

Material Issue 4

# Realization of Direct Sales in the US and Europe

## Management of Priority Issues

<b>Reason for being a priority issue</b>	We are committed to bringing medicines to patients around the world with our own hands. And to achieve sustainable growth, we will develop business in the U.S. and Europe, which have large markets.
<b>Vision over the medium to long term</b>	Aiming to become a globally competitive specialty pharmaceutical company, we are marketing new drugs in the U.S. and Europe.
<b>Indicators</b>	<ul style="list-style-type: none"> <li>Obtain approval and start our own sales in the U.S. and Europe</li> </ul>
<b>Major initiatives</b>	<ul style="list-style-type: none"> <li>Establish a sales structure for the launch of ONO-4059 in the U.S.</li> <li>Carry out development in Europe and establish a sales structure according to the progress of the development</li> </ul>

## Ono Pharmaceutical's Global Business

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. First, we are working on products in niche areas that do not require a large sales organization, with the aim of selling them ourselves overseas.

## Steps for Growing as a Global Company

We are taking the following three steps to become a global company that can compete on the world stage, and we are currently in Step 2 of realizing our own marketing in the U.S. and Europe.

### Step1: Globalizing Our Marketing Organizations

We started business expansion in Asia. We established two wholly

owned subsidiaries: ONO PHARMA KOREA CO., LTD. in South Korea in 2013, and ONO PHARMA TAIWAN CO., LTD. in Taiwan in 2014. Then, the subsidiaries established their own sales organizations, and we started our own sales operations for OPDIVO in South Korea in 2015 and in Taiwan in 2016, respectively. To date, OPDIVO has been approved for 10 cancers in South Korea and 11 cancers in Taiwan (as of the end of June 2022). In addition, VELEXBRU received approval and began our own marketing in South Korea in 2021 and in Taiwan in 2022 for the indication of relapsed or refractory primary B-cell CNS lymphoma. Furthermore, BRAFTOVI will be marketed by our own sales organization in South Korea in 2021 for the indication of advanced or relapsed colorectal cancer with BRAFV600E mutation, and the Company is steadily increasing its presence in Asia.

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

To solve various issues that arise when expanding our business in the U.S., our U.S. subsidiary, Ono Pharma USA, Inc., and

## Steps for Growing as a Global Company



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.

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 the development system for new compounds, such as ONO-4059, they hired executives for the marketing and sales organizations, the pharmacovigilance division, and the medical affairs division in FY2021, and they are working to strengthen our own sales organization and infrastructure for the launch of new products. We plan to increase the size of the organization from the current approximately 60 employees to more than 120 in five years.

In the U.S. and Europe we are currently conducting clinical trials for 5 products and are aiming to establish a PoC for development products following ONO-4059. In Europe, we currently have an organization of about 50 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 organization.

### Step3: Becoming a True Global Company

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.

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

Accelerate the construction of a self-sales organization in the US taking the launch of VELEXBRU into account  
Promote development and establish a self-sales organization in Europe

### ONO PHARMA USA

Approx. 60 people at present → After 5 years, expand to more than 120 people having a self-sales organization

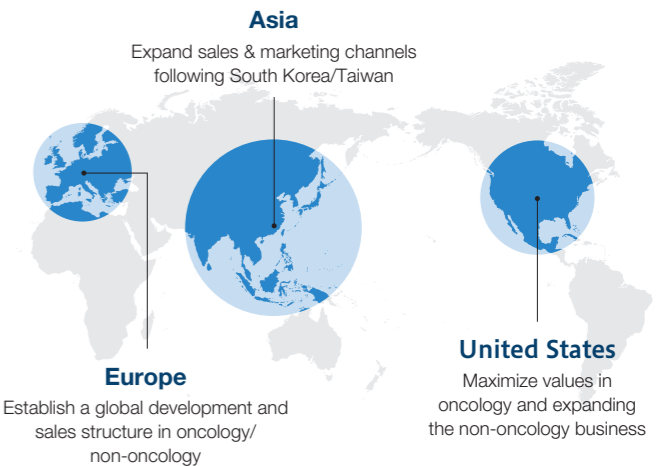
Clinical Development	Marketing	Sales	Market Access	Medical
PV	QA	CMC·Production	Company Infrastructure	

### ONO PHARMA UK

Approx. 50 people at present. Consider establishing a self-sales organization including marketing and sales etc. under the progress of development in Europe

Clinical Development	PV	QA	Company Infrastructure
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## ONO's Vision



## Continued expansion of global pipeline

	Global Development (Medium- and Long-term)	
Oncology	VELEXBRU	(BTK inhibitor / PCNSL)
	ONO-7475	(Axl / Mer inhibitor / Acute leukemia, etc)
	ONO-4685	(PD-1×CD3 bispecific antibody / T cell Lymphoma)
	ONO-4578	(EP4 antagonist / Solid tumor, Gastric cancer, etc )
Neurology	ONO-2808	(S1P5 receptor agonist / Neurodegenerative disease)
	ONO-2909	(DP1 antagonist / Narcolepsy)
	ONO-2910	(Schwann cell differentiation promoter / Diabetic polyneuropathy)
Immunology	ONO-4685	(PD-1×CD3 bispecific antibody / Autoimmune disease)
Specialty	ONO-7684	(FXIa inhibitor / Thrombosis)

New drug candidates created by Discovery & Research  
Newly in-licensed drug candidates for global development