

Passion for Innovation.  
Compassion for Patients.™



# **DS-8201 Strategic Collaboration**

**DAIICHI SANKYO CO., LTD**

**George Nakayama**  
**Chairman and CEO**

**March 29, 2019**

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# **DS-8201 Strategic Collaboration**

## **1. Overview**

## **2. Significance**

# DS-8201 Strategic Collaboration

## 1. Overview

## 2. Significance

Our Collaborator: **AstraZeneca** 

## Collaboration Overview

- ▶ Joint development and commercialization for HER2 targeting Antibody Drug Conjugate DS-8201

Region



Global

Period



From signing through commercial life of DS-8201

## Governance

- ▶ Development and commercialization strategies are planned and implemented based on
  - Joint executive committee, and
  - Functionally-aligned committees including development, commercialization, medical affairs, supply chain, and finance



## Development

- ▶ Joint development as monotherapy and combination therapy for HER2 expressing cancers including



- ▶ Equally share development costs and efforts
- ▶ Daiichi Sankyo will continue development of combination therapy that are currently being investigated

## Commercialization

- ▶ **Global** (excluding Japan): Both companies will jointly commercialize and share profits

- ▶ **Japan:** Daiichi Sankyo will commercialize on a stand-alone basis and pay royalties to AstraZeneca

### Sales booking by region

- **Daiichi Sankyo:** Japan, US, certain countries in Europe, and certain other markets where Daiichi Sankyo has affiliates
- **AstraZeneca:** All other markets worldwide, including China, Australia, Canada and Russia

## Manufacturing & Supply

- ▶ Daiichi Sankyo manufactures and supplies DS-8201



# Financial Terms of DS-8201 Collaboration

**Up to \$6.9 billion (¥759.0 billion) in total** (US\$1=¥110)

## Upfront payment

\$1.35 billion  
(¥148.5 billion)

- Half upon contract execution and balance received one year post-contract execution
- Deferred and will be booked as revenue over multiple fiscal years considering the exclusivity period

## Regulatory and other contingencies (max)

\$3.80 billion  
(¥418.0 billion)

- Regulatory milestone will be received at the time of approval for each cancer type and indication
- Deferred and will be booked as revenue over multiple fiscal years considering the exclusivity period

## Sales-related milestones (max)

\$1.75 billion  
(¥192.5 billion)

- Will be booked in revenue in the year of achievement

# DS-8201 Strategic Collaboration

1. Overview

**2. Significance**



# Significance of the Collaboration



- ◆ Accelerate DS-8201 development & commercialization to reach more patients earlier
- ◆ Accelerate the establishment of Daiichi Sankyo's global oncology infrastructure
- ◆ Expand resource allocation for other ADC programs following DS-8201



Reach more patients earlier

## Early market penetration

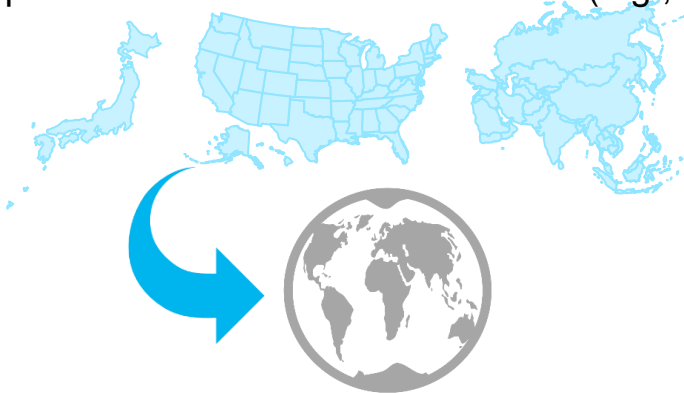
Cancer types and indications currently under development

### ▶ Accelerating market penetration in U.S. and Europe

Accelerate the pace of sales uptake

### ▶ Early launch in other markets other than Japan, U.S and Europe

Accelerate sales by advancing launch in countries where AstraZeneca has extensive development experience and commercial structure (e.g., China)



## Accelerate and expand development

Cancer types and indications for future development

### ▶ Advancing development plans

Early contribution to sales by accelerating development of new indications

### ▶ Further expansion of cancer types and indications

Increase sales by expanding cancer types and indications targeted for development

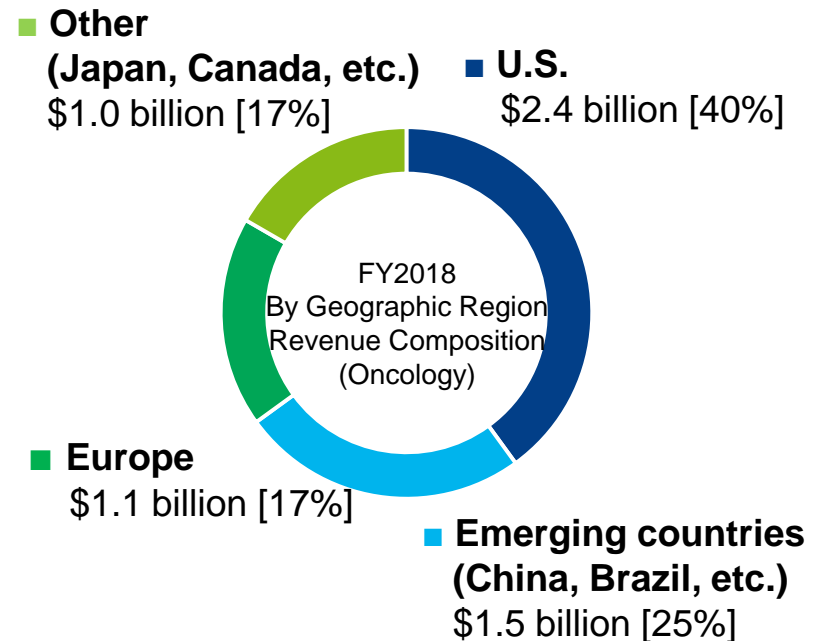


- ▶ **Accelerating market penetration in U.S. and Europe**  
for cancer types and indications currently under development
- ▶ **Early launch in other markets other than Japan, U.S and Europe**



## Collaborator has extensive expertise

- ▶ Global cancer revenue (FY2018):  
\$6 billion (29% of total revenue)
- ▶ Global commercial infrastructure with operations in over 70 countries (including Canada, Eastern Europe, Northern Europe, Oceania, Russia and CIS, Africa and Latin America)
- ▶ Market access (customer engagement with payers and oncology specialists),  
Medical Affairs





- ▶ **Advancing development plans**  
by accelerating development of new indications
- ▶ **Further expansion of cancer types and indications**



- ▶ **83 oncology development projects ongoing** as of December 31, 2018

- 25 Ph 1
- 20 Ph 2
- 13 Ph 3 / Pivotal Ph 2 / Registration
- 25 LCM

- ▶ **Extensive development and registration experience in global including emerging countries**



- ▶ **Breast Cancer:** Over the past 40 years, developed innovative and important drugs

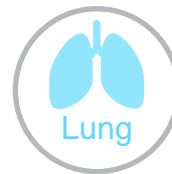
PARP inhibitor  
**Lynparza**<sup>®</sup>  
olaparib  
tablets

Antiestrogen  
**FASLODEX**<sup>®</sup>  
fulvestrant  
injection

Aromatase inhibitor  
**Arimidex**<sup>®</sup>  
anastrozole  
1mg tablets

GnRH antagonist  
**Zoladex**<sup>®</sup>  
goserelin acetate implant

SERM  
**Nolvadex**



- ▶ **Lung Cancer:** Hold state-of-the-art approved drugs and pipeline agents

Tyrosine kinase inhibitor  
**TAGRIS**<sup>®</sup>  
osimertinib

Genetically recombinant PD-L1 antibody  
**IMFINZI**<sup>™</sup>  
durvalumab  
Injection for Intravenous Use 50 mg/mL

EGFR tyrosine kinase inhibitor  
**IRESSA**<sup>®</sup>  
gefitinib

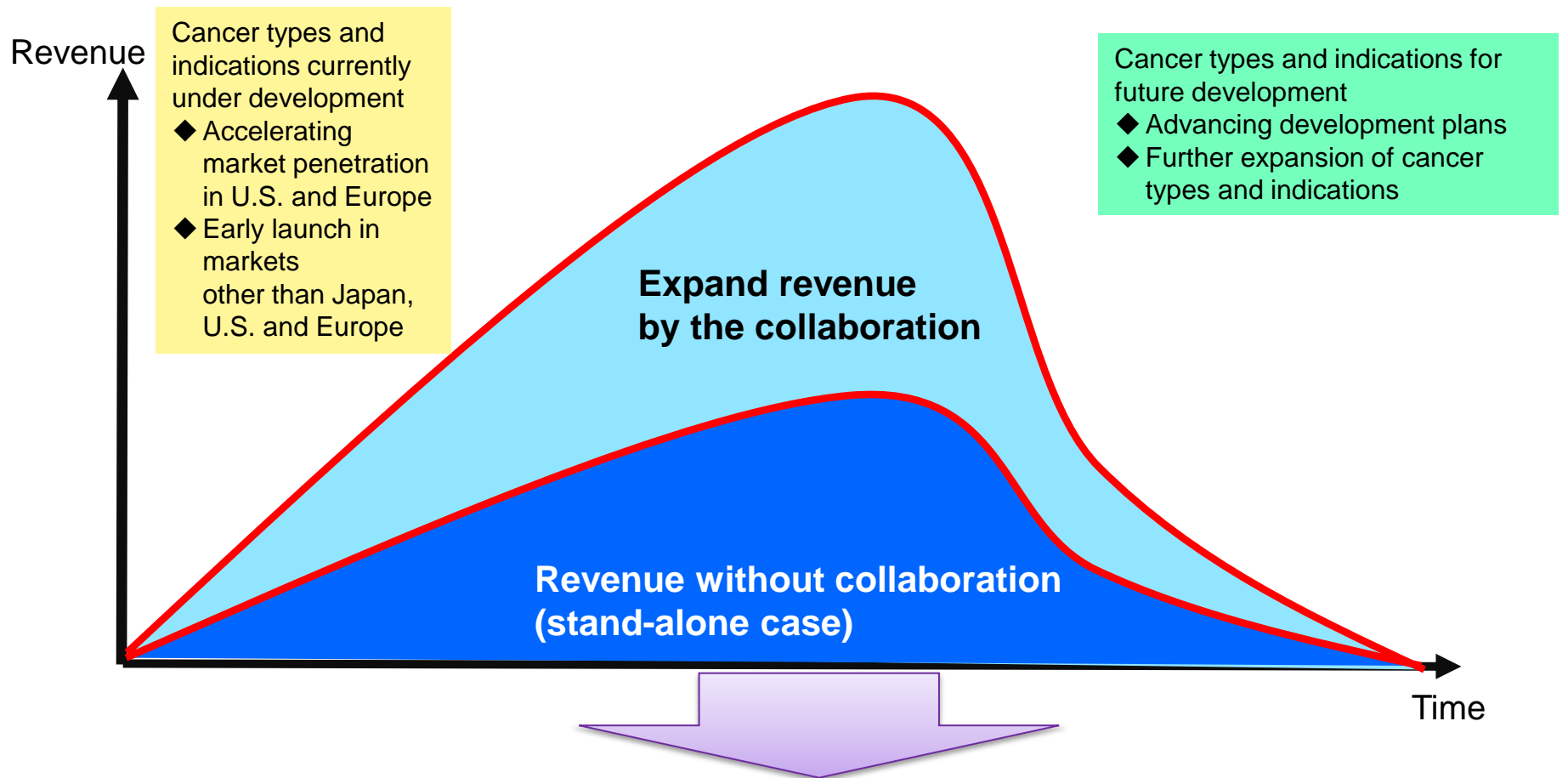
# Building DS-8201 in Breast Cancer and Beyond

	Neoadjuvant / adjuvant	1L metastatic	2L metastatic	3L metastatic
<b>HER2+ Breast</b>	Post neoadjuvant: Replace T-DM1  trastuzumab + pertuzumab + chemo	Replace trastuzumab + pertuzumab + chemo retreatment	Replace T-DM1	Post T-DM1
<b>HER2 Low Breast</b>	HR+: Endocrine ± chemo  HR-: Chemotherapy	Endocrine ± CDK4/6i  Replace 1L Chemo	Post CDK4/6i	
<b>Beyond Breast</b>	Gastric, NSCLC, CRC and others			

# Maximize the Product Value of DS-8201



## Expansion of DS-8201 revenue (illustrative image)



**Daiichi Sankyo will increase value through upfront payments, milestone payments and expanded revenue achieved by the collaboration comparing to the stand-alone case**



## Accelerate the establishment of in-house oncology business structure in global oncology market

- ◆ With AstraZeneca's experience and resources in global oncology, we jointly formulate and implement strategies for development, regulatory affairs, sales, marketing and medical affairs, allocating roles and responsibilities across both organizations
- ◆ DS accelerates the build and enhancement of in-house oncology business structure through this alliance
- ◆ We maximize the product value for subsequent in-house oncology products



Opportunities for strategic collaborations with excellent collaborator



Accelerate building of in-house oncology business structure

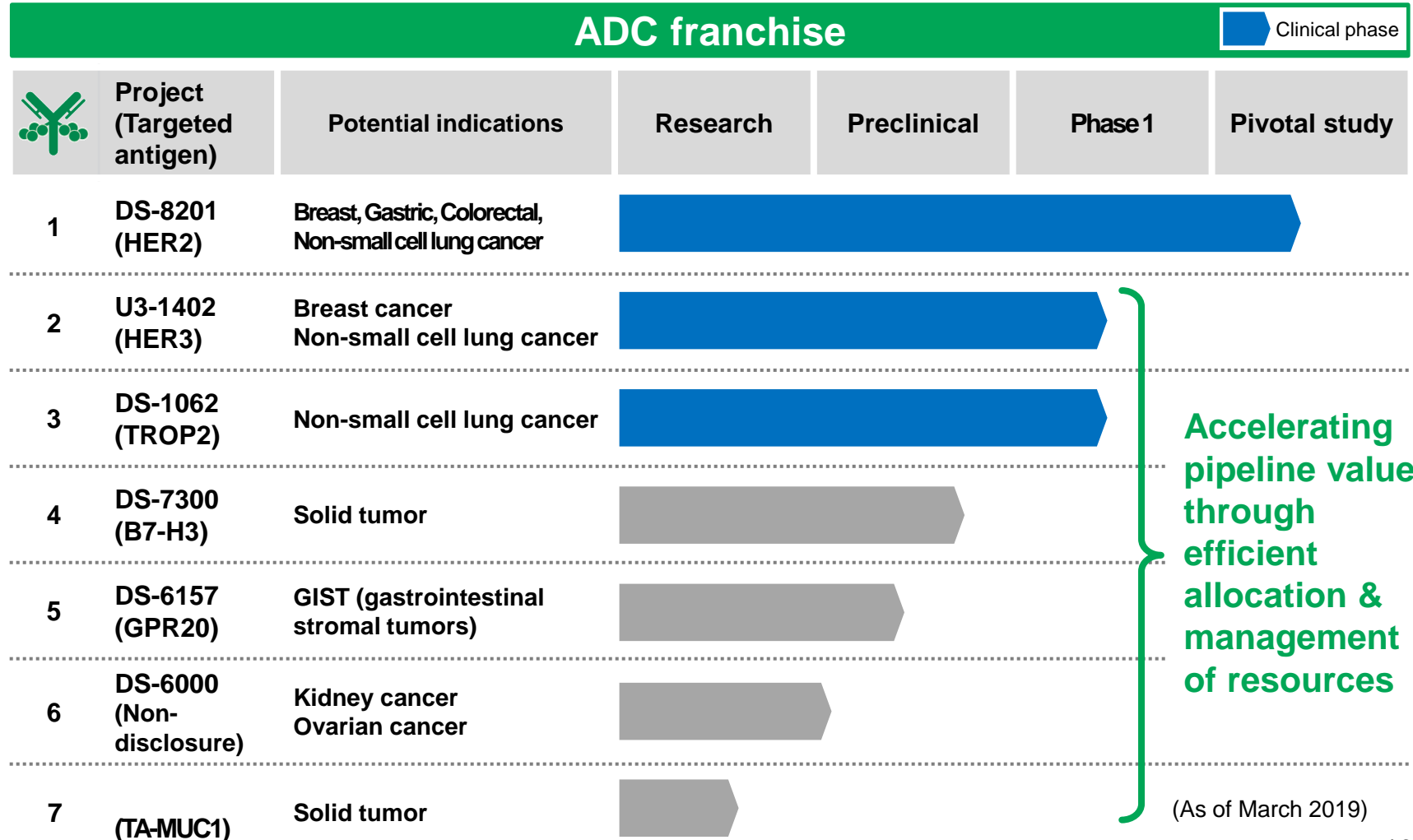


Maximize product value for subsequent in-house oncology products

# Expand Resource Allocation for Other ADC Programs



Accelerate development by allocating R&D expense and human resources that had been concentrated in DS-8201 to other ADC projects





- ◆ Daiichi Sankyo will deliver DS-8201 to more cancer patients earlier by penetrating the market more effectively, accelerating and expanding development through this collaboration
- ◆ Daiichi Sankyo will increase value through upfront payments, milestone payments and expanded revenue achieved by the collaboration comparing to the stand-alone case
- ◆ Daiichi Sankyo accelerates the establishment of in-house oncology business structure in global markets
- ◆ By allocating resources that had been concentrated in DS-8201 to other projects, we accelerate development of other internal assets

# **DS-8201: Acceleration of BLA Submission in U.S.**



## Confirm plans to accelerate BLA submission to U.S. FDA DS-8201 in HER2 positive metastatic breast cancer post T-DM1

Original Plan

BLA Submission  
2020



BLA Submission  
FY2019 H1

Acceleration

- ▶ Data from pivotal Ph 2 study to form basis of BLA submission will be presented at upcoming medical meeting



- ▶ Final determination of exact timing of the BLA submission will be based on the outcome of a pre-BLA meeting with the FDA

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