CEO message

Aiming at becoming a GSP that covers the entire range of business activities from drug discovery to development, manufacture and sales

The Kyowa Hakko Kirin Group has implemented four strategic pillars 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. The first pillar of our strategy is “Improvement of Global Competitiveness.” In FY2018, we expect to launch two global strategic products, burucosumab (KRN20) and mogamulizumab (KRN-0763), in the European and U.S. markets. Burucosumab (KRN20) is an anti-FGF 23 fully human monoclonal antibody currently being developed for the treatment of X-linked hypophosphatemia (XLH). On the other hand, mogamulizumab (KRN-0763) is an anti-CCR4 humanized monoclonal antibody that has been released already in the Japanese market. We have completed reorganization of our pharmaceuticals business production facilities in Japan. We have also restructured our bio-chemicals business production facilities in Japan, for example, by transferring manufacturing operations to Thai or Shanghai. The second pillar of our strategy is “Creating Innovation.” We promote open innovation with academic institutions through worldwide research activities centered in the R&D laboratories in Japan and the U.S. Also, in order to achieve our group management philosophy, we restructured our policy of securing and developing human resources that gives shape to “Core Values” and “Code of Conduct,” thereby formulating the Kyowa Hakko Kirin Group Talent Management Policy. This policy clearly defines our philosophy common to the whole group with a view to building organization that keeps challenging to reform and create new values based on the idea that the source of innovation lies in “people.”

The third pillar of our strategy is “Continuous Improvement for Operational Excellence.” First of all, we improved the production technology in FY2017. The Bio-Process Research and Development Laboratories take the lead to work closely with manufacturing sites in addressing technology improvement continuously. A cross-sectoral project involving the entire Kirin Group has been conducted in order to improve its business processes.

The fourth pillar of our strategy is “Contribution to Health and Well-being of People.” I believe that CSV will serve as the compass for the Kyowa Hakko Kirin Group down the road. The practice of CSV will have much to do with sustainable growth from this point onward. It is important not only to take up a challenge but to produce results by taking advantage of our strength to realize it as well. The Kyowa Hakko Kirin Group will face challenges and achieve sustainable growth by focusing on these four strategic pillars.

Nobuo Hanai
Representative Director
Chairman and CEO

COO message

Building a global business platform under the keyword “creating new value”

I believe that “creating new value” is important in order for the Kyowa Hakko Kirin Group to grow sustainably from now on. New value that the Group must create is to contribute to the health and well-being of patients and their families, as well as medical professionals, by providing new drugs. For the first objective to create new value that only the Group can offer, we must establish a system for the delivery of two new drugs to patients and medical professionals all over the world including Japan. These two drugs, namely burucosumab (KRN20) and mogamulizumab (KRN-0763), are likely to be launched in Europe and the U.S. in FY2018. From now on, Kyowa Kirin International will prepare for the sale of the new drugs in Europe and the U.S. We will develop a globally unified sales strategy, supply chain, and quality assurance system and thereby build a platform for the Group to aim to become a GSP. For the second objective, we will push forward with reinforcing R&D capabilities. More than 20 years have passed since we started the research on burucosumab and mogamulizumab. From the start, we have engaged in R&D in collaboration with the academia. Open innovation-based R&D, an inherited approach of Kyowa Hakko Kirin, is a major characteristic of these efforts. We will continue to link internal and external knowledge and expertise organically, thereby developing valuable and innovative drugs unique to the Group. For the third objective, we also expect that when we combine

Management Philosophy

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

Commitment to Life

Work for the most precious presence on this planet.
Create value for patients, caregivers, healthcare professionals, and customers.

Integrity

Do the right things. Be sincere and ethical consistently.
Make a better world through good business practices.

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

Vision

Kyowa Hakko Kirin will be a Japan-based Global Specialty Pharmaceutical Company contributing to human health and well-being 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.
With the aim of launching new drugs bearing our brand in the European and U.S. markets, and penetration of the KYOWA KIRIN brand globally, we will accelerate our overseas strategy.

Burosumab and mogamulizumab, the new drugs bearing our brand, are planned to be launched in the European and U.S. markets in 2018. In association with their launch, we will accelerate our overseas strategy by strengthening the sales teams in Europe and the U.S., and pursuing business expansion in Asia.

In view of their approval in Europe and the U.S., we will proceed with the development of a global distribution and sales structure, and additionally in Asia, we aim at sustainable growth by penetrating major products in the market.
Reforming our organizational culture, work style and technologies by translating our talent capabilities and technology into corporate power.

Kyowa Hakko Kirin promotes smart work in an effort to foster an organizational culture generating innovation and develop talent attaining it. Moreover, we pursue technological evolution in order to deliver unprecedented and innovative products to customers around the world.

Pursuing work style reform designed to improve productivity

Putting in place the Smart Work Promotion Plan, the Kyowa Hakko Kirin Group pursues an initiative to shift to an organizational culture that attaches importance to hourly productivity-focused work style, namely, smart work, and to build a highly-creative workplace environment with the aim of keeping employees healthy and ensuring thorough compliance. Under the Kyowa Hakko Kirin Group Talent Management Policy, the Group deploys various action plans for management challenges such as diversity and inclusion (D&I) efforts, including female empowerment and disability employment expansion, as well as health-centric business management. We seek to ensure that each employee exercises his or her competence to the maximum, contributing to the organization’s capabilities.

Assisting diverse work style

The Kyowa Hakko Kirin Group will further accelerate efforts to promote diversity and build a proper workplace environment through employees’ mutual understanding. Moreover, we aim to improve all employees’ work-life balance and enable the Group to grow in a sustained manner. The Group also holds various seminars to foster an organizational culture empowering diverse employees to work actively and enthusiastically. We organize the Diversity Management Seminar for organization heads including officers and the Diversity and Inclusion (D&I) Seminar designed for leaders in a position to manage staff members. Moreover, the Group assists employees’ diverse work style through a reinstatement aid seminar, which is intended for employees on a childcare leave of absence to consider their post-reinstatement work style and life in order to return to work smoothly and work actively, as well as a nursing care aid seminar.

Tackling new technologies through open innovation

One of Kyowa Hakko 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. We actively incorporate open innovation, which leverages external-entity data and knowledge, into our drug discovery research processes. We engage in research and development for new drugs from an early stage and jointly with universities, medical institutions and start-up companies with a sense of unity. In terms of open partnerships, it is very important to form an alliance in the information technology (IT) field as well. In recent years, artificial intelligence (AI) has made remarkable progress and its application in pharmaceutical development and personalized care has gained prominent attention. In the IT field, where new innovations are expected, such as increased speed and efficiency of drug discovery by using big data in the real world, including healthcare information, we will vigorously team up with leading-edge players. Through active communication between external researchers and our researchers, Kyowa Hakko Kirin tackles new technologies such as for nucleic acid drugs and regenerative therapeutics. As regards nucleic acid drugs, we have come to a stage of attaining results for research and development. In the regenerative therapeutics field, we are engaged in joint research on cancer immunotherapy with the Center for iPSC Cell Research and Application, Kyoto University. We aim to develop these activities into one of the pillars of our research and development programs, going forward.

Utilization of open innovation and development of four major modalities

- **Next Generation Therapeutic Antibodies**
  - Humanized antibody
  - Cell-fusing antibody

- **Nucleic Acid Drugs**
  - Nucleic acid-based drug delivery technology
  - RNA technology using lipid nanoparticles

- **Our Core Strengths**
  - Establishment by R&D and Production of Biopharmaceuticals
    - Genetic engineering technology
    - Microbiological engineering technology
    - Antibiotics in clinical and diagnostic applications
    - Gene therapy using lentivirus vectors
    - Glyco-engineering for improving bioavailability

- **New Small Molecule Drugs**
  - Medicated agent with cancer therapies
  - Precise drug design and development based on structure analysis of target molecule

- **Regenerative Therapeutics**
  - iPSC technology collaboration with other medical institutions
  - Skills in induced cell culture and differentiation culture
We have completed the reorganization of our production facilities and established a global product supply system.

Reorganization of production facilities that started in 2010 was completed. To accommodate the changing business environment in Japan and business expansion in the global market, we will continue proceeding with the establishment of the global product supply system centered on Ube Plant and Takasaki Plant.

**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. The production capacity of Ube Plant, including the manufacturing building for formulations that was additionally built in 2012 and the existing factory for formulations, reached 1.4 billion tablets per year. The manufacturing building for formulations entered a stable operation phase, efficiently producing products transferred from the Fuji Plant and smoothly proceeding with the preparation for production of new products.

**Takasaki Plant**

New manufacturing building for antibody bulk drug substances accommodates an increasing demand of therapeutic antibodies

Takasaki Plant supports Kyowa Hakko Kirin’s biopharmaceutical production by combining the start-of-the-art technologies with four technological essentials necessary for biopharmaceutical production, “creating,” “seeing,” “preserving,” and “purifying.” To accommodate the future increasing demand for therapeutic antibodies, a manufacturing building for antibody bulk drug substances of biopharmaceuticals (Building HB6) was additionally built in August 2016. For others, the manufacturing building for formulations (Building HA5) has been efficiently manufacturing multiple product items, which are mainly injections. Thereby, we are strengthening the manufacturing system. All the facilities comply with GMP standards*5 in three regions, Japan, the U.S., and Europe, and are thus qualified for global product supply.

*5 GMP refers to Good Manufacturing Practice, an international standard for manufacturing and quality control of pharmaceuticals, etc.

Factors in Biopharmaceuticals

Production Technology

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*6 CMC stands for Chemistry, Manufacturing, and Controls, which is the research and development activities including the drug formulation, manufacturing of investigational drug, and development of analytical methods for drug substance and drug products.
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 NESP® and a treatment for secondary hyperparathyroidism REGPARA® for dialysis patients. We also haveONGLYZA®, 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.

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.

For Parkinson’s disease, we propose new medications mainly including a non-dopaminergic agent NOURIAST® 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®.

Our world’s unique business synergy generated by integrating drug discovery business for pharmaceutical products as well as businesses for biosimilars and bio-chemicals into one group has been creating high-value-added products that contribute to the medical needs of the world.

Kyowa Hakko Bio

Kyowa Hakko Bio has been providing the pharmaceutical, medical, and healthcare fields with products and services to fulfill healthcare needs of people in the world. The company is also proceeding with collaboration with Kirin Group companies and academia.

Health food product lines

Group business synergy expands our potential

In this field, we are developing biosimilar drugs (bio-generic drugs) that are comparable to the original reference products. We will provide high-quality biosimilar products at low prices to meet medical needs.
Contributing to the health and well-being of people by deeming CSV as the compass for our business management.

Kyowa Hakko Kirin deems CSV aimed for by the Kirin Group as the compass for our business management. We contribute to the health and well-being of people around the world by putting CSV management into practice, thus addressing social challenges while meeting stakeholder expectations.

Provision of New Medical Value to Customers

Amid the growing interest in health, we will proceed with the discovery of innovative drugs that meet unmet medical needs, the expansion of new indications and dosage forms of existing products, and provision of stable supply of products with excellent quality.

Contribution to Kirin Group’s CSV

Meet Social Demands for Medical Cost Containment

We will actively contribute to healthcare through consideration to provide our nephrogenic anemia treatment NESP® as an authorized version*8 and promotion of the production and supply of biosimilar drugs.

Contribution of Preventive and Presymptomatic Healthcare

We will be aggressive also in the new business fields such as “preventive healthcare” to prevent diseases and “presymptomatic healthcare” before becoming a disease through expansion of the health food business and promotion of the self-care business utilizing the diagnostics business.

Creation of Shared Value

Kyowa Hakko Kirin deems CSV aimed for by the Kirin Group as the compass for our business management. We contribute to the health and well-being of people around the world by putting CSV management into practice, thus addressing social challenges while meeting stakeholder expectations.

Contribution to Health and Well-being of People

Kyowa Hakko Kirin deems CSV aimed for by the Kirin Group as the compass for our business management. We contribute to the health and well-being of people around the world by putting CSV management into practice, thus addressing social challenges while meeting stakeholder expectations.

Specific efforts

Patient aid activities: Provide “Information on Illness and Health” on website pages

- We participated in a charity marathon designed to support pediatric cancer patients, a gate ball (Japanese croquet) game for patients with renal failure, and a charity walk event intended to raise money for The Leukemia & Lymphoma Society.
- We provided website pages that outline information on illness and health as well as antibody and immunity functionality in an easy-to-understand manner.

Involvement with local communities / Fostering next generations

- We attach importance to communication, and thus actively participate in events held by local communities.
- We hold science experiment sessions for children, contributing to fostering the next generation. Through these activities, we hope that people in the local communities understand our business and strength, and thereby recognize us as a trustworthy and familiar neighbor.

Support for mega-solar power business / Run environmental preservation programs

- In sympathy with the endeavors of mega solar power business Solar Farm Ube and Solar Farm Hofu, Kyowa Hakko Kirin leased out part of the land of its production sites, thus aiming to improve the local community environment.
- As part of our environmental preservation efforts, Kyowa Hakko Kirin implemented programs to clean nearby rivers and water source forest conservation activities.

*8 Branded generic drugs that have been licensed by the patent holding company of the original drug for manufacturing and commercialization and are identical to the original drug in terms of active pharmaceutical ingredients, excipients and manufacturing method.
Kyowa Hakko Kirin is engaged in the manufacture and marketing of pharmaceuticals. As the holding company of the Kyowa Hakko Kirin Group and with the pharmaceuticals business as its core, it manages business activities such as biochemical business.

Main Business Offices

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Research Laboratories

| Tokyo Research Park       |                |                     |
| Fuj Research Park         | Bio Process Research and Development Laboratories |                   |
| CMC R&D Center            |                 |                     |

Plants

| Takasuki Plant | Ube Plant |

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.
- Kyowa Hakko Bio Co., Ltd.

Overseas

Asia

- Kyowa Hakko Kirin China Pharmaceuticals Co., Ltd.
- Kyowa Hakko Kirin Korea Co., Ltd.
- Kyowa Hakko Kirin (Taiwan) Co., Ltd.
- Kyowa Hakko Kirin (Hong Kong) Co., Ltd.
- Kyowa Hakko Kirin (Singapore) Pte. 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
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.