

Passion for Innovation.
Compassion for Patients.™



HER3-DXd, I-DXd (DS-7300), R-DXd (DS-6000)

Strategic Collaboration with Merck & Co., Inc., Rahway, NJ, USA

DAIICHI SANKYO CO., LTD.

Sunao Manabe

Representative Director, Executive Chairperson & CEO

October 20, 2023

Forward-Looking Statements

Management strategies and plans, financial forecasts, future projections and policies, and R&D information that Daiichi Sankyo discloses in this material are all classified as Daiichi Sankyo's future prospects. These forward-looking statements were determined by Daiichi Sankyo based on information obtained as of today with certain assumptions, premises and future forecasts, and thus, there are various inherent risks as well as uncertainties involved. As such, please note that actual results of Daiichi Sankyo may diverge materially from Daiichi Sankyo's outlook or the content of this material. Furthermore, there is no assurance that any forward-looking statements in this material will be realized. Regardless of the actual results or facts, Daiichi Sankyo is not obliged and does not have in its policy the duty to update the content of this material from the date of this material onward.

Some of the compounds under discussion are investigational agents and are not approved by the FDA or any other regulatory agency worldwide as a treatment for indications under investigation. Efficacy and safety have not been established in areas under investigation. There are no guarantee that these compounds will become commercially available in indications under investigation.

Daiichi Sankyo takes reasonable care to ensure the accuracy of the content of this material, but shall not be obliged to guarantee the absolute accuracy, appropriateness, completeness and feasibility, etc. of the information described in this material. Furthermore, any information regarding companies, organizations or any other matters outside the Daiichi Sankyo Group that is described within this material has been compiled or cited using publicly available information or other information, and Daiichi Sankyo has not performed in-house inspection of the accuracy, appropriateness, completeness and feasibility, etc. of such information, and does not guarantee the accuracy thereof.

The information described in this material may be changed hereafter without notice. Accordingly, this material or the information described herein should be used at your own judgment, together with any other information you may otherwise obtain.

This material does not constitute a solicitation of application to acquire or an offer to sell any security in the United States, Japan or elsewhere.

This material disclosed here is for reference purposes only. Final investment decisions should be made at your own discretion.

Daiichi Sankyo assumes no responsibility for any damages resulting from the use of this material or its content, including without limitation damages related to the use of erroneous information.

Agenda

1 **Background/Significance of the Collaboration**

2 Overview of the Collaboration

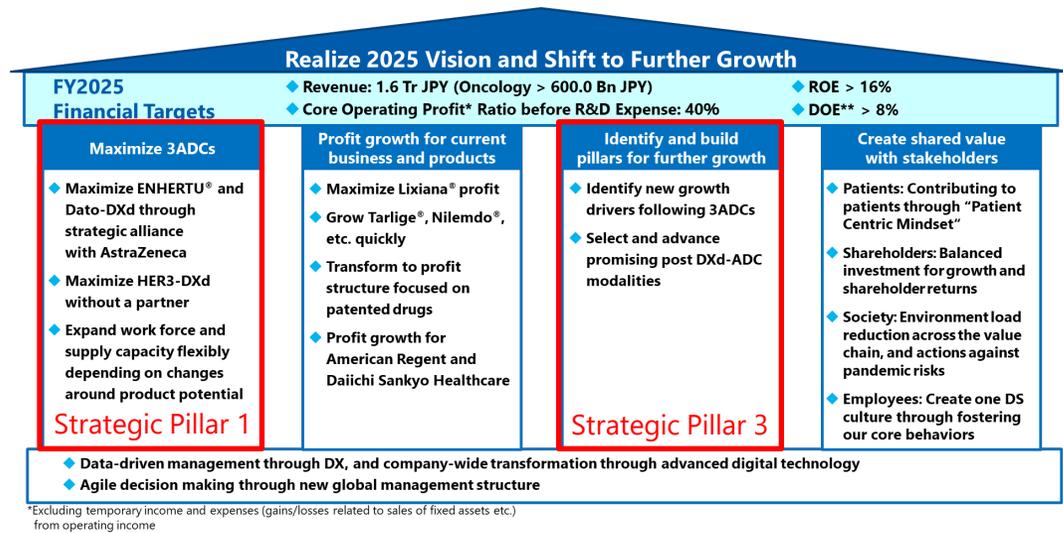
3 Q&A



Daiichi Sankyo's Oncology Business Growth Strategy

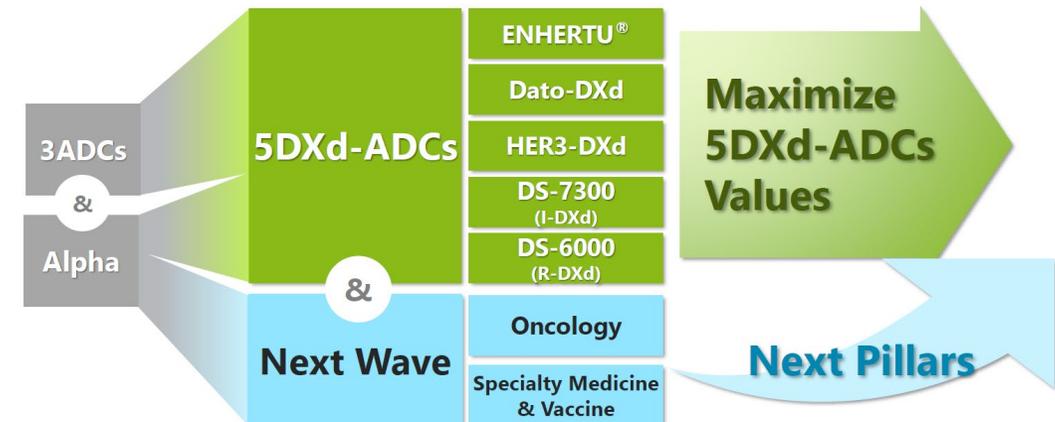
5-Year Business Plan (FY2021–FY2025) -Announced in April 2021-

- ◆ Strategic Pillar1: Maximize 3ADCs
- ◆ Strategic Pillar3: Identify and build pillars for further growth
 - Identify new growth drivers following 3ADCs
 - Select and advance promising post DXd-ADC modalities



5-Year Business Plan (FY2021–FY2025) Update -as of April 2023-

- ◆ Oncology revenue in FY2025: Expect to achieve **900.0 Bn JPY or more (150% of plan)**
- ◆ **Development of 3ADCs ahead of plan**
- ◆ **Emerging** new growth driver candidates following 3ADCs (**Rising Stars**)
- ◆ New R&D strategy "**5DXd-ADCs and Next Wave**"
- ◆ **R&D expenses** during the 5YBP: Aggressive investment of approximately **1.8 Tn JPY (120% of plan)**



Environmental Changes since April 2023

Internal environment: Further positive progress for DXd-ADC franchise

◆ HER3-DXd

➤ Success of HL-01 study

Started planning for further maximization

◆ I-DXd (DS-7300)

➤ Latest data announcement at WCLC/ESMO 2023

Started to discuss development plans further

◆ R-DXd (DS-6000)

➤ Latest data announcement at ESMO 2023

Started to discuss development plans further

◆ ENHERTU®

➤ Success of DPT-02 study

Expanding to various HER2-expressing solid tumors

◆ Dato-DXd

➤ Successes of TL-01/TB-01 studies

Started planning for further maximization

◆ DS-3939 (anti TA-MUC1 ADC)

➤ Initiated Ph1/2 trial

Another clinical stage ADC in the pipeline

External environment: Intensifying competitive pressure in ADC development

◆ Numerous oncology companies are focusing on ADC development

➤ ADC data gained significant attention at ASCO 2023 and WCLC 2023

Enhanced capacity, resources and capabilities have become necessary to maximize DXd-ADC franchise

Why a Strategic Collaboration?

Our Mission	Purpose	Contribute to the enrichment of quality of life around the world
	Mission	Create innovative pharmaceuticals addressing diverse medical needs

Internal/external environmental changes

Enhanced capacity, resources and capabilities have become necessary to maximize DXd-ADC franchise



Strategic collaboration will help us deliver on the promise of our next three DXd-ADCs by potentially enabling us to reach more patients more quickly than we could on our own

What We Aim to Achieve through Strategic Collaboration

Leverage collaborator's capacity, resources and capabilities

- ◆ Develop **more aggressive development plans** targeting **broader patient populations**
- ◆ **Accelerate development timelines** and **mitigate risk of delays**
- ◆ Gain opportunity to **contribute to patients in more countries/regions**

Further expand resources to create favorable cycle for sustainable growth

- ◆ **Optimal resource allocation** for new growth drivers following 5DXd-ADCs, post DXd-ADC modalities, etc.
 - DS-3939 (TA-MUC1 directed ADC), DS-XXXX (7th DXd-ADC)
 - DS-9606 (2nd generation ADC), New concept ADC, etc.
 - Early stage research projects

Create more corporate and product value through strategic collaboration

Why Merck & Co., Inc., Rahway, NJ, USA?

A world-leading oncology company with KEYTRUDA® as a foundation

- ◆ **Remarkable experience** in oncology, **proven expertise** in immuno-oncology
- ◆ **Strong capabilities and capacity, resources** in development
- ◆ Oncology business in **numerous countries/regions and tumor types**

KEYTRUDA[®]
(pembrolizumab) Injection 100 mg

A collaborator that is best-positioned to help us in our goal of establishing new standards of care across multiple tumor types

Extensive experience with strategic collaboration

A collaborator with **multiple successful global strategic collaborations**, gives us the highest probability **to achieve our goals**

High valuation and commitment for success

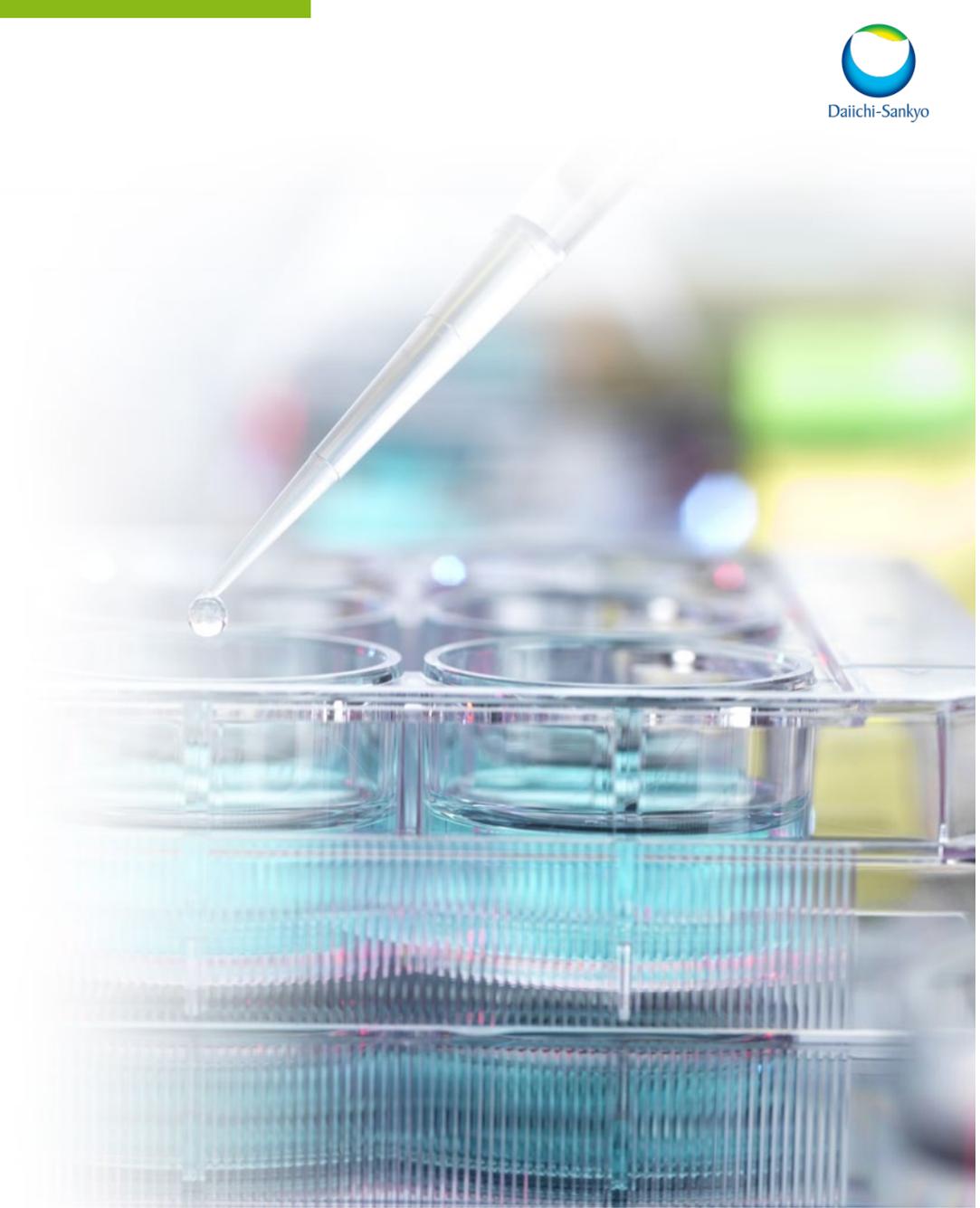
A collaborator with **highest valuation for 3 products (HER3-DXd, I-DXd and R-DXd)**, and **commitment for success** among the companies that expressed interest

Agenda

1 Background/Significance of the Collaboration

2 Overview of the Collaboration

3 Q&A



Collaboration with Merck & Co., Inc., Rahway, NJ, USA (MRK)

Overview

- ◆ **Co-development and co-commercialization of HER3-DXd, I-DXd (DS-7300), R-DXd (DS-6000)**

Territory: **Global** (excluding Japan)



Governance

- ◆ **Development and commercialization strategies** will be planned and implemented based on **mutual agreement**

Strategic Collaboration Overview

Development

- ◆ **Co-development** as monotherapy and combination therapy for **HER3-DXd**, **I-DXd (DS-7300)**, **R-DXd (DS-6000)**



- ◆ **MRK** will be responsible for **75%** of **the first 2 Bn USD** of R&D expenses for each product, and the companies will share R&D expenses **equally thereafter**

Manufacturing

- ◆ **Daiichi Sankyo** will **manufacture** and **supply** all 3 products

Commercial

- ◆ **Global (excluding Japan):**
The companies will **co-promote** and **share gross profit** and **promotional expenses etc.**
- ◆ **Japan:**
Daiichi Sankyo will **solely commercialize** and **pay royalty** to MRK
- ◆ **Sales booking**
Daiichi Sankyo will book product sales in **all countries/regions where Daiichi Sankyo has local operations (including Japan)**

Financial Terms for Strategic Collaboration

Up to 22.0 Bn USD (3,300.0 Bn JPY) in total

(1USD=150JPY)

Upfront payments **4.5 Bn USD (675.0 Bn JPY)** : 1.5 Bn USD×3 products

	HER3-DXd	I-DXd (DS-7300)	R-DXd (DS-6000)	Total
Upon contract execution	0.75 Bn USD	1.5 Bn USD	0.75 Bn USD	3.0 Bn USD
12 months after execution	0.75 Bn USD	-	-	0.75 Bn USD
24 months after execution	-	-	0.75 Bn USD	0.75 Bn USD
Total	1.5 Bn USD	1.5 Bn USD	1.5 Bn USD	4.5 Bn USD

MRK may elect not to pay the two upfront payments of 0.75 Bn USD each that are due after 12 months and after 24 months, respectively. If MRK opts out of HER3-DXd and/or R-DXd, the upfront payments already paid will be retained by DS and rights related to such products will be returned to DS

- ◆ Received upfront payments **will be deferred and booked as revenue** considering the estimated exclusivity period

R&D expenses related refundable upfront payments **1.0 Bn USD (150.0 Bn JPY)** : 0.5 Bn USD×2 products (HER3-DXd,I-DXd)

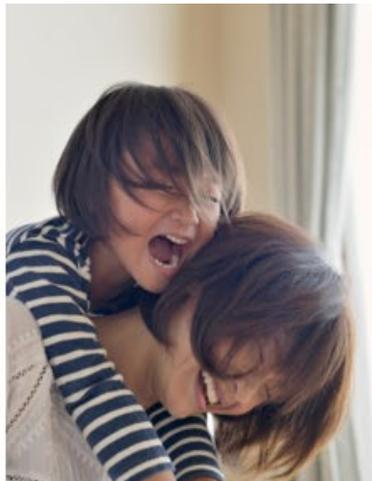
- ◆ MRK will be responsible for 75% of the first 2 Bn USD of R&D expenses for each product (MRK to bear 0.5 Bn USD more than DS compared to equal share)
 - ✓ 0.5 Bn USD for HER3-DXd and I-DXd, respectively to be paid upon contract execution as R&D expenses related refundable upfront payments (Pro-rated portion may be refundable in the event of early termination of development for both products).
As for R-DXd, 75% of R&D expenses will be paid by MRK as they are incurred
 - ✓ **Accounting treatment is not yet determined**

Sales milestones **Up to 16.5 Bn USD (2,475.0 Bn JPY)** : Up to 5.5 Bn USD×3 products

- ◆ Received sales milestones **will be booked as revenue in the year of achievement**



Daiichi Sankyo will contribute to the enrichment of quality of life around the world



Agenda

1 Background/Significance of the Collaboration

2 Overview of the Collaboration

3 **Q&A**



Q&A



Contact address regarding this material

Daiichi Sankyo Co., Ltd.

Corporate Communications Department

TEL: +81-3-6225-1125

Email: DaiichiSankyoIR@daiichisankyo.co.jp