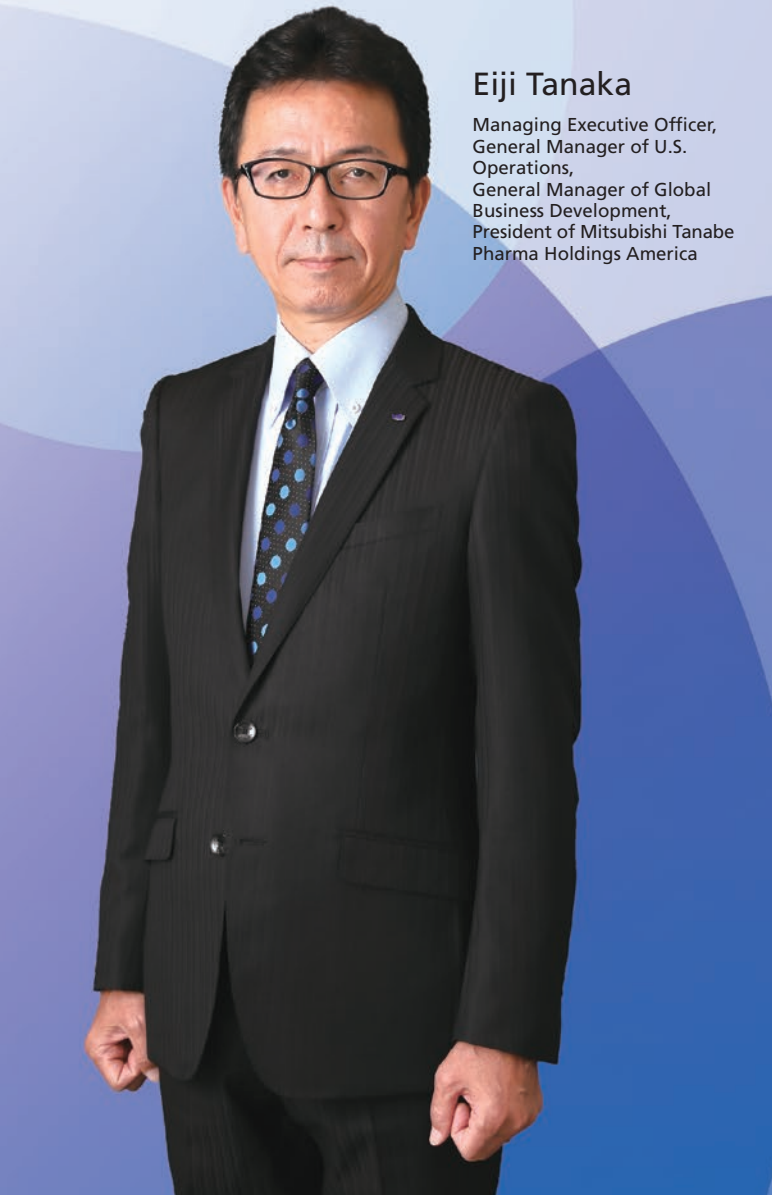
U.S. Business

We are implementing three deliberate steps to establish sustained growth in the world's largest pharmaceuticals market.



Eiji Tanaka

Managing Executive Officer,
General Manager of U.S. Operations,
General Manager of Global Business Development,
President of Mitsubishi Tanabe Pharma Holdings America

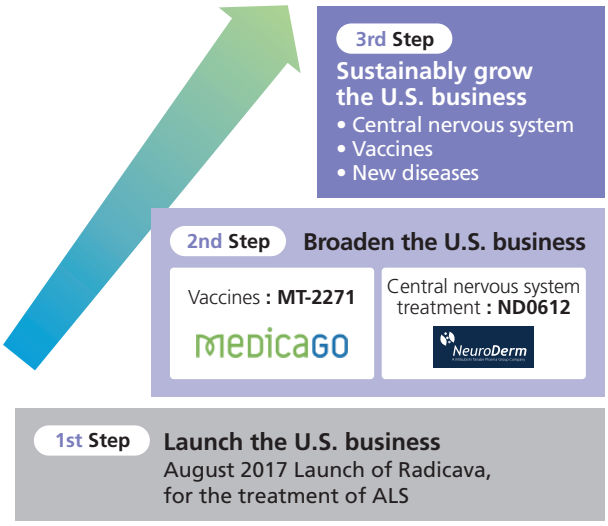
Basic policy

Expanding our business in the United States, which is by far the world's largest market for pharmaceuticals, is absolutely essential to fulfilling the goals of our Medium-Term Management Plan 16–20 and to achieving sustained growth.

The roadmap for establishing the U.S. business and generating sustained growth has three steps: launch, broaden, and sustainably grow. We will launch the U.S. business by introducing the ALS treatment agent Radicava to the market. Then we will broaden the business by aggressively investing in strategic areas. And finally, we will build on the first two steps to construct a business foundation for continual growth centered on in-house products.

We have already made progress with the first two steps under the medium-term management plan. Radicava was released in August 2017, and we invested ¥124 billion ($1.1 billion) to acquire and make a full subsidiary of NeuroDerm in October 2017.

We are also preparing to release the MT-1186 Radicava oral suspension and MT-2271 plant-based virus-like particle (VLP) seasonal influenza vaccine in fiscal 2021, followed by NeuroDerm's ND0612 treatment for Parkinson's disease in fiscal 2022. We expect these three products to be strong growth drivers and generate accelerated growth. Through these activities we will increase our presence in the U.S. market and firmly advance us to the third stage of establishing sustained business growth centered on our proprietary products. We will continue developing the U.S. business to make it the Company's second main earnings source behind our domestic operations.



Overview of the U.S. business

Mitsubishi Tanabe Pharma America (MTPA), which handles sales and marketing functions in the United States, executed the first step of our plan to launch the U.S. business with the August 2017 sales release of Radicava. MTPA has been improving the treatment environment and conducting biomarker trials to acquire new data to pave the way for a successful market launch in fiscal 2021 and maximize sales of Radicava. MTPA is also preparing to market the plant-based VLP vaccine being developed by Group company Medicago, of Canada, which will advance the second strategic step of broadening the U.S. business. The Parkinson's disease treatment ND0612 is also being developed by NeuroDerm.

Mitsubishi Tanabe Pharma Development America (MTDA) is also playing a central role in the Group's global aspirations. MTDA is developing the Radicava oral

Achieving success developing global pharmaceutical products

Mitsubishi Tanabe Pharma Development America (MTDA)

Hideki Kuki
President

Radicava sales in the United States have been steadily growing since the drug was introduced in August 2017. MTDA has been tenaciously supporting the Radicava business to succeed, including submitting a request after obtaining marketing approval to change a part of the approval details, managing safety information, and applying for and receiving authorization to market Radicava outside the United States. At the same time, it is leading the clinical research of the in-house developed MT-1186 oral agent.

MTDA has the important mission to follow-up the success with Radicava by developing new drug products for the global market to maximize pipeline value, which is one of the four strategic priorities in the Medium-Term Management Plan 16–20. The MTPC Group has assembled development project teams from its member companies, which is working closely with each company's functional organizations and related departments to plan and execute drug development projects for global markets.

MTDA has a highly efficient and effective operating structure that outsources the majority of clinical study operations so it can focus primarily on forming and managing drug development plans, regulatory affairs strategies, and safety risk assessments. With the increasingly strict requirements from regulatory authorities and demand from medical society, new drug development must take medical economics into account. MTDA is also playing a crucial role constructing a network of experts in various fields in the United States, Europe, and Japan that will raise the probability of success of our drug development activities while ensuring we accurately fulfill both the medical and economic needs. We remain dedicated to the full process of bringing new drugs to market starting with combining knowledge from inside and outside the Company, establishing project proof of concept at an early stage, steadily advancing drug development to the final stages, and successfully obtaining marketing approval.

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suspension and is advancing the in-house production of drugs for the third step to sustainably grow the U.S. business. The company has generated several projects with global potential and is contributing to strengthening the drug pipeline for the Group's future growth.

Expanding our business in the U.S. market, which is expected to remain the world's largest pharmaceuticals market, is essential to achieving sustained earnings growth for the Group.

Progress with the three steps

As mentioned above, after the first step to establish the U.S. business by releasing Radicava, we are now moving to launch the oral preparation and implement measures to maximize sales.

The second step is to continue preparing for the release of Medicago's plant-based VLP vaccine, for which we are aiming to receive approval in fiscal 2021, while also advancing the development of NeuroDerm's Parkinson's disease treatment ND0612 for a target release date in fiscal 2022.

The key tasks for the third step will be to formulate the operating structure and implement measures to establish ongoing growth for fiscal 2021 and beyond. That will require careful selection and concentration of investment in R&D with the clear aim of bringing in-house developed products to market as swiftly as possible.

Mitsubishi Tanabe Pharma Holdings America (MTHA) conducts market analysis to accurately identify the needs of patients and healthcare professionals. The company also contributes to developing strategies from the market's perspective by proposing market access strategies to construct compelling evidence to gain the backing of insurers and ultimately to enable access to all patients considered in need of the new drugs.

These activities are all geared to enhancing our ability to discover drugs matched to market needs and seamlessly progress to formulating marketing strategies while also accelerating in-house drug development to maximize the value in our drug development pipeline. MTHA is also strengthening the management infrastructure, including reinforcing governance and ensuring comprehensive compliance at companies doing business in the United States, which is essential to maintaining sustained business growth.

Growth drivers

(1) Radicava

Since the release of Radicava, MTPA has been providing educational opportunities about ALS and Radicava to the primary stakeholders of patients, doctors, and insurers and seeking to increase the number of medical institutions where Radicava is available to improve treatment options for ALS patients. As of June 2019, these efforts have helped increase the number of ALS patients benefiting from treatment using Radicava to over 4,000 people.

While continuing these activities, we will also seek to improve the ALS treatment environment and lay the groundwork for the release of the oral treatment in fiscal 2021 by increasing recognition of Radicava among

ALS Biomarker Research

Mitsubishi Tanabe Pharma America (MTPA)

Stephen L. Apple, MD
Senior Medical Director

Biomarkers are biological substances such as proteins or genes that may play a role in the diagnosis or prognosis of a disease, Biomarkers may also play an important role as indicators of treatment effectiveness. Biomarkers are attracting particular attention from healthcare professionals involved in amyotrophic lateral sclerosis (ALS) treatment and research as well as ALS patient communities. MTPA is collaborating in a study with Massachusetts General Hospital to identify and measure specific biomarkers in roughly 300 people using Radicava to treat ALS. The study, which is being conducted at roughly 40 sites in the United States, will seek to create a panel of biomarkers that may be associated with Radicava treatment in ALS, including those for oxidative stress, inflammation, muscle and neuronal injury and death.

We hope this research will deepen our understanding of how Radicava affects the progression of ALS. The companies participating in the collaboration each bring unique evaluation techniques. As part of the collaboration, MTPA in the United States conducted its first clinical research of biomarkers, which was an important milestone for our business. We are proud to be leading this research and to be able to come together with members of the ALS community. In 2019, the study plans to enroll patients to participate in the biomarker study, and we plan to conduct the first interim analysis by the end of the year.

healthcare professionals to promote effective use, creating environments conducive to prescribing it, and facilitating patient accessibility to it for treatment. Because the Radicava oral suspension will be much easier to administer than the current method of intravenous drip infusion, it will widen the scope of patient eligibility, which will both address unmet medical needs and maximize the value of the treatment.

(2) VLP Vaccine

Medicago is a biopharmaceutical company specializing in the research and development of new vaccines using plant-based virus-like particle (VLP) technology. VLP vaccines have the potential to provide strong and extremely safe protection against viruses. Because the external structures of VLPs resemble viruses, they stimulate the body's immune system but carry no threat of viral transmission because they contain no viral genetic material. VLP vaccine technology also offers the significant advantages of being less costly and quicker to manufacture than current vaccines.

Medicago has proprietary technology to grow VLPs in plant cells and efficiently extract and refine the VLPs. The company completed phase 3 testing of its seasonal flu VLP vaccine for adult patients in the United States and Canada during the 2017-2018 influenza season. In fiscal 2019, the company is expecting to receive the results of phase 3 trials for administering the flu vaccine to elderly patients in the second quarter and plans to apply for approval in the United States for administering the vaccine to adults in the same year with the objective of beginning sales in fiscal 2021.

(3) ND0612

NeuroDerm has proprietary production technology for liquefying insoluble compounds. The company is using its "designed pharmaceuticals" combining pharmaceuticals and devices to increase drug effectiveness and is also advancing development of ND0612, its Parkinson's disease treatment formulated to reduce side effects. There are estimated to be over a million people with Parkinson's disease in the United States alone, and the research and development of the ND0612 treatment has high clinical value for its potential to meet a vast worldwide unmet medical need.

The development plan for ND0612 had been under review but in fiscal 2018 the company and the United States Food & Drug Administration (FDA) discussed and reached a general agreement on the design of Phase 3 study. The company plans to simultaneously submit approval applications in Europe and the United States in fiscal 2021 with the aim of beginning sales in fiscal 2022.