Exploring the Innovative Promise of Glycoscience

Financial Results for the Fiscal Year 2018

(April 1, 2018 – March 31, 2019)

SEIKAGAKU CORPORATION

(TSE:4548)

Contents

- **FY2018 Results** P3
  - Net Sales / Income P4-7
- **FY2019 Forecasts** P8
  - Net Sales / Income P9-10
  - Trend in R&D Expenses P11
- **Sales by Business Segment**
  - Domestic Pharmaceuticals P12-13
  - Overseas Pharmaceuticals P14-15
  - LAL P16
- **Research and Development** P17
  - SI-6603 (Lumbar disc herniation) P18
  - SI-613 (Osteoarthritis / Enthesopathy) P19-22
  - SI-449 (Adhesion Barrier) P23
- **Mid-term Management Plan**
  - Summary of the Previous Mid-term Management Plan P24
  - Outline of the Next Mid-term Management Plan P25
- **Basic Policy on Profit Distribution** P26
- **Appendix** P27

< 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 of Fiscal Year 2018

(Millions of Yen)	FY2018 Results	Year-on-Year		Comparison with Revised Forecasts (4/23)	
		Change	% of Change	Change	% of Change
Net sales	28,384	-1,791	-5.9%	+34	+0.1%
Operating Income	977	-444	-31.3%	+27	+2.9%
Ordinary Income	2,859	-2,468	-46.3%	+59	+2.1%
Net Income	2,244	-1,678	-42.8%	+44	+2.0%
R&D Expenses (Ratio to net sales)	7,148 (25.2%)	-1,259 (-2.7pt)	-15.0%	-1 (-0.0pt)	-0.0%
Average Exchange Rate (1US$)	¥110.91	+¥0.05			

	FY2018 Results	FY2017 Results	FY2018 Revised Forecasts
Net Income per Share	**¥39.76**	¥69.30	¥38.97
Dividend per Share	**¥26.00**	¥26.00	¥26.00
Dividend Payout Ratio	**65.4%**	37.5%	66.7%
R O E	**3.1%**	5.4%	

Net sales by Business Segment (FY2018)

(Millions of Yen)	FY2018 Results	Year-on-Year	% of Change
Net sales	28,384	-1,791	-5.9%
Pharmaceuticals	21,893	-2,351	-9.7%
Domestic Pharmaceuticals	14,161	-1,963	-12.2%
Overseas Pharmaceuticals	6,511	-602	-8.5%
Bulk Products	1,220	+214	+21.4%
LAL Business	6,491	+559	+9.4%
(Overseas sales)	11,966	-85	-0.7%

*Foreign exchange impact on overall net sales: approx. -120 million yen

Domestic Pharmaceuticals

➢ ARTZ

(Joint function improving agent)

・Seikagaku sales down, reflecting the impact of NHI drug price reductions implemented in April 2018 (-14.3%)

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

➢ OPEGAN series

(Ophthalmic viscoelastic devices)

・Seikagaku sales up. Volume growth compensating for NHI drug price reductions (approx. -9%)

➢ HERNICORE

(Treatment for lumbar disc herniation)

・Seikagaku sales low during launch-year roll out

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

➢ MucoUp

(Submucosal injection agent for endoscopic surgery)

・Seikagaku sales up slightly due to the impact of carrying over FY2017 shipments into FY2018

Net sales by Business Segment (FY2018)

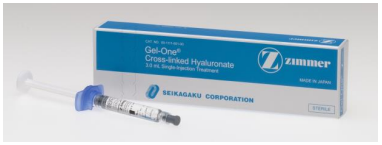
(Millions of Yen)	FY2018 Results	Year-on-Year	% of Change
Net sales	28,384	-1,791	-5.9%
Pharmaceuticals	**21,893**	**-2,351**	**-9.7%**
Domestic Pharmaceuticals	14,161	-1,963	-12.2%
Overseas Pharmaceuticals	**6,511**	**-602**	**-8.5%**
Bulk Products	1,220	+214	+21.4%
LAL Business	6,491	+559	+9.4%
(Overseas sales)	11,966	-85	-0.7%

*Foreign exchange impact on overall net sales: approx. -120 million yen

Overseas Pharmaceuticals

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

- **Gel-One in the U.S. (single injection)**
  Local sales and Seikagaku sales up



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

- **SUPARTZ FX in the U.S.**
  (Multiple injection)
  Sales down sharply due to soft local sales coupled with the impact of high shipment volumes in FY2017

- **ARTZ in China (Multiple injection)**
  Continuing upward trend in local sales

- **HyLink in Italy (Single injection)**
  Start of sales in March 2019

Net sales by Business Segment (FY2018)

(Millions of Yen)	FY2018 Results	Year-on-Year	% of Change
Net sales	28,384	-1,791	-5.9%
Pharmaceuticals	21,893	-2,351	-9.7%
Domestic Pharmaceuticals	14,161	-1,963	-12.2%
Overseas Pharmaceuticals	6,511	-602	-8.5%
Bulk Products	1,220	+214	+21.4%
LAL Business	6,491	+559	+9.4%
(Overseas sales)	11,966	-85	-0.7%

*Foreign exchange impact on overall net sales: approx. -120 million yen

Bulk Products

Higher sales of hyaluronic acid and chondroitin sulfate for pharmaceutical companies

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

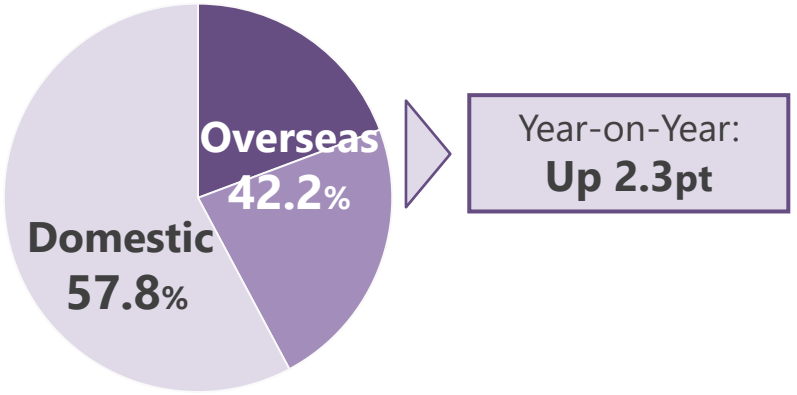
LAL Business

*Foreign exchange impact on LAL Business: approx. -90 million yen

Strong domestic and overseas sales of endotoxin-detecting reagents and other products

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

Overseas Sales Ratio



Income in FY2018 (Year-on-Year)

(Millions of Yen)	FY2018 Results	Year-on-Year	% of Change
Net sales	28,384	-1,791	-5.9%
Cost of Sales (Cost of Sales ratio)	13,114 (46.2%)	+105 (+3.1pt)	+0.8%
SGA expenses	14,292	-1,452	-9.2%
R&D Expenses (to Net sales ratio)	7,148 (25.2%)	-1,259 (-2.7pt)	-15.0%
Operating Income (to Net sales ratio)	977 (3.4%)	-444 (-1.3pt)	-31.3%
Ordinary Income	2,859	-2,468	-46.3%
Net Income	2,244	-1,678	-42.8%
Depreciation	2,902	-22	-0.8%

Operating Income

Cost of Sales Ratio (+3.1pt):

Increase due to the impact of NHI drug price reductions

SGA Expenses (-1,452):

- Increase at the overseas subsidiary accompanying more active overseas sales activities in the LAL business
- R&D expenses down due to decrease of SI-6603 in the U.S. although SI-613 in Japan increased （-1,259）
- Decrease at Seikagaku due to expense-cutting measures

Net Income

Non-operating Income / Expenses (-2,023):

- Increase in gain on sale of investment securities (+581)
- Decrease in royalty income (-2,390)

Income Taxes (Tax Rate: 21.5%):

Impact of a tax decrease in the U.S. (-4.9 pt)

Overview of Forecasts in FY2019

(Millions of Yen)	FY2019 Forecasts	FY2018 Results		
		Results	Change	% of Change
Net sales	28,250	28,384	-134	-0.5%
Operating Income	400	977	-577	-59.1%
Ordinary Income	2,300	2,859	-559	-19.6%
Net Income	2,000	2,244	-244	-10.9%
R&D Expenses (to Net sales ratio)	6,800 (24.1%)	7,148 (25.2%)	-348 (-1.1pt)	-4.9%
Average Exchange Rate (1US$)	¥105.00	¥110.91	-¥5.91	

	FY2019 Forecasts	FY2018 Results
Net Income per share	¥35.46	¥39.76
Dividend per share	¥26.00	¥26.00
Dividend Payout ratio	73.3%	65.4%

Exchange Rate Sensitivity (Impact of a change of ¥1against the US$)	
Net sales	Approx. ¥110 million
Operating income	Approx. ¥55 million

Forecasts (Net sales) in FY2019

(Millions of Yen)	FY2019 Forecasts	Year-on-Year Change	Year-on-Year % of Change
Net sales	28,250	-134	-0.5%
Pharmaceuticals	21,600	-293	-1.3%
Domestic Pharmaceuticals	14,000	-161	-1.1%
Overseas Pharmaceuticals	6,650	+138	+2.1%
Bulk Products	950	-270	-22.1%
LAL Business	6,650	+158	+2.4%
(Overseas sales)	12,250	+283	+2.4%

*Foreign exchange impact on overall net sales: approx. -610 million yen

Net Sales

Forecast of sales at the prior-year level due to NHI drug price reductions and exchange rate impact, despite higher pharmaceutical sales volume and LAL business sales

Pharmaceuticals Business

Domestic Pharmaceuticals:

- Forecast of a sales decrease, factoring in NHI price decreases during the term
- Forecast of small sales of HERNICORE, which is in the appropriate use and safety information gathering phase

Overseas Pharmaceuticals:

- Planning to compensate for exchange rate impact (approx. -310 million yen) and lower shipments of SUPARTZ FX in the U.S. with higher shipments of single-injection products

Bulk Products:

- Lower sales of hyaluronic acid and chondroitin sulfate

LAL Business

Planning for a sales increase, with overseas sales expansion compensating for exchange rate impact (approx. -300 million yen)

Forecasts (Income) in FY2019

(Millions of Yen)	FY2019 Forecasts	Year-on-Year	
		Change	% of Change
Net sales	28,250	-134	-0.5%
Operating Income (to Net sales ratio)	400 (1.4%)	-577 (-2.0pt)	-59.1%
Ordinary Income	2,300	-559	-19.6%
Net Income	2,000	-244	-10.9%
Cost of Sales ratio	47.1%	+0.9pt	
R&D Expenses (to Net sales ratio)	6,800 (24.1%)	-348 (-1.1pt)	-4.9%
Depreciation	2,950	+47	+1.6%

Income

Decrease in income due to higher other SGA expenses, despite a forecast of lower R&D expenses

Operating Income

Cost of Sales Ratio (+0.9pt):

- Increase due to NHI drug price reductions and the impact of yen appreciation

SGA Expenses (approx. +250):

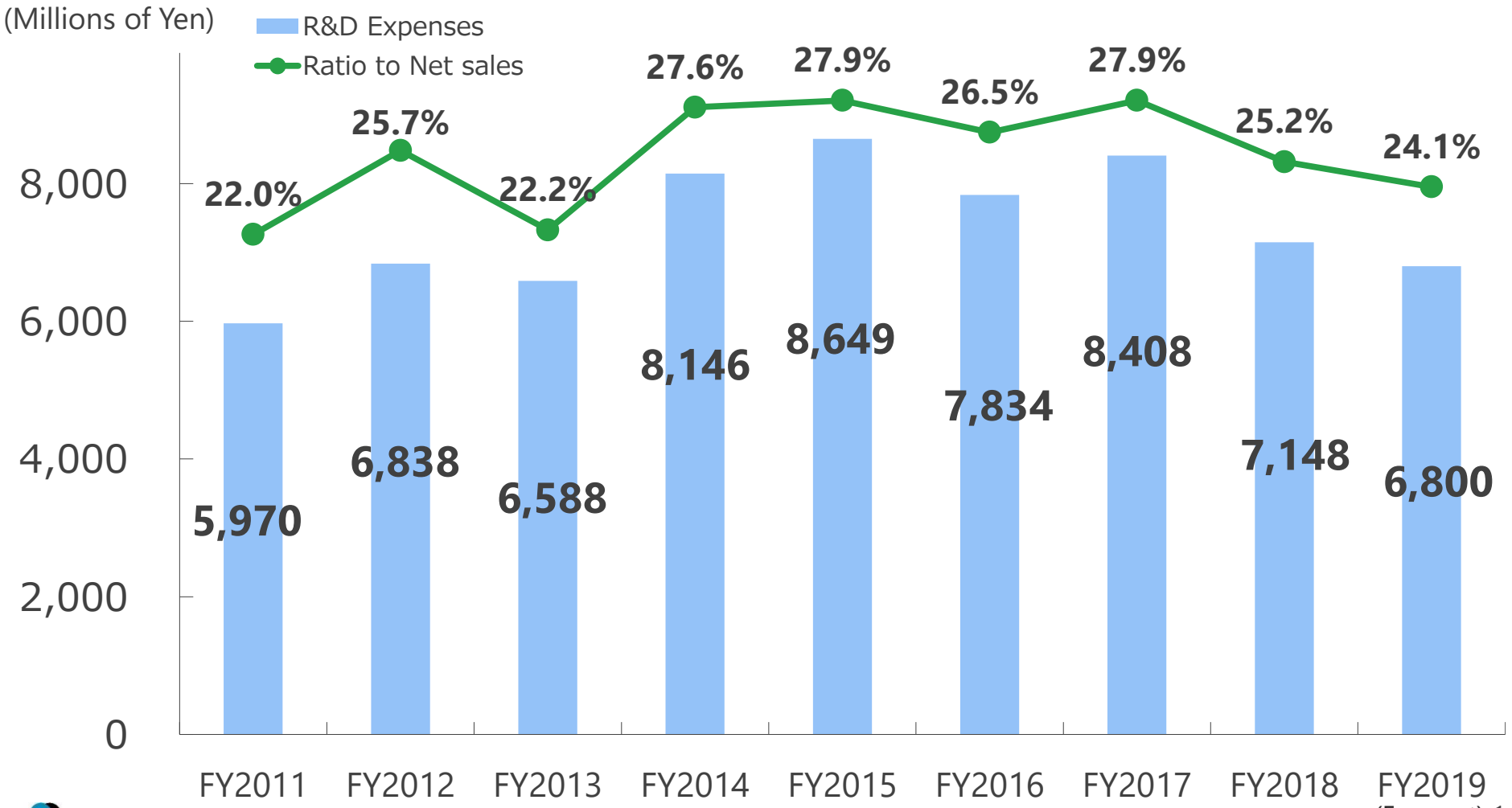
- R&D expenses (-348):
  Mainly lower clinical study expenses for SI-613
- Other SGA expenses: (approx. +600):
  Higher expenses for updating backbone systems and HERNICORE post-marketing study expenses

Net Income

- Non-operating Income/Expenses:
  Expected record of milestone royalties
- Extraordinary income:
  Partial sale of investment securities, etc.

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)

Joint-function improving agent

ARTZ

FY2018 Results

- Market contraction owing to expansion of treatment options due to the emergence of concomitant drugs and other factors
- Sales increase for ARTZ due to sales expansion measures for the modified product introduced in October

ARTZ growth rate:+1.3%
(Market growth rate:-0.5%)
Market share:59.2% (+1.0pt)

FY2019 Forecasts

- Aim to maintain sales volumes through the provision of academic information, such as reinforcement of evidence data

ARTZ growth rate	Market share
+0.2% (forecast)	**60.0%** (forecast)

Ophthalmic viscoelastic devices

OPEGAN (including SHELLGAN)

FY2018 Results

- Continued market penetration for SHELLGAN
- Market share expansion, with share reaching a record high

OPEGAN growth rate:+9.7%
(Market growth rate:+5.8%)
Market share:44.0% (+1.6pt)

FY2019 Forecasts

- Publicize SHELLGAN's product features
- Aim to capture share from competitors by continuing targeted sales promotion activities

OPEGAN growth rate	Market share
+5.4% (forecast)	**45.8%** (forecast)

HERNICORE in Japan

The first therapeutic agent for lumbar disc herniation in Japan
To aim for a phased rollout with promoting appropriate use

＜Status of Key Activities＞

- Engaging in information provision activities targeting physicians to promote appropriate use and ensure safety. Gathering safety information together with the sales partner as a post-marketing study
- Deliveries to medical institutions steadily increasing, although still low
- Start of use by supervisory physicians of the Neuralspinal Society of Japan (April 2019), as well as physicians of Japanese Society for Spine Surgery and Related Research
- Currently planning to gather and assess safety information and review it in collaboration with academic societies with the consent of the regulatory authorities to prepare for a review of use requirements

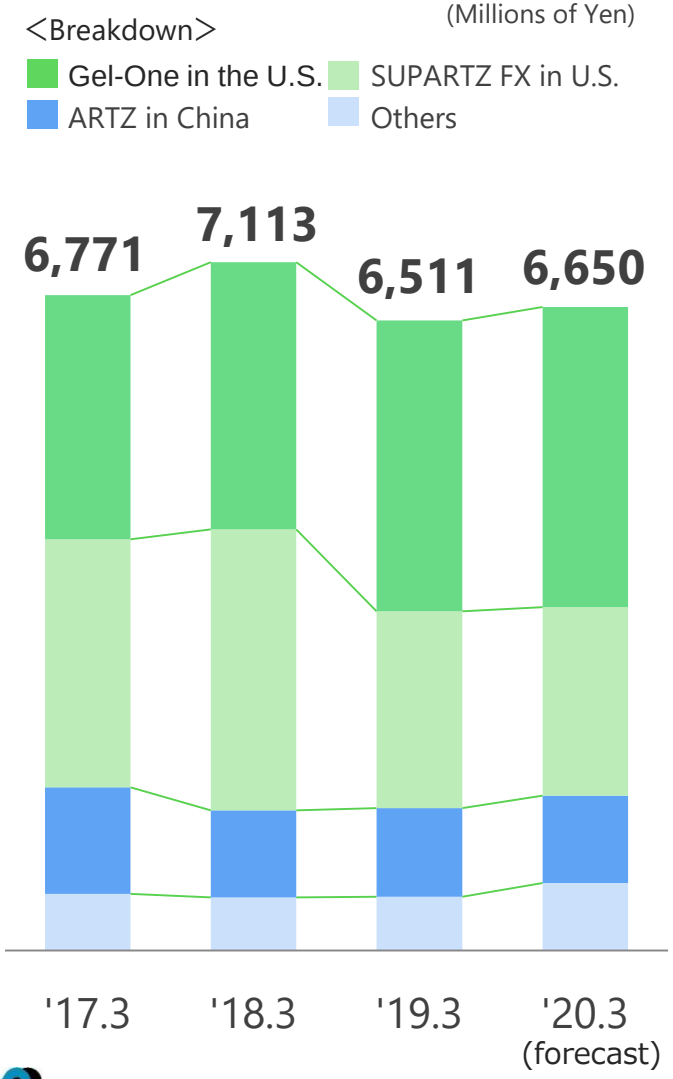
<Photograph of the HERNICORE>

Product name	HERNICORE® 1.25 Units for Intradiscal Injection	Generic name	Condoliase
Efficacy and effects	Lumbar disc herniation by prolapse of the posterior longitudinal ligament for which sufficient improvement cannot be obtained through conservative treatment		
NHI drug price	81,676 yen (1 bottle containing 1.25 units)	Launch date	August 1, 2018

Overseas Pharmaceuticals (FY2018 Results Year-on-Year / value basis)

Overseas Pharmaceuticals Sales trend

(Millions of Yen)



FY2018 Results -8.5%

Sharp sales decrease for SUPARTZ FX in the U.S. due to intensification of competition and suspension of reimbursement by some insurance companies

U.S.

● Sales in the U.S.

・Gel-One (Single injection)：Increase due to successful sales promotion measures and granted preferential reimbursement status by multiple private insurance companies in 2019 (Volume basis: +10%)

・SUPARTZ FX (Multiple injection)：Decrease due to the strong impact of suspension of reimbursement for HA* injectable treatments by some insurance companies (Volume basis: -12%)

➢ Seikagaku exports

Exports down due to a sharp decrease for SUPARTZ FX, despite an increase for Gel-One

China, Other Regions

● Local sales of ARTZ in China

Sales up due to stepping up of sales expansion activities targeting urban and surrounding areas (Volume basis: +14%)

➢ Seikagaku exports

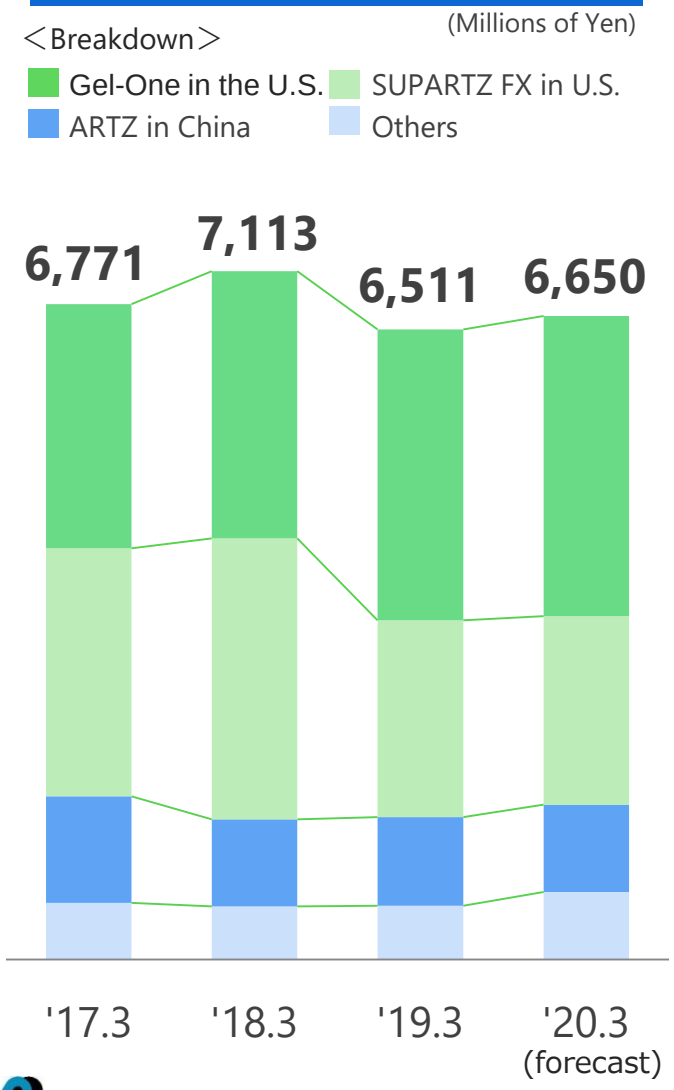
Exports to China slightly up, exports to other regions at the prior-year level

＊HA：Hyaluronic Acid

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

Overseas Pharmaceuticals Sales trend

(Millions of Yen)



FY2019 Forecasts +2.1%

Planning for an increase in sales of Gel-One and HyLink in Italy to compensate for a decrease in sales of SUPARTZ FX in the U.S.

U.S.

● Sales in the U.S.

・Gel-One (Single injection)：Planning for growth of approx. 4% (volume basis) to result from sales expansion aimed at new customer acquisition

・SUPARTZ FX (Multiple injection)：The impact of suspension of reimbursement is expected to run its course, but sales expected to continue to decrease due to intensification of competition for multiple-injection products (Volume basis: -3%)

➢ Seikagaku exports

Exports at the prior-year level, with an increase in shipments of Gel-One compensating for a decrease in shipments of SUPARTZ FX

China, Other Regions

● Local sales of ARTZ in China

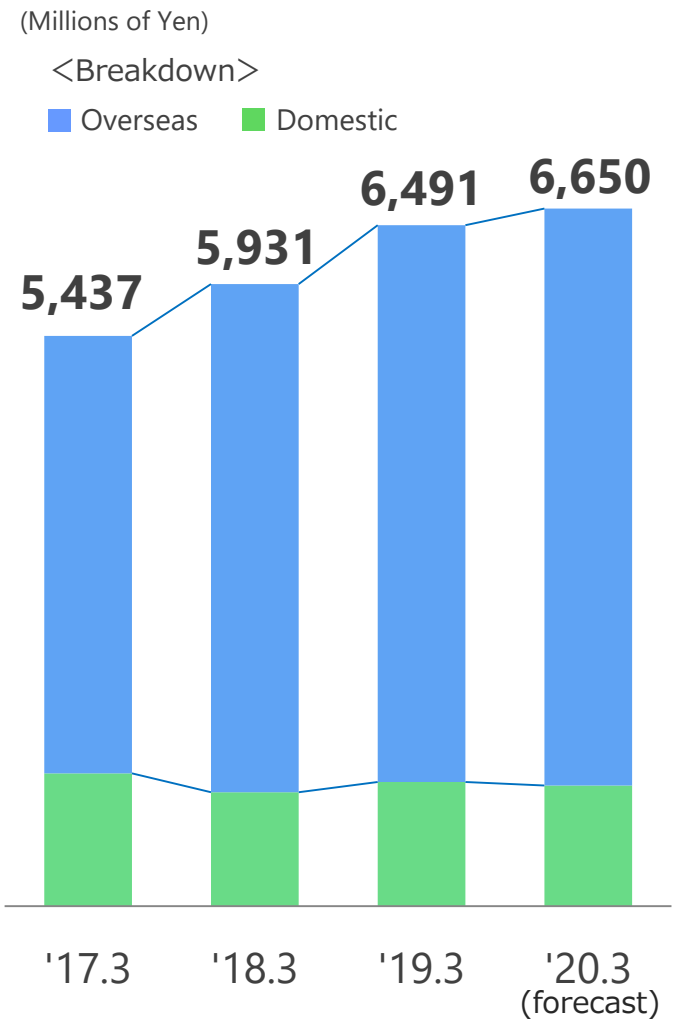
Planning for continuation of the sales uptrend and growth of approx. 7% (Volume basis)

➢ Seikagaku exports

Planning for an increase in exports. Shipments to China at the prior-year level due to exchange rate impact. Shipments of HyLink, a single-injection product newly launched in Italy, to increase

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

LAL Business Sales trend



FY2018 Results: +9.4% (Year-on-Year)

Overseas

Sales growth from endotoxin-detecting reagents and glucan-detecting in-vitro diagnostic reagents (products used for the diagnosis of fungal infections)

Domestic

Increase in sales of endotoxin detection equipment

FY2019 Forecasts: +2.4% (Year-on-Year)

Overseas

Forecast of a further increase in sales of glucan-detecting in-vitro diagnostic reagents due to strengthening of sales promotion activities

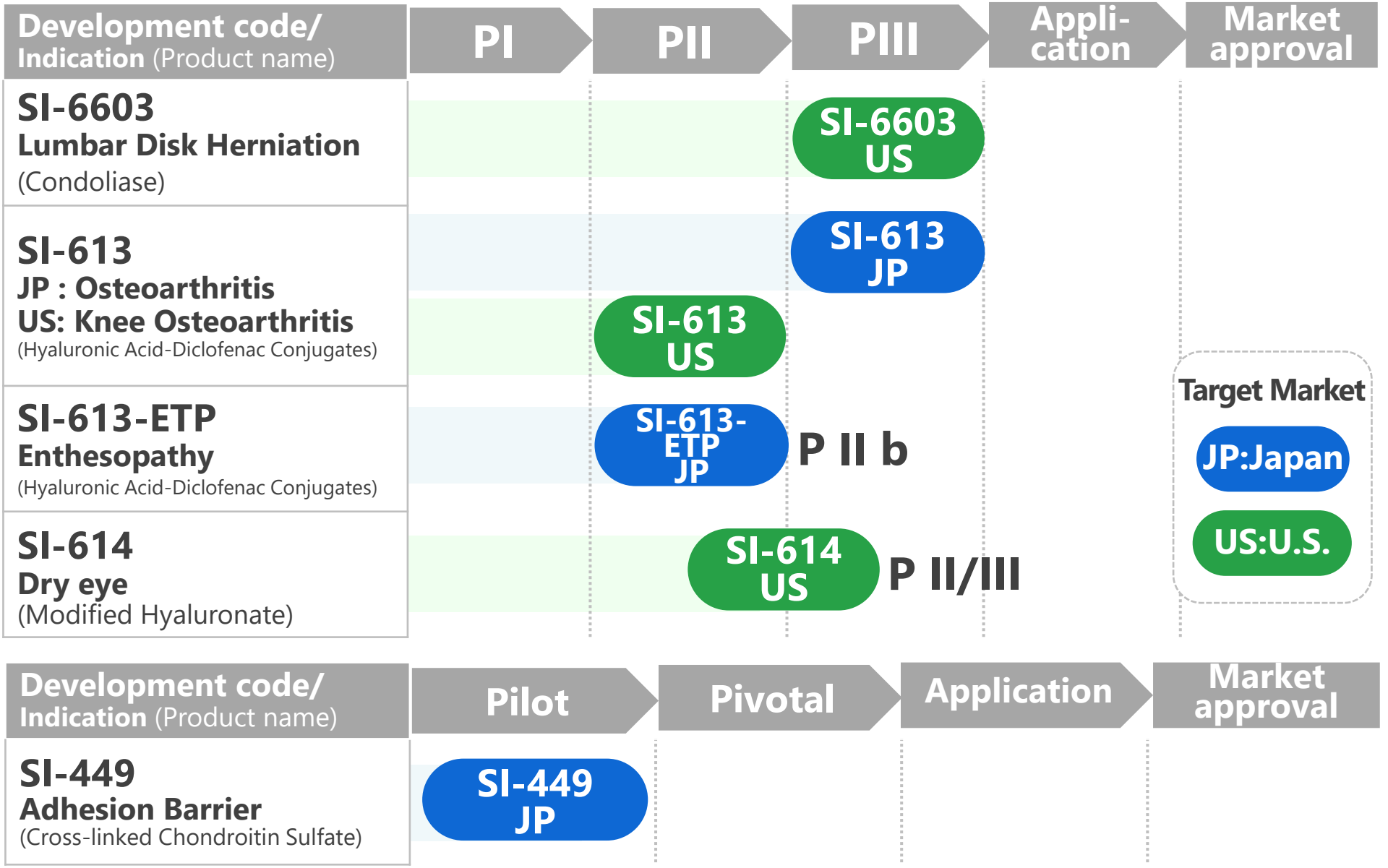
Domestic

Forecast of sales at roughly the 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).

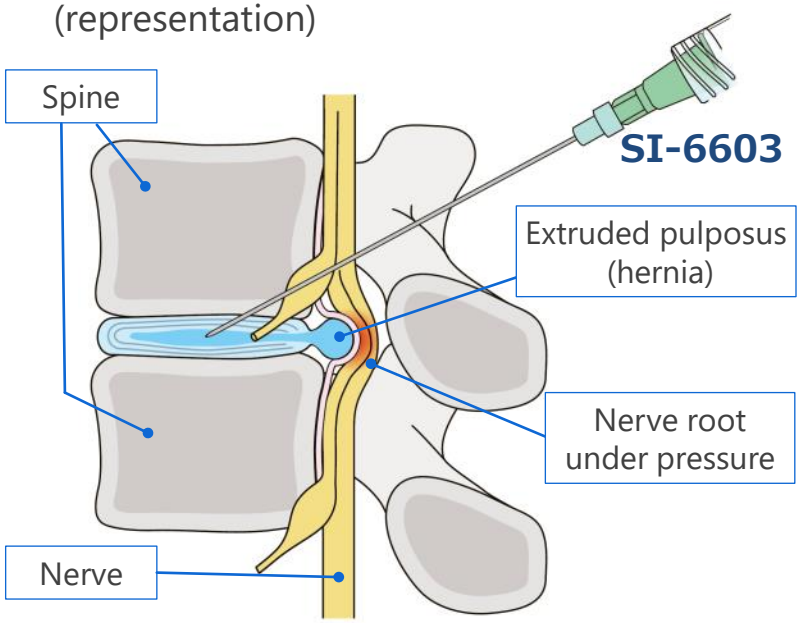
Pipeline List (Research and Development themes)



SI-6603 Outline (Treatment for Lumbar Disc Herniation)

Initiated a Phase III additional study in the U.S. in Feb 2018
Focusing on various measures for enrolling subjects

■ SI-6603 administration
(representation)



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

- Generic name: Condoliase
- Indication: Lumbar disc herniation
- Method of use: Injection into lumbar disc (under X-ray observation)

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 ⇨ approx. 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

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

SI-613 Outline (Treatment of Osteoarthritis/Enthesopathy)

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

- Substance: Hyaluronic Acid-Diclofenac Conjugates
- Formulation: Injection into the joint cavity or near the tendon or ligament enthesis
- Development Location ：Japan & U.S.

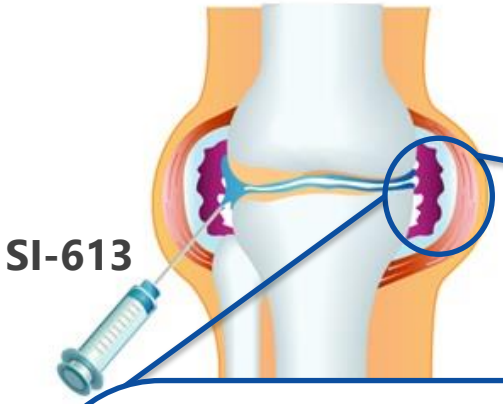
* Promote in co-development with Ono Pharmaceutical

Expected Features

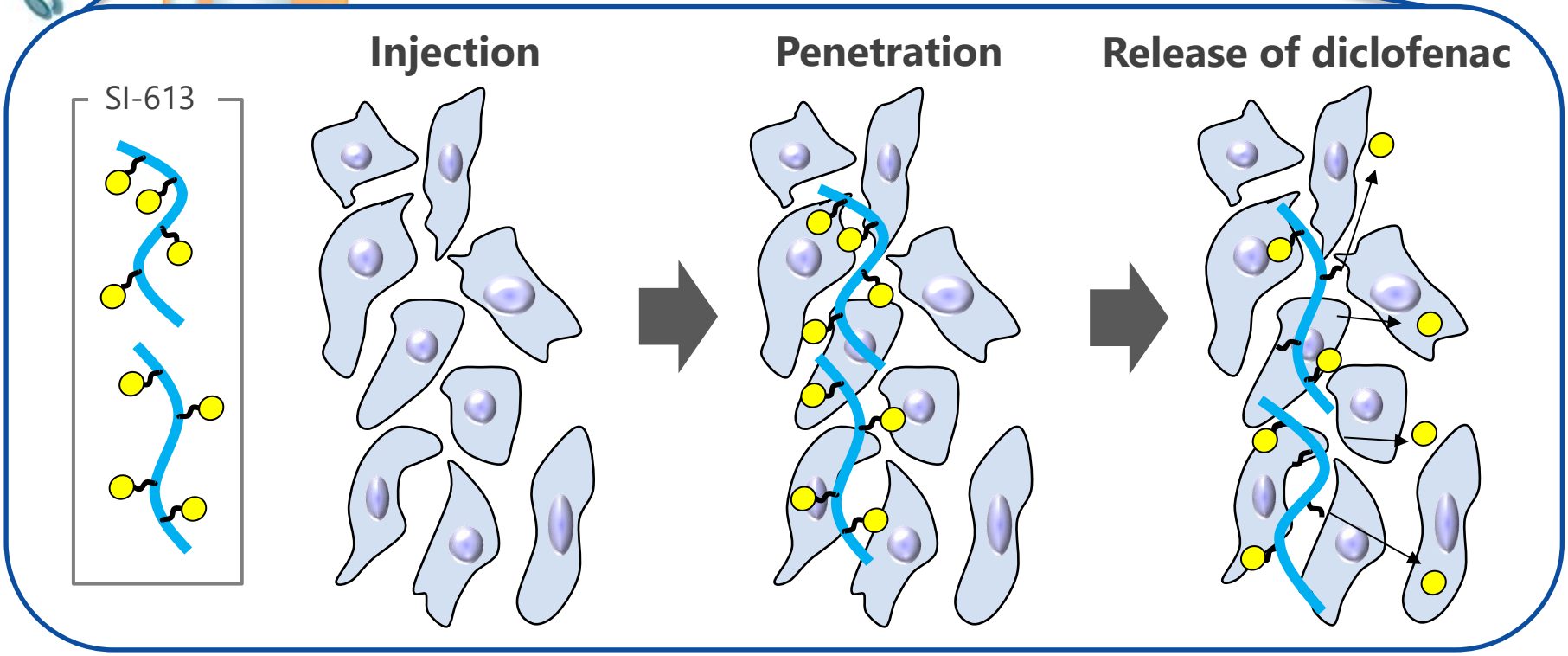
- Hyaluronic acid and diclofenac (an anti-inflammatory agent) are chemically bound. SI-613 is designed for sustained release * of diclofenac
  ❯**Prompt and sustained relief of pain and inflammation**
- Since SI-613 is directly injected into the affected area as an injectable treatment, systemic exposure 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

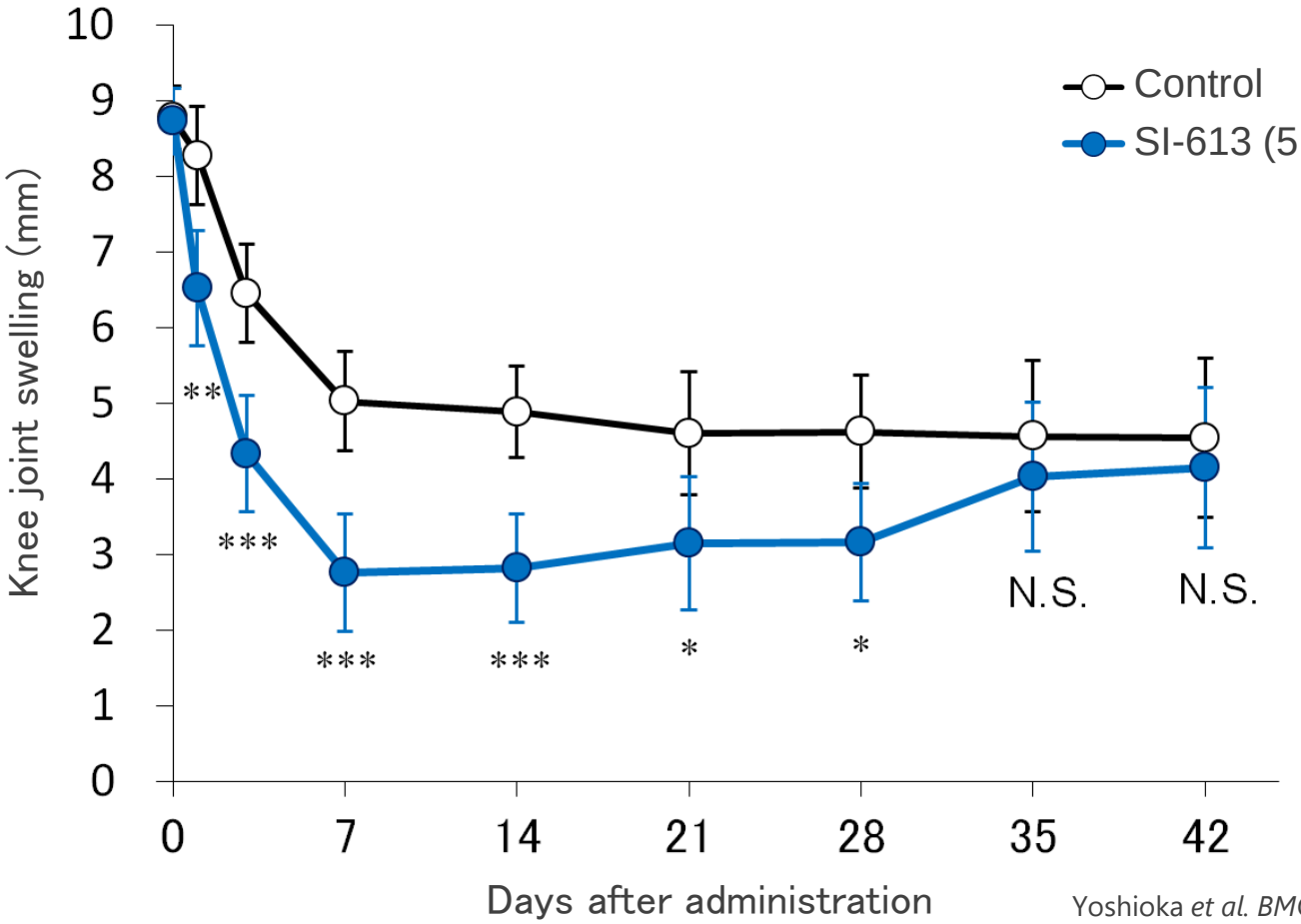


SI-613 (substance name: hyaluronic acid-diclofenac conjugate) is thought to penetrate the synovial membrane (connective tissue within the articular capsule) and gradually release diclofenac



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



Mean±S.E. (n=20)
*** P<0.001, ** P<0.01, * P<0.05
N.S.(not significant) :
Student's *t*-test with
Holm's correction (vs control)

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

SI-613 Development Status

Positive topline results obtained in a PIII confirmatory study with knee osteoarthritis in Japan. Now proceeding with two other studies and aiming for an NDA at the first half of 2020

Japan : P III (Indication: Osteoarthritis) P IIb (Indication: Enthesopathy)

- February 2017: Phase III study initiated (3 studies conducted)

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

- September 2017: Late-stage Phase II clinical trial for enthesopathy initiated

  ❯ Follow-up observation completed, results analysis ongoing

- Feb. 2019: **Positive topline results obtained in PIII confirmatory study with knee osteoarthritis**

  - **Overview of PIII confirmatory study in patients with knee osteoarthritis**

    The study confirmed superiority of SI-613 compared with a placebo when repeatedly injected into the knee joint cavity of patients with knee osteoarthritis once every four weeks

    ・Primary endpoint: WOMAC 3.1 Index Section A (knee only) ・Target number of cases: 440 cases

    ・Primary endpoint observation period: 12 weeks

    (three injections, one every four weeks when four weeks have passed)

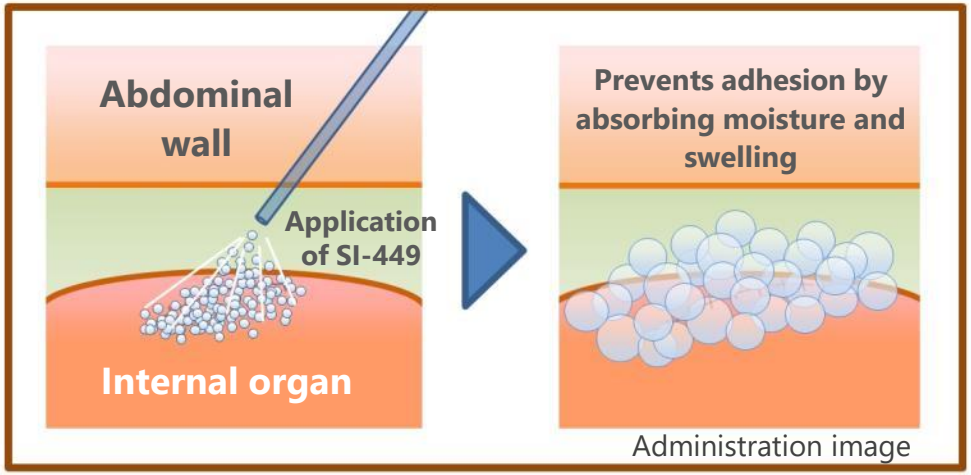
U.S. : P II (Indication: Knee osteoarthritis)

- June 2017: Phase II study initiated

  ❯ Follow-up observation completed, results analysis ongoing

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



- Substance: Cross-linked chondroitin sulfate
- Description: Adhesion barrier
- Method of use: Intra-abdominal application (powdered formulation)

Japan: Pilot study

May 2018: Pilot study initiated

- Enrollment completed, follow-up observation ongoing
  Proceed with development with a view to global development

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

Summary of the Previous Mid-term Management Plan (April 2016 to March 2019)

1. 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

2. 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

3. Enhancement of the development pipeline

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

4. 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

Responding to factors contributing to deterioration of profitability, such as drastic reform of the drug price system in Japan and intensification of competition in overseas markets, is a matter of urgent importance

Outline of the Next Mid-term Management Plan

Securing a new earnings foundation

- Pharmaceuticals business: Rapidly and reliably ensure the success of new business pillars (SI-6603(HERNICORE), SI-613. etc.)
- LAL business: Accelerate expansion into the worldwide market of LAL reagents utilizing gene ecombination technology
- Earnings model diversification
- Rigorous cost reduction
- Agile management strategy that utilizes the financial foundation

Pursuit of R&D, the source of growth

- Work to enhance the pipeline, continuing to position glycoscience at the core of drug discovery.
- Upgrade and expand basic technologies related to glycoscience, including drug delivery systems (DDS) technologies.
- Increase R&D efficiency by pursuing an open innovation strategy.

Planned announcement of the next mid-term management plan and numerical targets in November 2019

Basic Policy on Profit Distribution

Aim to enhance shareholder returns and realize sustained growth by engaging in well-balanced business investment

Shareholder Return Policy

- Aim for stable and continuous dividends from a medium to long term perspective
  - ❯ Continue to pay an annual dividend of ¥26 per share
- Consider purchases of treasury stock, as appropriate, taking into account future business development and the total return ratio
  - ❯ Treasury stock purchases in June-July 2018 (200,000 shares / ¥302 million)

Business Investment

- Business investment in R&D, production system development, and other areas

*The Company is currently formulating the next mid-term management plan and considering the dividend policy. Announcement of the next management plan is planned for November 2019.

	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019 (Forecast)
Net Income per share	¥64.27	¥45.39	¥31.55	¥69.30	¥39.76	¥35.46
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%	73.3%

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

Appendix

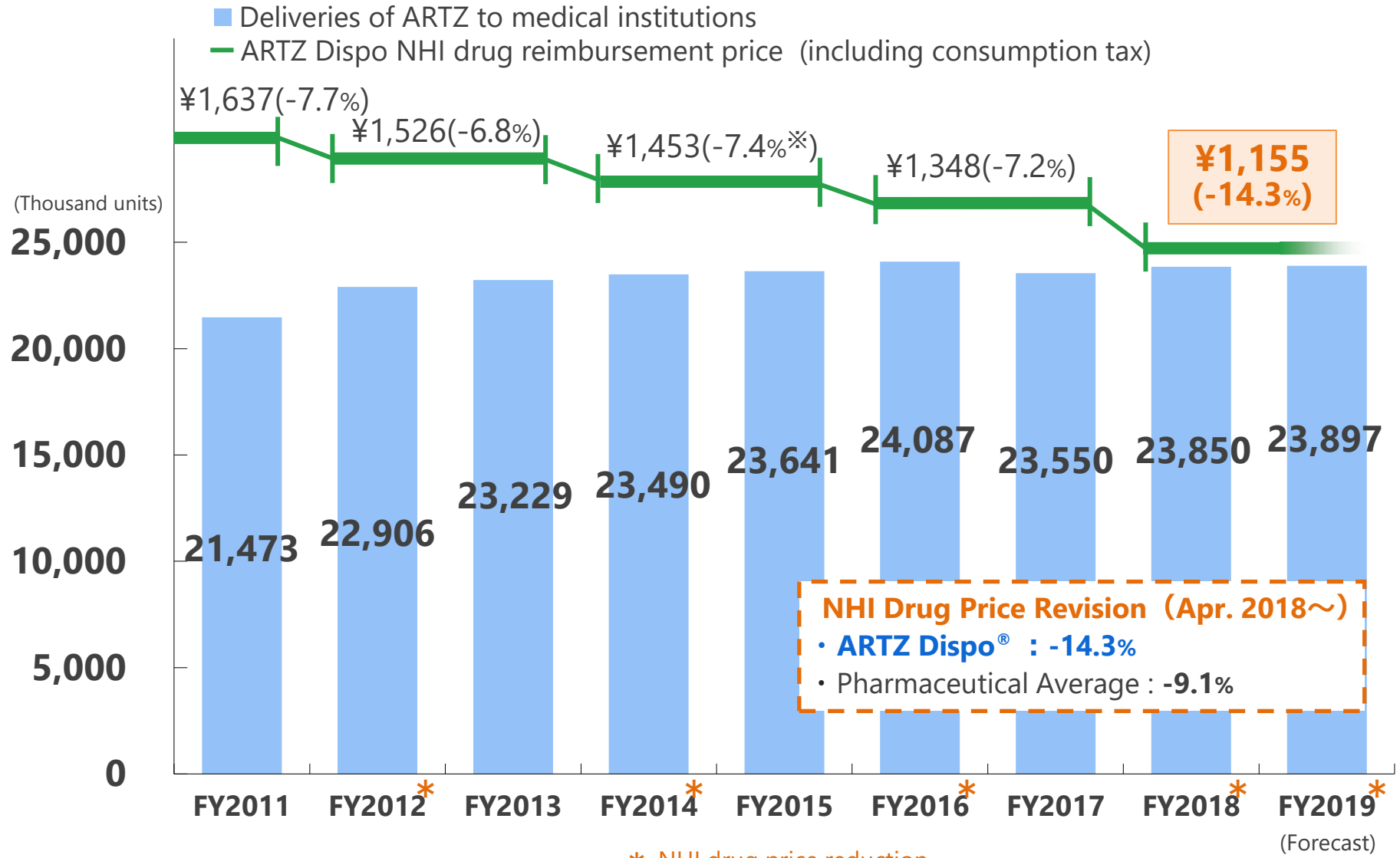
Clinical Study Information

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. 2020	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 –	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.

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



＊ NHI drug price reduction
Extraordinary drug price revision in FY2019 accompanying a consumption tax increase (scheduled for October 2019)

※ excluding the impact of consumption tax hike

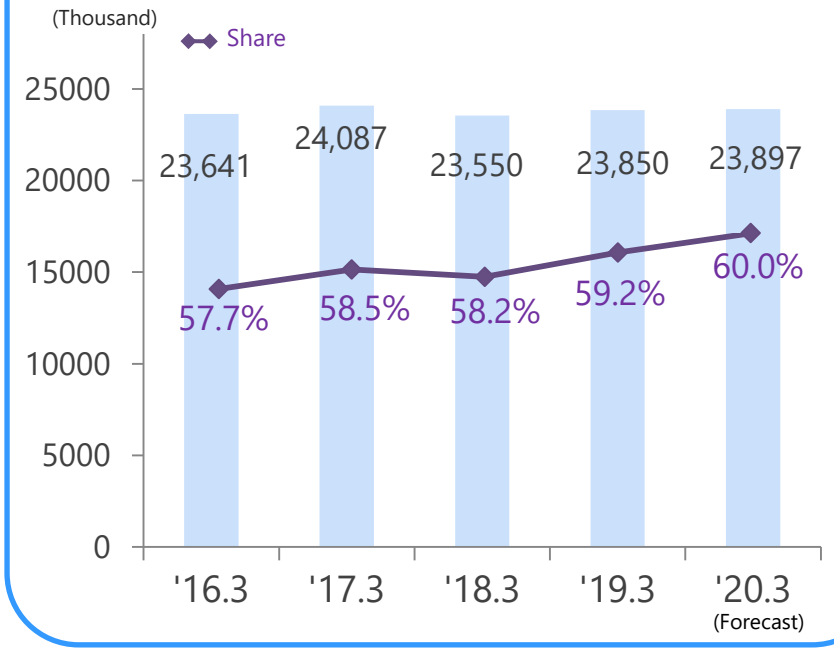
Trend in Deliveries of ARTZ / OPEGAN to Domestic Medical Institutions

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

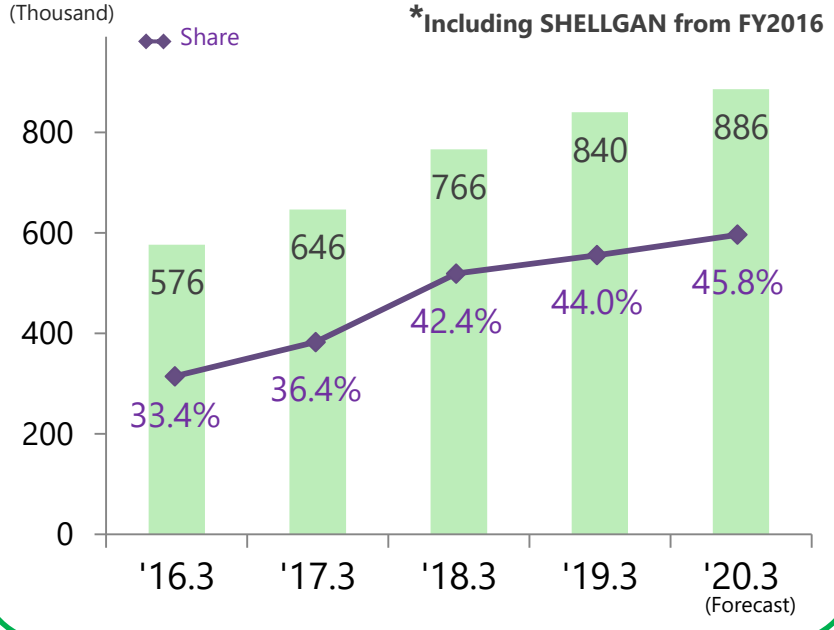


Ophthalmic viscoelastic devices

OPEGAN

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

Trend in unit deliveries to medical institutions



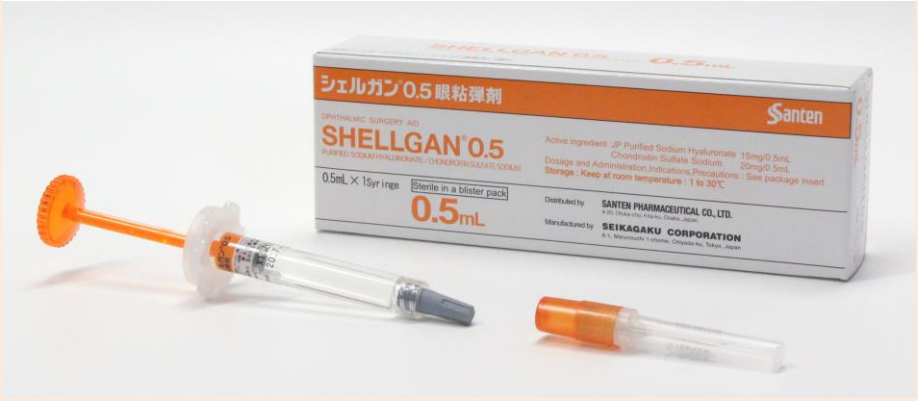
＊HA：Hyaluronic Acid

Ophthalmic viscoelastic devices SHELLGAN (Launched July 2016)

眼科手術補助剤　薬価基準収載

シェルガン®0.5眼粘弾剤

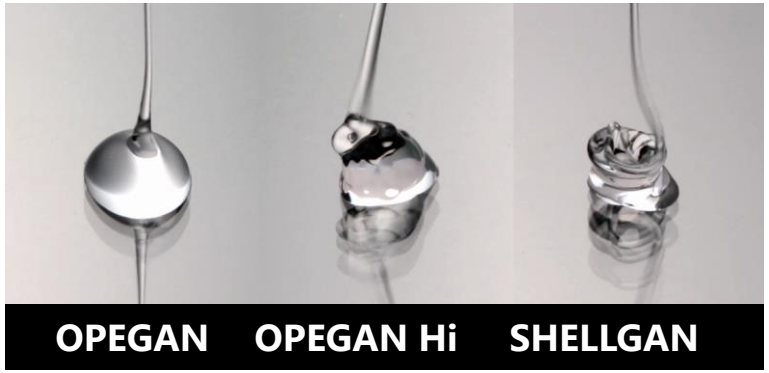
精製ヒアルロン酸ナトリウム/コンドロイチン硫酸エステルナトリウム



■ 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

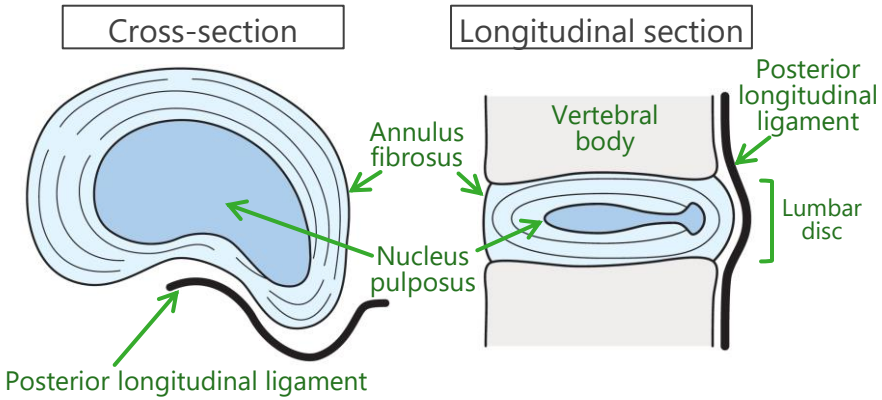


The OPEGAN series viscoelasticity comparison

Four types of lumbar disc herniation

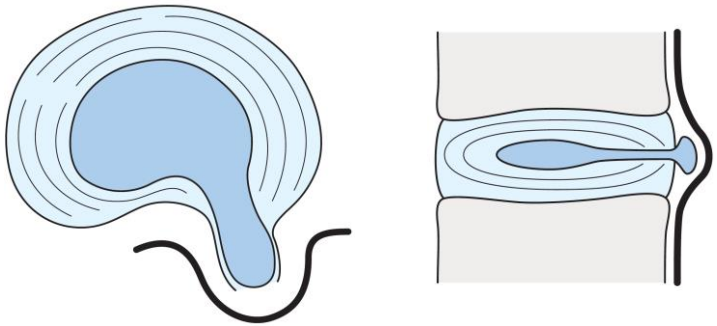
1. Protrusion

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



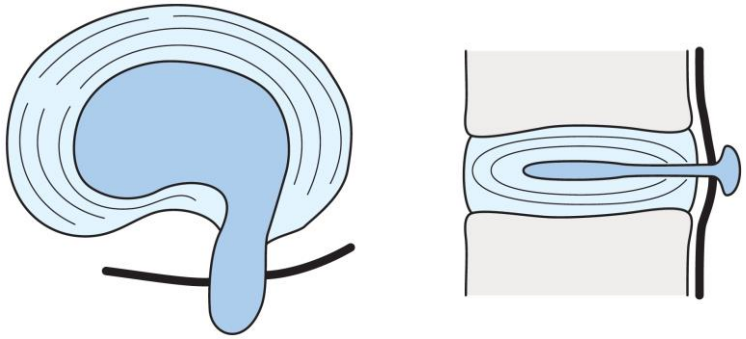
2. Subligamentous extrusion

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



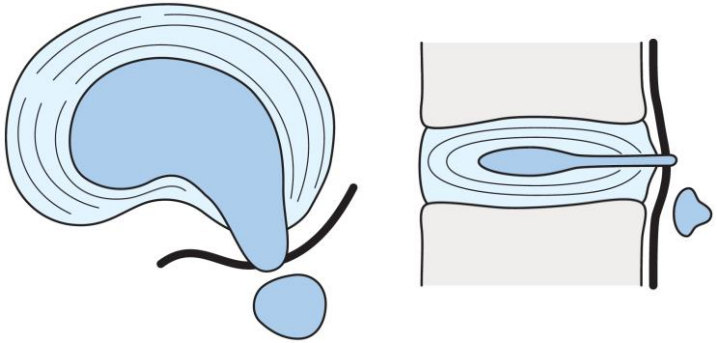
3. Transligamentous extrusion

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

(As of November 2018)

Physicians to whom any of 1 to 3 below applies and who have experience in performing lumbar puncture

1. Japanese Society for Spine Surgery and Related Research or Neurospinal Society of Japan accredited supervisory physician
2. Physician under the direction of a Japanese Society for Spine Surgery and Related Research or Neurospinal Society of Japan accredited supervisory physician
3. Physician who has participated in a HERNICORE clinical trial

Facility requirements

(As of November 2018)

Facilities that meet all of the conditions below

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

▶ **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.**

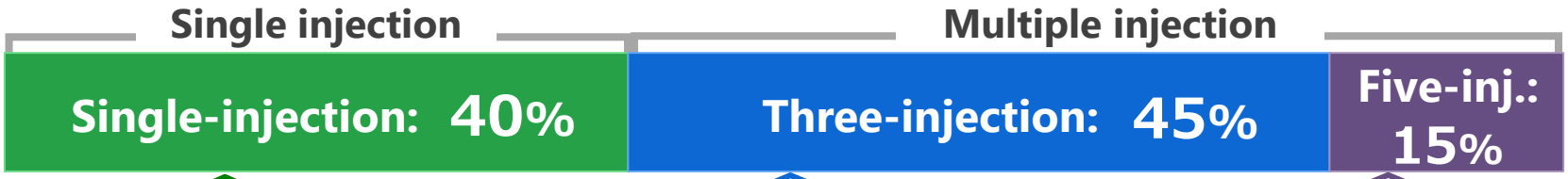
*PMDA: Pharmaceuticals and Medical Devices Agency

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)



Gel-One
(single-injection product)

- Full-scale sales since 2012
- September 2016:
  Efficacy extension label change
  (13 weeks ⇨ 26 weeks)

Gel-One® Cross-linked Hyaluronate
the only 3 mL single injection, cross-linked hyaluronate gel

VISCO-3
(three-injection product)

- December 2015：
  Market approval
- November 2016:
  Conclusion of an exclusive sales agreement with Zimmer Biomet

VISCO-3™
SODIUM HYALURONATE 25 mg
2.5 mL intra-articular injection.

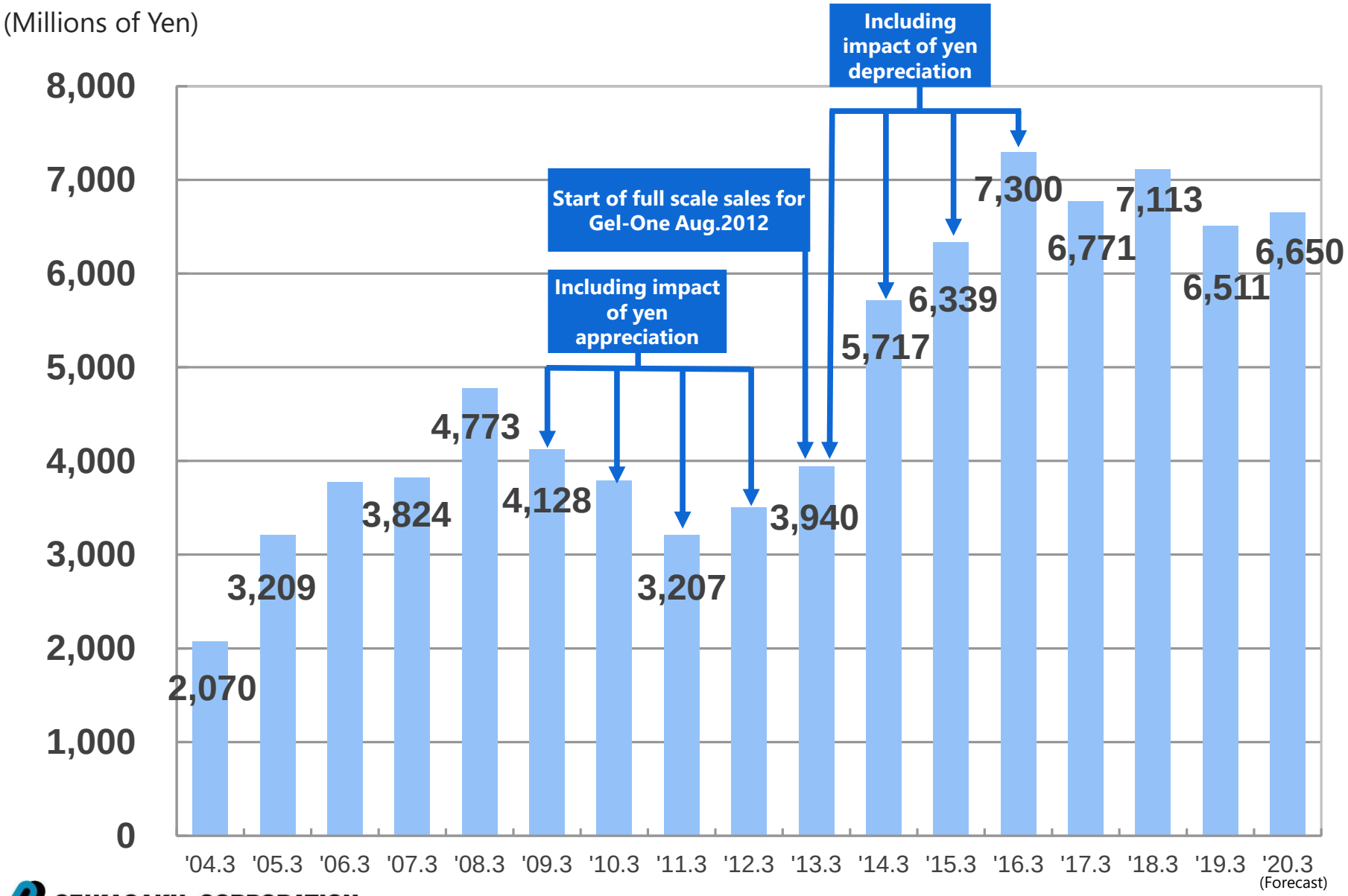
SUPARTZ FX
(five-injection product)

- Sales since 2001
- October 2015:
  Brand name changed from SUPARTZ

SUPARTZ FX™
sodium hyaluronate

*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)

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

Associates of Cape Cod, Inc. (ACC)

- U.S. subsidiary of Seikagaku Corporation (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

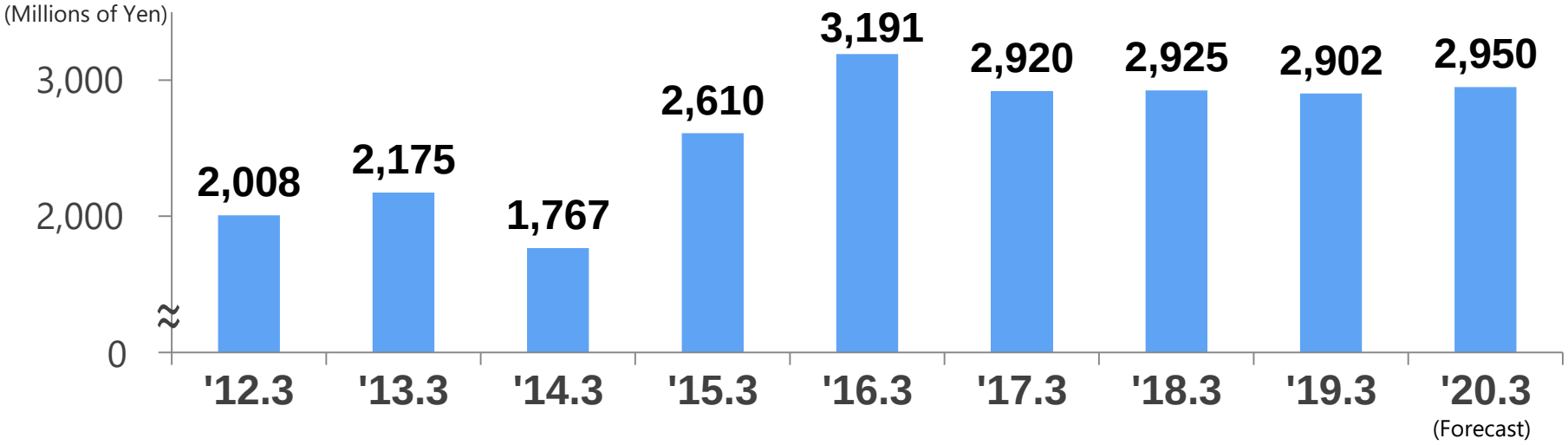
PYROCHROME®

Exterior of the ACC offices

Trends in Depreciation & Capital Investments

Depreciation peaked out at FY2015 and anticipate the level of ¥3,000 million in recent years

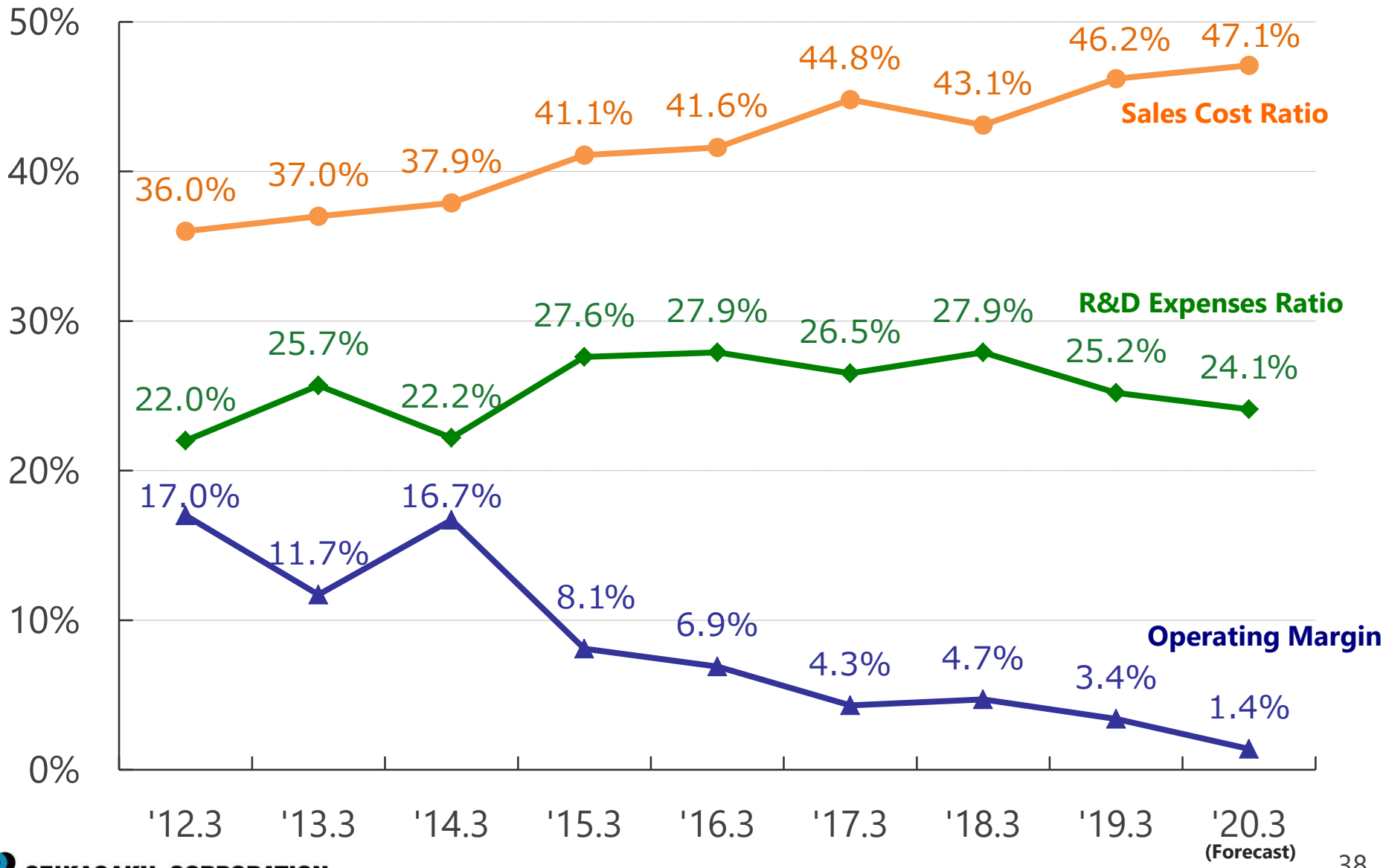
■ Trend in Depreciation



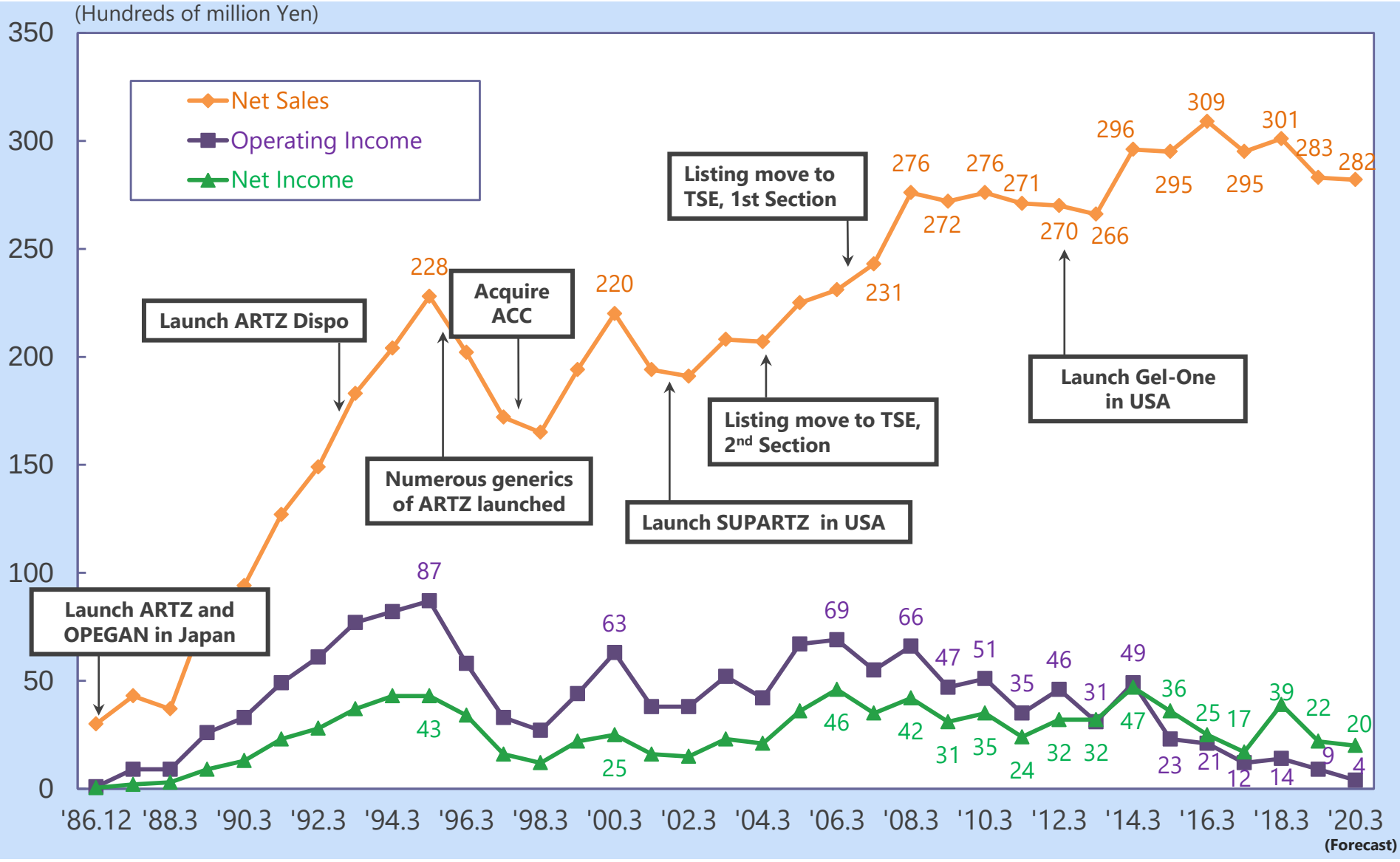
■ Trend in Capital Investments (Millions of Yen)

'12.3	'13.3	'14.3	'15.3	'16.3	'17.3	'18.3	'19.3	'20.3 (Forecast)
5,718	9,164	7,222	2,095	1,975	1,173	1,591	1,310	2,350

Trend in Financial Index

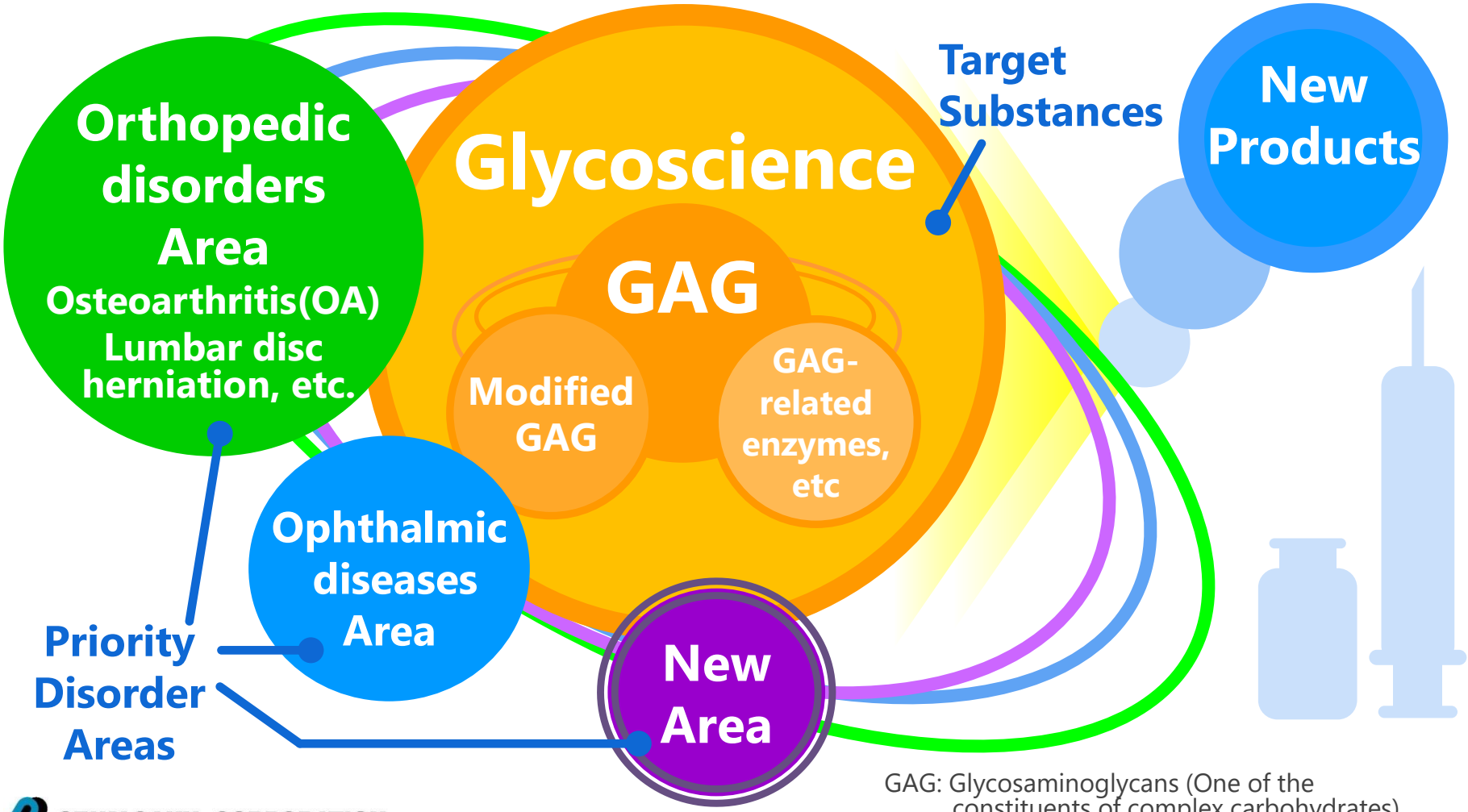


Business Progress & Highlights



Basic Policy on Research and Development

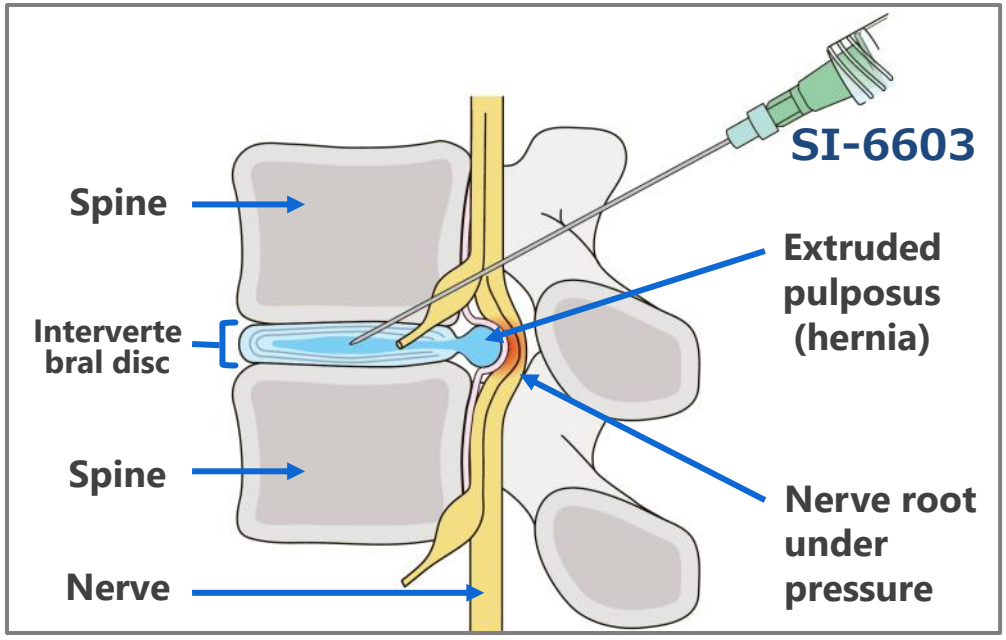
Aiming for the early, continuous introduction of new products that meet high treatment needs, focusing on glycoscience as an area of specialization



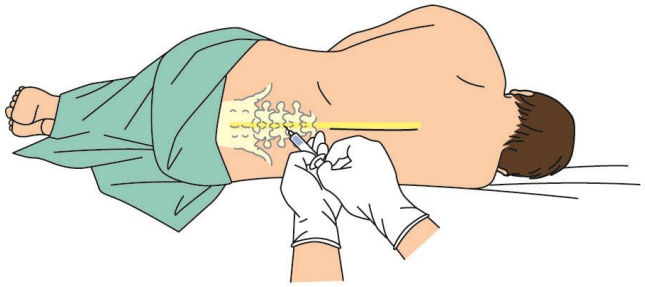
GAG: Glycosaminoglycans (One of the constituents of complex carbohydrates)

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

Single injection is to relieve pain by specifically degrading GAGs, the main components of the nucleus pulposus by decreasing intradiscal pressure and reducing the pressure on nerves



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



Expected Features:

- Single injection expected to relieve the pain of lumbar disc herniation
- Not required general anesthesia and less invasive to the patient than surgical treatment
- Expected to contribute to quality of life of the patient as new treatment option

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

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

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

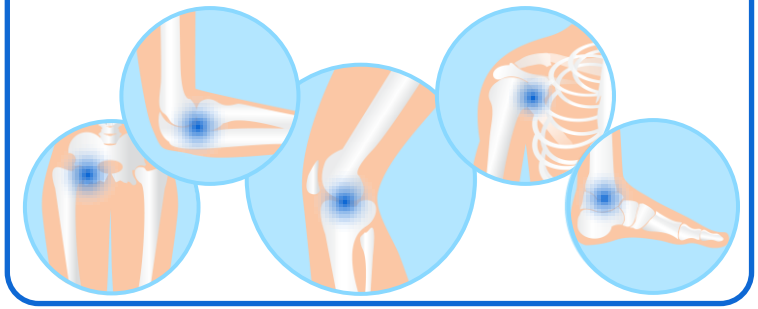
A disease in which joint tissue deteriorates due to abrasion of the articular cartilage, leading to inflammation and pain

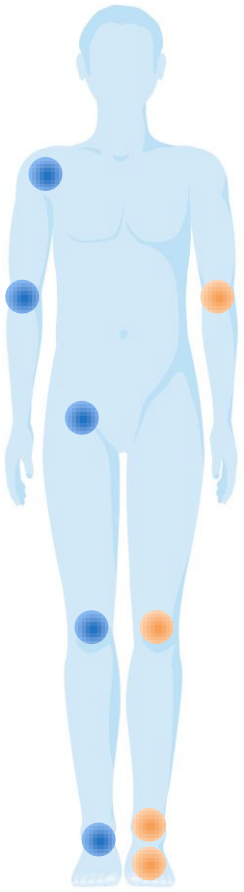
Conduct of three clinical trials

- 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: PII b

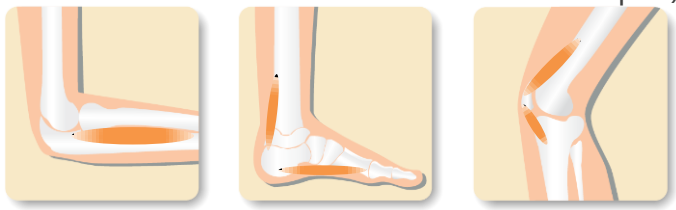
An inflammatory disease that occurs as a result of excessive load on sites of attachment of ligaments and tendons to other bone or muscle, such as the knee, elbow, heel

Typical examples

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

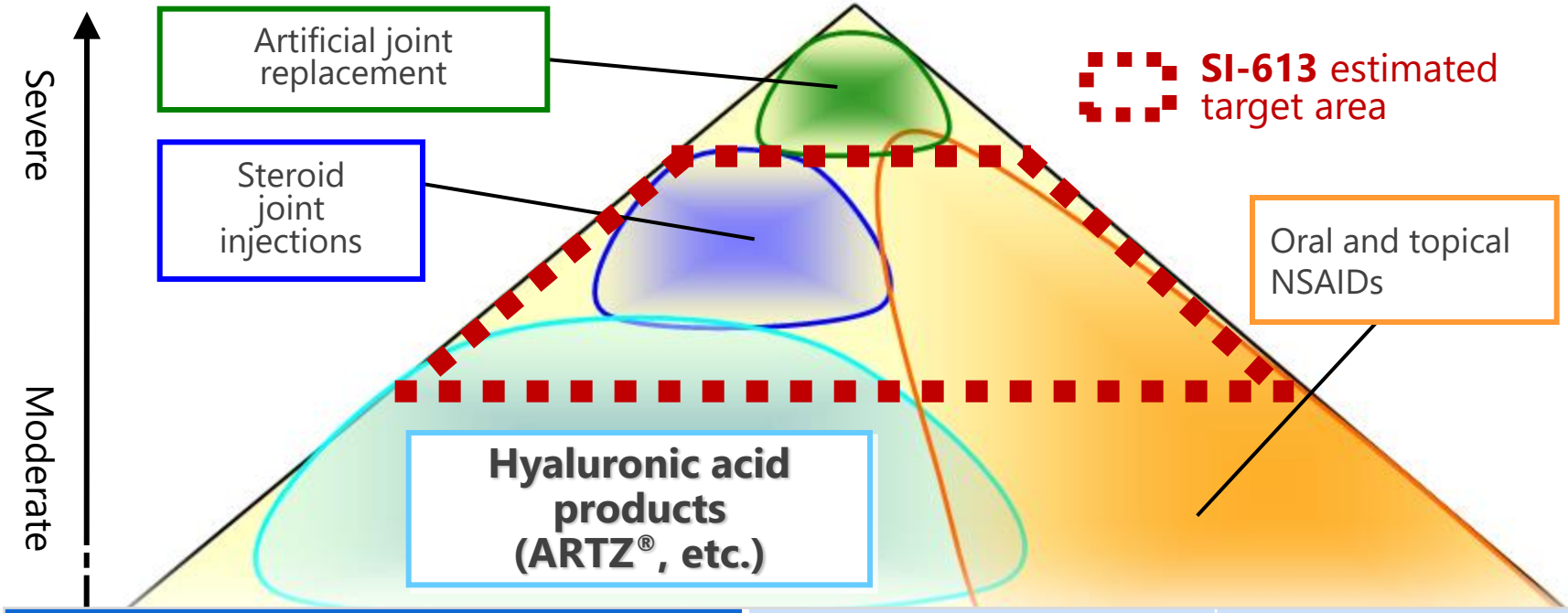
Number of patients receiving drug therapy per year: Approx. 0.9 million

(Seikagaku estimate for the above four diseases in Japan)



SI-613 Estimated Target Patients

Estimated patients with pain and being treated with oral or topical NSAIDs or intra-articular steroid injection



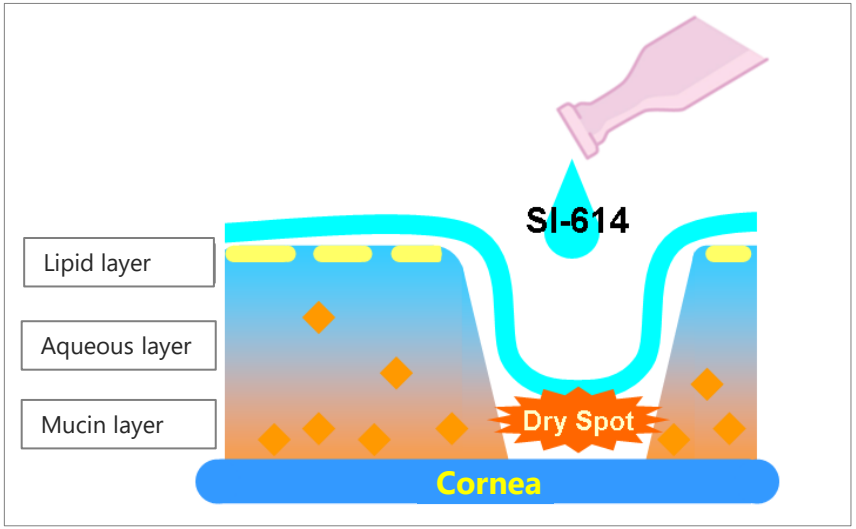
Target market size in Japan
＊Including applications outside the knee

Oral NSAIDs	¥83 billion
Topical NSAIDs	¥144 billion
HA injections	¥41 billion
Steroid injections	¥11 billion

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

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



- Substance：SI-614(Modified Hyaluronate)
- Indication ：Dry eye
- Formulation：Ophthalmic solution

U.S. ：P II/III

- January 2015: Phase II/III clinicaltrials 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.

Contract Status by R&D Theme

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

Development Code Indication	Develop-ment 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-449 Adhesion Barrier	Japan	–	–

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)

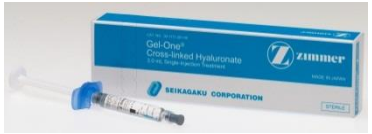
Our Business Segment

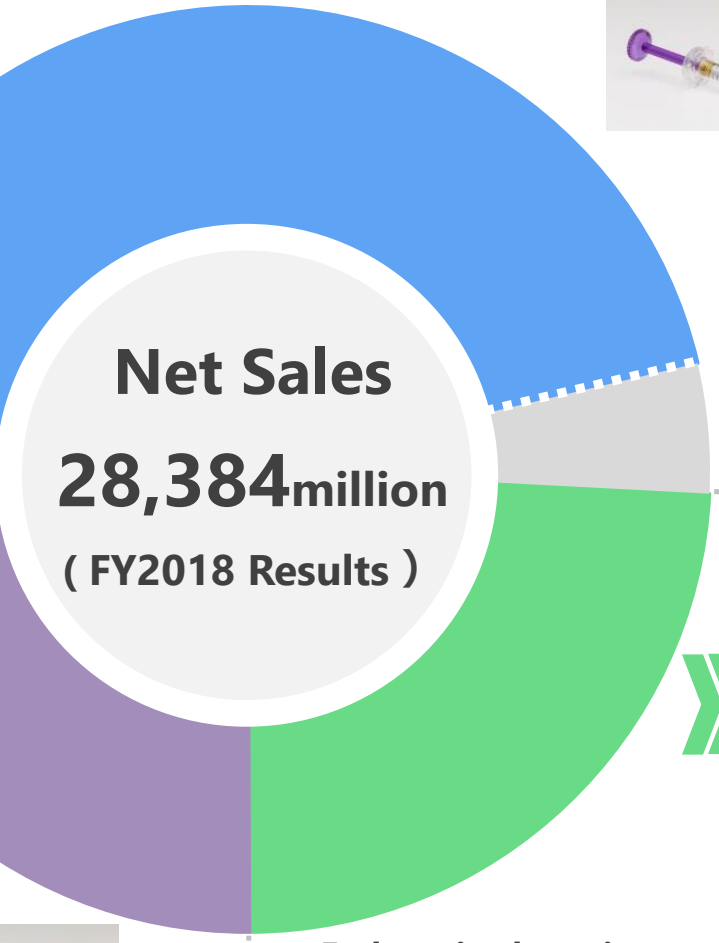
Pharmaceutical Business 77.1%

Domestic Pharmaceuticals ➡49.9%

Joint Function Improving Agents

Overseas Pharmaceuticals ➡22.9%





Ophthalmic Surgical Aids

Bulk Products

Bulk Products ➡4.3%

LAL Business 22.9%

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

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.

SEIKAGAKU CORPORATION