Game-changing R&D

Our Mission in Research and Development

Deliver our contribution to society by developing drugs that truly benefit patients

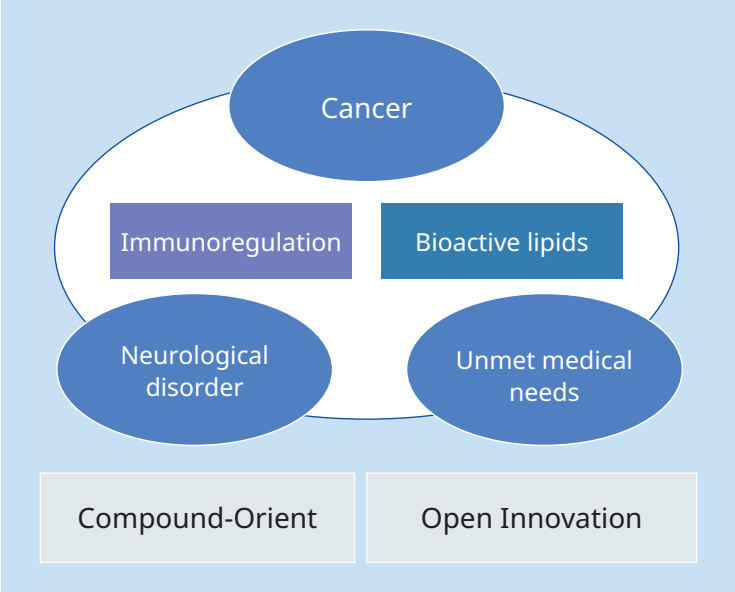
Keeping in mind our R&D mission "Deliver our contribution to society by developing drugs that truly benefit patients," we are tackling diseases that remain unconquered as yet, and addressing areas that are high in healthcare needs where patient satisfaction with current treatment is low. Our discovery research aims to identify and develop innovative and breakthrough pharmaceutical products.

Our Drug Discovery Research

ONO's approach – Areas of research

We have pursued our original path in drug discovery using the "Compound-Orient" approach to developing novel drugs by collecting a library of compounds that may act on various therapeutic targets such as lipids and enzymes, and, through screening the library, identifying new drug candidates that would lead to treatments against disease. Utilizing this unique approach as the foundation, we now focus our resources on the research and development of drugs for cancer, autoimmune disease and neurological disease. We have specified these areas that have high medical needs as our priority areas of research and development. In addition to drug discovery research with small molecular compounds and antibodies which we have focused upon and will continue to enhance, we will also focus on novel technologies including cell therapies and macrocyclic compounds, to keep tackling the challenge of developing breakthrough drugs.

Drug Discovery Research Domains



Open Innovation

ONO has been driving drug discovery research using world-leading technology and knowledge in various areas long before the words "open innovation" started to become widely used.
In order to pursue more vigorously the discovery of breakthrough drugs through our open innovation effort, ONO is driving research collaborations with universities, research institutions and biopharmaceutical companies, posting employees with extensive experience in discovery research to our overseas subsidiaries in the US and UK for the long haul, and ONO's scientists posted to collaborative research laboratories are working on challenging research programs.
In FY2017, we vigorously formed drug discovery alliances with biopharmaceutical companies with proprietary technology. We have initiated a drug discovery collaboration with Neurimmune AG (Switzerland), focusing on the development of human antibodies against a novel therapeutic target for neurodegenerative diseases. Other partnering activities successfully initiated include drug discovery collaborations with Cyclenium Pharma, Inc. (Canada) to exploit its proprietary next generation small molecule macrocyclic technology; with Schrödinger, Inc. (U.S.) to design novel small molecules against therapeutic targets selected by ONO, using Schrödinger's computational drug discovery platform; and with Merus N.V. (Netherlands) to develop human bispecific antibodies against therapeutic targets selected by ONO for the treatment of autoimmune diseases.
We will continue directing our drug discovery efforts into the future toward discovery and development of innovative new drugs in areas of diseases with as-yet unmet medical needs, focusing on cancer and neurological disease, and immunoregulation by maximizing our open innovation strategy.

A Research Capability Combining Knowledge with Technology

The development of innovative new drugs is driven by the spirit of challenge and the motivation of individual scientists and their ability to think creatively responding to change. We set high and achievable targets with clear outcomes, in order to enhance motivation and creative thinking among our researchers. ONO's research organization is based on project teams where members converge from different fields, bringing cutting-edge expertise from contrasting backgrounds. The interaction within the teams stimulates and mutually enhances our research achievements. Each project team actively promotes open innovation with the aim of discovering innovative drugs with top-class researchers all over the world.

We conduct drug discovery research through coordination of the efforts of three laboratories, the Minase Research Institute, the Fukui Research Institute and the Tsukuba Research Institute, and work to strengthen our research capability to further accelerate drug discovery. The new research building opened in March 2016 at the Minase Research Institute, is our center for invention and medicinal chemistry. Now we have integrated our compound synthesis and analysis functions, thereby driving R&D forward by building capability with consistency in chemistry research, from exploration of breakthrough drug seeds through to clinical investigations.

The Minase Research Institute

The Institute has a wide variety of research functions, including medicinal chemistry, research into the properties and efficacies of compounds, discovery research for cancer and neurological disease, exploratory research for analysis of disease-causing substances and new compounds that can control these substances, research aimed at the development of formulations whose quality and function as pharmaceutical products can be assured, as well as mass production and cost reduction for the supply of active pharmaceutical ingredients.

The Fukui Research Institute

The Institute focuses on compound safety assessment.

The Tsukuba Research Institute

The Institute undertakes research into immunoregulation, and the pharmacokinetics of discovered compounds. It carries out advanced medical research, unrestrained by the paradigm or status quo.

Accelerated Clinical Development

We are committed to promoting clinical development with enthusiasm to deliver new drugs that meet the needs of frontline healthcare as soon as possible, for the benefit of people suffering diseases throughout the world.

We have integrated the functions necessary to bridge from research to clinical development at the Translational Medicine Center (TMC), a part of the Clinical Development Division, after further evaluation of the efficacy, safety and quality of promising new drug candidates at the basic research and non-clinical stages to enable quicker decision making in development to shorten the period from commencement of drug development to establishment of efficacy and safety in humans (POC).

Clinical development plays a role in collecting the data required for filing Ministry of Health, Labour and Welfare applications for marketing approval for prescription drugs. With the aim of obtaining marketing approval in the shortest time, we are speeding up the clinical development process by advancing mutual use of results from multinational clinical trials and other overseas studies.

Under the awareness of being a pioneer in cancer immunotherapy, we focus our efforts on oncology as a key strategic area and are working to strengthen our development capability, for example, by establishing the R&D Unit for Immuno-Oncology in December 2015, where we are progressing investigation of biomarkers and combination therapies. In January 2018, we set up an Oncology Clinical Development Unit, which consists of the Oncology Early Clinical Development Planning for early clinical development stage and the Oncology Clinical Development Planning for late clinical development stage, to shorten the time of oncology projects from early clinical stage to market launch for further speeding up clinical development.

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Vigorous Activities for Licensing Initiatives

We continue to forge ahead with licensing activities to introduce new drug candidates with the aim of introducing compounds attractive for diseases with high therapeutic need, and compounds that have high value in terms of corporate strategy and efficiency, while taking into consideration the development pipeline and existing products. Our aim is to expand the development pipeline to provide a continuous stream of new market launches. In the oncology domain, we take advantage of our strength with OPDIVO in acquiring product candidate compounds in a wide range of areas such as molecular target drugs including antitumor drugs and cell therapies.
In FY2017, we signed a license agreement with Array Biopharma (U.S.) to develop and commercialize the MEK inhibitor Binimetinib and the BRAF inhibitor Encorafenib in Japan and South Korea. We also signed a definitive agreement with Seikagaku Corporation on co-development and marketing collaboration on SI-613 in Japan, a drug under development by Seikagaku for osteoarthritis treatment (and also for enthesopathy treatment). In addition, we entered into an exclusive license agreement with Karyopharm Therapeutics (U.S.) to develop and commercialize the XPO1 inhibitor Selinexor and the second-generation XPO1 inhibitor KPT-8602, both under development by Karyopharm, in Japan, South Korea, Taiwan, Hong Kong, and ASEAN countries.
Meanwhile, we are keenly pursuing out-licensing activities to partner companies so that we can deliver new drugs we develop to patients worldwide. We have expanded collaboration activities with our long-time alliance partner Bristol-Myers Squibb (U.S.), granting the company the rights to develop and commercialize ONO-4578 under development by ONO—a selective antagonist of EP_4 which is a Prostaglandin E_2 (PGE_2) receptor—worldwide, except Japan, South Korea, Taiwan, China and ASEAN countries.
By continuously and vigorously promoting licensing activities, we are making steady progress in expanding our development pipeline and developing a road map for global business to deliver the new drugs we develop.