

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

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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)

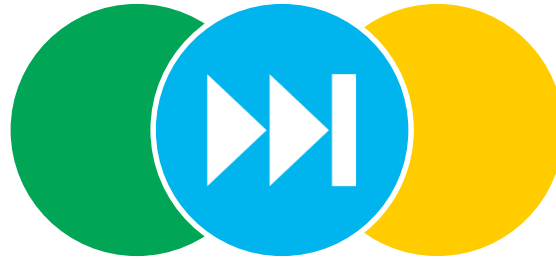
\$1.75 billion
(¥192.5 billion)

- Will be booked in revenue in the year of achievement

DS-8201 Strategic Collaboration

1. Overview

2. Significance



- ◆ 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

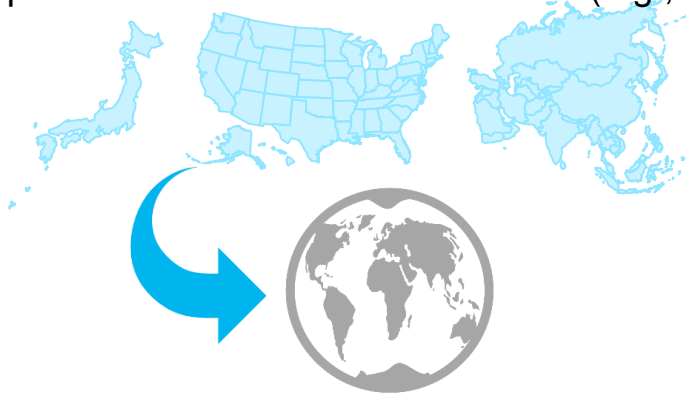
Cancer types and indications currently under development

▶ 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

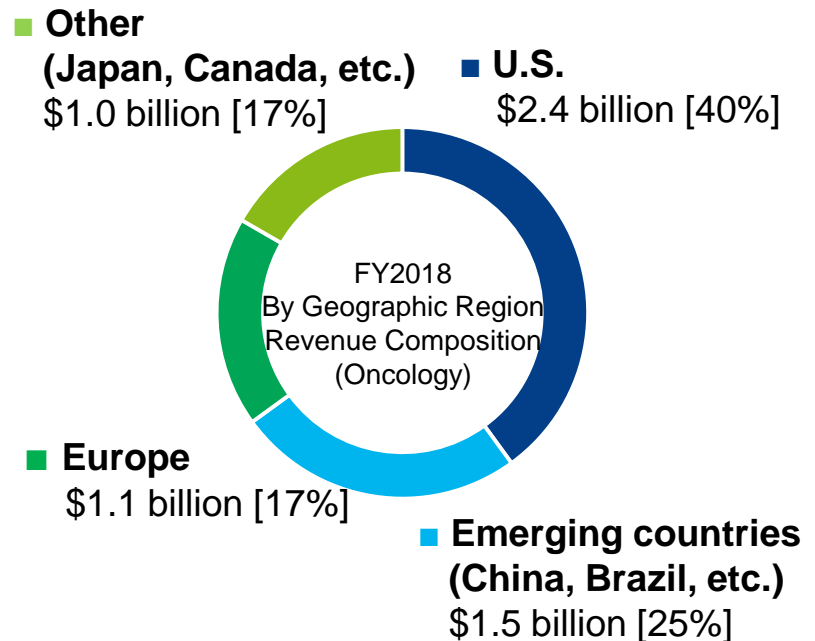


- ▶ **Accelerating market penetration in U.S. and Europe**
for cancer types and indications currently under development
- ▶ **Early launch in other markets other than Japan, U.S and Europe**



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[®]
olaparib
tablets

Antiestrogen
FASLODEX[®]
fulvestrant
injection

Aromatase inhibitor
Arimidex[®]
anastrozole
1mg tablets

GnRH antagonist
Zoladex[®]
goserelin acetate implant

SERM
Nolvadex



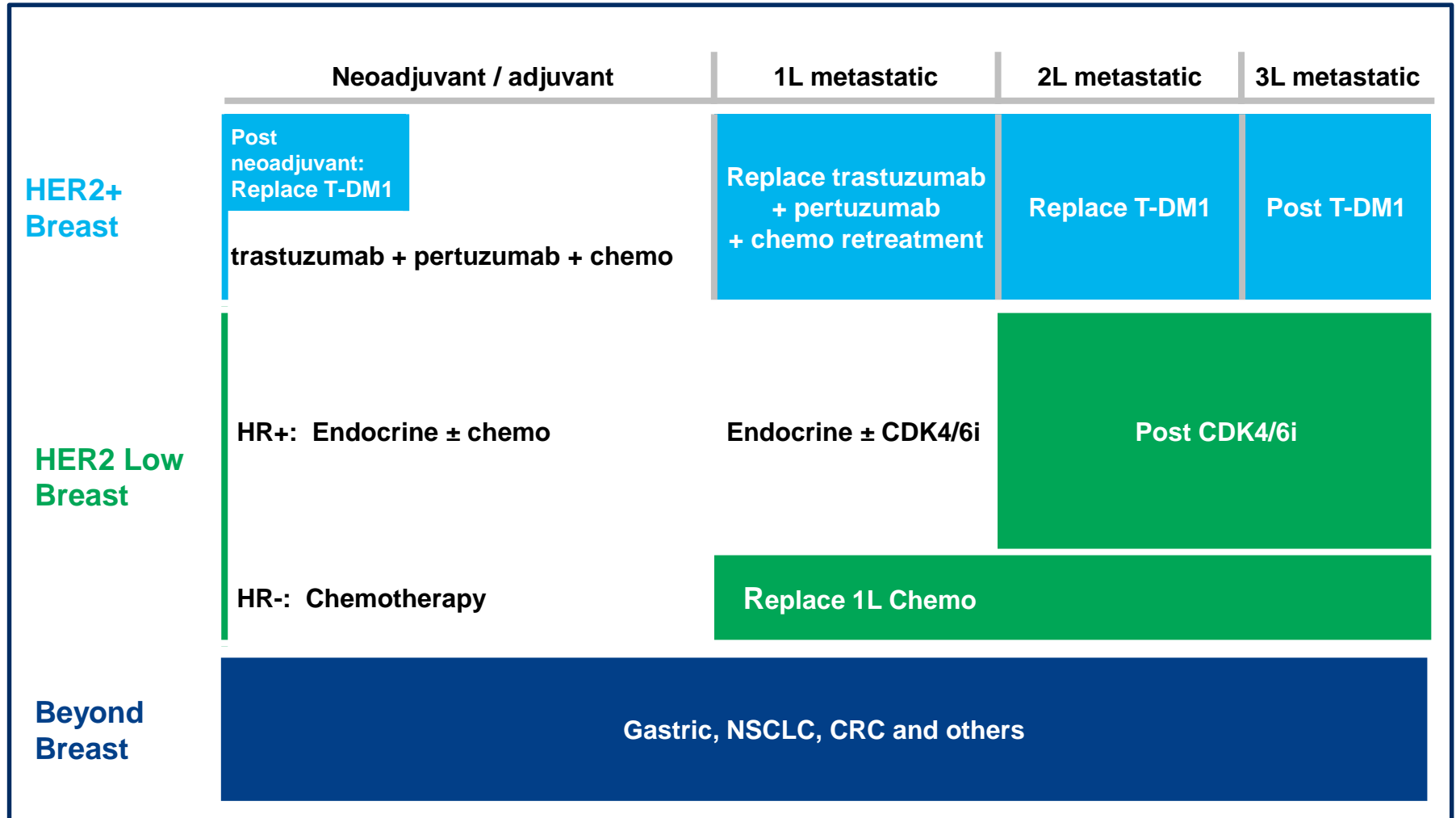
- ▶ **Lung Cancer:** Hold state-of-the-art approved drugs and pipeline agents

Tyrosine kinase inhibitor
TAGRIS[®]
osimertinib

Genetically recombinant PD-L1 antibody
IMFINZI[™]
durvalumab
Injection for Intravenous Use 50 mg/mL

EGFR tyrosine kinase inhibitor
IRESSA[®]
gefitinib

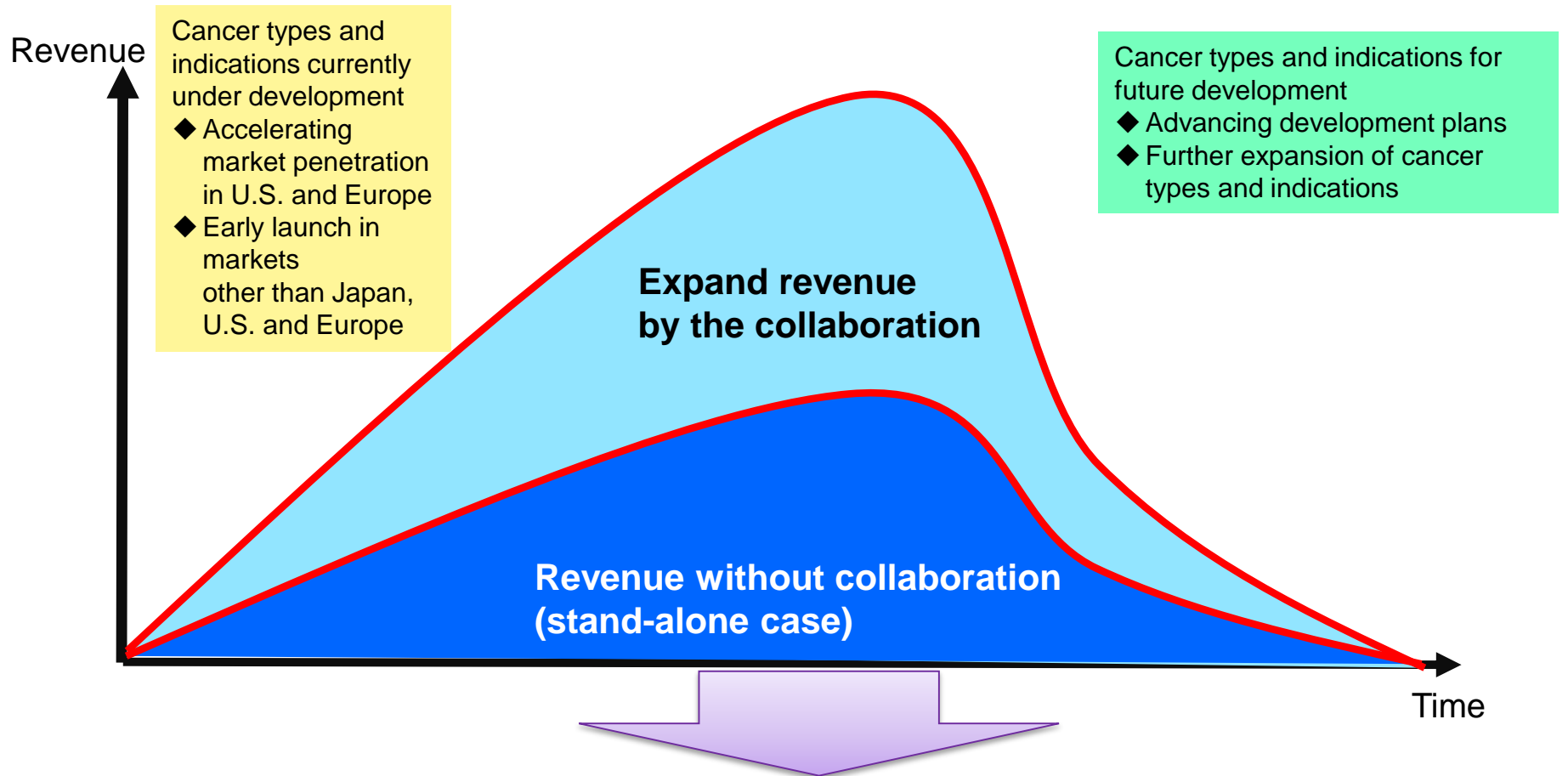
Building DS-8201 in Breast Cancer and Beyond



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

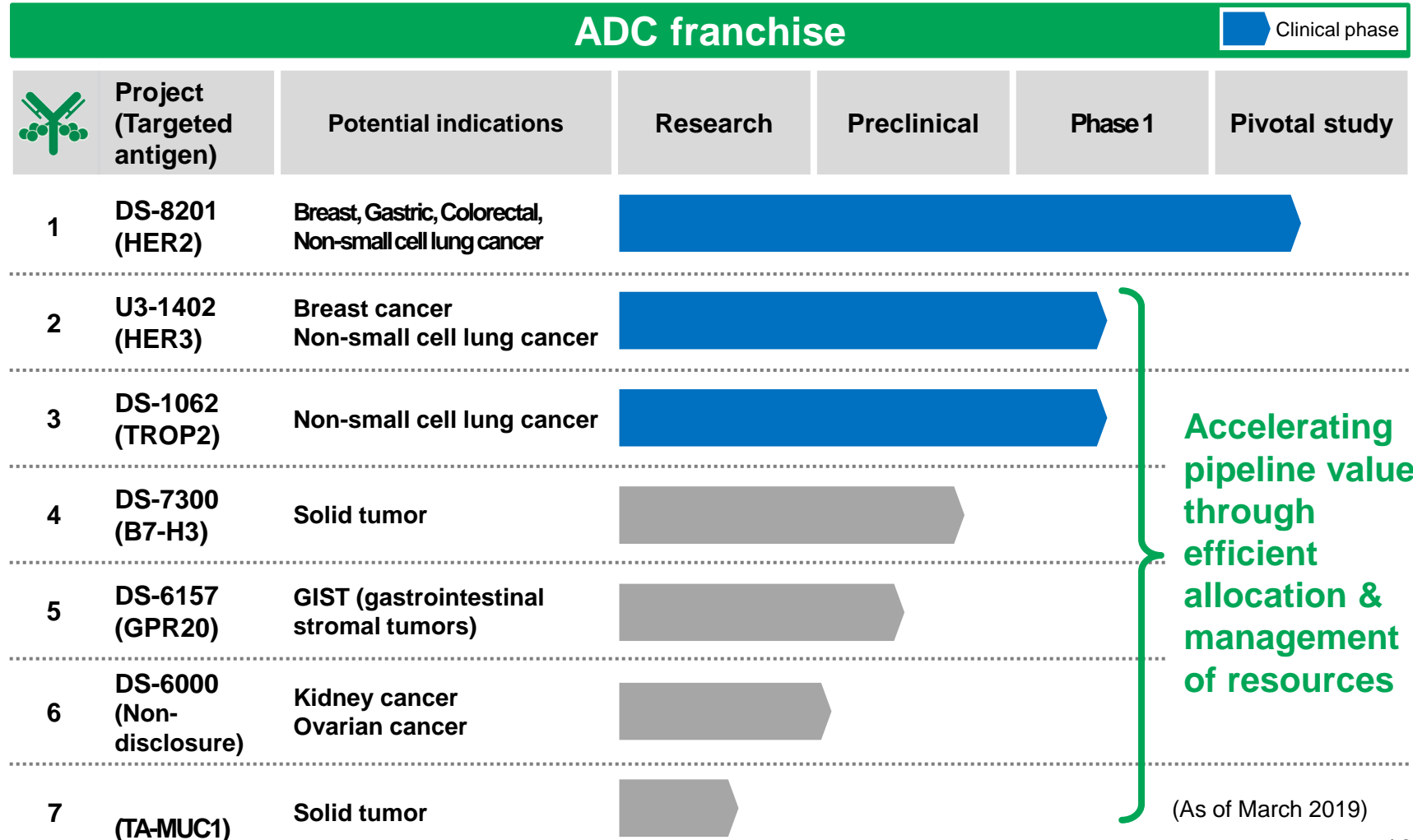


Maximize product value for subsequent in-house oncology products

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

Contact address regarding this material

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