

Passion for Innovation.
Compassion for Patients.™



DS-1062 Strategic Collaboration

DAIICHI SANKYO CO., LTD.

Sunao Manabe
President and CEO

July 27, 2020

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Agenda

1 Daiichi Sankyo's Current Business Environment

2 Changes in Environment

3 Significance of the Collaboration


4 Overview of the Collaboration

5 Q&A



Ensuring Achievement of 2025 Vision

Dec. 2019: Updated R&D Strategy

3 ADC			&	Alpha 		
DS-8201	DS-1062	U3-1402	Oncology	Specialty Medicine	Vaccines	

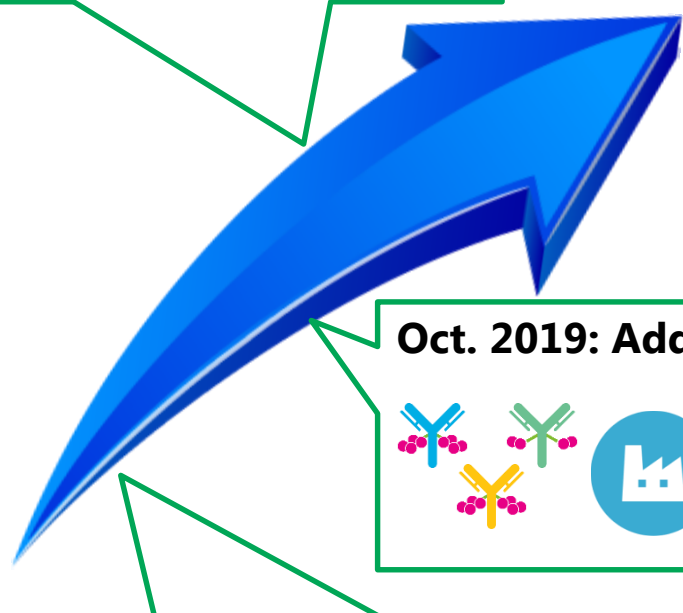
2025 Vision

**Global Pharma
Innovator
with Competitive
Advantage in Oncology**

5-Year Business Plan
2016-2020

Transformation

toward 2025 Vision



Oct. 2019: Additional investment for ADCs

  **Capital investment**  **R&D investment**

Mar. 2019: DS-8201 Strategic Collaboration

 **Daiichi-Sankyo**  **AstraZeneca** 

Increasing Value for Enhertu and DS-1062

Enhertu / DS-8201



Breast Cancer

- JP/US: **Strong market penetration** after launch
- EU: **Under review (accelerated assessment)**



Gastric Cancer

- JP: **Under review (SAKIGAKE)**
- US: **BTD/ODD**



Lung Cancer

- **Encouraging results in P2 study**
- US: **BTD** (HER2 mutation)



Colorectal cancer

- **Encouraging results in P2 study**

DS-1062



Lung Cancer

- **Encouraging data in Ph1 study (all comers)**
- **I/O combo** studies under preparation



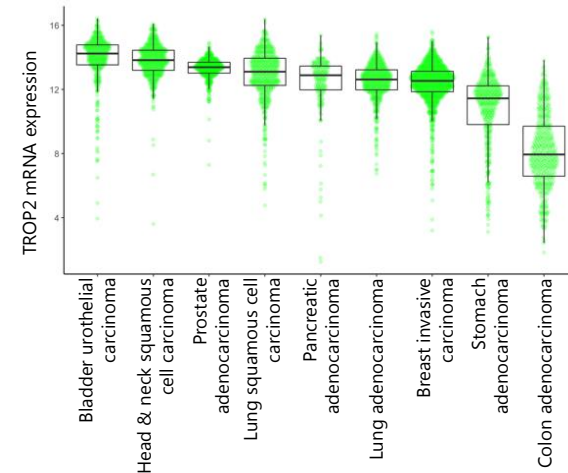
Breast Cancer

- **Initiated TNBC development**






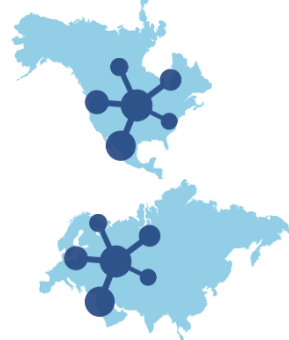
Other tumors

- **TROP2 is expressed in many different tumor types**



- ◆ Maximize the value of Enhertu is top priority
- ◆ Maximize the value of DS-1062 is next priority
- ◆ Goal is to leverage the strengths of and to maximize the value of both products

Daiichi Sankyo's Expertise and Organizational Strength post DS-8201 Strategic Collaboration

	Japan	US/Europe
Development	<p>Enhanced oncology pipeline</p> <p>▼</p> <p>Enhancement of expertise in oncology</p> 	<p>Enhanced oncology pipeline</p> <p>▼</p> <p>Acquisition of strong talent in oncology</p> 
Commercial	<p>Launch of Vanflyta and Enhertu</p> <p>▼</p> <p>Enhancement of commercial strength in oncology</p> 	<p>Launch of Turalio and Enhertu in US</p> <p>▼</p> <p>Commercial organization for oncology operational</p> 

- ◆ Our expertise and organizational strength for oncology advanced rapidly, and we have an option to develop DS-1062 in-house
- ◆ Also, we have an option to solely commercialize DS-1062 in JP/US/EU

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Internal Change

U3-1402

Lung cancer

Ph1 study progressing smoothly; plan to present updated data at ESMO in Sep. 2020

Breast cancer

Ph1 study enrollment completed; plan to present results at SABCS in Dec. 2020

DS-7300/DS-6157

Ph1

DS-7300 (anti-B7-H3 ADC)

Enrollment underway reaching 10 different tumor types to date

Ph1

DS-6157 (anti-GPR20 ADC)

Enrollment progressing for GIST

DS-6000/DS-3939

Pre-Clin

DS-6000 (target undisclosed)

Preparing for clinical trial initiation

Pre-Clin

DS-3939 (anti-TA-MUC1 ADC)

Preparing for clinical trial initiation



Other Alpha Projects

Ph1

Nucleic acid

DMD pipeline being enriched

Discovery

Gene therapy

In-house manufacturing of investigational products under preparation



◆ Due to **significant potential for DXd-ADC/Alpha portfolio**, it is critical to be able to **allocate resources rapidly with flexibility when needed**

Launch of TROP2 ADC



Sacituzumab govitecan launched in US in Apr. 2020

- ◆ TROP2 ADC concept validated
- ◆ First indication is TNBC
- ◆ In addition, **multiple monotherapy/combination therapy clinical trials are under way** for HR+/ HER2- breast cancer, urothelial cancer, NSCLC, ovarian cancer, H&N cancer, SCLC, hepatocellular carcinoma, and endometrial cancer

◆ **To maximize the value of DS-1062, acceleration of ongoing/ planned clinical trials and expansion of tumor types is critical**

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Significance of DS-1062 Strategic Collaboration

Challenge1: DXd-ADC/Alpha

Significant potential



**Optimization of resource allocation
across the portfolio necessary**

Challenge2: TROP2 ADC Launch

Competition



**Acceleration of lung studies and
expansion of tumor types critical**



Strategic collaboration




Why AstraZeneca?

Leading company in lung cancer



- ◆ Extensive experience and expertise through IRESSA, TAGRISSO and IMFINZI
- ◆ Collaboration enables **acceleration and expansion of development**

Tyrosine kinase inhibitor
 **TAGRISSO**[®]
osimertinib

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

2019 actual
\$3,189M*
\$1,469M*

* Source: AstraZeneca's financial results announcement material

Maximizing w/o conflict with DS-8201

- ◆ Both products could be maximized by optimizing overall resources throughout the lifecycle (e.g. resources for development, manufacturing, commercial)
- ◆ Enables efficient development and commercial activities



Trustful relationship through multiple alliance

- ◆ Strong relationship and trust has been established through multiple alliance
- ◆ Able to further develop DS-1062 with reliable collaborator



- ◆ **Maximize the value of DS-1062 through sharing resources and risks with a very reliable collaborator**

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Collaboration with AstraZeneca

Overview

- ◆ **Co-development and co-commercialization** of TROP2 ADC **DS-1062**

Territory



Global

Term



From signing throughout the commercial life of DS-1062

Governance

- ◆ Strategies are planned and implemented based on mutual agreement through the **governance structure similar to DS-8201**



Development

- ◆ **Co-development** as monotherapy and combination therapy



Lung Cancer



Breast Cancer



Other cancers

- ◆ **Equally share** development costs
- ◆ Combination studies with other companies' products possible

Commercial

- ◆ **Global (excluding Japan):**
The companies will co-promote and **share profits**
- ◆ **Japan:**
Daiichi Sankyo will solely commercialize and **pay royalty** to AstraZeneca
- ◆ **Sales booking**
 - **Daiichi Sankyo:**
Japan, US, certain countries in Europe and other markets with subsidiaries
 - **AstraZeneca:**
All other markets including China, Australia, Canada and Russia

Manufacturing

- ◆ Daiichi Sankyo will manufacture DS-1062



Up to US\$6.0 Bn (JPY660.0 Bn) in total

(US\$1=JPY110)

Upfront payment

**US\$1.0 Bn
(JPY110.0 Bn)**

- ◆ Received through three separate payments; 1) upon contract execution; 2) 12 months after execution; 3) 24 months after execution
- ◆ **Deferred and will be booked as revenue** considering the exclusivity period

Regulatory milestones (maximum)

**US\$1.0 Bn
(JPY110.0 Bn)**

- ◆ Regulatory milestones will be received **at approval of relevant cancer type and indication**
- ◆ **Deferred and will be booked as revenue** considering the exclusivity period

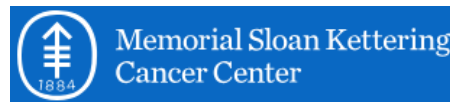
Sales-related milestones (maximum)

**US\$4.0 Bn
(JPY440.0 Bn)**

- ◆ Will be **booked as revenue in the year of achievement**

Towards 2025 and Beyond

Daiichi Sankyo will maximize our pipeline and corporate values through various alliances



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Q&A



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