Aiming to become a Global Specialty Pharmaceutical Company (GSP) anchored by the “One Kyowa Kirin” structure

Building a “One Kyowa Kirin” Structure

The Kyowa Kirin Group is overhauling its businesses and implementing management reforms to become a Global Specialty Pharmaceutical Company (GSP) engaged in drug discovery, development, manufacture and sales on its own in its FY2016-2020 Mid-term Business Plan.

One key part of those efforts is building a “One Kyowa Kirin” structure. Under our current operating structure, Kyowa Kirin International, headquartered in Europe, is responsible for sales in the North America region through its local subsidiary – in other words a sub-subsidiary of Kyowa Kirin. As part of our reforms, we overhauled that structure, making Kyowa Kirin USA Holdings the company responsible for operations in North America under the direct management of head office in Japan. The new structure ensures closer control over marketing in North America. Under that structure, head office and Kyowa Kirin USA Holdings will work together to accelerate growth in the promising US market, while also ensuring strong, effective governance.

In addition, we launched Kyowa Kirin Asia Pacific in Singapore in 2018 to oversee our operations in Asia and Oceania. Those changes have resulted in the creation of a regional-axis structure with four main regions – Japan, Europe, North America and Asia/Oceania.

In addition, we are also building a function-axis structure covering R&D, pharmacovigilance and quality assurance (PV&QA) on a global scale. We have put in place this organizational structure driven by both regional and functional matrices, as an important first step in creating a “One Kyowa Kirin” structure.

Kyowa Kirin’s Mission

As a pharmaceutical company, we have a vital public role to play in saving lives and improving QoL of patients. That role is a key element of Kirin Group’s commitment to CSV management. Crysvita, launched in 2018, is a drug for patients with X-linked hypophosphatemia (XLH), a hereditary disease. At the launch event for Crysvita in the US, I had the opportunity to meet people with XLH. One person expressed their thanks, saying that after anxiously waiting for the launch of Crysvita, the new drug would not only help them, but also their children and their grandchildren. I will never forget their tears and smile.

More than ever, I understand that the final value Kyowa Kirin provides must be putting smiles on as many patients’ faces as possible. Companies have to generate profits, but they also have a duty to make the world a better place. Developing a single drug takes immense time and effort. Before launching a new product, we have to overcome numerous obstacles and setbacks. Despite those challenges, everyone in the Kyowa Kirin Group will continue to do their best to contribute to the health and wellbeing of people worldwide.

Management Philosophy

The Kyowa Kirin Group companies strive to contribute to the health and wellbeing of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

Core Values

Commitment to Life

Work for the most precious presence on this planet.

Create value for patients, caregivers, healthcare professionals, and customer.

Innovation

Transform lives with passion and excitement.

Challenge the status quo in all of our work.

Teamwork/Wa

One for all, all for one. Work in diverse teams and respect each other.

Go beyond boundaries and collaborate with stakeholders.

* Harmony and loop among people

Integrity

Do the right things. Be sincere and ethical consistently.

Make a better world through good business practices.

Masashi Miyamoto, Ph.D.

Executive Director of the Board,
President and Chief Executive Officer
Who We Are

Vision
Kyowa Kirin will be a Japan-based Global Specialty Pharmaceutical Company contributing to human health and wellbeing worldwide through innovative drug discovery and global commercialization, driven by state-of-the-art antibody technologies mainly in the core therapeutic areas of oncology, nephrology and immunology.

Key Categories

Nephrology
As a leading company in nephrology, we are committed to the treatment of complications of chronic kidney disease through our drugs such as a treatment for nephrogenic anemia, Neyo, and treatments for secondary hyperparathyroidism, REGPARA and ORREDIA, for dialysis patients. We also have ONGIVZA, a treatment for diabetes, which is a cause of chronic kidney disease, in the product line to contribute to the total care of diabetes and chronic kidney disease.

Oncology
We are contributing to helping patients who are battling cancer by providing drugs such as a long-acting G-CSF product G-Lasta used for the inhibition of the onset of febrile neutropenia due to cancer chemotherapy, a therapeutic antibody Poteligeo, which applies our POTELLIGENT technology, and the cancer pain treatments.

Immunology/Allergy
We are contributing to improving patients’ satisfaction with treatment and to making their daily life comfortable, primarily through products such as an allergic disease drug ALLELOCK, which is established in the market and has a strong reputation, and an ulcerous colitis drug ASACOL. Recently, we have launched Dovobet and LUMICEF for dermatology to provide new treatment options for psoriasis.

Central Nervous System
For Parkinson’s disease, we propose new medications mainly including a nondopaminergic agent NOURIST, with a new mode of action, and a rescue agent Apokyn. We are also contributing to the treatment of central neurological diseases through products such as antiepileptic drugs DEPAKENE and Topina.

Fundamental technologies
Cutting-edge biotechnology based on the latest antibody technology
- Genetic engineering technology
- Protein/antibody engineering technology
- Excellence in analysis and control of carbohydrates
- Technology in cell culture and control of cell differentiation
- Technology for manufacturing of biologics

Objectives

Become a Global Specialty Pharmaceutical Company
Develop innovative new drugs such as therapeutic antibodies, small-molecule drugs and nucleic acid drugs
Global

Accelerating global expansion as “One Kyowa Kirin”

Kyowa Kirin has established a new global management structure. Organized under the four Japan, EMEA, North America (US/Canada) and Asia/Pacific regions and by the functions critical to a GSP, efforts are now geared toward further global expansion under the “One Kyowa Kirin” banner. Under that structure, we will harness our strengths in therapeutic antibodies and other areas to build an attractive pipeline as a pharmaceutical company that discovers new drugs.

Global regional-axis structure with four main regions

Improvement of Global Competitiveness

“Improving global competitiveness” is the first strategic priority in our five-year Mid-term Business Plan. In 2018, the Group successfully launched Crysvita, a long sought after global strategic product, in the European and US markets, as well as Poteligeo in the US market. The Group also filed an application for approval for Istradefylline, a therapeutic drug for the treatment of Parkinson’s disease, in the US. In order to maximize the value of these global strategic products, energies are being directed toward measures aimed at promoting market penetration and expanding business areas focusing on Europe and the US. Turning to the pharmaceuticals market in Asia, where growth is expected, Kyowa Kirin delegated the Asia/Pacific region’s central function to its local subsidiary Kyowa Kirin Asia Pacific Pte. Ltd. in April 2018. Working through this subsidiary, the Group is reinforcing its business base in a bid to secure stable growth.
Creating new value through innovation led by our people and technologies

Human Resources

Becoming a company that utilizes diverse human resources

The Kyowa Kirin Group sees employees as the source of innovation. The Group is therefore striving to unleash the full potential of each and every employee to develop individuals and organizations that will tirelessly tackle reform and create new value. In an effort to fulfill its management philosophy amid the increasingly drastic changes surrounding our business, we believe it to be critically important to recruit and foster people capable of exercising leadership and autonomously taking on the challenge of reform.

It is also imperative to help every one of our employees achieve healthy, fulfilling and high-quality lives and to harness the unique capabilities of employees with diverse backgrounds in order to create new value.

Empowering women is particularly important to increase the Group’s competitiveness. We are aiming to increase the proportion of female managers to 10% or more by 2020 (compared with 8.9% as of December 31, 2018). To achieve that target, we are actively running training programs to prepare female employees for managerial positions, as well as offering career education. Moreover, we provide employees with support for a smooth return to work after taking childcare leave by hosting the Back-to-Work Support Forum. To support employees with family members needing nursing care, we provide them with seminars regarding a balance between work and family and necessary information.

Kyowa Kirin is creating work environments that welcome people with diverse sexual orientations and gender identities. To adjust the mindset of the top management, we hold LGBT awareness lectures for senior executives and run seminars and e-learning programs for all employees on a continuous basis to improve their knowledge and understanding about the LGBT community. We have also revised personnel system and policies where same-sex partnership is recognized as marriage. The KKH Working Regulations also specifically forbid harassment on the basis of sexual orientation or gender identity. Additionally, we have set up a hotline to provide advice about sexual orientation and gender identity to all employees in need.

Technical Capabilities

Using open innovation and AI to enhance our technologies

One of Kyowa Kirin’s flagship technologies is its antibody technology, which is intended to use the human immunity protection system in a drug for disease treatment. We tap into this technology for new drug development while pursuing our antibody business through strategic alliance.

Also, as part of our drug discovery and research processes, we are actively embracing open innovation, which draws on information and expertise from outside the Kyowa Kirin Group.

In addition, to lay the groundwork for the active adoption of AI and other new technologies, we established a Clinical Data Science Research Group in the Biometrics Department in April 2018. To create new drugs, we will need to combine AI and other new technologies with existing R&D approaches. Our job is to take on the challenges to rapidly deliver effective and attractive new drugs to patients.

By combining cutting-edge technology platforms for drug discovery cultivated in the fields of therapeutic antibodies, one of the Group’s strengths, small molecule drugs, nucleic acid drugs, and regenerative therapies, as well as outside technologies from open innovation, the Kyowa Kirin Group is building an attractive pipeline as a pharmaceutical company that discovers new drugs.
Integrity

To drive business expansion in the global market, we will continue proceeding with the establishment of the global product supply system centered on the Takasaki Plant and the Ube Plant.

Takasaki Plant

Global supplies of biopharmaceuticals get underway

Our Takasaki Plant has manufacturing facilities of Drug Substance (DS) and Drug Product (DP) which are fitted with the latest biopharmaceutical manufacturing equipment for antibody drugs. Over the last few years, we have been preparing for the launch of global strategic products to ensure stable supplies of high-quality pharmaceuticals to patients worldwide, based on GMP* systems that conform to the strictest guidelines overseas. In 2017 and 2018, the Takasaki Plant passed Pre-Approval Inspections by US and European authorities, allowing us to begin supplying two global strategic products to the US and Europe after they were approved in 2018. We are now making preparations to supply the products to other markets worldwide.

* GMP (Good Manufacturing Practice): The practices required in order to conform to the guidelines of Manufacturing and Quality Control for pharmaceuticals and quasi-pharmaceuticals.

Topics

Expanding production facilities at the Takasaki Plant

We aim to increase the Takasaki Plant’s production capacity for antibody drugs to 2.5 times the current level by 2025. To reach that goal, we will continue to expand DS and DP manufacturing facilities from 2019. We will also start up a new manufacturing facility fitted with cutting-edge equipment. These expanding production facilities will give us the capacity to supply many different products to patients worldwide.

Projected increase in production capacity

2025
Roughly 2.5 times current level

Ube Plant

Stable operations of the manufacturing building for formulations push forward preparation for the production of new products

Ube Plant, which is specialized for oral solid formulations, is an automated plant for mass production based on leading-edge engineering technology. The most contemporary manufacturing technologies and advanced check systems have achieved efficient production and supply of quality drug products.

Cooperation between Ube Plant and CMC R&D Center

The CMC R&D Center mainly designs new formulations for small-molecule drugs, produces experimental drugs, develops testing methods for APIs and new formulations, files new drug applications and conducts research to cultivate new drugs.
Creating Shared Value

CSV management aimed at increasing corporate value

In our corporate philosophy, we at Kyowa Kirin Group are committed to creating new value by capitalizing on its strengths in life sciences and technologies with the aim of contributing to the health and well-being of people around the world. This “new value” is nothing but the value that can be shared with society, or in other words, “Creating Shared Value (CSV).”

We practice CSV management aimed at realizing improved corporate value through the creation of both social and economic value by addressing social issues.

Contribute to the SDGs

We are implementing measures to contribute to the Sustainable Development Goals (SDGs)*. “Contribute to the health and well-being of people around the world” in our corporate philosophy is consistent with Goal 3 in the SDGs: “Good health and well-being.” Therefore, this Goal 3 is positioned as the core issue of our group. Our CSV Materiality set from both social and business perspectives is responsible for all 13 SDGs including Goal 3.

* SDGs: A collection of 17 goals that international society should address over 15 years between 2016 and 2030 in order to realize sustainable global development. The SDGs were adopted by the United Nations summit in September 2015.

Involvement with stakeholders

Customers

Providing information about illnesses and health

We run a website that provides a wide range of information about illnesses and health, such as easy-to-understand explanations about the mechanisms of antibodies and immunology.

The Environment

Protecting biodiversity

The Kyowa Kirin Group works on a global scale to preserve ecosystems and protect biodiversity.

Introducing solar power systems

We are installing solar power generation systems at Group plants and research facilities. We are also working to reduce emissions of greenhouse gases on a global scale. One example is our use of the joint crediting mechanism (JCM) between Thailand and Japan when we constructed a new plant for Thai Kyowa Biotechnologies.

Society and Community

Fostering future generations

We run hands-on science laboratory sessions for children as part of our efforts to foster future generations. The sessions also give local people insights into our business and our strengths as a company, helping to enhance trust and a sense of community.

Interaction through sport

The Kyowa Kirin Group interacts with local communities through sports events. Our efforts to contribute to society through sport have been recognized by the Tokyo Metropolitan Government, which has certified Kyowa Kirin as a “Tokyo Sports Promotion Company” for four consecutive years from 2015.

Local communities

We run activities that emphasize engagement with people in communities near our business sites in order to deepen links with local communities as a good corporate citizen.
Corporate Data

Company Name: Kyowa Kirin Co., Ltd.

Established: July 1, 1949
* Date of establishment of former Kyowa Hakko Kogyo Co., Ltd. Company name changed from Kyowa Hakko Kogyo Co., Ltd. following merger with Kirin Pharma Company, Limited on October 1, 2008.

Capital: ¥26,745 million (As of December 31, 2018)

Number of Employees: 7,242 (Consolidated basis, as of December 31, 2018)

Executive Director of the Board: President and Chief Executive Officer Masashi Miyamoto

Head Office: Otemachi Financial City Grand Cube 17F
1-9-2, Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan
TEL: +81-3-5205-7200 FAX: +81-3-5205-7182

Revenue (consolidated): ¥146,531 million (Fiscal Year ended December 31, 2018)

Main Business: Kyowa Kirin Co., Ltd. is engaged in the manufacturing and marketing of pharmaceuticals.

Parent Company: Kirin Holdings Company, Limited

Main Group Companies

Japan
- Kyowa Medical Promotion Co., Ltd.
- FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.
- Kyowa Kirin Frontier Co., Ltd.
- Kyowa Kirin plus Co., Ltd.

Overseas

Asia
- Kyowa Kirin Asia Pacific Pte. Ltd.
- Kyowa Hakko Kirin China Pharmaceuticals Co., Ltd.
- Kyowa Hakko Kirin Korea Co., Ltd.
- Kyowa Hakko Kirin (Taiwan) Co., Ltd.
- Kyowa Hakko Kirin (Thailand) Co., Ltd.

U.S.A.
- Kyowa Kirin USA Holdings, Inc.
- Kyowa Kirin Pharmaceutical Development, Inc.
- Kyowa Kirin Pharmaceutical Research, Inc.
- BioWa, Inc.

Europe
- Kyowa Kirin International plc.

Main Business Offices

Brances
- Sapporo Branch
- Tohoku Branch
- Tokyo Branch
- Chiba-Satama Branch
- Kita-Kanto Branch
- Koshinetsu Branch
- Yokohama Branch
- Nagoya Branch
- Osaka Branch
- Keih-Hokuriku Branch
- Chugoku Branch
- Shiokoku Branch
- Kyushu Branch

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

Plants
- Takasaki Plant
- Ube Plant

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Europe
- Kyowa Kirin International plc.

Our corporate website
https://www.kyowakirin.com/
Commitment to Life

Countless precious lives surround us.
Brought into this world, blessed, raised with loving care – full of dreams, happiness as the goal of life.
Deeply instilled in us, and know that what we work for – the most precious presence of all on this planet.
Infinite possibilities for us, a pharmaceutical company.

Believe in ourselves, believe in our power, believe in what we have built together.
Not a large company, but with qualities like none other.
History so unique we can be proud of, technology unmatched,
And superior human beings that cannot be found elsewhere.

Be brave; do not shy away from challenges. Have passion; break away from the norm.
Innovation is not just about growth – but instead a leap towards the future, a grand growth with wings.
Wings never to be given to those who settle for the status-quo.

Don't just make medicine. Make people smile, bring light to their lives.
How strongly one longs to live. How deeply one is loved by their loved ones.
How sincerely one desires to help the one life they dedicate themselves to in the field of medicine.
Stay receptive, sharpen your sensitivities.
Let us become the top company in the world who cares the most for life.
Strength is not what saves the world. A caring heart is what the world calls for.

Strive to become a superb team.
One human being, excellent or not, is ever so powerless, as a power of one, mistakes, even a possibility.
Show the world the excellence of coming together. Amazing results, when we become one.
Be driven. Think of those fighting for their lives every day.
Their strong devotion to life speaks to our hearts.
Hurry – do not scurry, but we must not stand still. Stay sincere, always – may that be our vow.
We make medicine. This is, our walk of life.

Work, can bring happiness. Remember this, always.
Born on this planet in various parts of the globe, passing through life in different ways,
And like a miracle we found one another – our jobs, our team, our company.
Know this, and be fulfilled, always.
Be thankful of what you have, pour your heart and soul into the mission you were given,
Be proud of your work, the work to save precious lives.

We are, each and everyone of us, Kyowa Kirin.

Taking the walk of life, one life at a time.