

Passion for Innovation.
Compassion for Patients.™



ENHERTU[®] Business Briefing

DAIICHI SANKYO CO., LTD.

Sunao Manabe
President and CEO

March 15, 2023

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5-Year Business Plan (FY2021-FY2025) for Sustainable Growth

We will achieve our 2025 Goal, **Global Pharma Innovator with Competitive Advantage in Oncology**, and will shift to further growth towards our 2030 Vision

2030 Vision

Innovative Global Healthcare Company Contributing to the Sustainable Development of Society

5-Year Business Plan (FY2021-FY2025)

Achieve FY2025 Goal "Global Pharma Innovator with Competitive Advantage in Oncology" and shift to further growth

As of FY2020

- ◆ Oncology business launched
- ◆ Edoxaban growing
- ◆ Regional value being enhanced
- ◆ AZ strategic alliance
- ◆ Increased RD investment

- ◆ Global top 10 in Oncology
- ◆ Additional growth pillars being source of revenue and profit
- ◆ New products being source of profit in each business unit
- ◆ Contributing to sustainable development of society through our business

Achieve FY2025 Goal "Global Pharma Innovator with Competitive Advantage in Oncology" and Shift to Further Growth

Maximize 3ADCs

- ◆ Maximize ENHERTU® and Dato-DXd through strategic alliance with AstraZeneca
- ◆ Maximize HER3-DXd without a partner
- ◆ Expand work force and supply capacity flexibly depending on changes around product potential

Profit growth for current business and products

- ◆ Maximize Lixiana® profit
- ◆ Grow Tarlige®, Nilemdo®, etc. quickly
- ◆ Transform to profit structure focused on patented drugs
- ◆ Profit growth for American Regent and Daiichi Sankyo Healthcare

Identify and build pillars for further growth

- ◆ Identify new growth drivers following 3ADCs
- ◆ Select and advance promising post DXd-ADC modalities

Create shared value with stakeholders

- ◆ Patients: Contributing to patients through "Patient Centric Mindset"
- ◆ Shareholders: Balanced investment for growth and shareholder returns
- ◆ Society: Environment load reduction across the value chain, and actions against pandemic risks
- ◆ Employees: Create one DS culture through fostering our core behaviors

- ◆ Data-driven management through DX, and company-wide transformation through advanced digital technology
- ◆ Agile decision making through new global management structure

Major Achievements in FY2022

Steady progress maximizing product value of ENHERTU® based on approval of new indications and strong market penetration

Transform the course of HER2+ BC

- Approved for **HER2+ BC 2L** in US based on DESTINY-Breast03 study which showed unparalleled improvement in PFS compared to T-DM1; started promotion in May 2022
- Established **leadership** in **HER2+ BC 2L** in US market
- **Expanding market to other areas and regions**

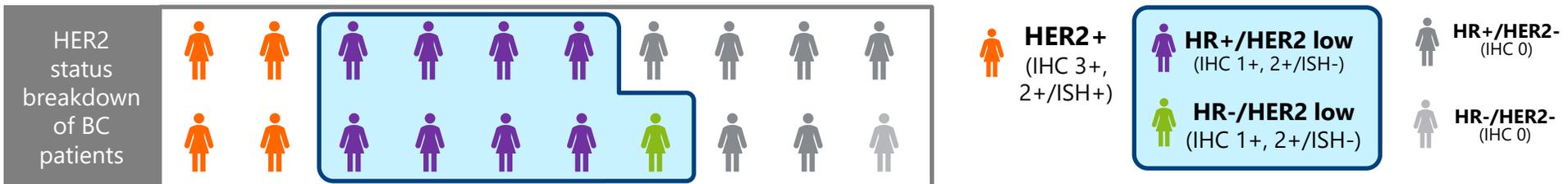
Pioneer HER2 low BC as a new clinically meaningful patient segment

- Approved for **HER2 low BC previously treated with chemotherapy** in US based on DESTINY-Breast04 study which showed potential to transform treatment for HER2 low patients; started promotion in August 2022
- **Rapid uptake and achieved No.1 new patient share** for HER2 low BC in US market
- **Accelerating market expansion to other areas and regions**

Expand leadership across other HER2 targetable tumors

- Approved for **HER2 mutant NSCLC 2L+** in US based on DESTINY-Lung01 and 02 study; started promotion in August 2022
- **Approval for the third cancer type following BC and GC**
- **Accelerating market expansion to other areas and regions**

Provide new treatment option for previously “un-targetable” HER2 low BC patients; approximately half of all BC patients



ENHERTU[®]

Business Briefing



Ken Keller

*Global Head, Oncology Business
President & CEO, Daiichi Sankyo, Inc.*

- Joined Daiichi Sankyo in 2014
- Revamped U.S. business structure to focus on multiple oncology launches including ENHERTU® as part of Daiichi Sankyo's 2025 Goal
- More than 30 years of experience in the pharmaceutical industry including 22 years at Amgen
- Held senior regional and global leadership roles supporting major biologics including Aranesp, Enbrel, Neulasta, Neupogen, Prolia, Vectibix, and Xgeva

Building Momentum



46 Countries/Regions

Robust commercial footprint
(including 29 countries/regions with
direct Daiichi Sankyo presence)



4 Indications

Across Breast, Lung and
Gastric cancer



Market Share

Achieved leading market share
in all indications (US)



> \$1B in Revenue

Delivered in CY 2022 with US
and EU leading the way



258% YOY

Accelerating momentum
throughout the globe and major
catalysts in place for 2023

Daiichi Sankyo OBU Leadership

- DS Oncology presence in 29 countries/regions
- In 28 of 29 countries/regions, DS co-promotes with AZ
- In Japan, DS has exclusive rights
- ~1,200 employees in OBU



Mary Pinder-Schenck, MD

*Vice President,
Head of Global Oncology
Medical Affairs*



Ken Keller

*President and CEO,
Daiichi Sankyo, Inc.

Global Head of
Oncology Business*



Dan Switzer

*Head of US Oncology
Business Division*



Nagatomo Hamahata

*Vice President,
Global Head of
Oncology Alliance
Management*



Rich Jones

*Vice President,
Global Oncology
Business Strategy
& Analysis*



Nadine Sprangers

*Vice President, Head
of Global Oncology
Market Access & Pricing*



Markus Kosch

*Head of EU Oncology
Business Division*



Kenji Shigeta

*Vice President,
Head of Global
Oncology Marketing*

* = EU areas/regions coverage: FR, DE, ES, IT, UK, Nordics (FI, NO, DK, SE), MSC (AT, CH, NL, BE, LUX, PT, TR, IE), CAN (opening April 1st, 2023); (AZ-led in Europe: GR, IS, PL, BU, CR, CZ, HU, RO, SI, Baltics, SK, RS)

Roadmap to Transforming HER2 Targetable Cancers

Establish Foundation

Achieve 3L HER2+ mBC and 2L/3L HER2+ mGC market leadership in all launch countries/regions



2020 - 2021

Build Market Leadership

Establish ENHERTU® as HER2 medicine of choice for 2L HER2+ mBC and become market leader worldwide

#1

2022

Redefine the HER2 Treatment Paradigm

Rethink HER2 targetable population with ENHERTU® efficacy in HER2 low mBC and *HER2* mutant NSCLC



2022 - 2023

Elevate Outcome Expectations

Push new boundaries with further development in neoadjuvant/adjuvant eBC, 1L mBC, combination strategies and other cancers

2024 +

Obtained 4 New Indications in US & EU in 2022

U.S. APPROVAL: MAY 2022



2L HER2+ Metastatic Breast Cancer

EU APPROVAL: JULY 2022

U.S. APPROVAL: AUG 2022



HER2 low Metastatic Breast Cancer

EU APPROVAL: JAN 2023

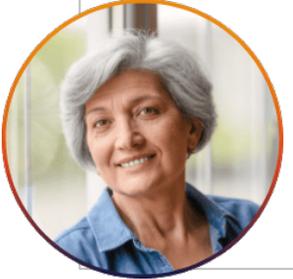
U.S. APPROVAL: JAN 2021



2L HER2+ Metastatic Gastric Cancer

EU APPROVAL: DEC 2022

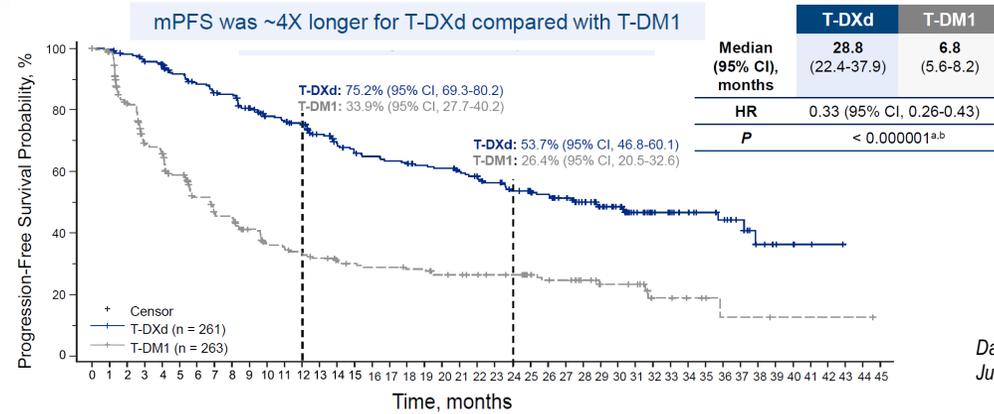
U.S. APPROVAL: AUG 2022



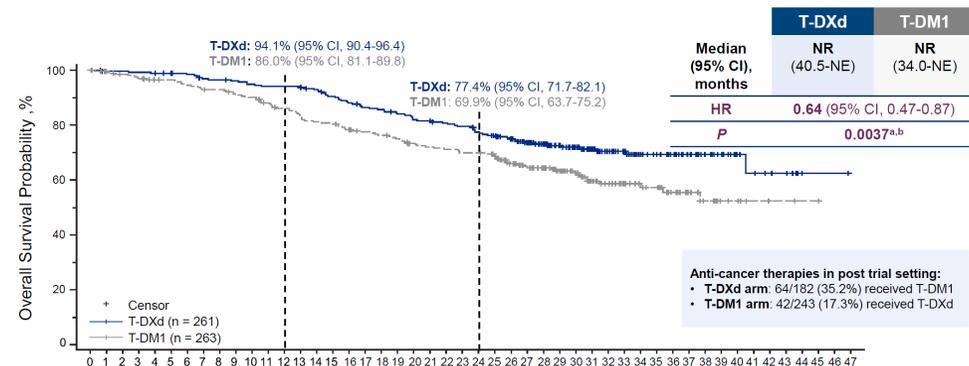
2L HER2 Mutant Metastatic Lung Cancer

ENHERTU® Has Quickly Become the New 2L HER2+ MBC Standard of Care in the U.S.

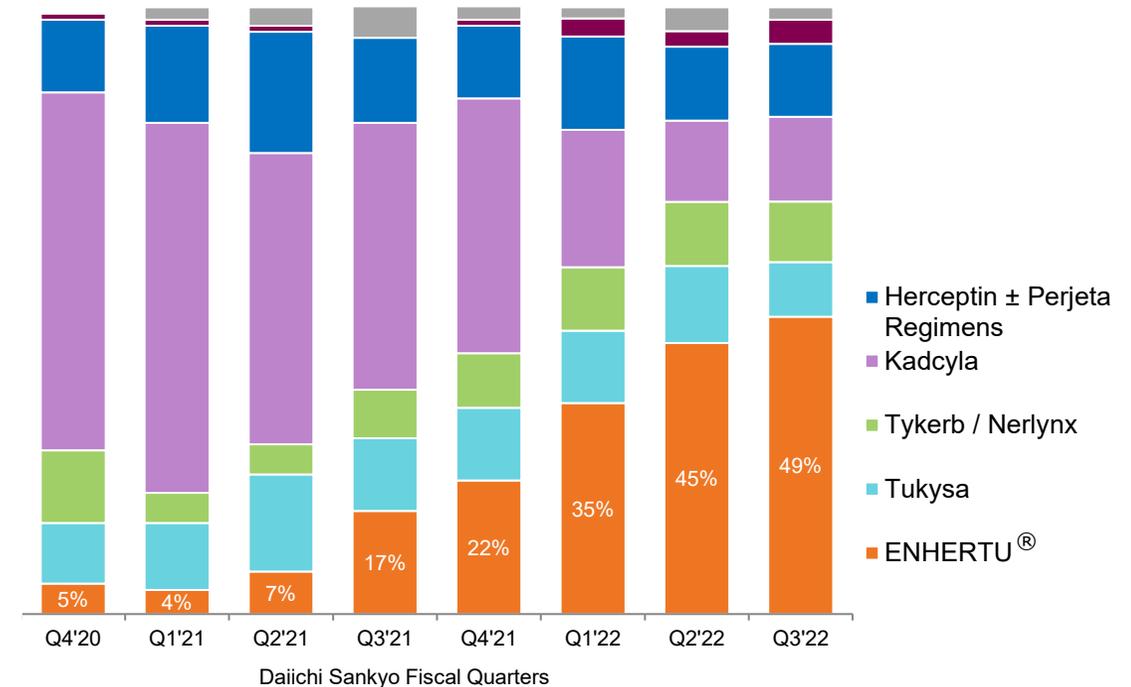
MPFS WITH T-DXd WAS 4 TIMES LONGER THAN WITH T-DM1



T-DXd SIGNIFICANTLY REDUCED THE RISK OF DEATH BY 36%



#1 NEW PATIENT SHARE IN 2L HER 2+ MBC



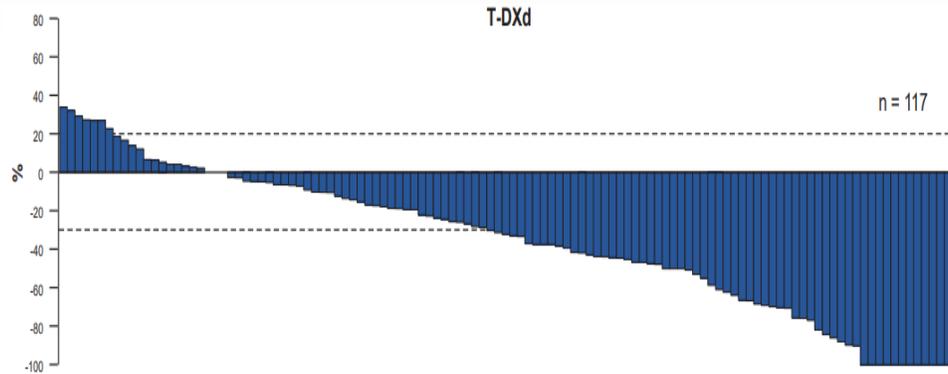
DESTINY-Breast03 data presented at SABCS 2022

BC: breast cancer, HR: hazard ratio, mPFS: median progression-free survival, NE: not estimable, NR: not reached, SABCS: San Antonio Breast Cancer Symposium, T-DM1: trastuzumab emtansine, T-DXd: trastuzumab deruxtecan

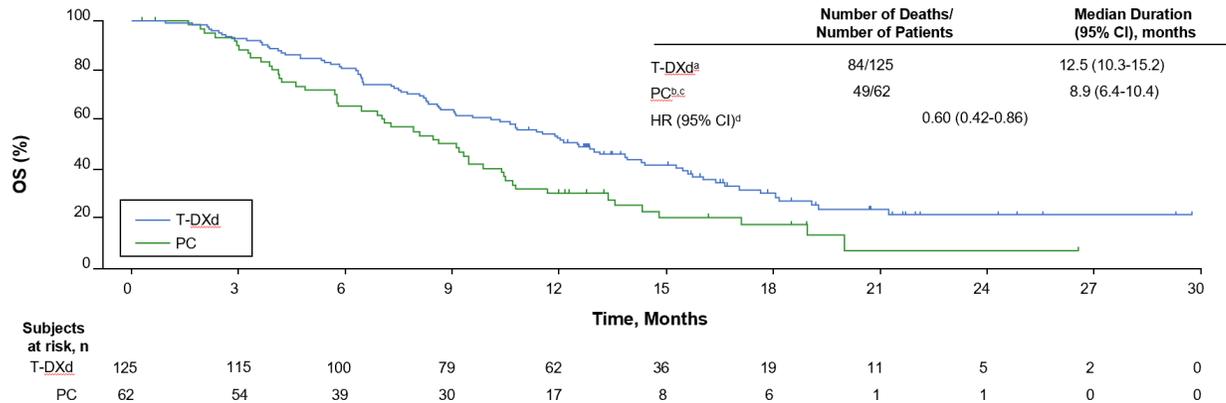
Market share data is based on internal research with limited sample size

ENHERTU® is the New 2L HER2+ Gastric Care Standard of Care in the U.S.

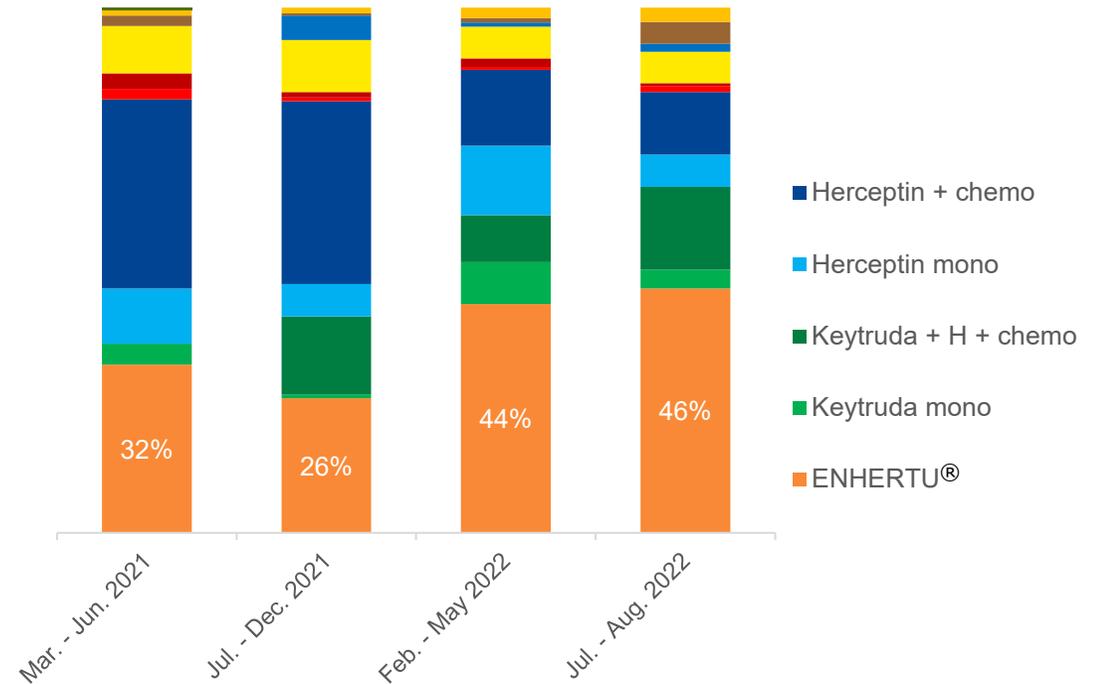
51.3% OVERALL RESPONSE RATE



T-DXD SIGNIFICANTLY REDUCED THE RISK OF DEATH BY 40%



#1 NEW PATIENT SHARE IN 2L HER 2+ GC

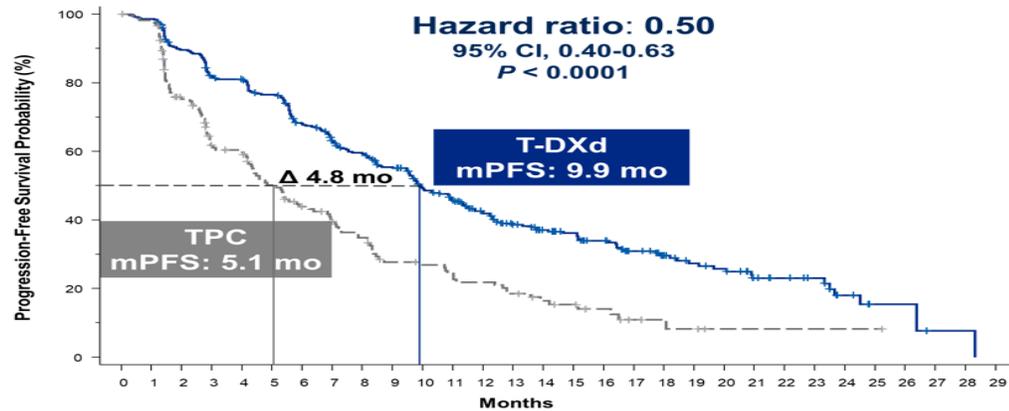


ENHERTU[®] Has Transformed the Treatment Landscape for MBC and is the New Standard of Care for HER2 low patients

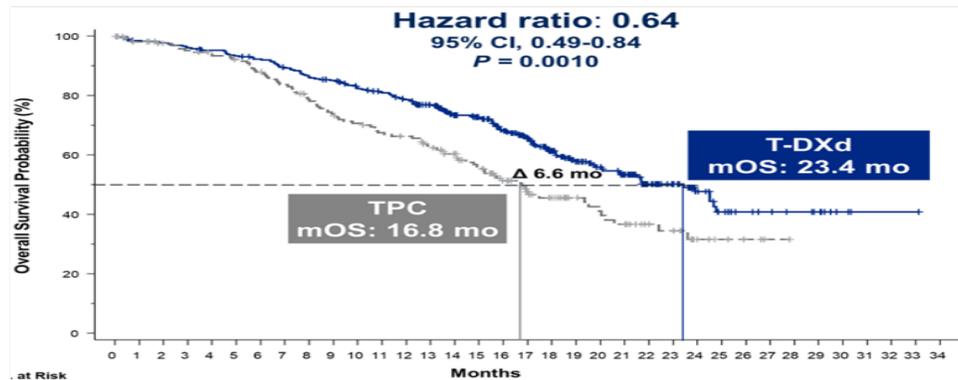
THE SPEED OF ADOPTION HAS ACCELERATED COMPARED TO EARLIER INDICATIONS



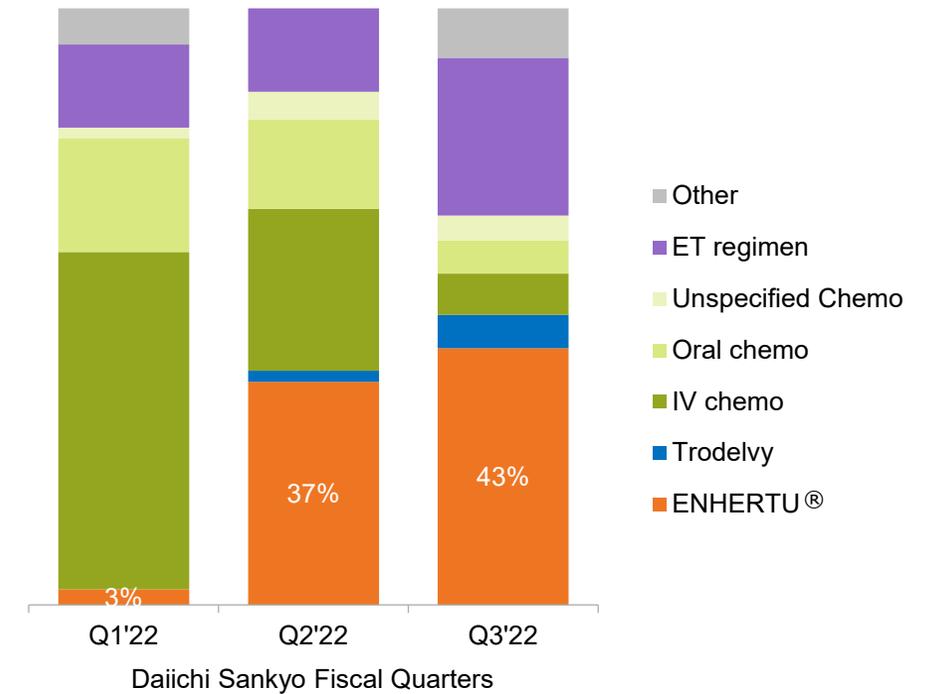
50% REDUCTION IN RISK OF PROGRESSION OR DEATH



36% REDUCTION IN RISK OF DEATH



#1 HR+ HER2 LOW MBC ENHERTU-NAÏVE POST-CHEMO SHARE

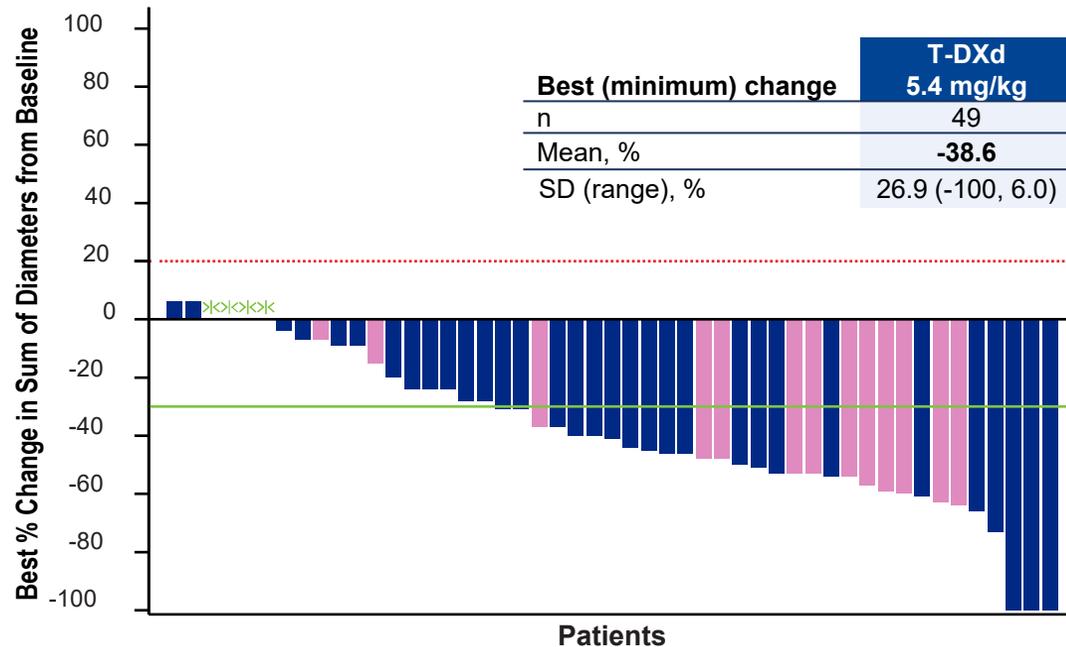


ENHERTU[®] is the 2L Standard of Care in HER2 Mutant Lung Cancer

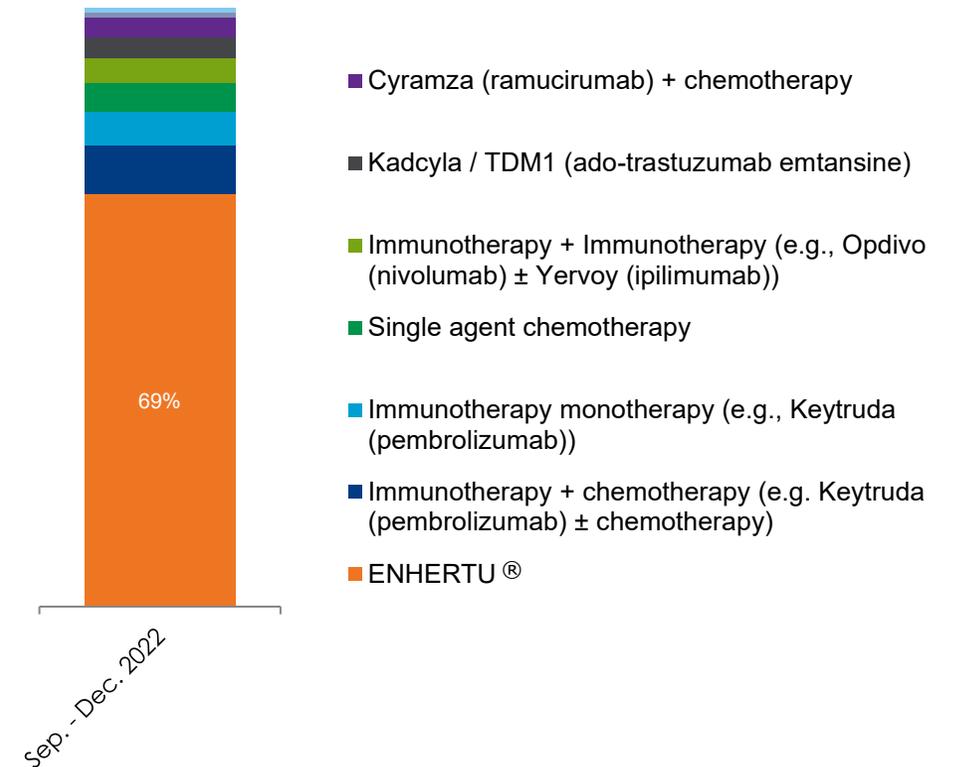
APPROVED IN US FOR HER2 MUTANT NSCLC 2L+ IN AUGUST

57.7 % ORR AND 8.7 MONTHS DURATION OF RESPONSE

- Both prior platinum therapy and PD-(L)1 therapy (n = 37)
- Prior platinum therapy but no PD-(L)1 therapy (n = 15)
- ✱ Patient with best percent change of zero

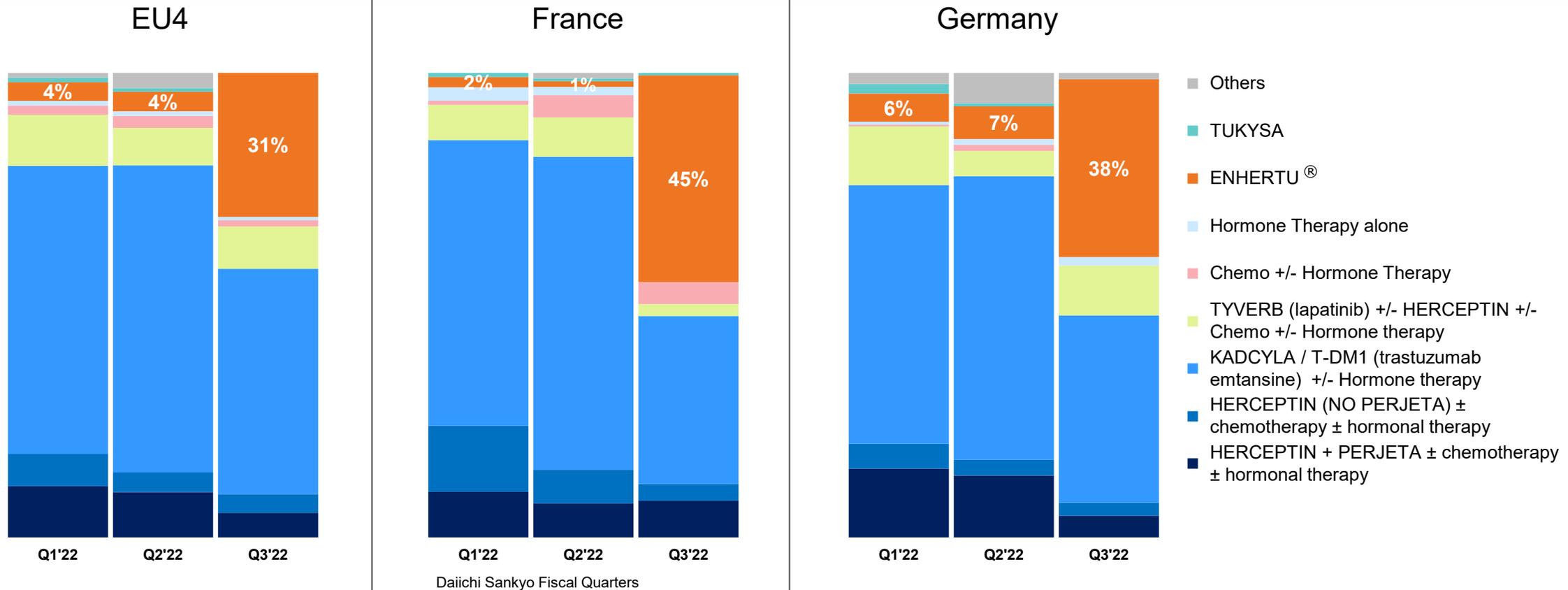


#1 NEW PATIENT SHARE IN 2L HER2+ NSCLC



In all EU Markets where ENHERTU® Became Available for 2L HER2+ mBC Patients, Treatment Initiation Grew Rapidly After Launch

HER2+ 2L Market Share Overview



Global Net Sales have Exceeded 60 Bn JPY Per Quarter

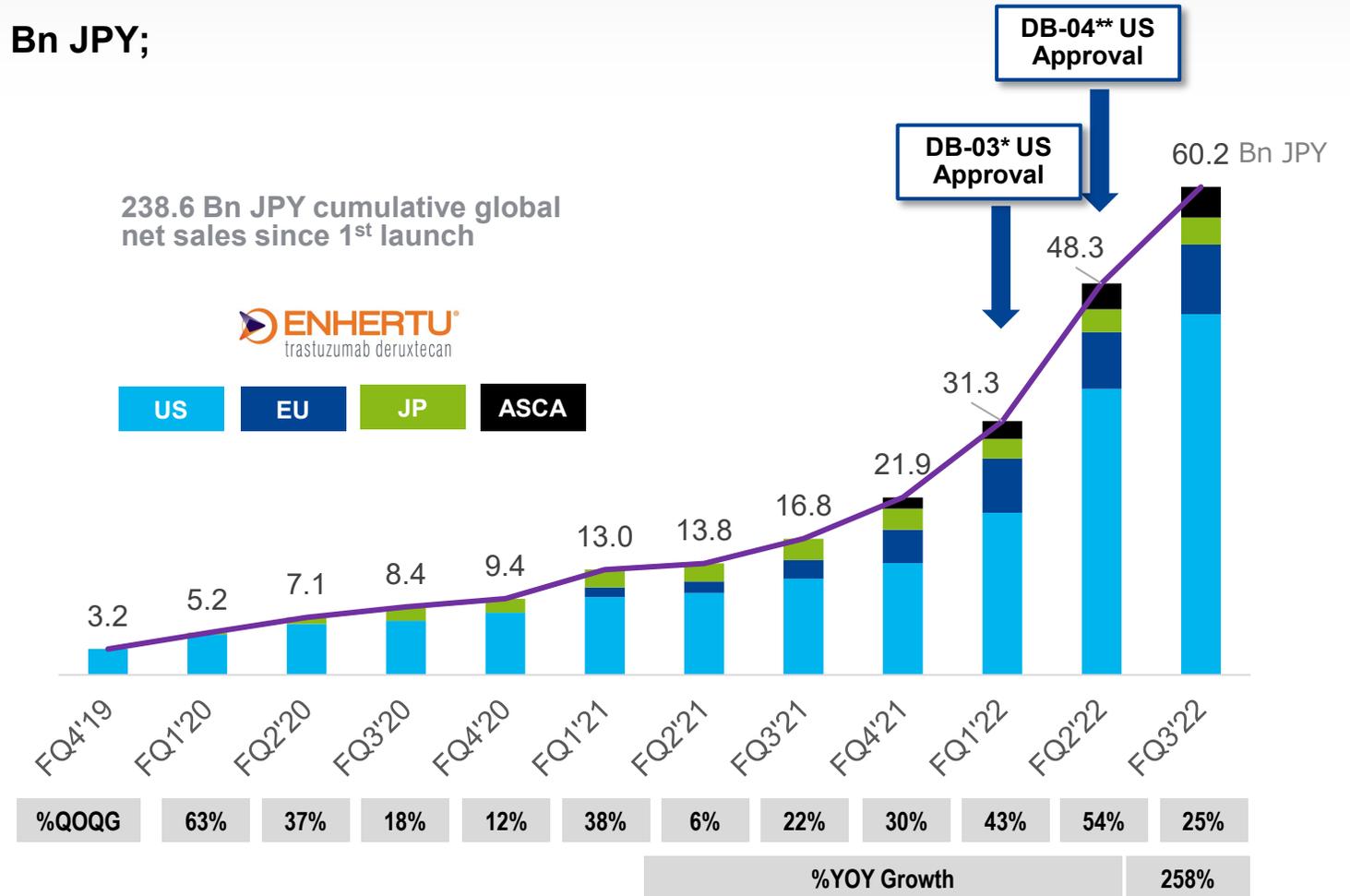
Overall, global net sales in FY2022 Q3 was 60.2 Bn JPY;
+ 25% sequential q-o-q growth driven by US

US

- In the US, FY2022 Q3: 44.5 Bn JPY
+26% vs. prior quarter;
+32.6 Bn JPY (+274%) vs. prior year

EU

- In the EU, FY2022 Q3 : 8.6 Bn JPY
+23% vs. prior quarter;
+6.3 Bn JPY (+274%) vs. prior year



* DB-03: 2L HER2+ Metastatic Breast Cancer, ** DB-04: HER2-low (post chemo) Metastatic Breast Cancer
q-o-q growth – quarter over quarter growth QOQ growth ; YOY growth – year over year growth

Utilization in HER2+ mBC and HER2 low Patients in the US are the Key Drivers of ENHERTU® Growth

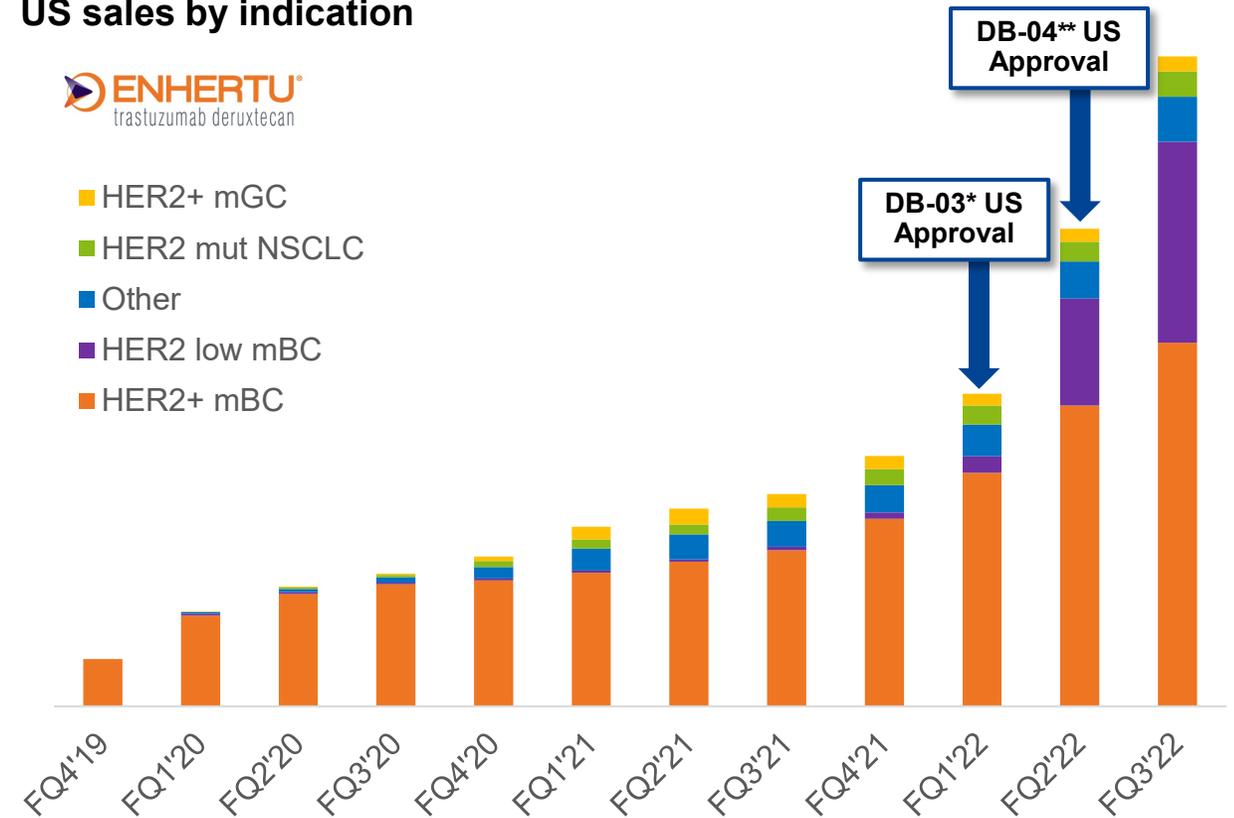
US

- q-o-q growth post DB-03 and DB-04 driven by HER2-low mBC
 - 3Q'22 q-o-q growth HR+ HER2-low mBC was 89.7%
 - 3Q'22 q-o-q growth HR- HER2-low mBC was 78.9%
- FY2022 Q3 YTD revenues for HER2-low mBC: \$149.7M
- Other areas of notable q-o-q growth (>20%) include HER2+ mBC and HER2 mut NSCLC

US sales by indication



- HER2+ mGC
- HER2 mut NSCLC
- Other
- HER2 low mBC
- HER2+ mBC



* DB-03: 2L HER2+ Metastatic Breast Cancer, ** DB-04: HER2-low (post chemo) Metastatic Breast Cancer
q-o-q growth – quarter over quarter growth 18

Success Can Be Attributed to Four Key Success Factors

BUILDING MOMENTUM AND CONFIDENCE

1

Standard of Care Clinical Data

Presentations in major meetings;
publications in leading journals; and
appropriate recognition in guidelines

ILD Awareness and Management

Education to physicians,
nurses, caregivers and patients
have increased confidence

2

3

HER2 low

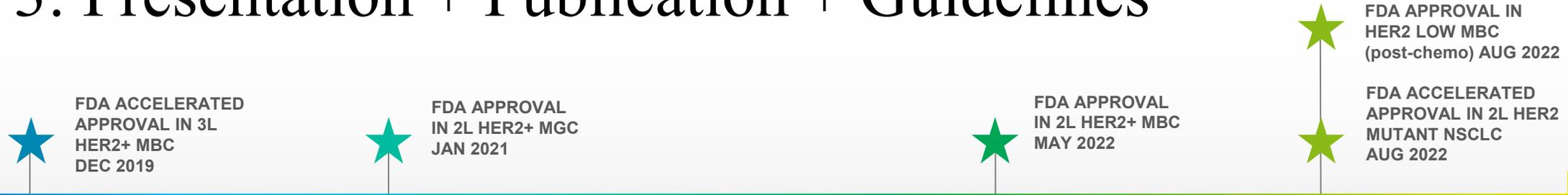
Raise awareness of
HER2 low as an identifiable
patient segment

Expectation of “More”

Clinical development program
yields enthusiasm for improving
outcomes in earlier disease
and other settings

4

Key 3: Presentation + Publication + Guidelines



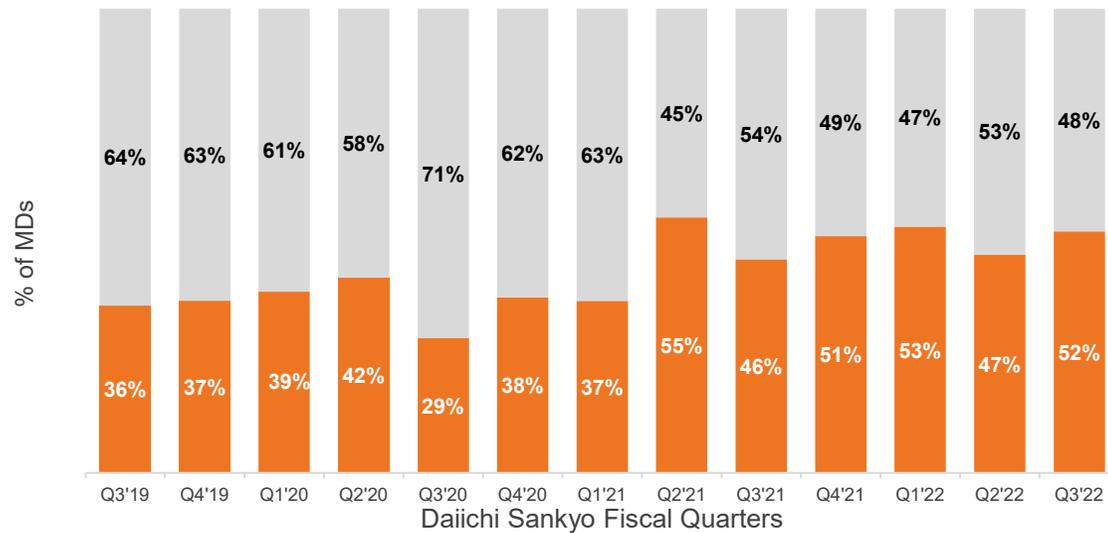
2019	2020	2021	2022	2022
<p>DEC 2019</p> <p>ORIGINAL ARTICLE</p> <p>Trastuzumab Deruxtecan in Previously Treated HER2-Positive Breast Cancer</p> <p>S. Modi, C. Saura, T. Yamashita, Y.H. Park, S.-B. Kim, K. Tamura, F. Andre, H. Iwata, Y. Ho, J. Tsurutani, J. Sohn, N. Denduluri, C. Perrin, K. Aogi, E. Tokunaga, S.-A. Im, K.S. Lee, S.A. Hurvitz, J. Cortes, C. Lee, S. Chen, L. Zhang, J. Shahidi, A. Yver, and I. Krop, for the DESTINY-Breast01 Investigators*</p>	<p>JUNE 2020</p> <p>ORIGINAL ARTICLE</p> <p>Trastuzumab Deruxtecan in Previously Treated HER2-Positive Gastric Cancer</p> <p>K. Shitara, Y.-J. Bang, S. Iwasa, N. Sugimoto, M.-H. Ryu, D. Sakai, H.-C. Chung, H. Kawakami, H. Yabusaki, J. Lee, K. Saito, Y. Kawaguchi, T. Kamio, A. Kojima, M. Sugihara, and K. Yamaguchi, for the DESTINY-Gastric01 Investigators*</p>	<p>JAN 2022</p> <p>ORIGINAL ARTICLE</p> <p>Trastuzumab Deruxtecan in HER2-Mutant Non-Small-Cell Lung Cancer</p> <p>Bob T. Li, M.D., Ph.D., M.P.H., Egbert F. Smit, M.D., Ph.D., Yasushi Goto, M.D., Ph.D., Kazuhiko Nakagawa, M.D., Hiroki Udagawa, M.D., Julien Mazieres, M.D., Misako Nagasaki, M.D., Ph.D., Lyudmila Bacherova, M.D., Andreas N. Salmos, M.D., Enriqueta Felip, M.D., Ph.D., Jose M. Pacheco, M.D., Maurice Perol, M.D., Luis Paz-Ares, M.D., Kapil Saena, M.D., Ryoa Shiga, B.Sc., Yinglin Cheng, M.D., Ph.D., Siddhanta Acharyya, Ph.D., Parik Vyasika, M.D., Ph.D., Javad Shahidi, M.D., David Planchard, M.D., Ph.D., and Pasi A. Janne, M.D., Ph.D., for the DESTINY-Lung01 Trial Investigators*</p>	<p>MAR 2022</p> <p>ORIGINAL ARTICLE</p> <p>Trastuzumab Deruxtecan versus Trastuzumab Emtansine for Breast Cancer</p> <p>J. Cortés, S.-B. Kim, W.-P. Chung, S.-A. Im, Y.H. Park, R. Hegg, M.H. Kim, L.-M. Tseng, V. Petry, C.-F. Chung, H. Iwata, E. Hamilton, G. Curigliano, B. Xu, C.-S. Huang, J.H. Kim, J.W.Y. Chiu, J.L. Pedrini, C. Lee, Y. Liu, J. Cathcart, E. Bako, S. Verma, and S.A. Hurvitz, for the DESTINY-Breast03 Trial Investigators*</p>	<p>JUNE 2022</p> <p>ORIGINAL ARTICLE</p> <p>Trastuzumab Deruxtecan in Previously Treated HER2-Low Advanced Breast Cancer</p> <p>S. Modi, W. Jacot, T. Yamashita, J. Sohn, M. Vidal, E. Tokunaga, J. Tsurutani, N.T. Ueno, A. Prat, Y.S. Chae, K.S. Lee, N. Niikura, Y.H. Park, B. Xu, X. Wang, M. Gil-Ci, W. Li, J.-Y. Pierga, S.-A. Im, H.C.F. Moore, H.S. Rugo, R. Yusushalmi, F. Zagoni, A. Gombos, S.-B. Kim, Q. Liu, T. Luo, C. Saura, P. Schmid, T. Sun, D. Gambhire, L. Yung, Y. Wang, J. Singh, P. Vitazka, G. Meinhardt, N. Harbeck, and D.A. Cameron</p>

NCCN CLINICAL GUIDELINE RECOMMENDATIONS:

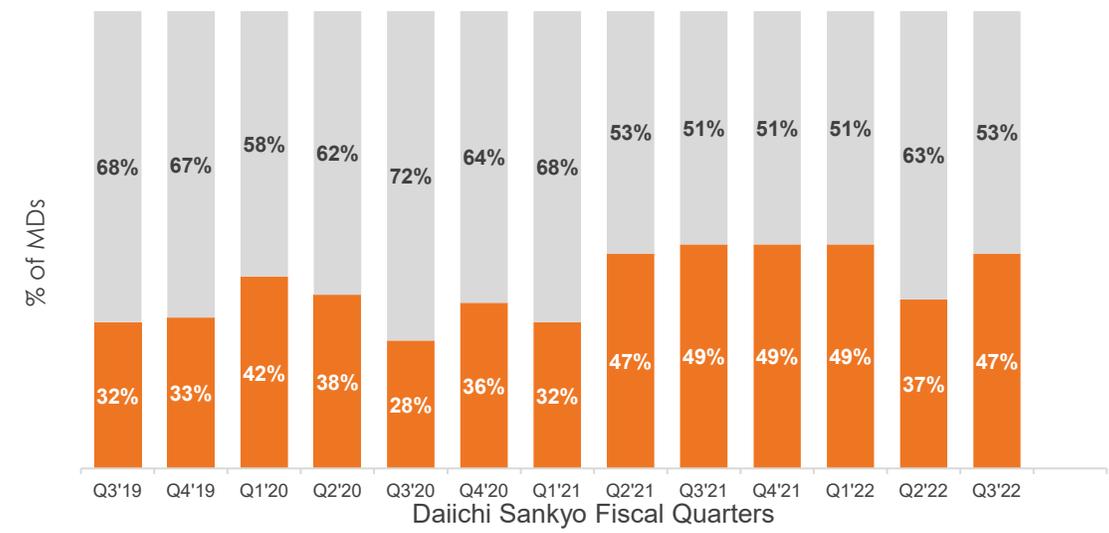
BREAST	<ul style="list-style-type: none"> NCCN CATEGORY 1 – NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) recommends fam-trastuzumab deruxtecan-nxki (ENHERTU®) as the preferred Category 1 treatment for patients with HER2 IHC 1+ or 2+/ISH negative breast cancer NCCN CATEGORY 1, Preferred 2L Option – NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) recommends fam-trastuzumab deruxtecan-nxki (ENHERTU®) as the Category 1 preferred regimen over T-DM1 as second-line therapy for recurrent unresectable (local or regional) or stage IV HER2+ breast cancer NCCN CATEGORY 2A – NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) recommends fam-trastuzumab deruxtecan-nxki (ENHERTU®) as a Category 2A regimen as a treatment option for patients with brain metastasis with HER2+ breast cancer
LUNG	<ul style="list-style-type: none"> NCCN CATEGORY 2A, Emerging Therapy Option – NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) recommends fam-trastuzumab deruxtecan-nxki (ENHERTU) as a Category 2A targeted therapy option for metastatic NSCLC with ERBB2 (HER2) mutations
GASTRIC	<ul style="list-style-type: none"> NCCN CATEGORY 2A, Emerging Therapy Option – NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) recommends fam-trastuzumab deruxtecan-nxki (ENHERTU®) as a Category 2A targeted therapy option for metastatic NSCLC with ERBB2 (HER2) mutations
ADDITIONAL REC'S	<ul style="list-style-type: none"> NCCN CATEGORY 2A, 2L+ Option – NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) recommends fam-trastuzumab deruxtecan-nxki (ENHERTU®) as a Category 2A regimen for 2L+ HER2+ advanced gastric/GEJ/EC cancer NCCN CATEGORY 2B, Useful in Certain Circumstances – NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) recommends fam-trastuzumab deruxtecan-nxki (ENHERTU®) as a Category 2B regimen useful in patients with HER2+ recurrent or metastatic salivary gland tumors with no surgery of radiotherapy options

Awareness and Education Efforts Have Resulted in Growing Confidence in Identifying and Managing ILD

% OF MDs WITH HIGH CONFIDENCE IN IDENTIFYING OF ILD / PNEUMONITIS IN PATIENTS RECEIVING ENHERTU®



% OF MDs WITH HIGH CONFIDENCE IN MANAGING ILD / PNEUMONITIS IN PATIENTS RECEIVING ENHERTU®



■ % of MDs rating 6,7 ■ % of MDs rating below 6



Confidence in identifying and managing ILD has increased post launch

Clinical Trial Experience With ILD

ADJUDICATED DRUG-RELATED ILD/PNEUMONITIS BY TUMOR TYPE AND GRADE

n (%)	All patients (N = 1150)	HER2+ Breast cancer 5.4 mg/kg (n = 245)	Gastric cancer (n = 294)	Lung cancer (n = 203)	Colorectal cancer (n = 107)	Other cancer (n = 34)
GRADE 1	48 (4.2)	9 (3.7)	5 (1.7)	7 (3.4)	0	4 (11.8)
GRADE 2	89 (7.7)	22 (9.0)	15 (5.1)	16 (7.9)	5 (4.7)	2 (5.9)
GRADE 3	14 (1.2)	2 (0.8)	3 (1.0)	2 (1.0)	1 (0.9)	1 (2.9)
GRADE 4	1 (0.1)	0	1 (0.3)	0	0	0
GRADE 5	25 (2.2)	7 (2.9)	1 (0.3)	6 (3.0)	3 (2.8)	0
Total	177 (15.4)	40 (16.3)	25 (8.5)	31 (15.3)	9 (8.4)	7 (20.6)

137 of 177 patients with ILD/pneumonitis (77%) had grade 1 or 2 events

Enhanced ILD Education & Management Has an Impact

Incidence of ILD/pneumonitis over time^a

Updated toxicity management guidelines implemented (December 2019)

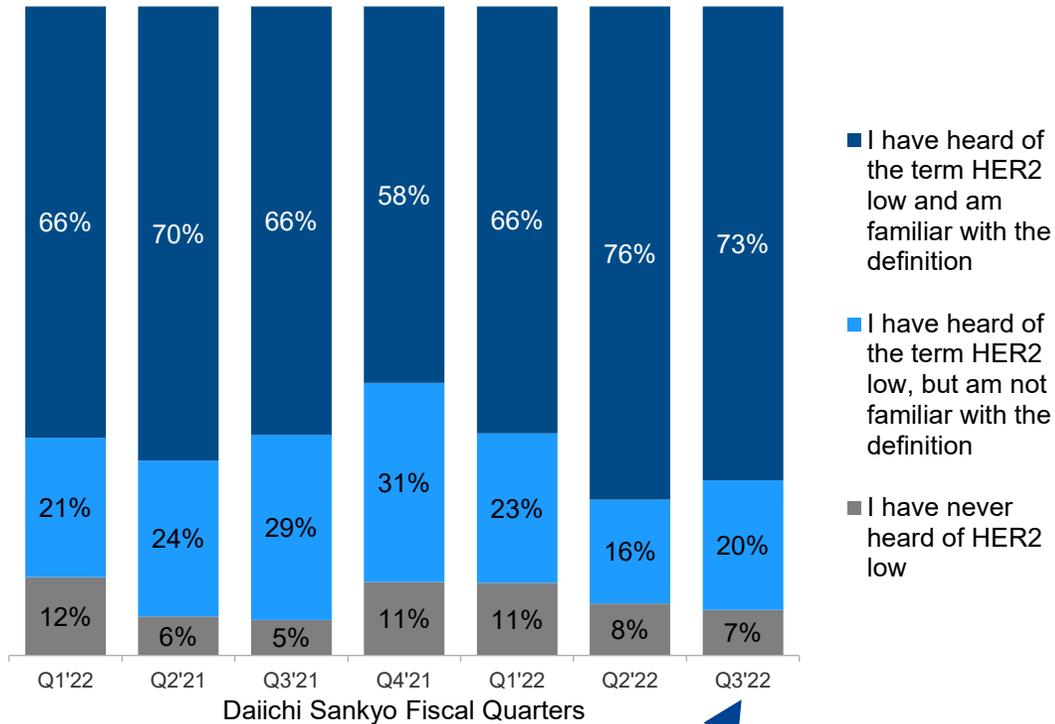
	2016 (n = 74)	2017 (n = 168)	2018 (n = 569)	2019 (n = 179)	2020 (n = 160)
Any Grade ILD/pneumonitis, n (%)	18 (24.3)	33 (19.6)	87 (15.3)	28 (15.6)	11 (6.9)
Grade ≥ 3 ILD/pneumonitis, n (%)	2 (2.7)	6 (3.6)	21 (3.7)	8 (4.5)	3 (1.9)
Grade 5 ILD/pneumonitis, n (%)	1 (1.4)	5 (3.0)	12 (2.1)	5 (2.8)	2 (1.3)

Patients enrolled in 2020 (after implementation of toxicity management guidelines) appear to have had lower rates of all grade (6.9%), grade ≥ 3 (1.9%) and grade 5 ILD/pneumonitis (1.3%) compared with those enrolled in previous years.

Data cutoff: December 2020

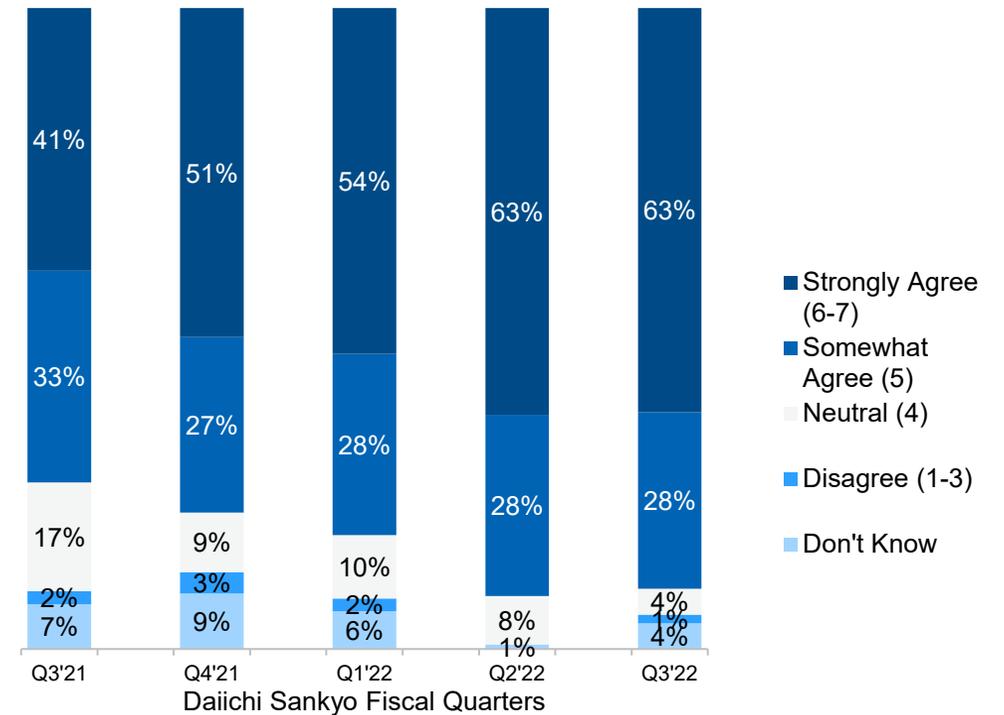
The Oncology Community Quickly Embraced The Need to Identify Their HER2 Low Patients

FAMILIARITY WITH THE HER2 LOW TERM



DB-04* US Approval

AWARENESS: SPECTRUM OF HER2 POSITIVITY



* DB-04: HER2-low (post chemo) Metastatic Breast Cancer

Achievements in FY 2022

Multiple Publications and Congress Presentations

- Appropriately Reflected In Guidelines

Several Medical/Oncology Organization Accolades

- DESTINY-Breast04 ASCO standing ovation
- DESTINY-Breast02 and DESTINY-Breast03 OS at SABCS

4 New indications

- HER2+ mBC 2L, HER2 low post chemo, HER2m NSCLC 2L, HER2+ mGC 2L

>\$1B in Global Revenue in CY 2022

- +258% YOY growth

Established #1 market share for 100% of launches in the US

European launches of HER2+ and HER2 low mBC, HER2+ mGC progressing well

2023 Growth Drivers

Optimize adoption in recent new indications to change the standard of care across the globe

US

- Expansion of Market Leadership in 2L HER2+ mBC HER2 low mBC, establishing a new standard of care
- Grow in 2L HER2 mutant NSCLC
- Grow in 2L/3L HER2+ mGC

JAPAN

- Establish and expand of 2L HER2+ mBC market leadership
- Launch HER2 low mBC as new standard of care
- Launch HER2 mutant NSCLC



EUROPE

- Launch 2L HER2+ mBC across all countries/regions
- Launch HER2 low mBC
- Launch HER2 mutant NSCLC

ASCA

- Approved 2L HER2+ mBC in China, Feb 2023



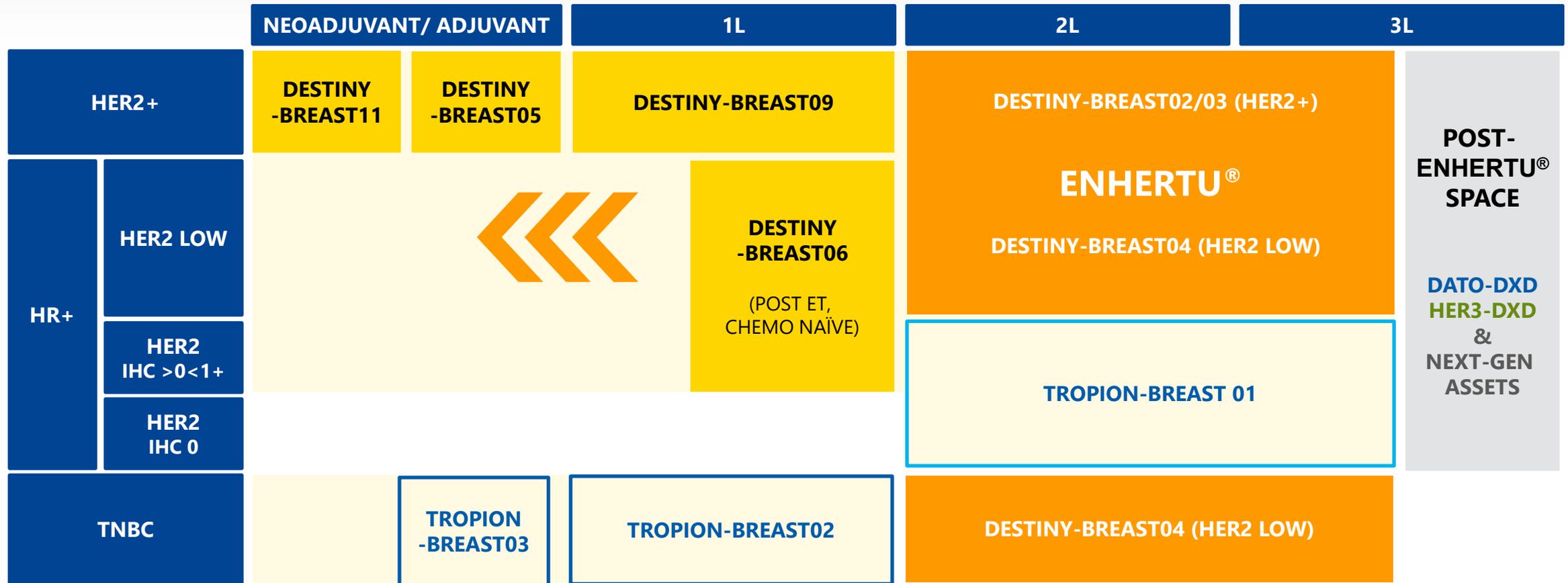
1 Growth Opportunity: ENHERTU® has Demonstrated Standard of Care Changing Benefit ~70% of mBC Patients



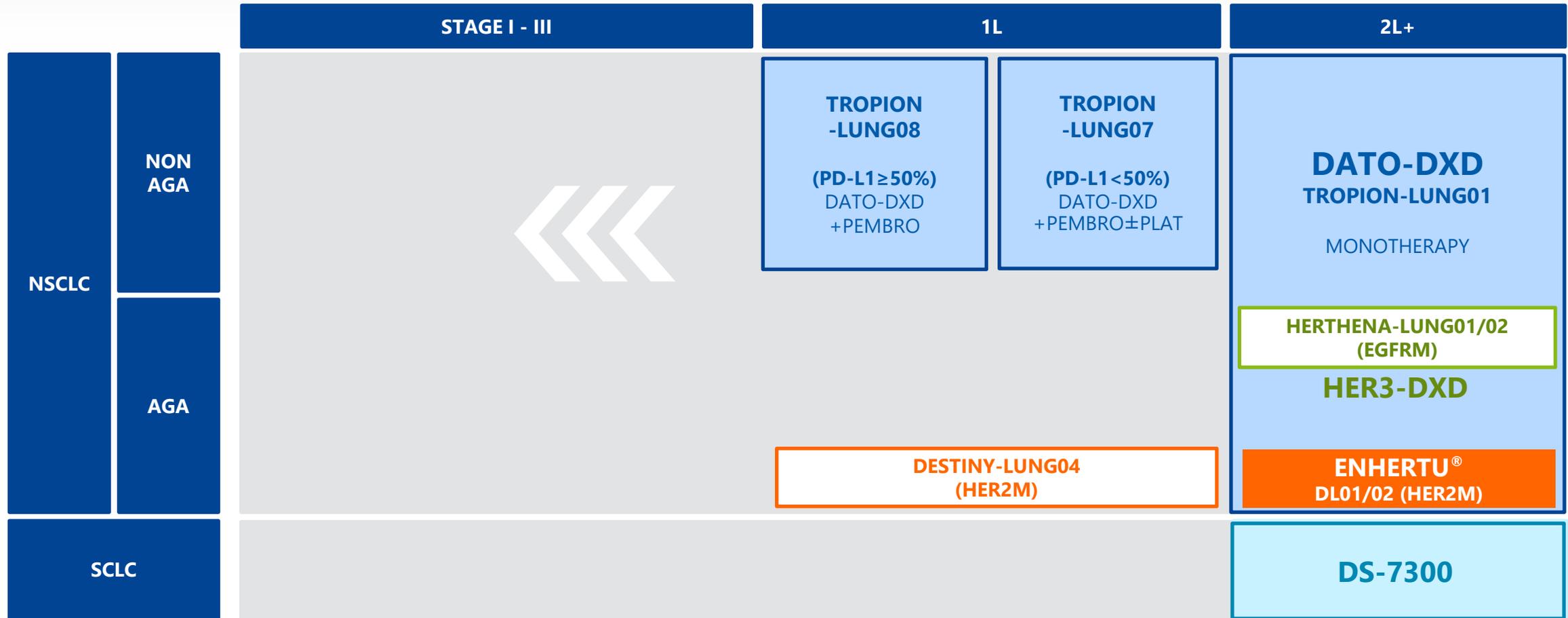
Development Plan Expands ENHERTU® Opportunity To Earlier Stage Disease



Development Plan Expands ENHERTU® Opportunity To Earlier Stage Disease



Daiichi Sankyo Aims to Establish and Expand DXd-ADCs as New Treatment Options in Lung Cancer

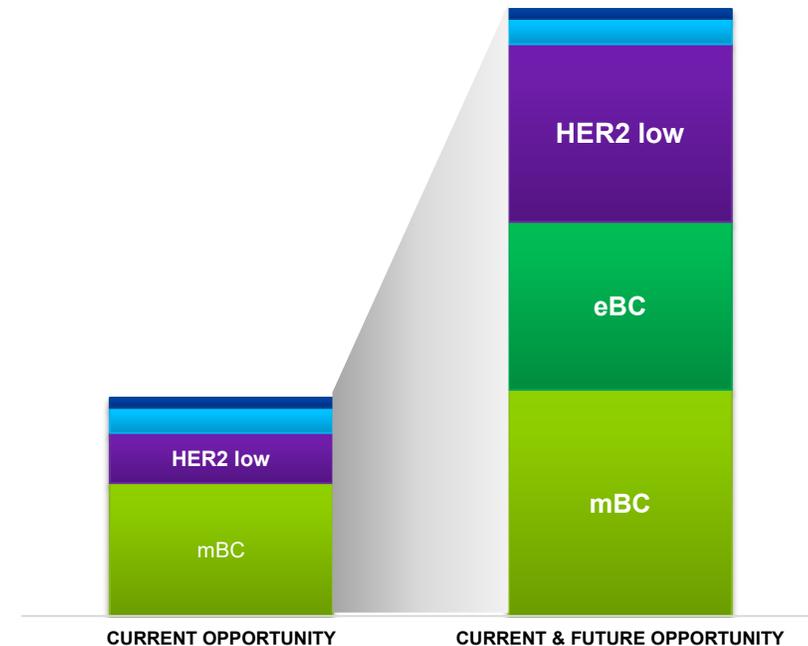


Transforming Treatment and Outcomes for Patients

With ENHERTU[®], Daiichi Sankyo Aims to Transform Treatment and Outcomes for Patients with HER2-targetable Tumors and Become the #1 Agent of Choice

Ongoing clinical development plan may expand the opportunity to establish new standards of care in both 1L metastatic and early-stage Breast Cancer

Addressable US patient population (directional image)



*Addressable US patient population based on current indications. **Potential addressable US patient population based on ongoing trials. The safety and efficacy of these products have not been established in these future potential indications, and future regulatory approval or commercial availability is not guaranteed.

On Track to Transforming HER2 Targetable Cancers

Establish Foundation

Achieve 3L HER2+ mBC and 2L/3L HER2+ mGC market leadership in all launch countries/regions

 ENHERTU®
fam-trastuzumab deruxtecan-nxki
20 mg/mL INJECTION FOR INTRAVENOUS USE

EXTEND HER2+ EXPECTATIONS
IN MULTIPLE TUMOR TYPES



2020 - 2021

Build Market Leadership

Establish ENHERTU® as HER2 medicine of choice for 2L HER2+ mBC and become market leader worldwide

#1

2022

Redefine the HER2 Treatment Paradigm

Rethink HER2 targetable population with ENHERTU® efficacy in HER2 low mBC and HER2 mutant NSCLC

2022 - 2023

Elevate Outcome Expectations

Push new boundaries with further development in neoadjuvant/adjuvant eBC, 1L mBC, combination strategies and other cancers

2024 +

Contact address regarding this material

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