Passion for Innovation. Compassion for Patients.™



## The 5<sup>th</sup> 5-year Business Plan Update

### **Excerpt from Top Management Presentation, Financial Results of FY2022 Q4 on April 27th**, 2023

### **Strategic Pillars for the 5-Year Business Plan (FY2021-FY2025)**



	Realize 2025 Vision and	Shift to Further Growt	th
FY2025 Financial Targets	<ul> <li>Revenue: 1.6 Tr JPY (Oncology &gt; 600.0 Bn JPY)</li> <li>Core Operating Profit* Ratio before R&amp;D Expense: 40%</li> <li>DOE** &gt; 8%</li> </ul>		
Maximize 3ADCs	Profit growth for current business and products	Identify and build pillars for further growth	Create shared value with stakeholders
<ul> <li>Maximize ENHERTU<sup>®</sup> and Dato-DXd through strategic alliance with AstraZeneca</li> <li>Maximize HER3-DXd without a partner</li> <li>Expand work force and supply capacity flexibly depending on changes around product potential</li> </ul>	<ul> <li>Maximize Lixiana<sup>®</sup> profit</li> <li>Grow Tarlige<sup>®</sup>, Nilemdo<sup>®</sup>, etc. quickly</li> <li>Transform to profit structure focused on patented drugs</li> <li>Profit growth for American Regent and Daiichi Sankyo Healthcare</li> </ul>	<ul> <li>Identify new growth drivers following 3ADCs</li> <li>Select and advance promising post DXd-ADC modalities</li> </ul>	<ul> <li>Patients: Contributing to patients through "Patient Centric Mindset"</li> <li>Shareholders: Balanced investment for growth and shareholder returns</li> <li>Society: Environment load reduction across the value chain, and actions against pandemic risks</li> <li>Employees: Create one DS culture through fostering our core behaviors</li> </ul>

Data-driven management through DX, and company-wide transformation through advanced digital technology

Agile decision making through new global management structure

\*Excluding temporary income and expenses (gains/losses related to sales of fixed assets etc.) \*\*DOE: Dividend on Equity = Total dividend amount / Equity attributable to owners of the company from operating income

### **5-Year Business Plan: Progress in FY2021-FY2022**



#### Maximize 3ADCs

- Maximize product value of ENHERTU<sup>®</sup>
  - > Approval of new indication
    - HER2+ BC 2L (DB-03)
       HER2 low BC post-chemo (DB-04)
       HER2 mutant NSCLC 2L+ (DL-01, DL-02)

#### Sales growth in each country/ region

 Sales expansion exceeding initial plan based on the results of DB-03 and DB-04

#### Progress of LCM

HER2+ BC 1L (DB-09)
 HER2+ BC neoadjuvant (DB-11)
 HER2 low BC chemo naïve (DB-06) etc.

#### Maximize product values of Dato-DXd and HER3-DXd

#### Progress of pivotal study for launch

- Dato-DXd : NSCLC 2L+ (TL-01)
- HER3-DXd : EGFR mutated NSCLC 3L (HL-01)

#### Initiation of new Ph3 studies

- Dato-DXd : NSCLC (without actionable genomic alteration) 1L (TL-07 and TL-08) etc.
- HER3-DXd : EGFR mutated NSCLC 2L (HL-02)

#### **Profit growth for current business and products**

#### Growth of current products

- Steady sales expansion of Lixiana<sup>®</sup>
  - Increase product value with additional dosage and administration (Prevention for stroke and systemic embolism in elderly patients with non-valvular atrial fibrillation and high bleeding risk: ELDERCARE-AF study)

#### Sales increase of current products in each countries/ regions

- Tarlige<sup>®</sup>, Injectafer<sup>®</sup>, Venofer<sup>®</sup>, Nilemdo<sup>®</sup>/Nustendi<sup>®</sup> etc.
- Increase product values of current products by additional indication/ formulation
- Transformation of business structure focused on patented drugs
  - Launch of new drug
    - Emgality<sub>®</sub>, Reyvow<sup>®</sup>, Ezharmia<sup>®</sup> etc.
  - Progress of product divesture after loss of exclusivity in each country/region

### **5-Year Business Plan: Progress in FY2021-FY2022**



### Identify and build pillars for further growth

- Emerging candidates for new growth driver (Rising Stars) following 3ADCs
  - Progress of development for DS-7300 (B7-H3directed ADC)
    - Obtained interim analysis data which showed early efficacy signals in multiple cancer types (SCLC, CRPC, ESCC, sqNSCLC)
    - Started new Ph2 study for ES-SCLC 2L+
  - Progress of development for DS-6000 (CDH6-directed ADC)
    - Obtained interim analysis data which showed early efficacy signals in multiple cancer types (OVC, RCC)
- Advancement to select post DXd-ADC modalities
  - Started clinical study for the next generation ADC, DS-9606

CRPC: castration-resistant prostate cancer, ESCC: esophageal squamous cell carcinoma, ES-SCLC: extensive-stage small cell lung cancer, NSCLC: non-small cell lung cancer, OVC: ovarian cancer, RCC: renal cell carcinoma, SCLC: small cell lung cancer, sqNSCLC: squamous non-small cell lung cancer,

#### **Create shared value with stakeholders**

- Strengthening shareholder returns
  - Increase dividend with profit growth
    - Increase FY2022 annual dividend per share from 27 JPY to 30 JPY
- Actions against pandemic risks
  - Regulatory submission for DS-5670 (COVID-19 mRNA vaccine)
    - Regulatory submission for original strain booster vaccination
- Environment load reduction across the value chain
  - Progress initiative for environmental issues
    - Joined RE100, a global initiative aiming to use 100% renewable energy for electricity consumed in business activities
    - Converted electricity consumed in bases in Japan to renewable energy
- Penetration of Core Behavior for fostering one DS culture
  - Further understanding of three Core Behaviors through workshop by management and employees

### **Expectation on achieving FY2025 KPIs** (as of 2023 Apr.)





### Expectation on Oncology Revenue (as of 2023 Apr.)



With the revenue growth of ENHERTU<sup>®</sup> and Dato-DXd, and progress of 3ADC development exceeding initial plan, oncology revenue\* in FY2025 is estimated > 900.0 Bn JPY



\*Revenue includes alliance revenue (50% of gross profit in countries/regions where AZ books revenue ) upfront/Quid payment, development/sales milestones etc. for ENHERTU<sup>®</sup> and Dato-DXd

**Profit Share Increase for ENHERTU® and Dato-DXd** 



Along with the growth of product sales of ENHERTU<sup>®</sup> and Dato-DXd, SG&A expenses increase with profit share\* based on the strategic alliance with AZ



\*For splitting profit of product sales, DS pays AZ 50% of gross profit in countries/regions where DS books revenue excluding Japan.

### **3ADC launch plan**



# Proactive investment in R&D, based on the exceeded progress in 3ADCs clinical development

FY2026 & Beyond

#### **ENHERTU**®

DESTINY-Breast05

- Combo with DS internal asset,
   I/O or targeted therapy in
   BC and NSCLC
- Other cancer types

#### Dato-DXd

TROPION-Lung07

**TROPION-Breast03** 

- Combo with I/O in BC and NSCLC
- Other cancer types

#### HER3-DXd

- Combo with targeted therapy in NSCLC
- Other cancer types

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A study approved the indication during 5-Year Business Plan

A study accelerated to expect an approval during 5-Year Business Plan (including a new study)

Major study only (ref., appendices)

Timeline indicated is based on the current forecast and subject to change.

### From "3 and Alpha" to "5DXd-ADCs and Next Wave"





### Well-balanced Investment for Growth and Shareholder Returns **Cash Allocation**



#### **Increase R&D expense and CAPEX for further growth in future**



#### Image for cash allocation

approx.

### **Expectation on achieving FY2025 KPIs** (as of 2023 Apr.)





FY2025 Currency rate assumptions: 1 USD=130 JPY, 1 EUR=140 JPY

\*Excluding temporary income and expenses (gains/losses related to sales of fixed assets etc.) from operating income