to introduce and improve measuring instruments and software

Gene-recombinant endotoxin-detecting reagents

New reagents composed of gene-recombinant proteins extracted from the blood cells of horseshoe crabs instead of endotoxin-detecting reagents made from limulus ameocyte lysate (LAL)

Ⅲ. Productivity Improvement Reforms

Thorough cost reductions / Diversifying the profit model

Maximizing the Value of Resources

Implement measures and reforms to improve profitability

1. Thorough cost reductions

Manufacturing cost

- Ensuring profitability of existing products through efficient and optimized production and revising procurement costs

SGA Expenses

- Improving work efficiency and actually reducing costs
- Making efficient use of R&D expense for continuous drug discovery

2. Diversifying the profit model

Regardless of the business model up to now, carry out a vigorous examination of schemes to produce new profits

3. Creating an organization for maximizing resource value

Flexible responses to changes in the business environment

Development of talent that can create new value

Organizational reform that enables each person to make the fullest use of their potential

**Numerical targets
/Basic policy on profit distributions**

Numerical targets

	FY2018 results	FY2021 targets
Net sales	¥28.3 billion	¥28.3 billion
Ordinary income	¥2.8 billion	¥4.5 billion
SKK EBITDA *	¥4.6 billion	¥5.0 billion
Overseas sales ratio	42.2%	50.0%

« Assumptions »

- Expansion of overseas sales in the LAL business makes up for the effects of the NHI drug price revisions in Japan
- Depreciation declines as a result of impairment loss
- R&D expenses are 25–30% of sales
- Various royalty income is included as non-operating income
- Exchange rate: ¥105 to the U.S. dollar

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

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

Summary of Mid-term Management Plan

Our vision

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

Corporate slogan of the new mid-term business plan

Innovative Thinking
Creating value based on innovative thinking

Our Three Important Measures

Accelerating new drug
discovery to become
the pillar of new profits

Solidifying the profit
foundation through
market expansion of
new products

Productivity
improvement reforms

**Solidifying profit foundation and continual new drug development
essential for sustainable growth**

**Regardless of the existing framework ,
each key measure to have vigorous initiatives**

Appendix

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.

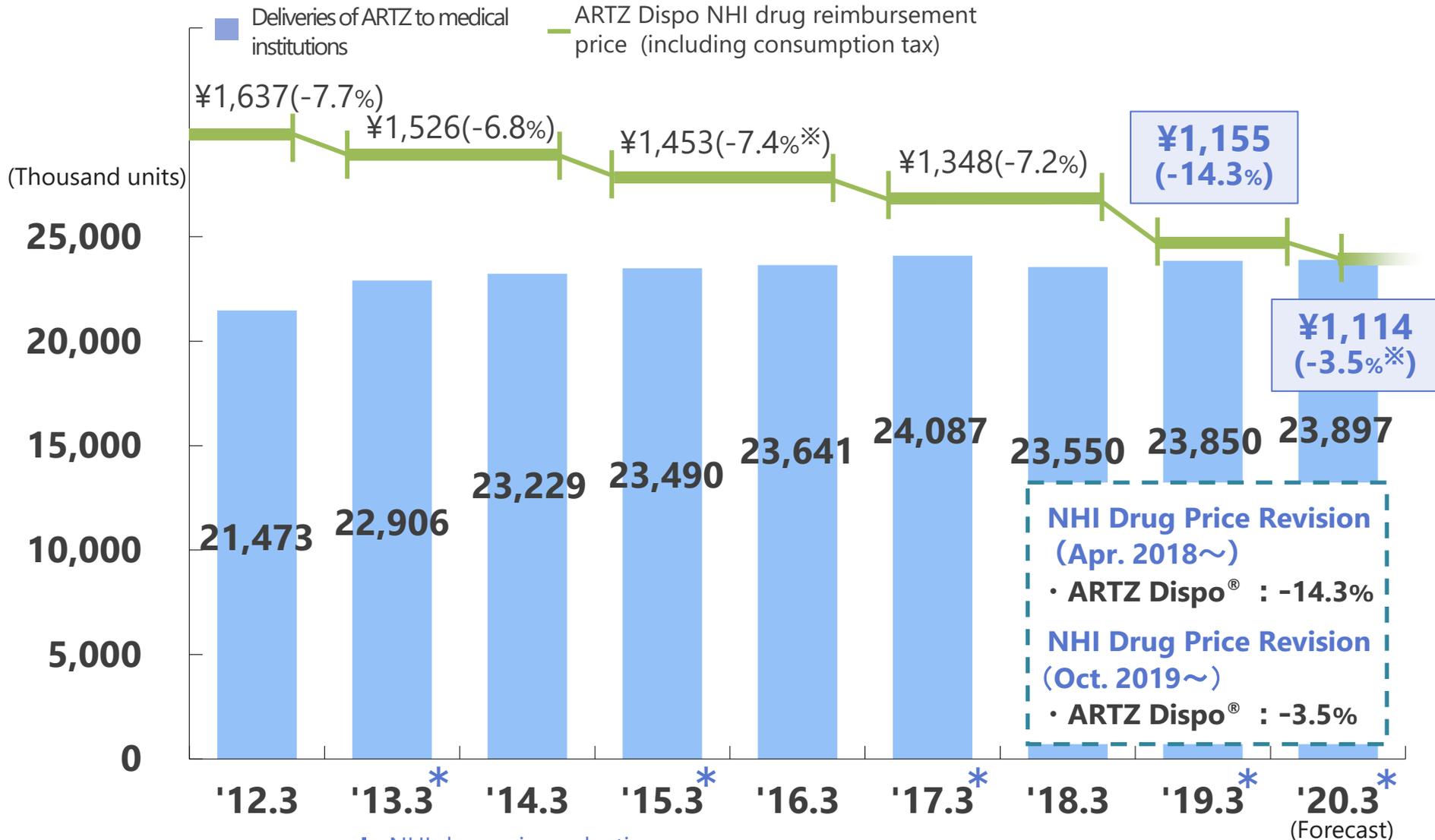
Mission statement

"Glycoscience for human well-being"

Corporate slogan of the new mid-term management plan

"Innovative Thinking"
Creating value based on innovative thinking

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



Trend in Deliveries of ARTZ / OPEGAN to Domestic Medical Institutions

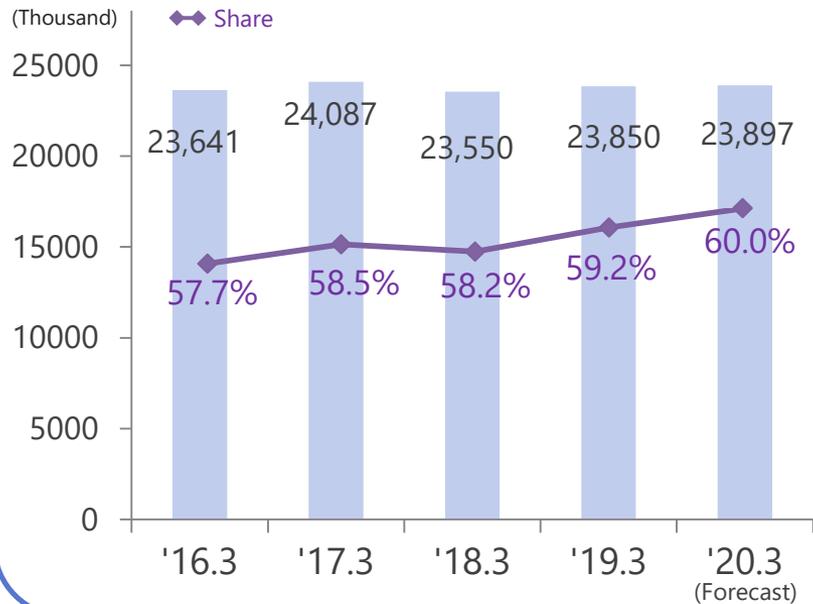
Joint-function improving agent

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



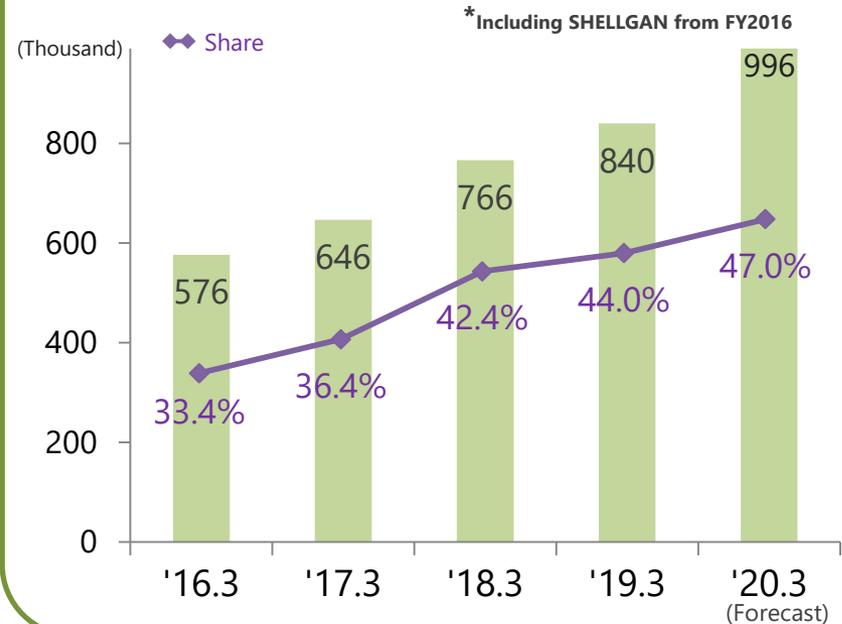
Ophthalmic viscoelastic devices

OPEGAN



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

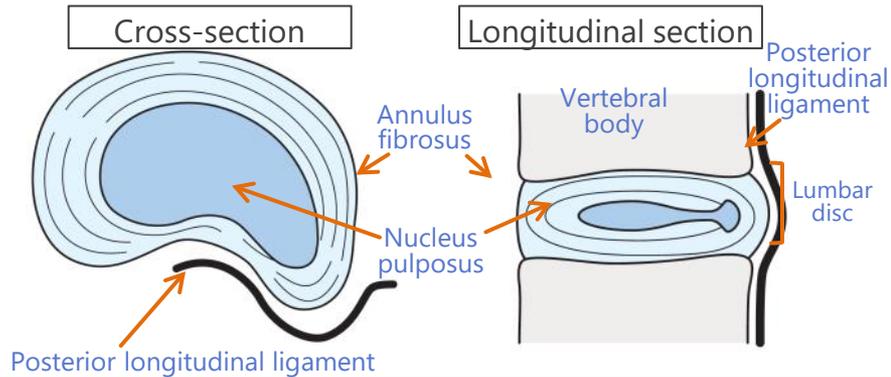
Trend in unit deliveries to medical institutions



Four types of lumbar disc herniation

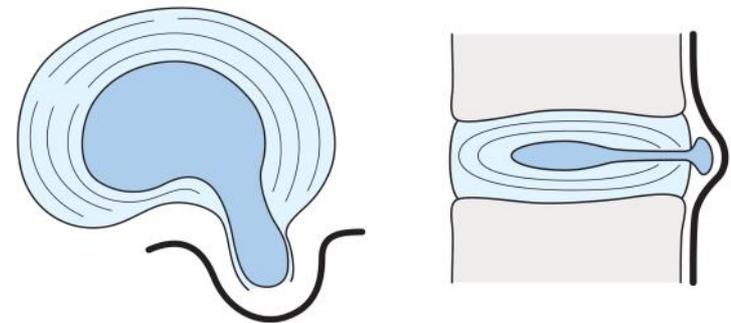
1. Protrusion

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



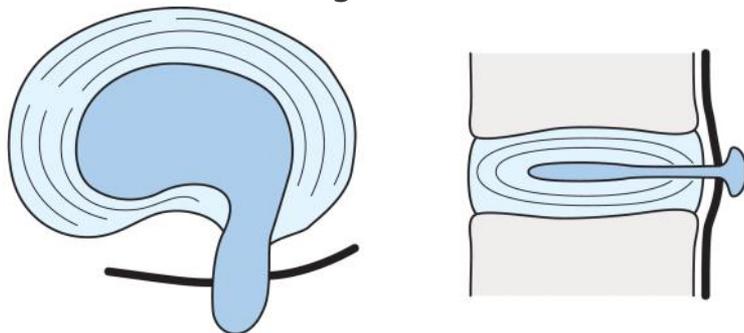
2. Subligamentous extrusion

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



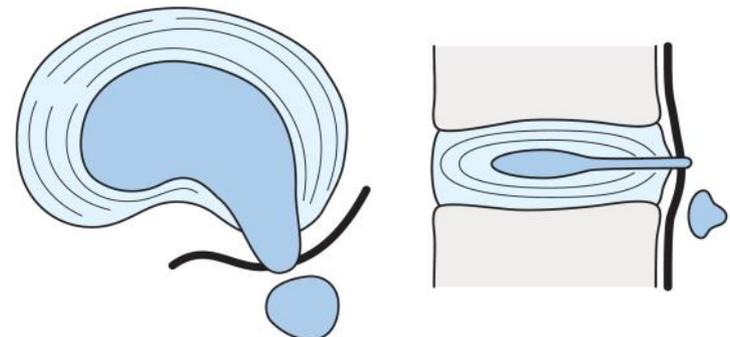
3. Transligamentous extrusion

The hernia perforates the posterior longitudinal ligament



4. Sequestration

The hernia migrates outside the dura mater



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

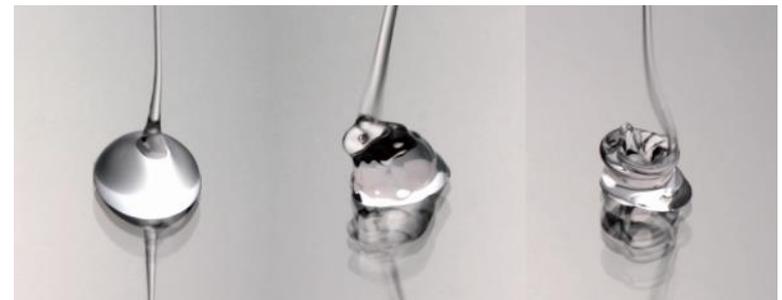


■ Product SHELLGAN Outline

- 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



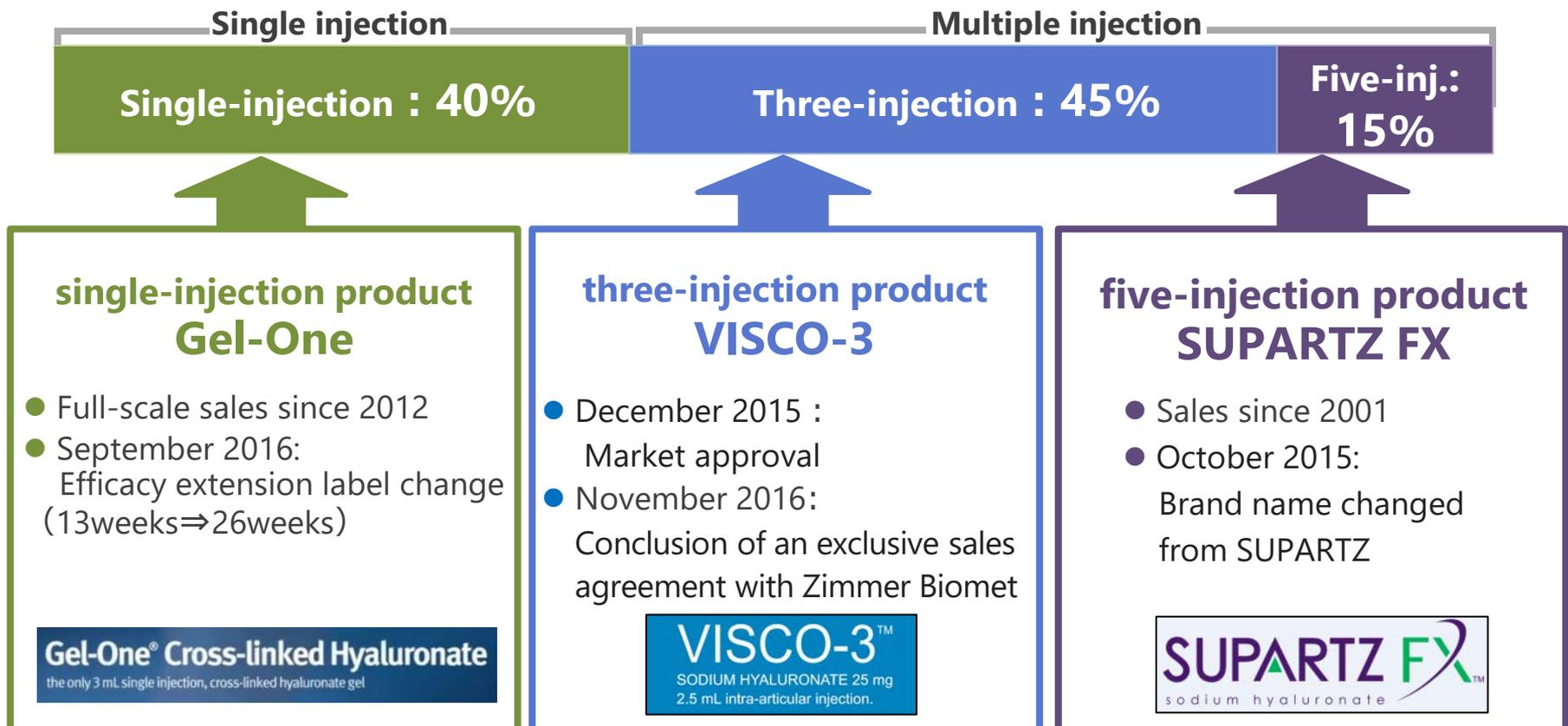
OPEGAN OPEGAN Hi SHELLGAN

The OPEGAN series viscoelasticity comparison

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

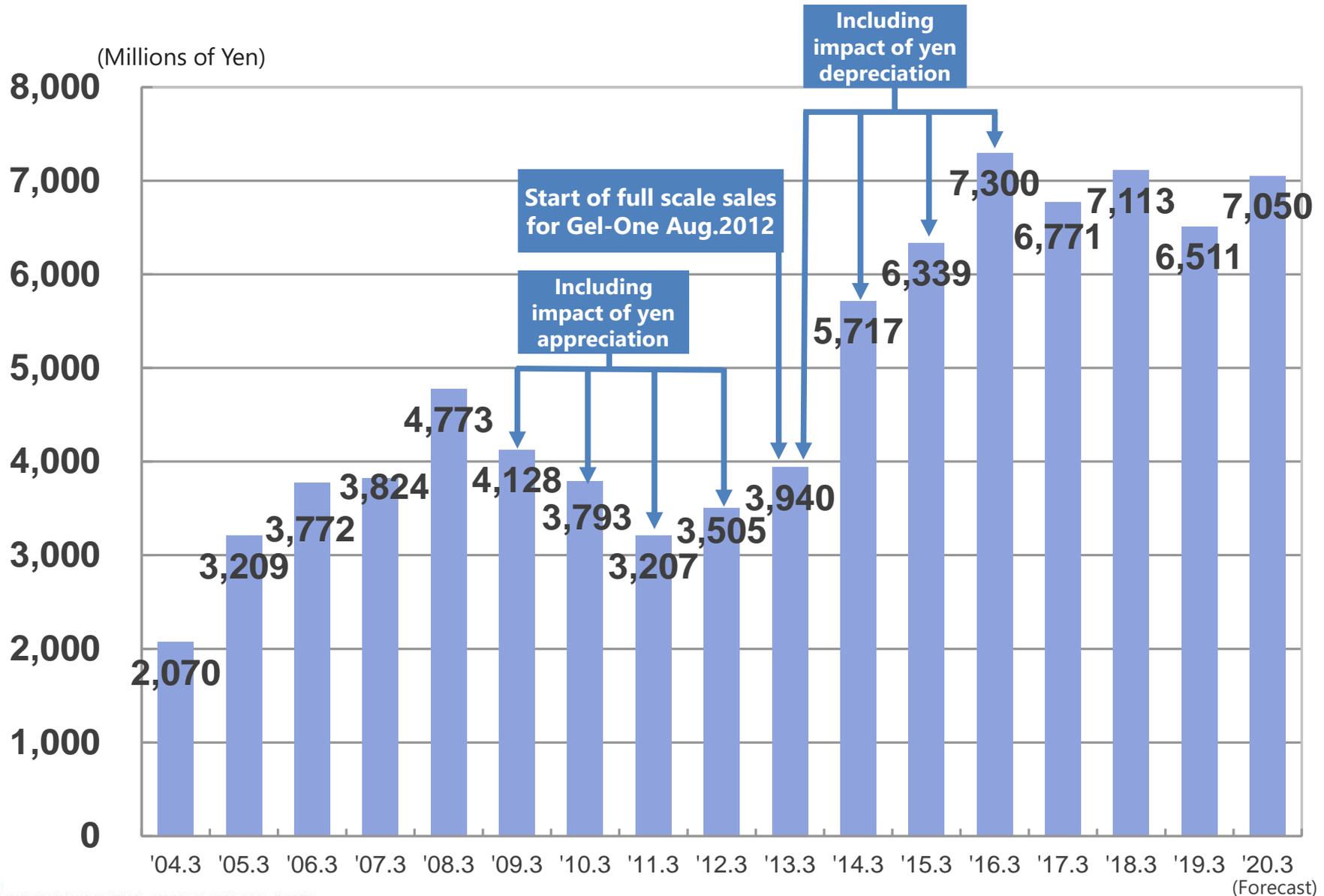
**Market size of US\$1,000 mil. in 2018 (-6.5% year-on-year)
The market contracted for the first time.**

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



*Figures for 2018, 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)

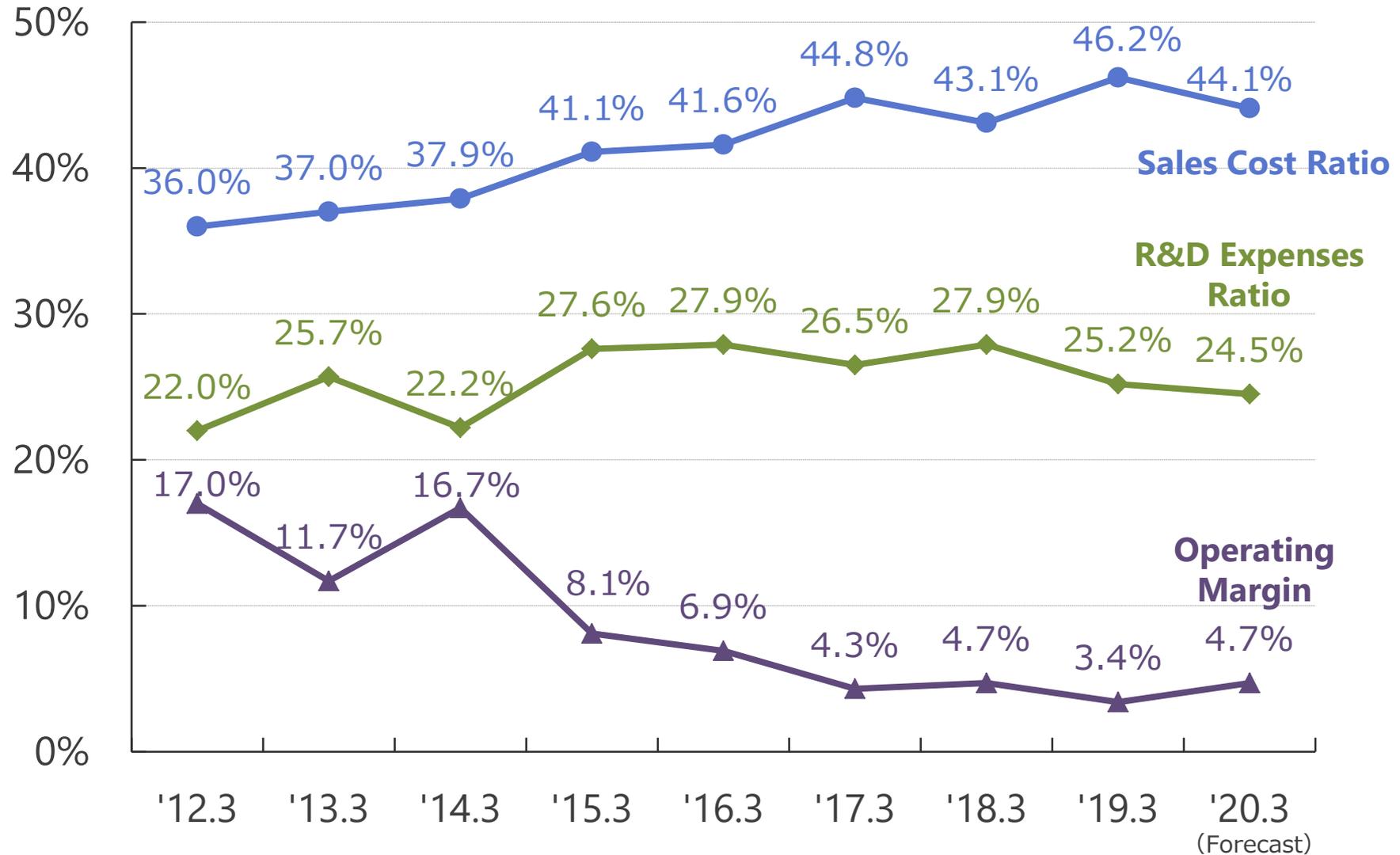


Exterior of the ACC offices



PYROCHROME®

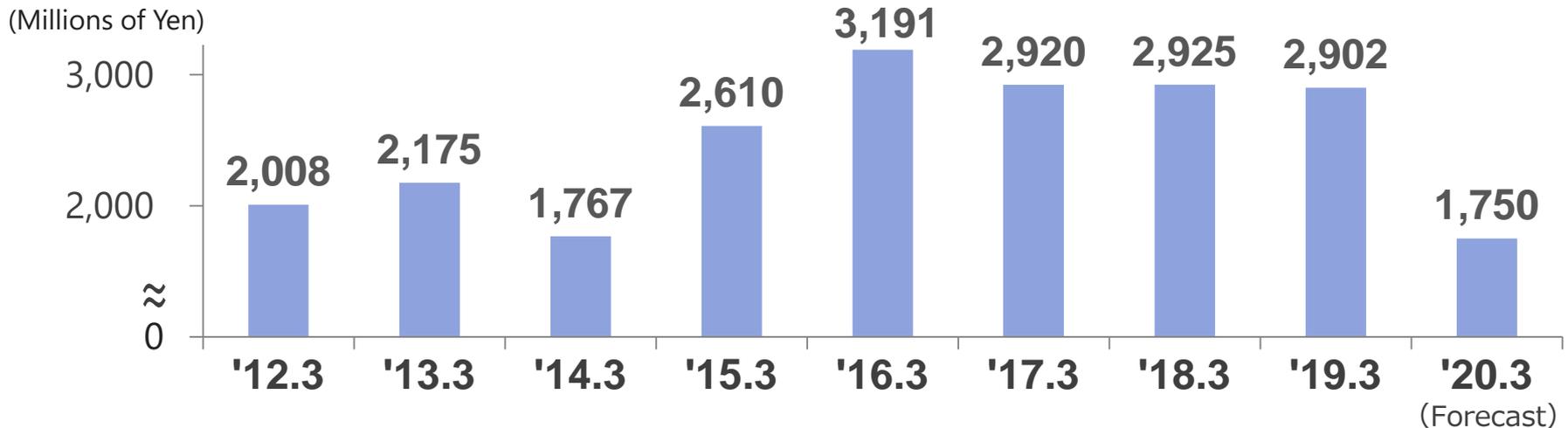
Trend in Financial Index



Trends in Depreciation & Capital Investments

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

■ Trend in Depreciation



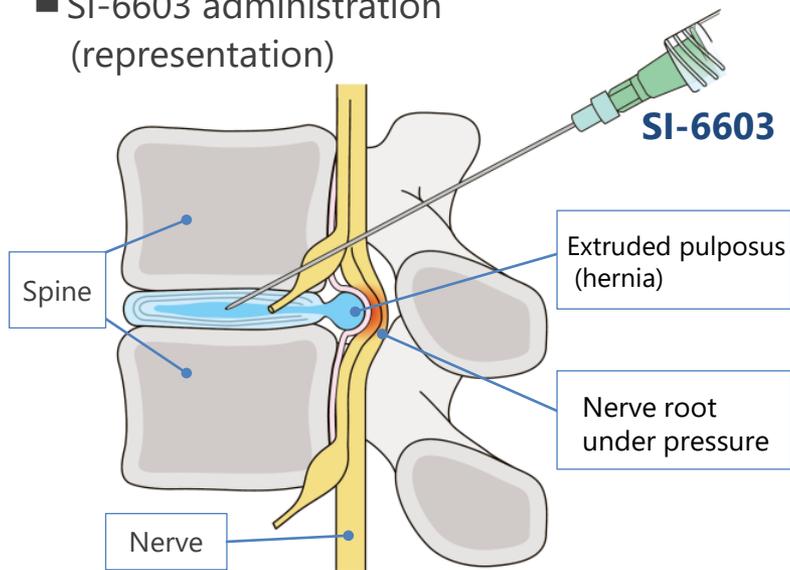
■ Trend in Capital Investments (Millions of Yen)

Fiscal Year	'12.3	'13.3	'14.3	'15.3	'16.3	'17.3	'18.3	'19.3	'20.3 (Forecast)
Capital Investments (Millions of Yen)	5,718	9,164	7,222	2,095	1,975	1,173	1,591	1,310	2,400

Outline of SI-6603 (Treatment for Lumbar Disc Herniation)

**Initiated a Phase III additional study in the U.S. in Feb 2018
Extending the study period and promoting the enrollment of subjects**

■ SI-6603 administration
(representation)



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

U.S. :P III

▶ November 2017: Announcement of PIII (previous) study results

- No statistically significant improvement in the primary endpoint found

▶ February 2018: PIII additional study initiated Increase the probability of success by making changes from the previous study

- Decrease the number of cases. (385⇒320 cases)
- Shorten the follow-up period. (2 years⇒1 year)
- Introduce a more objective hernia evaluation and confirmation method at the pre-enrollment stage

▶ Extending enrollment by two years, aiming for November 2022 completion

※Consider expansion into markets other than Japan and the U.S. once prospects for a U.S. NDA are in sight

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)

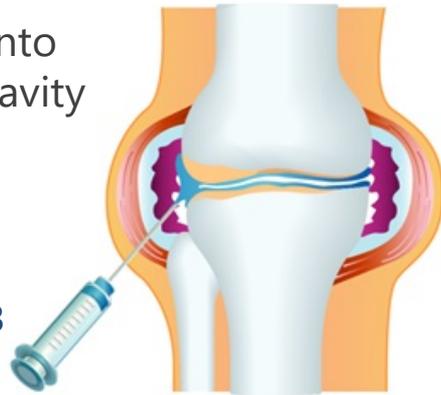
- Statistically significant improvement of leg pain at 13 weeks by VAS was not demonstrated
- ▶ ① There is a guideline for diagnostic and pathology of lumbar disc herniation in Japan, however there is no widely used guideline in the U.S. Therefore, there is possibility that some patients out of Japanese 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 Outline (Treatment of Osteoarthritis/Enthesopathy)

Aiming at prompt and sustained relief of the pain and inflammation associated with osteoarthritis or Enthesopathy

Injection into
the joint cavity



SI-613

<SI-613 summary>

Dev. code : SI-613

Generic name : Hyaluronic Acid-Diclofenac onjugates

Indication : Osteoarthritis

Method of use : Injection into joint

Expected Features

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

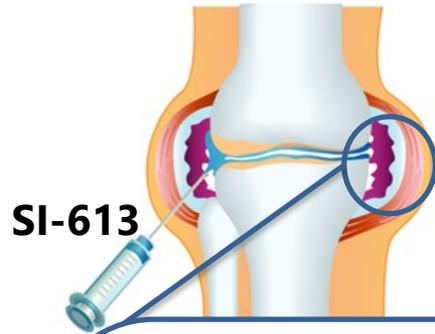
Prompt and sustained relief of pain and inflammation

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

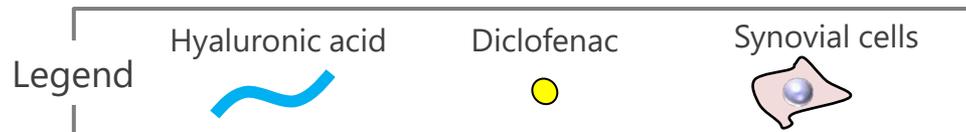
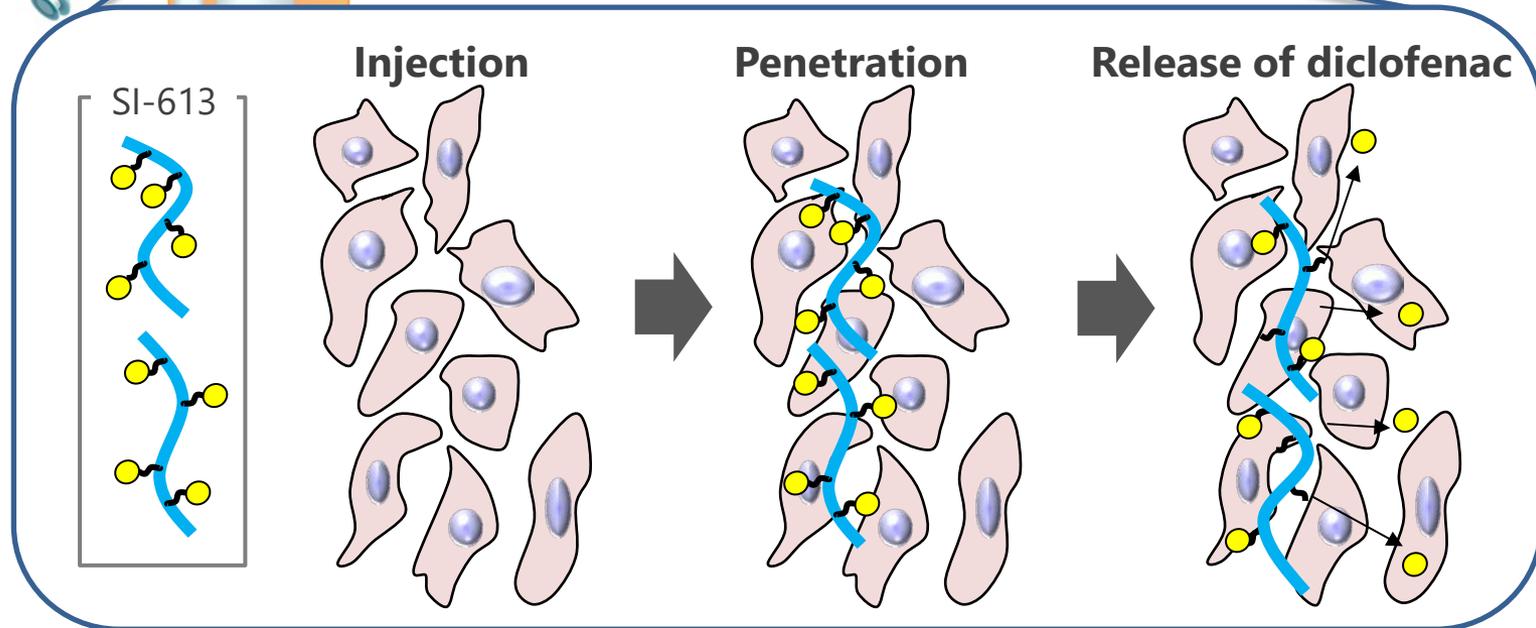
Low risk of systemic side effects

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

Sustained Release of Diclofenac in SI-613

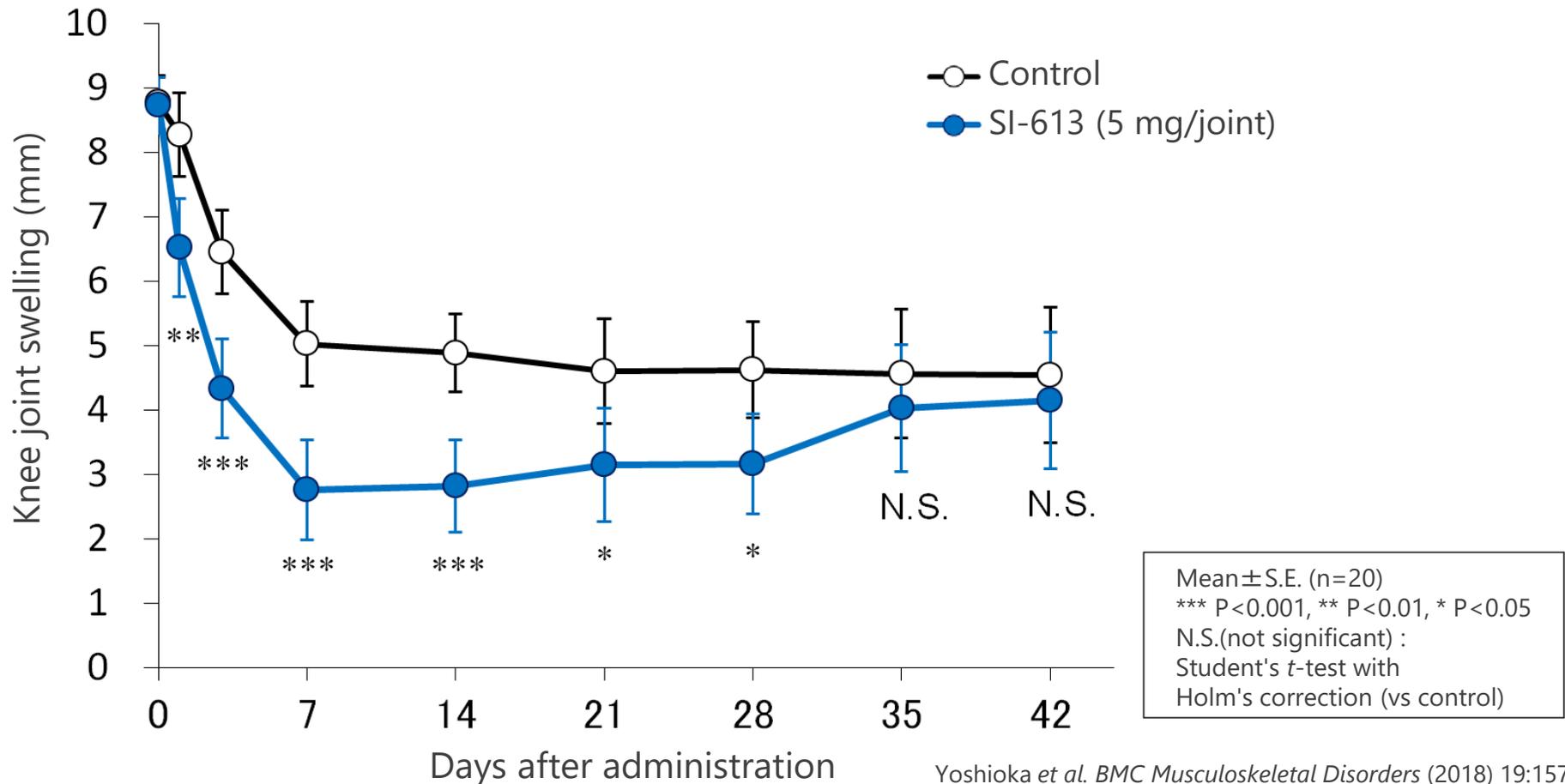


SI-613 (substance name: hyaluronic acid-diclofenac conjugate) is thought to penetrate the synovial membrane (connective tissue within the articular capsule) and gradually release diclofenac



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>

Initiatives to maximize the product value of SI-613

**Promote in co-development with Ono Pharmaceutical,
the product that can be administered to greater numbers of patients**

Osteoarthritis: PIII

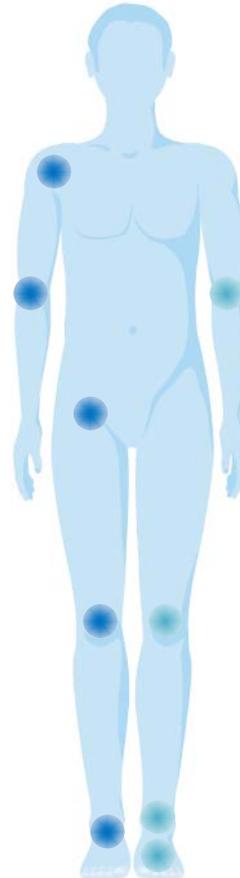
A disease in which joint tissue deteriorates due to abrasion of the articular cartilage, leading to inflammation and pain

Conduct of three clinical trials

- Confirmatory study (knee joint)
- Study for four sites (hip, ankle, elbow, shoulder)
- Long-term administration study (knee joint)

Number of patients examined per year : Approx. 8.7 million

(Seikagaku estimate for five main sites:
knee, hip, ankle, elbow, shoulder in Japan)



Enthesopathy: PIIb

An inflammatory disease that occurs as a result of excessive load on sites of attachment of ligaments and tendons to other bone or muscle, such as the knee, elbow, heel

Typical examples

- Lateral epicondylitis (tennis elbow)
- Plantar fasciitis
- Patellar tendinitis (jumper's knee)
- Achilles tendonitis, etc.

Number of patients receiving drug therapy per year:

Approx. 0.9 million

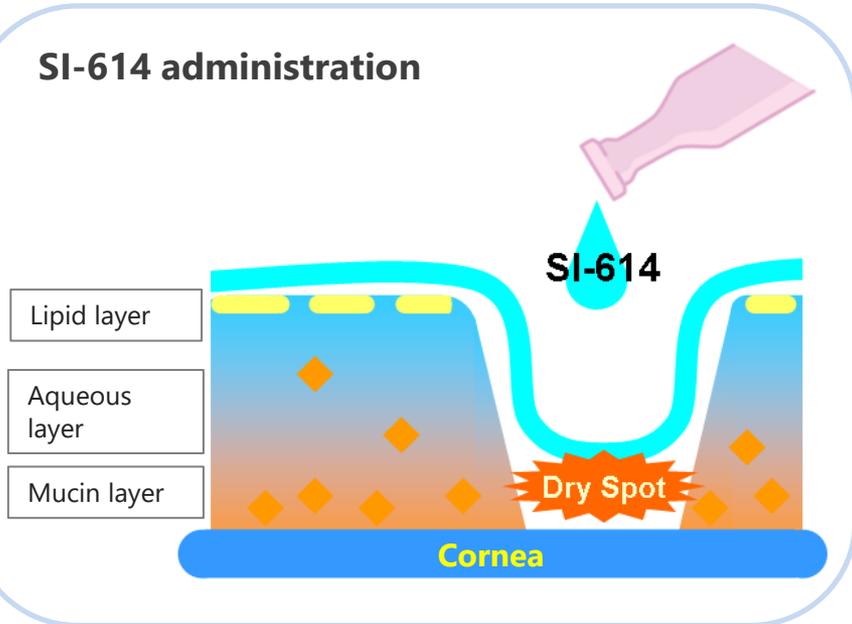
(Seikagaku estimate for the above four diseases in Japan)



SI-614 Outline (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



< SI-614 summary >

Dev. Code	: SI-614
Generic name	: Modified Hyaluronate
Indication	: Dry eye
Formulation	: Ophthalmic solution
Estimated U.S. patient	: 4.9 million (Seikagaku estimates)

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

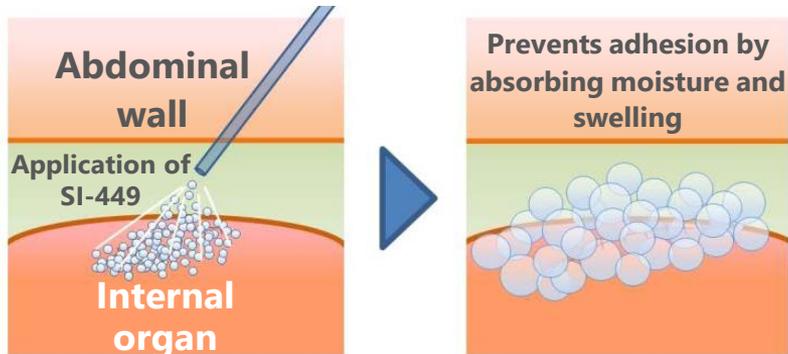
Expected Features

- ▶ SI-614 is a modified hyaluronate produced by Seikagaku's proprietary technology
- ▶ SI-614 Improves symptoms of dry eye by protecting the ocular surface and promoting corneal epithelial wound healing
- ▶ Many factors are involved in dry eye, and SI-614 has the potential to provide a therapeutic option based on a new mechanism unavailable from products with anti-inflammatory mechanisms now on the market in the U.S.

SI-449 Outline (Adhesion Barrier / Medical Device)

Powdered formulation for preventing or mitigating post-operative adhesions by forming a barrier between the surgical wound site and surrounding tissues

SI-449 usage



<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)

Expected Features

- ▶ By absorbing moisture and swelling, SI-449 forms a barrier between the surgical wound site and the surrounding tissues and is expected to prevent or mitigates post-operative adhesions
- ▶ It consists of substances naturally present in the body, including the cross-linking agent, and is highly biocompatible
- ▶ Since SI-449 is a powdered formulation, it adheres well to uneven tissue surfaces and is thought to offer excellent utility in laparoscopic surgery, a common surgical procedure

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 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-449 Adhesion Barrier	Japan	Pilot study (UMIN000033294)	20	Jul. 2018 – Nov. 2019	Safety, Manageability (–)

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. ¥10.0 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	—	—

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

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)

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

Basic Policy on Profit Distribution

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

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

	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019 (Forecast)
Net Income per share	¥64.27	¥45.39	¥31.55	¥69.30	¥39.76	¥-194.99
Annual Total Dividend	¥26.00	¥26.00	¥31.00 [※]	¥26.00	¥26.00	¥26.00
Dividend Payout Ratio	40.5%	57.3%	98.3%	37.5%	65.4%	—

※including a 70th anniversary commemorative dividend of ¥5 per share

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 77.1%

Ophthalmic Surgical Aids



Bulk Products



Domestic
Pharmaceuticals
→ 49.9%

Joint Function Improving Agents



Bulk Products
→ 4.3%

Overseas
Pharmaceuticals
→ 22.9%



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



LAL Business 22.9%

Net Sales
28,384million
(FY2018 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

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.



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