

Value Creation

Our mission is to provide new value to patients through the creation of innovative drugs. We are striving to create value required by companies and society, which includes strengthening R&D, expanding our pipeline, building our own marketing operations in U.S. and Europe to deliver medicines to more patients, and further expanding our business domain.

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Material Issue 1

Creation of Innovative Drugs

Vision over the medium to long term

Cooperate with top scientists and accelerate the creation of new drugs that can change the world.

Indicators

- The number of new drug candidates going to clinical trials

ONO's History is the Challenge of Drug Discovery Achieving extremely aggressive open innovation

We strive to create innovative drugs to succeed prostaglandin-related products and OPDIVO by valuing the ideas and teamwork of researchers and leveraging top science knowledge from throughout the world and bio-venture leading technology as much as possible. In order to link science and technology, which evolves at an astounding speed, to drug discovery, we actively promote such activities as study abroad in academia where we conduct research collaboration, and assignments in the U.S. and European bases, and raise the level of and engagement with each researcher. We will take on the challenge of creating an environment to promote quick drug discovery of world-class quality.

Toichi Takino

Member of the Board of Directors, Senior Executive Officer / Executive Director, Discovery & Research



Basic Approach

Contribute to society by developing pharmaceutical products that bring true benefit to patients

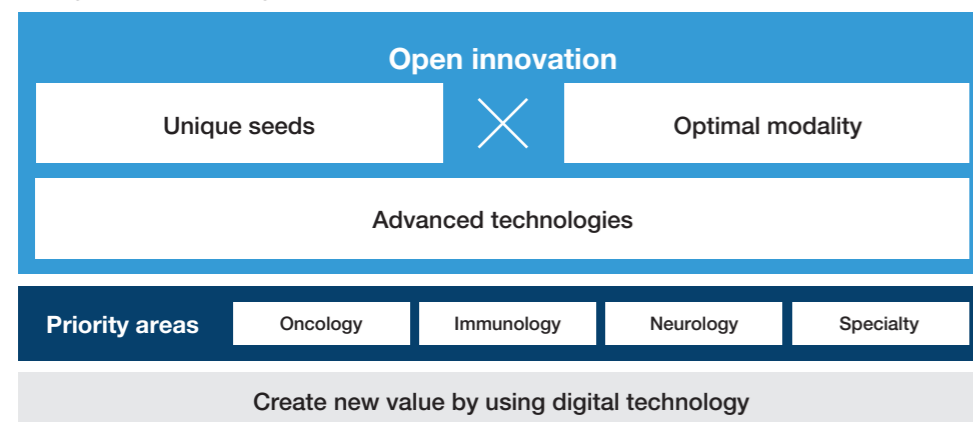
ONO aims to "contribute to society by developing pharmaceutical products that bring true benefit to patients". We are striving to create original and innovative drugs by taking on the challenges of diseases that have not yet been conquered and areas of high medical need where patient satisfaction with treatment is still low.

Drug Discovery Strategy

Promoting open innovation in multiple fields and aiming to create innovative new drugs that meet medical needs

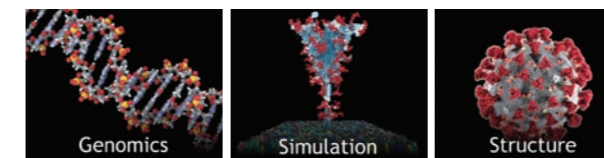
ONO focuses on the areas of oncology, immunology, neurology and specialties; all of which include diseases with high medical needs. In each of these areas, we are working to strengthen our drug discovery capabilities by delving into the biology of human disease with the aim of discovering new drugs that can satisfy medical needs. In particular, by actively promoting open innovation, which is one of our strengths, we aim to create breakthrough new drugs with medical impact by not only utilizing a variety of cutting-edge technologies, such as informatics, robotics, and genome editing, but also selecting the optimal modality (therapeutic

Drug Discovery Strategy



Create unique and innovative new drugs

approach), including small molecule compounds, antibodies, and cells for the unique drug discovery seed. In addition, we are working to improve the quality and speed of drug discovery research through the use of digital technology. As of June 2023, a total of 10 new drug candidates in our priority therapeutic areas have proceeded to the clinical stage, and we are also continuing to bolster our efforts in translational research bridging the gap between basic and clinical research to accelerate drug discovery timelines and boost success rates. By



The above photo is a supercomputer used for drug discovery. It is possible to process and analyze vast amounts of chemical data and biological information at high speed and search for drug candidates.

organically leveraging informatics and research tools, such as human genome data and human iPS cells in the early stages of research, we are working to analyze the relationship between target molecules and diseases to find biomarkers that can more accurately predict and evaluate the efficacy of new drug candidates in humans.

Strengthening technology platform Making aggressive use of digital technology Promoting reforms to the drug discovery process

In recent years, there have been prominent advances in digital technology, which has resulted in innovative changes in the drug discovery process. At ONO, we use various advanced technologies to conduct rapid, detailed analysis of large volumes of data, such as genetic data of patients, and actively use that from the initial stages of drug discovery, including deciding on the value of our unique seeds. Furthermore, we use computer simulations to analyze molecular structure and predict mutual interactions between molecules. Through these efforts, we are working to quickly create new, high-quality drug candidates. In addition to building an AI model that uses high calculation capabilities, such as image analysis, video analysis, and natural word processing, we are taking on the challenge of revolutionizing the complex drug discovery process, a process that requires much time and labor.

Major Initiative(s) and Development Products in Each of the Four Priority Areas

| Priority Area | Major Initiative(s) | Major New Drug Candidates under Development | Target Diseases |
|---------------|--|---|---|
| Oncology | As a pioneer in cancer immunotherapy, ONO works toward discovering innovative drugs for cancer patients with the experience, expertise, and know-how we nurtured through R&D of the immune checkpoint inhibitor OPDIVO. We are also striving to find unique drug discovery seeds through open innovation and translational research. Furthermore, we are taking on the challenge of using new drug discovery modality. | ONO-4578 | Solid tumor, Gastric cancer, Pancreatic cancer, Colorectal cancer, Hormone receptor-positive, HER2-negative breast cancer |
| | | ONO-7475 | Solid tumor, EGFR-mutated non-small cell lung cancer |
| | | ONO-7914 | Solid tumor |
| | | ONO-4685 | T cell Lymphoma |
| | | ONO-7018 | Non-Hodgkin lymphoma, chronic lymphocytic leukemia |
| Immunology | Based on many years of its experiences in immunology research, which contributed to creating OPDIVO, ONO is working toward drug discovery with a main focus on biopharmaceutical development. We are taking on the challenge of creating breakthrough new drugs for both autoimmune and allergic diseases. | ONO-4685 | Autoimmune disease |
| Neurology | ONO conducts research focused on various topics, including not only neurons, a major components of the nervous system, but also glial cells, which maintain and support the environment necessary for the survival and function of neurons. We are dedicated to discovering innovative drugs to provide disease-modifying therapies, as well as symptomatic treatment, to patients with neurodegenerative diseases, psychiatric disorders or chronic pain. | ONO-2910 | Diabetic polyneuropathy, Chemotherapy-Induced Peripheral Neuropathy |
| | | ONO-2808 | Multiple system atrophy |
| | | ONO-1110 | Pain |
| | | ONO-2020 | Neurodegenerative diseases |
| Specialty | ONO is working toward discovery of clinically valuable pharmaceutical products for diseases for which treatment is high in unmet needs, regardless of the disease indication. We have taken up the challenge of accurately identifying those needs in patients, medical professionals, and society, and then leveraging this knowledge to discover and develop highly original new drugs. | ONO-7684 | Thrombosis |

Material Issue 2

Pipeline Expansion

Vision over the medium to long term

The speed and accuracy of establishing PoC* for new drug candidates are improving, and the pipeline is enriched through licensing activities.

* PoC (Proof of Concept): PoC studies are an early stage of clinical drug development to confirm whether the drug candidates demonstrate the clinical safety and efficacy expected during the drug discovery phase.

Indicators

- The number of products in the clinical development stage
- The number of newly introduced products
- Obtain approval in the U.S. and Europe

Flexibly conducting clinical trials in Japan, the U.S., and Europe

We will continue to increase the number of new drug candidates by energizing in-house drug discovery research and conducting aggressive licensing activities. Efforts will also be made to obtain approval for these new drug candidates throughout the world, including the U.S. and Europe. To do that, it is first necessary to confirm that the safety and efficacy of the compounds are as expected, and we will quickly ascertain the potential value of the compounds by flexibly using bases in Japan, the U.S., and Europe to conduct clinical trials. Therefore, we are building a system to promote development between regions and countries so that we can deliver even more innovative new drugs to patients throughout the world even one day quicker.

Kiyooki Idemitsu

Member of the Board of Directors, Corporate Executive Officer / Executive Director, Clinical Development



Early establishment of PoC

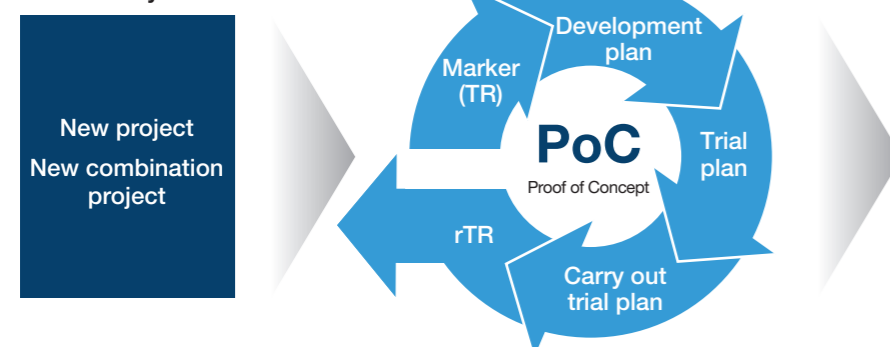
Undertaking speedy clinical development and improving the success rate

ONO is working to undertake speedy clinical development and improve the success rate of drug candidates in order to fast-track the delivery of our in-house and in-licensed compounds to patients suffering from diseases around the world. We are flexibly utilizing our clinical development infrastructure in Japan, the U.S., and Europe to quickly establish PoC to expediently identify the potential product value of candidates. To do this, we formulate appropriate clinical development plans, including target disease selection, propose study plans to accurately evaluate efficacy, and promote studies according to the plan. Also, while reinforcing our search for clinical markers through TR,*1 we conduct rTR*2 that links the results obtained from clinical trials to the launch of new discovery research projects by feeding those results back into research, creating an R&D virtuous cycle.

*1 Abbreviation of translational research. Method that applies knowledge obtained through basic research to various activities, including conducting diagnosis, treating, and determining efficacy during clinical trials.

*2 Abbreviation of reverse translational research. A method for feeding knowledge obtained during clinical trials back into basic research.

The R&D Cycle



Licensing Activities

Licensing with an eye toward global introduction

We are also actively pursuing licensing activities with the aim of in-licensing new candidates under development by pharmaceutical or bio-venture companies around the world. To do this, we are acquiring the global rights of new candidates with characteristics that can be of use to a global specialty pharmaceutical company, taking into consideration the areas targeted by our own products, with a view to global development in the U.S. and other countries.

Number of products in the clinical development stage

Maximizing product value and reinforcing pipeline

We are moving forward with clinical development to add functions to existing products in order to increase product value. For

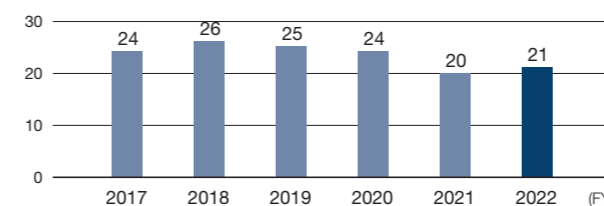
Confirmatory study



OPDIVO, we are conducting clinical trials aimed at expanding the indications and usage for many cancers, using the drug at earlier lines of treatment, and establishing combination therapies to enhance therapeutic efficacy. We are also aggressively moving forward with global research on new compounds to reinforce our pipeline. In FY2022, there were 21 products at the clinical trial stage.

We will continue to aggressively pursue clinical development not only in Japan but also worldwide for the benefit of patients awaiting new therapeutic agents.

Number of Products in the Clinical Development Stage



Global Pipeline and In-licensed Products

Creating and reinforcing system for quick decision making

In each of these fields, we are promoting development with an eye toward global commercialization. As for new drug candidates

in the field of oncology, there are 4 of our own products and 1 in-licensed product in addition to the VELEXBRU Tablets (BTK inhibitor), which are already on the market in Japan. In the field of neurology, we launched phase 1 trials for both ONO-2020 (epigenetic regulation) and ONO-1110 (endocannabinoid regulation), which means that a total of 4 compounds are in at the clinical trial stage. As for immunology and specialty fields, development of candidates is progressing on an individual basis. For a total of 12 projects, the goal of which is to commercialize globally, we are now conducting clinical trials. We are also moving forward with creating and reinforcing a system to make visible projects throughout the world and undertake quick decision making.

In addition, ONO-7913 (anti-CD47 antibody) and ONO-2017 (voltage-dependent sodium current inhibition/GABA_A ion channel function enhancer), which are in late-stage development and were obtained through licensing activities, are being developed for approval (launch) in Japan.

In addition to our own drug discovery, we are actively working to capture assets from overseas, and in December 2022, we obtained exclusive option rights related to development and commercialization of the anti-CD6 antibody itolizumab in the U.S., Canada, and several other countries. Development of itolizumab, which has therapeutic indications for acute graft versus host disease (acute GVHD) and lupus nephritis, is moving forward, and this will contribute to a broader pipeline for the immunology field.

Global pipeline (As of July 27, 2023)

| Development Area | Product Name (Development Code) | Mechanism | Target Disease | Development Stage | | In-house / In-licensed |
|------------------|---------------------------------|---|---|-------------------|-------------|------------------------|
| | | | | (Japan) | (Overseas) | |
| Oncology | Velexbru Tablets (ONO-4059) | BTK inhibitor | Primary central nervous system lymphoma | Launched | US : Phase2 | In-house |
| | ONO-4578 | EP4 antagonist | Solid tumor* Gastric cancer etc. | Phase1 | - | In-house |
| | ONO-7475 | Axl/Mer inhibitor | EGFR-mutated non-small cell lung cancer | Phase1 | - | In-house |
| | ONO-7914 | STING agonist | Solid tumor | Phase1 | - | In-house |
| | ONO-4685 | PD-1×CD3 bispecific antibody | T-cell lymphoma | - | US : Phase1 | In-house |
| | ONO-7018 | MALT1 inhibitor | Non-Hodgkin lymphoma, Chronic lymphocytic leukemia | - | US : Phase1 | In-licensed (Chordia) |
| Neurology | ONO-2808 | S1P5 receptor agonist | Multiple system atrophy | - | US : Phase2 | In-house |
| | ONO-2910 | Enhancement of Schwann cell differentiation | Diabetic polyneuropathy, Chemotherapy-Induced Peripheral Neuropathy | Phase2 | - | In-house |
| | ONO-2020 | Epigenetic regulation | Neurodegenerative disease | - | US : Phase1 | In-house |
| Immunology | ONO-1110 | Endocannabinoid regulation | Pain | Phase1 | - | In-house |
| Specialty | ONO-4685 | PD-1×CD3 bispecific antibody | Autoimmune disease | Phase1 | EU : Phase1 | In-house |
| | ONO-7684 | FXIa Inhibitor | Thrombosis | Phase1 | EU : Phase1 | In-house |

In-licensed products (Phase 2 or later)

| Product Name (Development Code) | Mechanism | Target Disease | Development Stage (Japan) | In-licensed |
|---------------------------------|--|---|---------------------------|-----------------------|
| ONO-7913 | Anti-CD47 antibody | TP53-mutant acute myeloid leukemia | Phase 3 | Gilead Sciences, Inc. |
| ONO-2017 | Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABA _A ion channel | Primary generalized tonic-clonic seizures | Phase 3 | SK Biopharmaceuticals |
| | | Partial-onset seizures | Phase 3 | |
| Braftovi Capsules | BRAF inhibitor | Thyroid cancer | Filed | Pfizer Inc. |
| Mektovi Tablets | MEK inhibitor | Thyroid cancer | Filed | Pfizer Inc. |

Development Pipeline (As of July 27, 2023)

Oncology

| Product Name/ Development Code/ Generic Name | Mechanism | Dosage Form | Target Indication | Phase | | | | Area | Licensor |
|--|------------------------------|-------------|--|-------|----|-----|-------|----------|----------------------------------|
| | | | | I | II | III | Filed | | |
| Opdivo Intravenous Infusion | Anti-PD-1 antibody | Injection | Malignant mesothelioma (Excluding Pleura) | → | | | | JP | In-house (Co-developed with BMS) |
| | | | Epithelial skin malignancies | → | | | | JP | |
| | | | Hepatocellular carcinoma | → | | | | JP-KR | |
| | | | Ovarian cancer | → | | | | JP-KR-TW | |
| | | | Bladder cancer | → | | | | JP-KR-TW | |
| Braftovi Capsules | BRAF inhibitor | Capsule | Thyroid cancer | → | | | | JP | Pfizer |
| Mektovi Tablets | MEK inhibitor | Tablet | Thyroid cancer | → | | | | JP | Pfizer |
| Yervoy Injection* | Anti-CTLA-4 antibody | Injection | Gastric cancer | → | | | | JP-KR-TW | BMS |
| | | | Urothelial cancer | → | | | | JP-KR-TW | |
| | | | Hepatocellular carcinoma | → | | | | JP-KR | |
| ONO-7913/ Magrolimab | Anti-CD47 antibody | Injection | TP53-mutant Acute myeloid leukemia | → | | | | JP | Gilead |
| | | | Acute myeloid leukemia | → | | | | KR-TW | |
| | | | Pancreatic cancer* | → | | | | JP | |
| | | | Colorectal cancer* | → | | | | JP | |
| | | | Solid tumor | → | | | | JP | |
| | | | Myelodysplastic syndrome | → | | | | JP | |
| ONO-4686* | Anti-TIGIT antibody | Injection | Solid tumor | → | | | | JP | BMS |
| ONO-4482*/ Relatlimab | Anti-LAG-3 antibody | Injection | Melanoma | → | | | | JP | BMS |
| ONO-7226* | Anti-ILT4 antibody | Injection | Solid tumor | → | | | | JP | BMS |
| ONO-7475/ Tamnorzatinib | Axl/Mer inhibitor | Tablet | Solid tumor* | → | | | | JP | In-house |
| | | | EGFR-mutated non-small cell lung cancer | → | | | | JP | |
| ONO-4578 | PG receptor (EP4) antagonist | Tablet | Colorectal cancer* | → | | | | JP | In-house |
| | | | Pancreatic cancer* | → | | | | JP | |
| | | | Non-small cell lung cancer* | → | | | | JP | |
| | | | Solid tumor • Gastric cancer* | → | | | | JP | |
| | | | Hormone receptor-positive, HER2-negative breast cancer | → | | | | JP | |

| Product Name/ Development Code/ Generic Name | Mechanism | Dosage Form | Target Indication | Phase | | | | Area | Licensor |
|--|--|-------------|--|-------|----|-----|-------|------|----------|
| | | | | I | II | III | Filed | | |
| ONO-7119* Atamparib | PARP7 inhibitor | Tablet | Solid tumor | → | | | | JP | Ribon |
| ONO-7122* | TGF-β inhibitor | Injection | Solid tumor | → | | | | JP | BMS |
| ONO-7914* | STING agonist | Injection | Solid tumor | → | | | | JP | In-house |
| ONO-4059 | Bruton's tyrosine kinase (BTK) inhibitor | Tablet | Primary central nervous system lymphoma | → | | | | US | In-house |
| ONO-4685 | PD-1×CD3 bispecific antibody | Injection | T-cell lymphoma | → | | | | US | In-house |
| ONO-7018 | MALT1 inhibitor | Tablet | Non-Hodgkin lymphoma, Chronic lymphocytic leukemia | → | | | | US | Chordia |

*Combination with Opdivo.
* In the case of clinical development of the oncology drugs in the same indication, the most advanced clinical phase is described.

Areas other than Oncology

| Product Name/ Development Code/ Generic Name | Mechanism | Dosage Form | Target Indication | Phase | | | | Area | Licensor |
|---|--|-------------|--|-------|----|-----|-------|-------|----------|
| | | | | I | II | III | Filed | | |
| Velexbru Tablets/ Tirabrutinib Hydrochloride | Bruton's tyrosine kinase (BTK) inhibitor | Tablet | Pemphigus | → | | | | JP | In-house |
| ONO-2017/ Cenobamate | Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABA _A ion channel | Tablet | Primary generalized tonic-clonic seizures | → | | | | JP | SKBP |
| | | | Partial-onset seizures | → | | | | JP | |
| ONO-2910 | Enhancement of Schwann cell differentiation | Tablet | Diabetic polyneuropathy | → | | | | JP | In-house |
| | | | Chemotherapy-Induced Peripheral Neuropathy | → | | | | JP | |
| ONO-2808 | S1P5 receptor agonist | Tablet | Multiple System Atrophy | → | | | | US | In-house |
| ONO-4685 | PD-1×CD3 bispecific antibody | Injection | Autoimmune disease | → | | | | JP-EU | In-house |
| ONO-7684 | FX1a Inhibitor | Tablet | Thrombosis | → | | | | JP-EU | In-house |
| ONO-2020 | Epigenetic Regulation | Tablet | Neurodegenerative disease | → | | | | US | In-house |
| ONO-1110 | Endocannabinoid regulation | Oral | Pain | → | | | | JP | In-house |

Material Issue **3**

Maximization of Product Value

Vision over the medium to long term

We have addressed our goal of achieving the well-being* of patients and their families in cooperation with healthcare professionals, and as a result, our new drugs are spreading promptly.

* "Well-being" refers to a state in which satisfaction in mental, physical, social, and life conditions are achieved.

Indicators

- Number of patients to whom our new drugs are delivered
- Sales by major product
- Number of approvals received in Japan, Korea, and Taiwan

Maximization of product value from a patient-centered perspective

For us, a patient-centered perspective is indispensable. This is because patients bear not only physical but also mental and social concerns and worries. After gaining a deep understanding of various aspects of patients, including their symptoms, concerns, and worries, we promote the appropriate use of our drugs. We will further deepen cooperation between our numerous divisions. The whole company, particularly the Sales and Marketing Division, has united to maximize product value by sharing unmet medical needs in the medical field and opinions of patients with all divisions. Thus, we will take on the challenge of realizing the well-being of patients and their families there.

Satoshi Takahagi

Corporate Executive Officer / Executive Director, Sales and Marketing, Primary Care Business Division



to maximize product value by working with healthcare professionals to spread disease awareness, diagnosis, and treatment, and by reaching as many patients as possible.

Ascertaining Patient Needs and Providing Information with Digital Technology

Reinforcing the Omnichannel Information Provision System

One of our initiatives to ascertain patient needs is to regularly hold "patient voice sharing meetings." Through these meetings, we deepen our understanding of the various problems faced by patients, not only physical ones but also mental and social ones, which leads to better communication with healthcare professionals. Gathering accurate information and providing appropriate information through channels required by healthcare professionals are important to enhance product value. The channels through which healthcare professionals obtain information are also growing increasingly diverse. Therefore, for information provision activities, we are promoting information provision via omnichannel that links the various real and digital channels based on accumulated data. With marketing automation, we are also moving forward with automating information provision in a manner appropriate for how healthcare professionals come into contact with digital content. In addition, for our members websites "ONO Medical Navi" and "ONO Oncology," we are implementing various measures, including expanding content such as personalized display and webinars and automatically linking member accounts with other companies' member sites.

Basic Approach

Realizing the Well-being of Patients and Their Families

Working with healthcare professionals, we aim to maximize product value and thus realize the well-being of patients and their families, resulting in the rapid penetration of our new drugs. Each department works to strengthen cooperation and linkages to maximize product value and engage in activities from the patient's perspective.

Bringing New Drugs to New Patients

Conducting Awareness Activities With Healthcare Professionals

We have a number of products that have been newly launched or had indications added in recent years, and we will continue to contribute to patients' well-being by promptly delivering new drugs to patients who need them.

To this end, the Sales and Marketing promotes the development of specialty personnel who can communicate with healthcare professionals from their perspective, and promote the use of digital technology to not only promote appropriate use, but also to work with healthcare professionals to solve medical issues from the patient's perspective.

There are many patients with unmet medical needs to which our drugs can contribute, such as those with chronic kidney disease, cancer cachexia, and cancer of unknown primary origin. We aim

Furthermore, we are reinforcing information provision that leverages digital technology, including expanding online meetings and email tools, assigning MRs who handle only the provision of information through digital channels (9 MRs as of March 2023), and providing free access to the side-effect search tool (Ae NAVI).

Division Cooperation from the Patient's Perspective

Whole Company Moving Forward, Centered on Patients

The goal of Maximization of product value is not only to increase the number of patients using the product but also to realize the well-being of patients. The related divisions cooperate and work together to pursue the optimal dosage forms for patients, enhance the value by generating evidence, and collect and disseminate information on side effects.

Reflecting the Needs of Patients and Healthcare Professionals

Introducing Side-Effect Management Application for all of Japan

Patients who receive treatment with immune checkpoint inhibitors are often concerned that they cannot properly communicate their physical condition to healthcare professionals and health professionals want to quickly detect changes in patient's physical condition.

To resolve these issues, we launched the side-effect management application FukuSapo® throughout Japan in FY2022. Promoting interactive communication between patients and healthcare professions via FukuSapo® makes it possible to promptly discover immune-related adverse events and leads to appropriate response by healthcare professionals.

Maximizing OPDIVO's Product Value

Four Perspectives, Including Adding Indicated Tumors

We are working with our partner Bristol Myers Squibb to maximize OPDIVO's product value, and focusing on the four perspectives of 1: Adding indicated tumors; 2: Adding treatment lines; 3: Developing combination therapies; and 4: Searching for biomarkers.

Generating Evidence Focused on Extending Healthy Life Expectancy

Leveraging the Opinions of Many Patients

As part of our efforts to generate evidence (efficacy, safety, QOL) focused on extending healthy life expectancy, Medical Affairs conducts clinical research from the patients' perspective, including surveys of patients and medical professionals. Specifically, we are collecting the opinions of many patients regarding their concerns after cancer surgery, issues they face in post-operative treatment, and their preferences in treatment choices. We plan to publish the collected data as scientifically objective data by using multiple statistical methods, such as sensitivity analysis, rather than simply tabulating patient questionnaires. In FY2022, we launched seven clinical studies along with publishing one research paper and presenting two papers at academic conferences. Each healthcare professional listens to the patient in front of him or her, but providing the opportunity to recognize this as objective data obtained from many patients across Japan reinforces the experience of the healthcare professional and we expect that sometimes it will lead to new insights, which will help the practice to deliver better medical care to patients and improve the product value. In addition, by identifying medical issues that have received little attention in the past through large-scale data on patients' comments, the project will uncover new unmet needs and lead to multifaceted activities aimed at solving them.

Activities to Maximize the Value of OPDIVO through Cooperation with Bristol Myers Squibb

| | Activities |
|---|---|
| Adding indicated tumors | We have already obtained approval for 11 cancers in Japan and are continuing to work on development to obtain approval for additional cancer indications. In FY2022, we applied for approval for malignant mesothelioma (excluding malignant pleural mesothelioma) in Japan, and it is currently under review. On June 15, 2023, we will apply for approval for epithelial malignant tumors. |
| Adding treatment lines | We are moving ahead with clinical trials to enable OPDIVO to be used at earlier stages in patients with advanced or recurrent cancer, and in FY2022, we received approval for first line treatment of esophageal cancer in Japan, South Korea, and Taiwan. We are also developing the drug for adjuvant therapy given before or after primary treatments, such as surgery, to reduce the chance of cancer recurrence. In FY2022, the drug was approved for neoadjuvant therapy for non-small cell lung cancer in Japan, Korea and Taiwan. |
| Developing combination therapies | We are proceeding with development, searching for combinations with other drugs or treatments that boost OPDIVO's therapeutic effects. In FY2022, the drug was approved in Japan, Korea, and Taiwan for use in combination with chemotherapy, the existing standard of care for first-line treatment of esophageal cancer, as well as in combination with Ipilimumab. |
| Searching for biomarkers | We are advancing the search for optimal biomarkers that will predict which patients are more likely to be expected to exhibit the therapeutic effects of OPDIVO. |

Material Issue 4

Realization of Direct Sales in the US and Europe

Vision over the medium to long term

Aiming to become a global specialty pharma, we are marketing new drugs in the U.S. and Europe.

Indicators

- Start our own sales in the U.S. and Europe

Three steps to becoming a global company



ONO's Global Business

Working to establish our own marketing operations in the U.S. and Europe to become a true global company

We aim to be a true global company that competes internationally. Specifically, in order to deliver pharmaceuticals discovered and developed by our company to patients around

the world, we are building a system that enables us to develop and market our own products on a global basis. In recent years, we have been strengthening our global pipeline not only for our own products but also for globally in-licensed products. We have defined three steps that will transform us into a global company. Currently, we are in step two working to establish our own marketing operations in the U.S. and Europe for our niche products that do not require large-scale sales organizations.



Building a business foundation in the U.S. believing in Ono Pharma's R&D strength and limitless potential

In order to successfully establish operations in the U.S. for the first time, we drew up a medium- to long-term vision and strategy, and opened a new office in Cambridge, Massachusetts in 2021. In the U.S., we aim to continue to bring first-in-class products to market. Currently, we are hiring strong leaders, building our organization, and working on development and product launch preparatory activities. Believing in our R&D strength and limitless potential, we are establishing a platform for our business foundation in the U.S. in each value chain. We aim to be a global specialty pharma that truly benefits patients. This is a big dream that requires all hands on deck.

Kunihiko Ito President & CEO, ONO PHARMA USA, INC.

Step1: Globalizing Our Marketing Organizations

Steadily increasing presence in Asia with our own marketing organizations in South Korea and Taiwan

Our global expansion began in earnest with the establishment of ONO PHARMA KOREA CO., LTD. located in South Korea in FY2013 followed by ONO PHARMA TAIWAN CO., LTD. in FY2014, both of which are wholly owned subsidiaries of ONO. The subsidiaries established their own sales organizations, and we started our own sales operations for OPDIVO in South Korea in FY2015 and in Taiwan in FY2016, respectively.

To date, OPDIVO has been approved for 10 cancers in South Korea and 11 cancers in Taiwan (as of the end of June 2023). In addition, VELEXBRU received approval and began our own marketing in South Korea in FY2021 and in Taiwan in FY2022 for the indication of relapsed or refractory primary B-cell CNS lymphoma.

Furthermore, since FY2021 BRAFTOVI has been marketed by our own sales organization in South Korea for the indication of advanced or relapsed colorectal cancer with BRAF^{V600E} mutation, and the Company is steadily increasing its presence in Asia.

Step2: Realization of Our Own Sales organizations in the U.S. and Europe

Strengthening our systems for marketing and development

To solve various issues that arise when expanding our business in the U.S., our U.S. subsidiary, Ono Pharma USA, Inc., and Corporate Development & Strategy play a central role in strengthening cooperation with Clinical Development, Corporate Regulatory Compliance, Safety and Quality Assurance, Corporate Strategy & Planning, Sales and Marketing, CMC & Production, Medical Affairs, and other divisions in an effort to build a related system.

ONO Pharma USA, Inc. is taking the opportunity of its office relocation to Cambridge, Massachusetts in April 2021 to acquire talented human resources with extensive experience in the pharmaceutical industry and create a competitive organizational structure. In addition to expanding our development structure for new compounds such as ONO-4059, we will strengthen our system for bringing products to market by hiring human resources from Commercial, Pharmacovigilance, and Medical to

establish our own sales system.

In the U.S. and Europe we are currently conducting clinical trials for 6 products and are aiming to establish a PoC (Proof of Concept : PoC studies are an early stage of clinical drug development to confirm whether the drug candidates demonstrate the clinical safety and efficacy expected during the drug discovery phase) for development products following ONO-4059. In Europe, we currently have an organization of about 60 people, mainly in development, but we will continue to improve and strengthen the organization, including development, to build a development structure so we will be able to do the work from late-stage clinical trials to regulatory filings, in-house. In addition, in light of the status of ongoing clinical trials, we are also moving forward with the establishment of our own sales system.

Establish Our Own Sales System in the U.S. and Europe

ONO PHARMA USA, INC.

The company aims to increase the number of employees from about 100 in FY2022 to at least 160 in FY2025. It has the following departments.

| Clinical Development | Marketing | Sales | Market Access | Medical |
|----------------------|-----------|----------------|------------------------|---------|
| PV | QA | CMC·Production | Company Infrastructure | |

ONO PHARMA UK LTD.

The company had about 60 employees in FY2022. In addition to the following departments, it plans to build a network for its own sales, which includes marketing and sales.

| Clinical Development | PV | QA | Company Infrastructure | Market Access |
|----------------------|----|----|------------------------|---------------|
| | | | | |

Step 3: Becoming a True Global Company

Growing market share by continuously introducing new drugs and expanding sales network to China and ASEAN

In the regions where we established sales bases by proceeding up to Step 2, we will continue to introduce new drugs that satisfy further unmet needs, and we will consider expanding our sales network to China, ASEAN, and other regions.

“Aiming at a Global Specialty Pharma“

At ONO US, we believe that one of the key steps towards doing the best for patients with unmet needs is to hire passionate people. We have built a formidable US leadership team with extensive experience in Oncology and continue to hire exceptional talent to achieve our goals. We are leveraging Ono's leadership and commercial success in Japan to bring first-in-class drugs to the US and make them accessible to patients. We are building a robust commercial, access and operational infrastructure including best-in-class omnichannel strategy for effective stakeholder engagement. With our functional and market expertise, we feel confident in our capabilities to launch our drug pipeline in the US.



Archana Sondhi Vice President, Sales & Marketing, ONO PHARMA USA, INC.

Material Issue 5

Expansion of Business Domains

Vision over the medium to long term

Contributing to solving social issues and realizing next-generation healthcare by leveraging digital technologies and our strengths.

Indicators

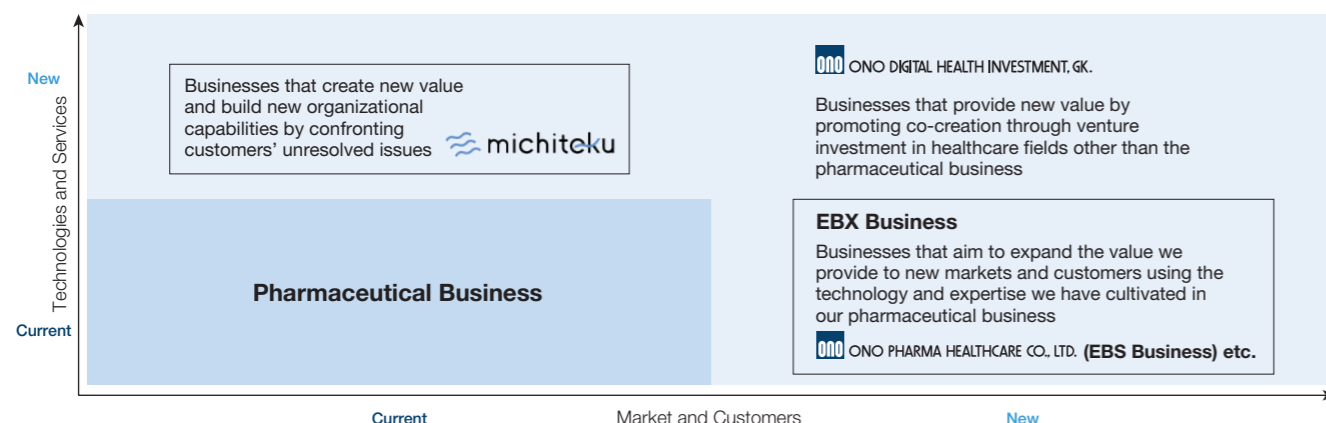
- The number of new businesses started
- The number of new products and services provided

For Sustainable Growth

Focusing on developing new businesses that leverage research assets, etc.

In order to achieve sustainable growth, we will continue to focus not only on the creation of innovative new drugs, but also on increasing the number of our business domains by developing new businesses and investing in the growth of startups. We aim to make our revenue base strong and at the same time become a company that is even more useful to society. In developing new businesses, we will focus on leveraging our uniqueness and superiority and being useful to society. The needs in the healthcare field are growing, and we will continue to search for businesses with solid evidence, starting from our assets, such as research results and know-how cultivated in the pharmaceutical business. In creating new businesses, it is essential for us to utilize the open innovation that is deeply rooted in our company. In particular, we will actively invest in venture companies that possess technologies and ideas that we do not have, such as in the fields of digital technology and new services, and form alliances with them. In the future, we intend to develop these businesses into pillars of business, comparable to the pharmaceutical business, and link them to human health, and innovation in next-generation healthcare.

Discovery of New Businesses



Expanding the Scope of Value Provided

Contributing to greater QOL over the long term through prevention, post-treatment, etc.

The scope of our new businesses is not limited to pharmaceutical treatment, but also includes businesses that can contribute to disease prevention and post-treatment support. Through this, we hope to contribute not only during the period from the creation of a pharmaceutical product until it reaches the patient and demonstrates its value, but also over a long period of time to the improvement of quality of life (QOL). By making more effective use of our assets and diversifying our business portfolio through the creation of new businesses, we will expand the scope of our contribution to people's health and lives. We are also looking to develop businesses other than the pharmaceutical business that will contribute to the stability of our operations.

Major Initiatives

Ono Pharma Healthcare Co., Ltd. Promoting Evidence-based X (EBX) Business

To address social issues in the healthcare field, such as the aging of society and the extension of healthy life expectancy, we are promoting the development and commercialization of products and services (=X) based on solid evidence, such as clinical trial results, by effectively utilizing knowledge obtained through pharmaceutical R&D. In March 2022, as the first product of our Evidence-based Supplement (EBS) business, our wholly owned subsidiary Ono Pharma Healthcare Co., Ltd. launched REMWELL, a functional food sleep supplement made from functional lipids. With the mission of "Getting closer to your health with the power of lipids," the EBS business launched the "Lipid-supply" brand of supplements that contribute to health by providing high-quality lipids, which are often lacking in the diets of modern people. With the goal of further spreading the brand, we intend to continue to develop supplements that make the most of our research findings.



Web Ono Pharma Healthcare Co., Ltd. <https://www.ono-hc.co.jp/>

Ono Digital health Investment, GK Accelerating investments in startups engaged in the healthcare field

In March 2022, we established Ono Digital health Investment, GK, a corporate venture capital, to increase investments in venture healthcare businesses other than pharmaceuticals.* Ono Digital health Investment, GK invests in venture companies that work to solve healthcare issues. In FY2022, we invested in Rehab for JAPAN Corporation (provides rehabilitation support that automatically suggests evidence-based goals and exercise program tailored to individual users) and aetherAI Co., Ltd., (develops and provides digital pathology image management systems that incorporate AI and a pathologic diagnosis support AI application). We will not only make investments but also support entrepreneurs through collaboration with our investment partners, aiming to expand our business domain and extend healthy life expectancy and realize a sustainable society.

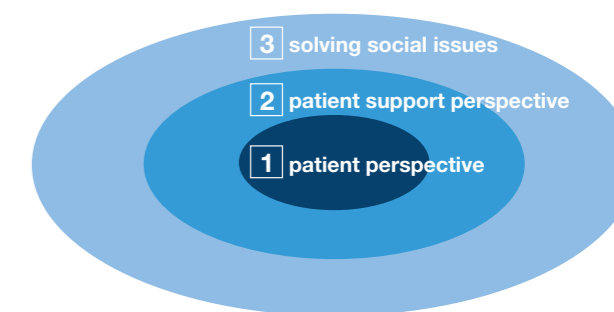
* A CVC (Ono Venture Investment Inc.) established in the US in 2020, invests in startups related to drug discovery

Web Ono Digital health Investment, GK <https://www.onodigitalhealth.com/en/>

Investment partners (as of March 2023)

| Investment partners | Business |
|-------------------------------------|--|
| Xenoma Inc. (Tokyo) | Provides healthcare services using the smart apparel e-skin |
| Rehab for JAPAN Corporation (Tokyo) | Plans, develops, sells, and operates the scientific nursing software Rehab Cloud |
| BMG Incorporated (Kyoto) | Develops products such as medical devices that make use of distinctive characteristic of the medical adhesive LYDEX® |
| aetherAI Co., Ltd. (Taipei, Taiwan) | Develops and provides digital pathology image management systems that incorporate AI |

Focus of Ono Digital health Investment, GK investments



- 1 Business to meet patient needs
- 2 Business that pursues the health of people who support such patients
- 3 Business that promotes ONO's CSR activities or that contributes to the SDGs

michiteku Co., Ltd.
Promoting platform business

In the field of oncology (academic field related to various types of tumors, with the core of cancer), we focused on the physical, mental, and psychological problems of cancer patients that cannot be solved with drugs. To lessen the burden on cancer patients and solve social problems, it is necessary to expand information processing and information provision service businesses in the field of healthcare. Therefore, we established the wholly owned subsidiary michiteku Co., Ltd., in November 2022.

As a company independent from our drug R&D and sales activities, michiteku will provide services to as many cancer patients and their families as possible by leveraging, to the greatest extent possible, the experience, know-how, and other assets we have acquired through our research and development in the field of immunology. As for particulars, the company will develop and provide information processing and supply activities in the field of healthcare.



TOPICS Introducing the β version of the treatment life support tool michiteku on May 2023

Cancer patients can find it difficult to find reliable information appropriate for themselves from the sea of information. Many patients also have to quickly decide on a treatment method after receiving a diagnosis from the doctor while dealing with various worries. In addition, many also have to think about non-treatment issues, such as work and future life. The michiteku β version is a treatment life support tool that delivers information that patients need in this kind of situation and provides support that makes it possible to start treatment while minimizing concerns. The tool is now only for colorectal cancer and gastric cancer patients, but there are plans to expand the scope of value provided, which includes handling a broader range of cancers and extending support through post treatment decision (during treatment, follow-up, recurrence, etc.).



michiteku provides its services in Japan. The above image is taken from the michiteku official website.

Taking on the challenge of corporate philosophy of ONO in a new form

michiteku, a subsidiary of ONO primarily involved in software development, is taking on the challenge of solving problems faced by cancer patients. Despite required organizational capabilities and activities that differ from those for drugs, the basic idea of “for people’s battle with disease and suffering” is the same. While valuing the value and life view of each individual patient, the company gives shape to the questions of what is the best decision making process and what is necessary. The work of michiteku to provide even one more patient with a fulfilling mindset and life has just begun.



Hitoshi Mito President, michiteku Co., Ltd.