

A commitment to life





We are, each and every one of us, Kyowa Kirin

For several years, ProStrakan has been a member of Kyowa Kirin, a Japan-based Pharmaceutical company. As part of its commitment to become a global pharmaceutical specialty organisation, Kyowa Kirin is harmonising all its affiliates across the globe, and from April 2016, ProStrakan became known as Kyowa Kirin.

Kyowa Kirin aims to contribute to the health and comfort of people around the world. Our mission is to respond to the needs of patients suffering from diseases for which no effective treatments are available, their families and the healthcare professionals fighting those diseases on the front line.

A company with qualities like no other

Specialising in the core fields of oncology, nephrology, immunology / allergy and the central nervous system, we develop leading-edge biotechnologies, focussing on the use of antibodies, to develop and discover innovative new drugs, which Kyowa Kirin market worldwide.

Biotechnology is our greatest strength, driving sustained growth. We will maintain our leading-edge in this field, continue to innovate and emphasise our passion for science. Our business model allows us to combine the strengths of each company in the group and respond to changes in the external environment.

As a global company, we must earn the trust of society by excelling in our social responsibilities. We work to maintain transparency, fairness, compliance and co-existence with our local communities.



We want to be known as a company that cares for quality of life

Our vision is to be a global specialty pharmaceutical company, contributing to human health and wellbeing worldwide through innovative drug discovery and global commercialisation.

This work will be driven by leading-edge antibody technologies in the core therapeutic areas of oncology, nephrology, immunology/allergy and the central nervous system. We are currently focussing on launching pipeline products originated by Kyowa Kirin in Europe and the United States.





Taking the walk of life one life at a time

Our values are the foundation of our success and are reflected in the strength and dedication demonstrated by our team every day. We inspire and challenge our people to think creatively and work together to create a better world and help people live healthier, more fulfilling lives.

We cultivate a strong culture and provide a working environment that promotes collaboration, innovation, respect, diversity, teamwork and ethics. Our respect for life, health and wellness inspires everything we do.

These are our values:

- Believe in ourselves
- Find strength in numbers
- Celebrate and take pride in our shared mission
- Strive to be fearlessly innovative
- Accelerate our efforts
- Pursue our objectives with honesty and integrity
- Support wellness and quality of life





History we can be proud of

With expertise based on a history of innovation, Kyowa Kirin and ProStrakan have worked together 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.

1995

Strakan founded.

2004

Strakan and ProSkelia merge to form ProStrakan.

ProStrakan acquires OTL Pharma (Paris) and Elfar and Devon Farmacéutica (Spain).

2005

ProStrakan floats on the London Stock Exchange.

ProStrakan acquires APS Pharma (Germany).

2010

Kyowa Kirin completes one of Japan's leading facilities for producing investigational therapeutic antibodies at the Bio Process Research and Development Laboratories as well as new research buildings in the Tokyo Research Park.

2011

ProStrakan acquired by Kyowa Kirin.

2012

Kyowa Kirin constructs a new facility for formulation of solid dosage forms at the Ube Plant.



2006

ProStrakan collaborates with Novartis (bone) and Amgen (renal).

ProStrakan sells Drug Discovery Unit (formerly ProSkelia).

2007

ProStrakan announces a collaboration in the United States with NovaQuest and a Nordic sales joint venture with Orexo AB.

2008

Kyowa Hakko Kirin (Kyowa Kirin) was formed through the merger of Kyowa Hakko and Kirin Pharma.

2014

ProStrakan completes acquisition of Archimedes.

Kyowa Kirin completes construction of Drug Product Manufacturing Facility in the Takasaki Plant.

2015

Kyowa Kirin completes the construction of a new research building at the Fuji Research Park.

2016

ProStrakan rebrands as Kyowa Kirin.

Be proud of your work, the work to save precious lives

Through growth, evolution and acquisition we are well on our way to becoming a truly global specialty pharmaceutical company, enabling us to market a range of products in Europe and the United States. Some of our specialist therapy areas in Europe and the United States are outlined below.

Oncology and supportive care

Oncology is one of Kyowa Kirin's core therapeutic areas. In Europe and the United States we provide a large range of supportive care products which aim to improve patient quality of life.

Our portfolio includes chemotherapy and oestrogen agonist/antagonist products to help prevent disease progression, as well as supportive oncology medicines that help relieve breakthrough cancer pain.

We also provide products that treat the side effects of cancer treatments, such as antiemetics to reduce patient suffering from chemotherapy-induced nausea and vomiting.

Novel supplementary and supportive medicines

We have a long and successful history with bone health and micronutrient deficiency treatment. We are continually developing our products and expanding our ranges to ensure the needs and preferences of patients are met.

We hope to address deficiencies affecting patient health, as well as help patients receiving specific therapy for osteoporosis, to protect their bones.

We strive to make novel therapies available to ensure patients receive the most appropriate treatment options.



Infinite possibilities

Building on our strengths, we will follow category-based strategies in our core therapeutic areas, while using our worldwide network to become a global specialty pharmaceutical company.



A global network

Expanding our global business platform from drug discovery to development and marketing.

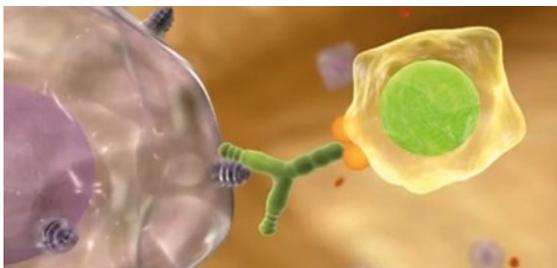
Kyowa Kirin's drug discovery network around the world is integrated. We are expanding marketing channels in the United States and Europe.



Therapeutic antibody

Using cutting-edge biotechnology.

Kyowa Kirin uses its core proprietary technology, POTELLIGENT®, in strategic alliances with other companies in order to rapidly expand its antibody business.



Product development

Kyowa Kirin is executing a category-based strategy in the therapeutic areas of nephrology, oncology, immunology/allergy and the central nervous system.

We encourage collaboration between research and development, manufacturing and sales, which accelerates new discoveries, drives development, and maximises product value.



A solid management foundation

Creating an organisation and corporate culture appropriate for a global specialty pharmaceutical company.

Our relationships with shareholders, investors and partners are based on fairness and transparency. We seek to fulfil our social responsibilities and create a culture in which our people can grow.

Amazing results when we become one

To achieve our vision of becoming a global specialty pharmaceutical company, Kyowa Kirin is expanding our business operations worldwide, from drug discovery to development and marketing.

In Europe, the United States and Asia, we are expanding our business operations in accordance with business strategies tailored to each country and region.

Clinical development network

Kyowa Kirin has an extensive clinical development network spanning Europe, the United States and Asia to ensure that pipeline products are developed and launched on a global scale.



4 San Diego

In every step of the process, we exploit our technology and know-how.

● Step one: Drug discovery research

We will pursue new research possibilities into genes, proteins and other substances at the molecular level for the development of new drugs based on new mechanisms.

● Step four: Clinical development

At Kyowa Kirin's development centres in Europe, the United States and Asia, we undertake clinical quality assurance to evaluate the efficacy and safety of pharmaceuticals in accordance with the standards of each country.

● Step two: Screening and optimisation

Using synthetic chemistry and biotechnology we explore hidden potential, allowing us to develop new ideas from diverse perspectives.

● Step five: Production and quality assurance

To ensure our products meet global quality standards, the four Kyowa Kirin plants in Japan feature the latest technology and equipment, and employ a quality assurance system which rigorously checks every step in the manufacturing process, from drug substance to drug products.

● Step three: Pre-clinical research

By evaluating new ideas from every angle, from their effectiveness to their safety as a medicinal drug, we aim to create valuable, high-potential pharmaceuticals.

● Step six: Sales and marketing

A local presence in major markets provides high-quality sales and marketing support.



Our global locations:

North America and Europe

- ① Kyowa Kirin USA Holdings, Inc.¹
- ② Kyowa Kirin Pharmaceutical Development, Inc.
- ③ BioWa, Inc.²
- ④ Kyowa Kirin Pharmaceutical Research, Inc.
- ⑤ Kyowa Kirin International plc.
- ⑥ Kyowa Kirin Pharma S.A.S.
- ⑦ Kyowa Kirin Farmacéutica, S.L.U.
- ⑧ Kyowa Kirin GmbH.
- ⑨ Kyowa Kirin Pharma B.V.
- ⑩ Kyowa Kirin S.r.l.
- ⑪ Kyowa Kirin AB.
- ⑫ Kyowa Kirin, Inc.

Asia

- ⑬ Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.
- ⑭ Kyowa Hakko Kirin Korea Co., Ltd.
- ⑮ Kyowa Hakko Kirin (Taiwan) Co., Ltd.
- ⑯ Kyowa Hakko Kirin (Hong Kong) Co., Ltd.
- ⑰ Kyowa Hakko Kirin (Singapore) Pte. Ltd. / Singapore Translational Research Laboratory
- ⑱ Kyowa Hakko Kirin (Thailand) Co., Ltd.

Japan

- ⑲ Head Office
- ⑳ Tokyo Research Park
- ㉑ Takasaki Plant
- ㉒ Bio Process Research and Development Laboratories
- ㉓ Fuji Plant
- ㉔ CMC Research and Development Center
- ㉕ Fuji Research Park
- ㉖ Ube Plant

1. United States holding company. 2. Licensing of therapeutic antibodies and alliance activities intended to acquire promising external innovations and technologies.



Innovation is not just about growth, but a leap towards the future

A core strength of Kyowa Kirin, therapeutic antibodies are designed to use the immune system to treat diseases. We are establishing proprietary antibody technologies to move our business forward with strategic alliances, as well as for our own new drug development.

Developing POTELLIGENT® technology into an antibody business

To maximise the value of the therapeutic antibodies in our pipeline, we are taking multiple approaches to development, including out-licensing candidates at early stages and concluding antibody technology licensing contracts with other companies.

Having multiple approaches allows us to accelerate the commercialisation of therapeutic antibodies to develop a world-class business, while providing new drugs for diseases that do not yet have effective treatments.

We are moving forward with recently concluded product-level development alliance agreements for the humanised antibody KW-0761 that was created using our POTELLIGENT® technology.

This product is gaining attention as a potential cancer immunotherapy, which is a treatment designed to harness and enhance the innate powers of the immune system to fight cancer.

KW-0761 is a strategic product for us in becoming a global specialty pharmaceutical company. We have concluded an agreement with AstraZeneca in the United Kingdom, Pfizer and Bristol-Myers Squibb in the United States and Ono Pharmaceutical in Japan to study its possible efficacy as an immunotherapy for solid tumours.

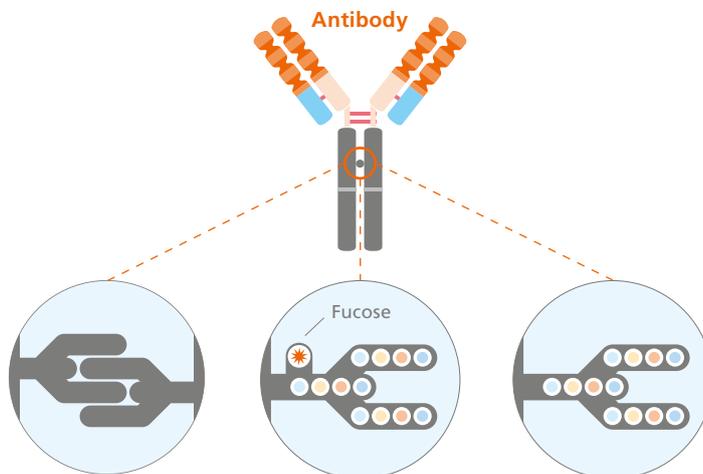


POTELLIGENT®

Antibody-dependent cellular cytotoxicity (ADCC)¹ enables more effective elimination of target cells.

A key feature of POTELLIGENT®, a proprietary Kyowa Kirin technology, is its ability to increase ADCC activity by reducing the amount of fucose in the sugar chain of antibodies.

Testing has shown that POTELLIGENT® dramatically enhances effectiveness in attacking cancer cells and other targets compared to conventional therapeutic antibodies.



1. An immune response that mobilises natural killer cells, monocytes, and other leukocytes to destroy cancer cells and other target cells tagged with antibodies.

1. There is a sugar chain in the lower part of antibodies.

2. A sugar residue called fucose is found on the sugar chain of normal antibodies.

3. POTELLIGENT® technology enhances ADCC activity by reducing fucose.

Countless precious lives surround us

Kyowa Kirin's patented therapeutic antibody technology enables efficient, high-quality production using advanced manufacturing equipment. We actively conduct research leading to new and improved production and formulation technologies for our products. This innovative approach allows us to deliver consistently good value to our customers.



KRN23

KRN23 is an investigational recombinant fully human monoclonal IgG1 antibody, discovered by Kyowa Kirin, against the phosphaturic hormone fibroblast growth factor 23, known as FGF23.

FGF23 is a hormone that reduces serum levels of phosphorus and vitamin D by regulating phosphate excretion and vitamin D production by the kidney.

XLH is a disorder of phosphate metabolism caused by phosphate wasting in the urine leading to severe hypophosphatemia. XLH is the most common heritable form of rickets (the softening and weakening of bones) that is inherited as an X-linked dominant trait affecting both males and females, though some reports indicate that the disease may be more severe in males.

Human Antibody-Producing Technology

As this technology has enabled us to generate fully human antibodies with the same diversity as naturally produced human antibodies, we have opened up new opportunities for clinical application.





Believe in what we have built together

Promising pharmaceutical candidates are emerging from our development pipelines – the result of our never-ending efforts to hone our state-of-the-art technologies and deliver innovation in medical care.

Research and Development pipeline. All data current at 22 January 2016.

Key: ● Antibody ● Protein ● Small molecule ● New molecular entity

	Filed /approved	Phase II and Phase III
NEPHROLOGY	<p>KRN321 Darbepoetin Alfa Injection ●</p> <p>MOA: Long-Acting Erythropoiesis Stimulating Agent Therapy area: Renal Anemia (on Dialysis) Stage: Filed in CN Licensed from: Kirin-Amgen</p>	<p>RTA 402 Bardoxolone Methyl Oral ●●</p> <p>MOA: Antioxidant Inflammation Modulator Therapy area: CKD in patients with Type 2 Diabetes Stage: Phase II in JP Licensed from: Reata</p>
ONCOLOGY	<p>Granisetron Patch ●</p> <p>MOA: 5-HT₃ Serotonin Receptor Antagonist Therapy area: Chemotherapy induced nausea and vomiting Stage: Filed in MY Licensed from: Solasia Pharma (ProStrakan) Remarks: Already launched in US and EU</p>	<p>KW-0761 Mogamulizumab Injection ●</p> <p>MOA: Anti-CCR4 Humanised Antibody Therapy area: Adult T-cell Leukemia/Lymphoma Stage: Phase II in US, EU and others Therapy area: Cutaneous T-cell Lymphoma Stage: Phase III in US, EU, JP and others Developed: In-House Remarks: POTELLIGENT®</p>
IMMUNOLOGY/ALLERGY	<p>KHK4827 Brodalumab Injection ●●</p> <p>MOA: Anti-IL-17 Receptor Fully Human Antibody Therapy area: Psoriasis Stage: Filed in JP Licensed from: Kirin-Amgen</p>	<p>KHK4563 Benralizumab Injection ●●</p> <p>MOA: Anti-IL-5 Receptor Humanised Antibody Therapy area: Asthma Stage: Phase III in JP and KR Therapy area: Chronic Obstructive Pulmonary Disease (COPD) Stage: Phase III in JP Developed: In-House Remarks: POTELLIGENT®. Jointly developed with AstraZeneca/ MedImmune in JP and KR</p>
CENTRAL NERVOUS SYSTEM		<p>KW-6002 Istradefylline Oral ●</p> <p>MOA: Adenosine A_{2A} Receptor Antagonist Therapy area: Parkinson's Disease Stage: Phase III in US, CA, EU and others Developed: In-House</p>
OTHER	<p>AMG531 Romiplostim Injection ●</p> <p>MOA: Thrombopoietin Receptor Agonist Therapy area: Idiopathic (Immune) Thrombocytopenic Purpura Stage: Filed in TH, MY Licensed from: Kirin-Amgen</p>	<p>KRN23 Injection ●●</p> <p>MOA: Anti-FGF23 Fully Human Antibody Therapy area: X-linked Hypophosphatemia (XLH) in adult patients Stage: Phase III in US, CA, EU, JP and KR Therapy area: X-linked Hypophosphatemia (XLH) in pediatric patients Stage: Phase II in US and EU Therapy area: Tumor Induced Osteomalacia (TIO) / Epidermal Nevus Syndrome (ENS) Stage: Phase II in US Developed: In-House Remarks: Jointly developed with Ultragenyx in US and EU</p>

KHK7580 Oral ●●

MOA: Calcium Receptor Agonist

Therapy area: Secondary Hyperparathyroidism

Stage: Phase III in Japan

Licensed from: Mitsubishi Tanabe Pharma

ARQ 197 Tivantinib Oral ●●

MOA: c-Met Inhibitor

Therapy area: Hepatocellular Cancer

Stage: Phase III in JP

Licensed from: ArQule

BIW-8962 Injection ●●

MOA: Anti-GM2 Humanised Antibody

Therapy area: Cancer

Stage: Phase I/IIa in KR

Developed: In-House

Remarks: POTELLIGENT®

ASKP1240 Injection ●●

MOA: Anti-CD40 Fully Human Antibody

Therapy area: Organ Transplant Rejection

Stage: Phase I in JP, Phase II in US

Developed: In-House

Remarks: Jointly developed with Astellas

Z-206 Mesalazine Oral ●

MOA: pH Dependent Controlled Release Tablet

Therapy area: Ulcerative Colitis

Stage: Phase III in JP

Licensed from: Zeria Pharma

Remarks: Jointly developed with Zeria Pharma

AMG531 Romiplostim Injection ●

MOA: Thrombopoietin Receptor Agonist

Therapy area: Aplastic Anemia

Stage: Phase II in KR

Therapy area: Idiopathic (Immune) Thrombocytopenic Purpura

Stage: Phase III in CN

Licensed from: Kirin-Amgen

Don't just make medicine, make people smile

We aim to be a trusted global specialty pharmaceutical company and are building the necessary robust foundations by ensuring global compliance and by executing a Corporate Social Responsibility (CSR) programme that meets the expectations of society.

Management philosophy and CSR

In our group management philosophy, we promise 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. We consider it part of our CSR to realise our management philosophy through activities consistent with these guidelines.

Business partners

We promote fair transactions, partnering and CSR procurement to become a global specialty pharmaceutical company.

Environment

We make efforts to be environmentally responsible, including reducing our CO₂ emissions and promote activities which support the achievement of a sustainable society.

Society and community

We want to earn the trust of society and the community, and are dedicated to activities that contribute to both, making use of the assets we have acquired through our businesses.

Employees

We respect the human rights and individuality of our people, and seek to be a company that not only promotes diversity, but grows along with them.



Our team, our company

Our business is global in vision and scale. We are working in close collaboration with our group companies in the pharmaceutical and biochemical industries to bring exciting new products to markets around the world.

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