

# Future Growth Strategy

~Overcoming Opdivo Patent Expiration toward Further Growth~

November 2, 2023



# Cautionary Notes

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Forecasts and other forward-looking statements included in this document are based on information currently available and certain assumptions that the Company deems reasonable.

Actual performance and other results may differ significantly due to various factors. Such factors include, but are not limited to:

- ( i ) failures in new product development**
- ( ii ) changes in general economic conditions due to reform of medical insurance system**
- ( iii ) failures in obtaining the expected results due to effects of competing products or generic drugs**
- ( iv ) infringements of the Company's intellectual property rights by third parties**
- ( v ) stagnation of product supply from the delay in production due to natural disasters, fires and so on**
- ( vi ) onset of new side effect of post-licensure medical product and,**
- ( vii ) currency exchange rate fluctuations and interest rate trend.**

Information about pharmaceutical products (including products currently in development) included in this document is not intended to constitute an advertisement of medical advice.

- 1. Impact of Patent Expiration**
- 2. Growth Strategy through Direct Sales in the U.S. and Europe**
- 3. Candidates for launch in the U.S. and European markets**
- 4. Promoting Open Innovation**

# Impact of Patent Expiration 1

## ◆ Overseas royalty income will gradually decline

### ➤ January YR2024 ~

Decline royalty income from Merck (Rate change)

1.625% (Current) ⇒ 0.625%

\*Royalty income from Roche and others will decline as well (Rate not disclosed)

### ➤ December YR2026 ~

Termination of royalty income from Merck, Roche and others

### ➤ YR2028

Patent expiration in North America (Decline royalty income from BMS)

### ➤ YR2030

Patent expiration in major European countries (Termination of royalty income from BMS)

\* YR2022~ Increase of Opdualag related royalty income

## Impact of Patent Expiration 2

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- ◆ **Domestic sales will increase with the approval of indications**  
**Forecast to be halved in a few years after the patent expiration in 2031**
- **Expansion of indications**
  - Urothelial carcinoma 1 L (CheckMate-901)
  - Non-small cell lung cancer, with CRT, Stage III (CheckMate-73L)
  - Hepatocellular carcinoma 1 L (CheckMate-9DW)
  - Hepatocellular carcinoma, adjuvant (CheckMate-9DX)
- **Development of combination drug (ONO-7121) with anti LAG-3 antibody**
  - Colorectal cancer 3L (Phase III)
- **Development of combination drug with PG receptor (EP4) antagonist (ONO-4578)**
  - Gastric cancer (Phase II)

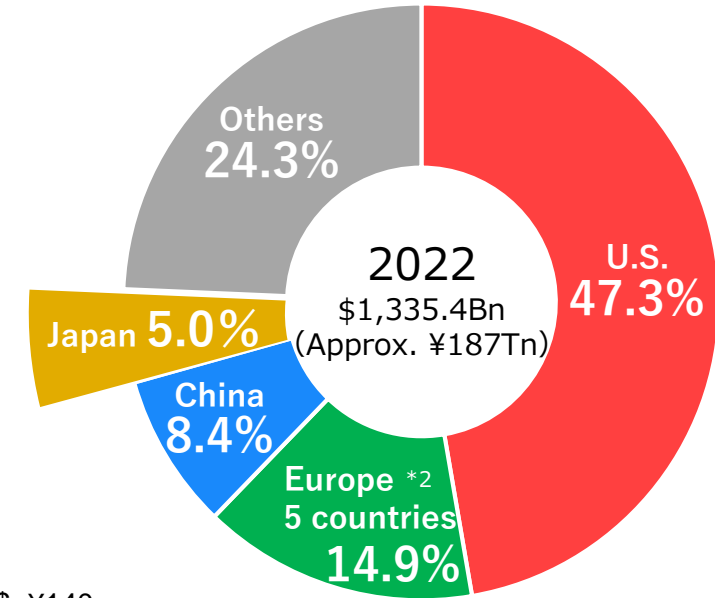
# Growth strategy through direct sales in the U.S. and Europe

Comparison of sales composition with other pharma  
(FY2022 : Billion yen)

	Domestic sales	Overseas sales	Total
Company A	2,848	12,338	15,186
Company B	2,503	4,941	7,444
<b>ONO</b>	<b>2,882</b>	<b>1,590</b>	<b>4,472</b>

\* Based on each financial announcement materials

Sales Share by Region \*1



\*1. \$=¥140

\*2. Germany, France, UK, Italy, Spain

- **Approximately 50% of pharmaceutical market sales in FY2022 were in the U.S. (Approx.5% in Japan)**
- **ONO will overcome Opdivo patent expiration toward further growth by launching multiple products in the U.S. and Europe with large markets**

\*1.Calculated in-house based on 「IQVIA Analytics Link (2022) 」  
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# Candidates for launch in the U.S. and European markets

Therapeutic Area	~YR2026	YR2027~2031	YR2032~
<b>Oncology</b>	<p>ONO-4059 (Blood cancer)</p>	<p>ONO-4685 (Blood cancer)</p> <p>ONO-7018 (Blood cancer)</p>	<p>ONO-4578 (Solid tumors)</p> <p>ONO-7914 (Solid tumors)</p> <p>ONO-7475 (Solid tumors)</p>
<b>Neurology</b>		<p>ONO-2910 (DPN, CIPN)</p> <p>ONO-2020 (Neurodegenerative disease)</p>	<p>ONO-2808 (Multiple system Atrophy)</p> <p>ONO-1110 (Pain)</p>
<b>Immunology</b>	<p>Itolizumab (Acute GVHD)</p>	<p>ONO-4685 (Autoimmune disease)</p>	
<b>Specialty</b>			

DPN : Diabetic Polyneuropathy  
 CIPN : Chemotherapy-Induced Peripheral Neuropathy

**Research collaborations and discovery partnerships  
with world-leading researchers and biopharma  
in the U.S. and Europe**



**Acquisition original drug discovery seeds  
Discovery of new drug candidates**

**Research collaborations**

Area	Number
Domestic	195
Overseas	167
Total	362

**Number of drug discovery collaborations**

YR2020	YR2021	YR2022
1	4	11

**Initiated 110 research collaborations and  
11 drug discovery collaborations in 2022**





**ONO PHARMACEUTICAL CO.,LTD.**

Dedicated to the Fight against Disease and Pain