CONTENTS

Kirin Group Investor's Guide

Basic Information

Company Name

Kyowa Kirin Co., Ltd.

Business

Research, development, manufacturing, marketing and import / export of pharmaceuticals

Operating Country

Japan, North America, EMEA, APAC

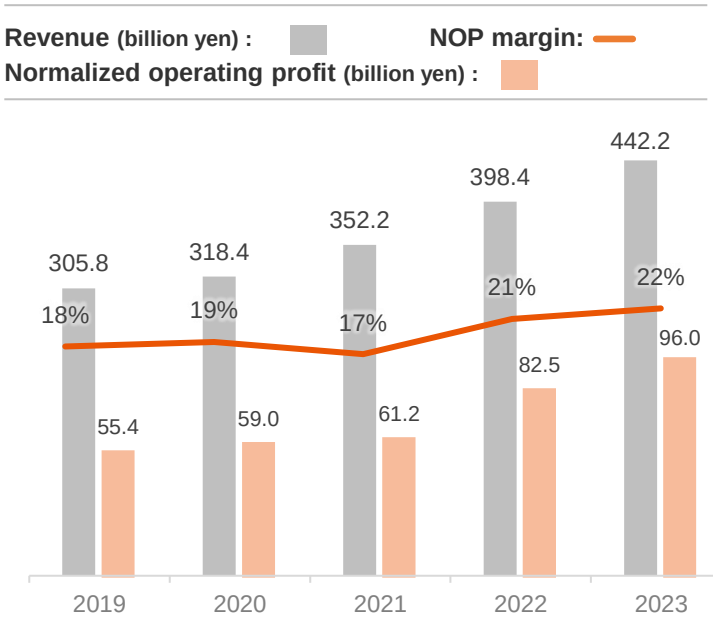
Principal Plants ／ R&D Network

Tokyo Research Park, Fuji Research Park
CMC R&D Center, Bio Process Research and Development Laboratories

Takasaki Plant, Ube Plant

Revenue and Normalized Operating Profit (2023)

Revenue 442.2 billion yen
Normalized operating profit 96.0 billion yen



Share of equity

Kyowa Kirin is a listed subsidiary of Kirin Holdings, which owns approximately 53% of the company.

History

Began researching pharmaceuticals in the 1980s.
Later, Kirin Pharma merged with Kyowa Hakko Kogyo and became the current Kyowa Kirin Co., Ltd.

Main Products

CRYSVITA® burosumab
POTELIGEO® (mogamulizumab)
NOURIANZ® (istradefylline) tablets

Establish a Strong Global Business Foundation as a Japan-based Global Specialty Pharmaceutical Company

Our New Vision toward 2030

Kyowa Kirin will realize the successful creation and delivery of life-changing value that ultimately makes people smile, as a Japan-based Global Specialty Pharmaceutical company built on the diverse team of experts with shared passion for innovation.

Pharmaceuticals domain

Materiality

- Provide pharmaceuticals for unmet medical needs
- Address patient-centric healthcare needs
- Retain the trust of society
- Strengthen human resources and infrastructure to realize life-changing value

Establish a Strong Global Business Foundation as a Japan-based Global Specialty Pharmaceutical Company

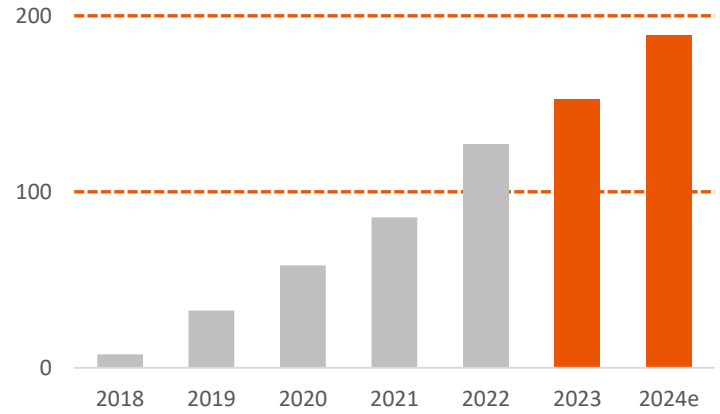
Joy brings us together KIRIN

Maximize value of Global Strategic Brands

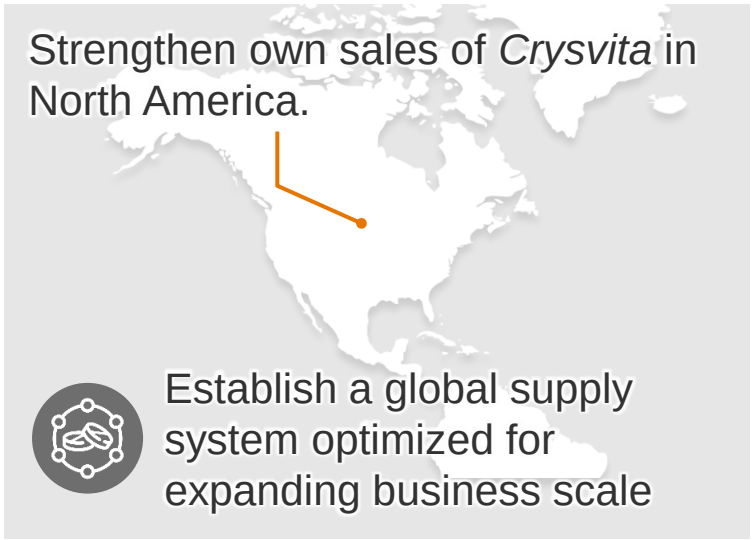
CRYSVITA® burosumab

Sales Forecast in 2023

approx.189.0 bn yen



Invest in business infrastructure centered on global production and sales



Steady development progress of next-generation pipeline

- **KHK4083 /AMG 451** (rocatinlimab)
  Atopic dermatitis: Ph3 Initiation
  Asthma: Ph2 Preparation
- **KHK4951**
  Neovascular age-related macular degeneration*: Ph2 Initiation
  Diabetic macular edema**: Ph2 Initiation

ROE

ROE 10.2% in 2023.
Medium- to long-term maintenance and improvement of ROE of 10% or more from 2026 onward.

10%+

After FY2025 Core OP margin 25%+

(Core Operating Profit Margin)

(Core OP margin of 22% in 2023)

* A disease in which the macula is affected by abnormal angiogenesis. Rapid progression leads to significant vision loss. Number of drug-treated patients Domestic: approx. 0.2 million, Global: approx. 1.6 million

** A complication of diabetic retinopathy is damage to the capillaries in the macula, causing edema of the macula, which leads to vision loss.

Pharmaceuticals domain

Main Development Pipeline Products

As of February 7, 2024

	Diseases under development*1	Planned Approval Year*2	Development status	Total addressable market*3	No. of Patients*4
KHK4083/AMG 451 rocatinlimab	Moderate and severe Atopic Dermatitis	2026/2027	P3 (Global)	★★★★★	16M
KHK4083/AMG 451 rocatinlimab	Moderate and severe Asthma*5	TBD	Preparation underway for P2 (Global)	★★★★★	13.5M
KHK4951 tivozanib	nAMD	TBD	P2 (JP, US)	★★★★	2,600K
KHK4951 tivozanib	DME	TBD	P2 (JP, US)	★★★★	3,400K
OTL-200 Libmeldy®	MLD	2024 (US)	Filing to FDA	★	(1 in 40K-160K live birth)
OTL-203	MPS-IH (Hurler syndrome)	2029	Registrational study*5 (US, EU)	★	(1 in 100K live birth)*6
OTL-201	MPS-IIIA (Sanfilippo syndrome type A)	TBD	Proof-of-concept*7	★	(1 in 100K)

*1 Expected indications as of the date of this document; indications may ultimately differ to expectations due status of approvals from regulatory authorities
*2 Expected year of first approval
*3 Expected total addressable market estimated by Kyowa Kirin, which is the sum of all products for the indications shown in *1, not projected sales or the Company's targets. **Colored areas represent estimates for global, and the rest are for Japan.** ★: less than ¥50Bn、★★: ¥50Bn-¥100Bn、★★★: ¥100Bn-¥500Bn、★★★★: ¥500Bn-¥1Tn、★★★★★: Over ¥1Tn
*4 Total number of estimated patients by Kyowa Kirin. **Colored areas represent in-house estimates for global, and the rest are in-house estimates for Japan.**
*5 Equivalent to P3 study. *6 "1 in 100k live birth" is estimated incidence for all of MPS-I, of which approximately 70 percent are cases of Hurler syndrome. *7 Equivalent to P1/2 study.

Main Development Pipeline Products: Future plans

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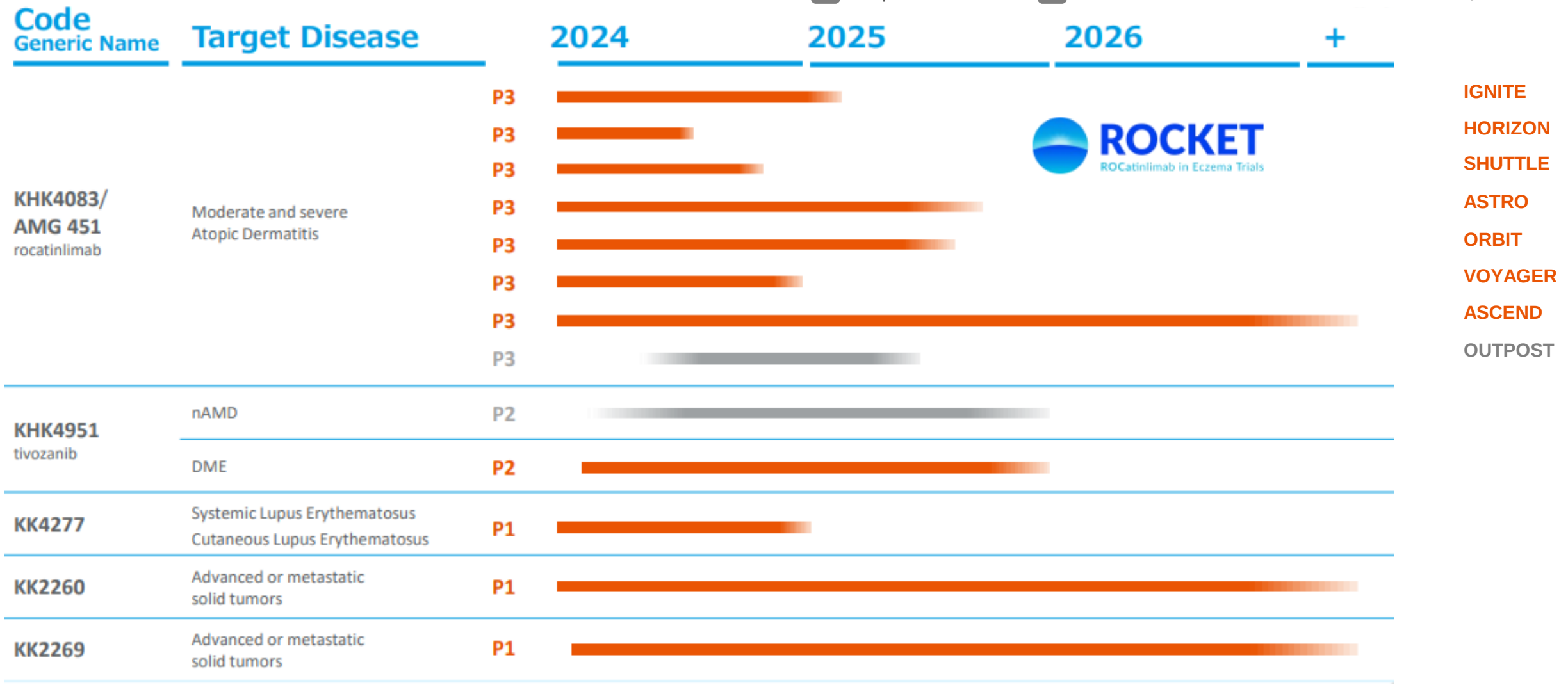
T : Topline data　D : Detailed data

As of February 7, 2024



CONTENTS

Kirin Group Investor's Guide

Collaboration with Kyowa Kirin in Health Science Domain

Strengthen API business with Kyowa Hakko Bio's initiative

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Before

KYOWA

Advantage	Industrial production of APIs using unique fermentation technology

Decisions made in accordance with KV2027

Transferred Kyowa Hakko Bio directly to Kirin Holdings

Kyowa Kirin	Kirin Holdings
Focus on in-house drug development in areas where advantages can be leveraged as a GSP*	Establish and foster health science businesses

Invest in API development for external use by leveraging Kyowa Hakko Bio's advantages, which could not be realized under Kyowa Kirin.

Value creation by multiplying the use of Group assets

Proprietary process development capabilities through fermentation biotechnology

Portfolio management that enables maximum utilization of Group assets

Knowledge of global drug development (CMC**, Pharmaceuticals affairs)

Development of high value-added APIs for new drugs in collaboration with pharmaceutical companies and global deployment

- As a CDMO***, it works as not just a contract manufacturer, but is responsible for process development and manufacturing of APIs for clinical trials in collaboration with pharmaceutical companies to develop APIs for new drugs.
- Develop high value-added APIs for new drugs using proprietary fermentation technology.
- Differentiate by APIs that have high social value through manufacturing methods with low environmental impact.

2022 Construct investigational drug manufacturing facilities
2025 Start operation
2029 Manufacture and sell APIs for marketing

Aim for 100 bn yen of Sales Revenue

* Global Specialty Pharmaceutical company
** CMC=Chemistry, Manufacturing, and Control
*** CDMO=Contract Development and Manufacturing Organization

Creation of added value through Group R&D and collaboration with other companies

Obtained a patent for a compound in collaboration with Otsuka Pharmaceutical Factory

Collaborative research since 2017

Otsuka Pharmaceutical Factory, Inc.

KIRIN BioMaterials

Powerful partner with strengths in the area of clinical nutrition

Maximize value creation by combining Kirin Group's fermentation biotechnology, knowledge of pharmaceutical development, and health science

Obtained a basic patent on the manufacturing process and began construction of an API facility for clinical trials in 2023

- Obtained a patent for manufacturing in 2023 to strengthen the API business announced at the end of FY2021.
- Establishment of a socially meaningful process that solves the problems of existing compounds through biotechnology by combining the knowledge of Kirin Group and Otsuka Pharmaceutical Factory, Inc.

Mass Production with the Roller Bottle Method

In 1993, Kirin Brewery filed an application to expand the indications for erythropoietin (EPO), which had been approved for the treatment of renal anemia in patients on dialysis to include chronic renal failure before dialysis and anemia in premature infants, among other conditions. However, there was a concern that if these applications were approved, the use of active pharmaceutical ingredients would increase dramatically and that it would be highly difficult to ensure the supply with the existing production capacity.

▲Roller bottle system　(Original bottle system)

- Construction of an EPO API building on the premises of the Takasaki Plant proceeded, and a fully automated roller bottle system for animal cell mass culture was in place by February 1995.
- The new roller bottle system consisted of a culture rack for culturing cells, a filling and harvesting unit for filling, exchanging, washing, and collecting culture media, and an automatic system for loading/unloading and transferring roller bottles that connected the culture rack with the filling and harvesting unit. This allowed use of 8,000 roller bottles to perform a series of tasks aseptically and automatically.
- This quadrupled Kirin Brewery's EPO production capacity.

※EPO is currently manufactured with cutting-edge technology and no longer with a roller bottle process.

Bioreactors & Fermentation

- Biopharmaceutical fermentation of cell culture shares the same technology with health food/alcohol fermentation in terms of maximizing the production of target enzymes, proteins, or metabolites.
- Kirin Engineering's technology is being utilized.

Bioreactor
Kyowa Kirin Takasaki Plant
(Gunma Prefecture)

Active ingredients of biopharmaceuticals are produced from cell culture in the bioreactor.

Lactobacilli culture tank
iMUSE Health Science Factory
(Saitama Prefecture)

Lactobacilli are grown from sugar and other raw materials.

Beer fermentation tanks
Pilot Plant
(Kanagawa Prefecture)

Sugar is metabolized by brewer's yeast to produce ethyl alcohol and carbon dioxide.

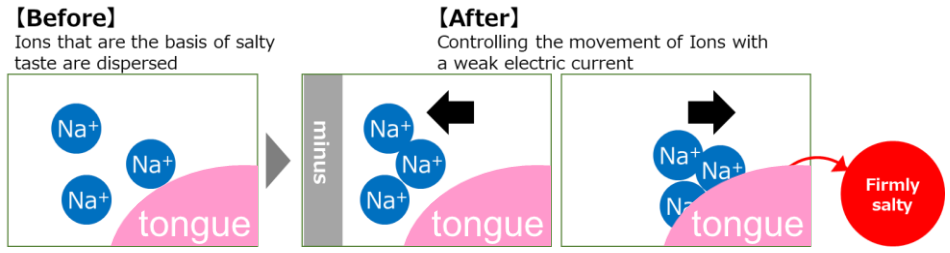
[Case study of creating added value for the Kirin Group]

"Electric salt" device

Initiative Overview

- Kirin Holdings and the Meiji University Dr. Homei Miyashita Laboratory jointly developed the “Electric Salt" a tableware-type device, which uses electric current waveforms, to solve the social issue of "excessive salt intake".
- It aims to achieve "a society that enables to improve eating habits in a delicious way" by controlling the movement of sodium ions in food with a weak electric current to enhance the saltiness.
- Demonstration experiments are being conducted with Orange Page, Softbank, Tokyu Hands, Odawara City, etc., and preparations for the project are underway with the goal of starting sales in the summer of 2024.

Mechanism of saltiness enhancement in food and beverages



For more information, access here

Creating Added Value for the Kirin Group

- Patients with a chronic kidney disease, which Kyowa Kirin is committed to treating, require dietary treatments such as salt restriction. We will utilize the “Electric Salt" a tableware-type device, which enhances the salty taste of low-sodium foods, to allow patients to feel the strong salty taste of low-sodium food so that they can experience the pleasure of eating well while continuing the diet recommended by the medical institution.

※The above design is for demonstration purposes only.

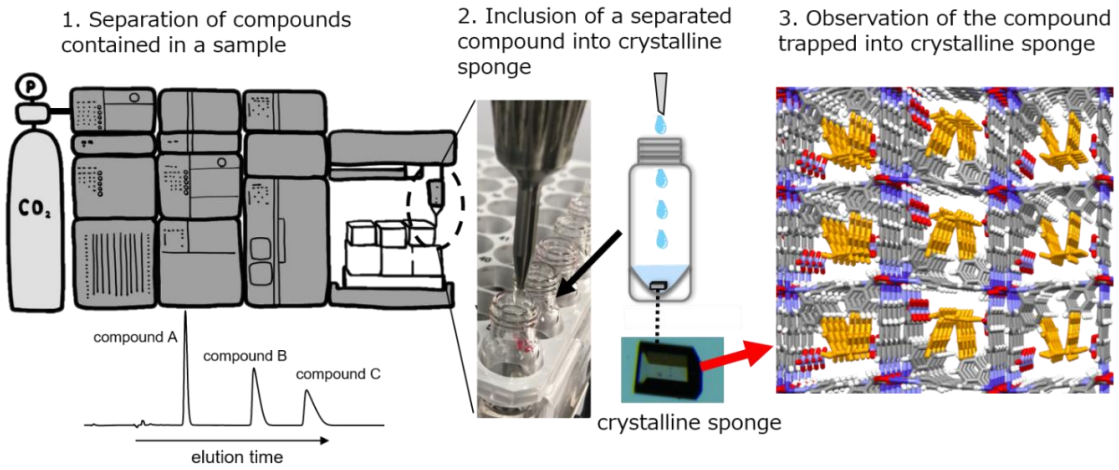
[Case study of creating added value]

Reduced R&D duration by developing a supercritical fluid chromatography CS method

Initiative Overview

- Kirin Central Research Institute and Kyowa Kirin have established the world's first analysis platform that enables swift separation of compounds to be analyzed from investigated samples containing various compounds and rapid structural determination of unknown compounds by coupling "supercritical fluid chromatography" and "crystalline sponge method".

For more information, access here



Creating Added Value for the Kirin Group

- In the Pharmaceuticals domain, there are examples of the use of this technology in various evaluations for the purpose of streamlining the search process for active substances.
- With FANCL, we utilize this with the structural analysis of active ingredients in functional materials, and with Kyowa Hakko Bio Group, we utilize the results of the structural analysis in the development of substance production methods.

【reference】

- In the Food & Beverages domain, succeeded in identifying the chemical reactions, reaction pathways, and reaction mechanisms of alpha acids associated with the oxidative aging of hops for the first time in the world and succeeded in the mass production of Kirin's unique material, "matured hop extract".
- Contributed to the launch *of KIRIN KARADA FREE* in October 2019, which contains "matured hop extract".

*The first product launched with matured hop-derived bitter acid as a functionally active ingredient.

Share knowledge of production management and human capital development (supply chain)

Outline of Initiatives

- Utilize the Kirin Group's know-how and expertise in production-related management systems and human capital development in Kyowa Kirin's supply chain.
- Under the high-quality assurance system for pharmaceuticals, Kyowa Kirin has strengthened its pharmaceutical supply system by collaborating with the Kirin Group, and based on this, it is now able to focus its resources on drug discovery and global market expansion that create core added value.

KIRIN

- **Leveraging Knowledge in the Food & Beverages Domain**
  - Production Management Know-how.
  - Factory operations and production management.
  - Establishment of human capital development system and training for new technical staff.
- **Engineering Support.**
- **Cross-business experience is possible by transferring personnel from the Food & beverages domain to the Pharmaceutical domain.**

※Collaboration with other companies or outsourcing to other companies as needed