

Passion for Innovation.
Compassion for Patients.™



Oncology Business Briefing FY2024

DAIICHI SANKYO CO., LTD.

February 26, 2025

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Oncology Business Briefing – Agenda

Agenda	Presenter
Opening Remarks	Sunao Manabe <i>Executive Chairperson & CEO</i>
Oncology Business Overview	Ken Keller <i>Global Head of Oncology Business</i>
US Oncology Overview <ul style="list-style-type: none">- <i>US Business Performance</i>- <i>Establishing Daiichi Sankyo's Position in Oncology</i>- <i>Launch Readiness for Key Events in 2025</i>	Dan Switzer <i>Head of US Oncology Business Division</i>
EU Oncology Overview <ul style="list-style-type: none">- <i>EU Business Performance</i>- <i>Establishing Daiichi Sankyo's Position in Oncology</i>- <i>Launch Readiness for Key Events in 2025</i>	Markus Kosch <i>Head of EU Oncology Business Division</i>
Closing Remarks	Ken Keller <i>Global Head of Oncology Business</i>
Q&A	All

Presenters



Sunao Manabe

Executive Chairperson
and CEO



Ken Keller

Global Head, Oncology
Business



Dan Switzer

Head, US Oncology
Business Division



Markus Kosch

Head, EU Oncology
Business Division

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®
- Board Member of the PhRMA (Pharmaceutical Research and Manufacturers of America)



Dan Switzer

*Head, US Oncology Business Division,
Daiichi Sankyo, Inc.*

- Joined Daiichi Sankyo in 2005 (20 years)
- Responsible for the commercialization and performance of all in-line and near-term oncology assets in the U.S.
- Launched multiple pharmaceuticals and biologics at DSI and oversaw multi-billion-dollar franchises
- Serves as member of the Daiichi Sankyo, Inc. Board of Directors
- Held various leadership roles with increasing responsibility across marketing, market access and business analytics



Markus Kosch

*Head, EU Oncology Business Division,
Daiichi Sankyo Europe*

- Joined Daiichi Sankyo in 2021
- Leads European and Canada oncology business at Daiichi Sankyo governing 18 countries
- Boarded physician in internal medicine, practiced in nephrology and oncology at the University Hospital in Münster until 2005 where he still teaches
- Over 20 years' experience in pharmaceutical industry in senior global, regional and country leadership roles at Wyeth and Pfizer
- Launched medicines in lung, GI cancers, hematology and breast including Palbociclib across Europe
- Board Member of the EFPIA (European Association of Pharmaceutical Industry)



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**

- ◆ 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



**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

Ken Keller

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

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Our DESTINY clinical development program has transformed the oncology treatment landscape and Daiichi Sankyo

ENHERTU[®] revenue > \$3.7B per annum*

Strong commercial execution across the globe and prepared to optimize our new growth opportunities in FY25

- ENHERTU[®] has achieved leadership positioning in its first 4 indications in every fully launched country/region
- US approvals for new indications expand the eligible patient opportunity in HER2+ tumor agnostic and chemo naïve HR+/HER2 low and ultralow mBC (DESTINY-Breast06)

Multiple new ENHERTU[®] growth catalysts expected near term

- High unmet need patients would benefit from earlier use of ENHERTU[®]
 - 1L HER2+ mBC (DESTINY-Breast09)
 - Neoadjuvant HER2+ BC (DESTINY-Breast11)
 - Adjuvant*** HER2+ BC (DESTINY-Breast05)

Expanding Oncology Portfolio

DATROWAY[®]

- Approved in US/JP
 - 2/3L HR+/HER2 low or negative BC (TROPION-Breast01)
- Submitted and accepted for priority review in US**
 - EGFRmut mNSCLC with prior systemic therapies (TROPION-Lung05)
- Expected TLR in FY2025
 - 1L PD-1/PD-L1 ineligible TNBC (TROPION-Breast02)
 - 1L Non-AGA NSCLC (AVANZAR)

Global Oncology Business is nearing an inflection point with multiple new growth catalysts approaching

*CY2024 Internal sales report: Global sales (DaiichiSankyo and AstraZeneca total revenue)

**Granted Breakthrough Therapy Designation in U.S

***Adjuvant therapy for patients with residual invasive disease following neoadjuvant therapy

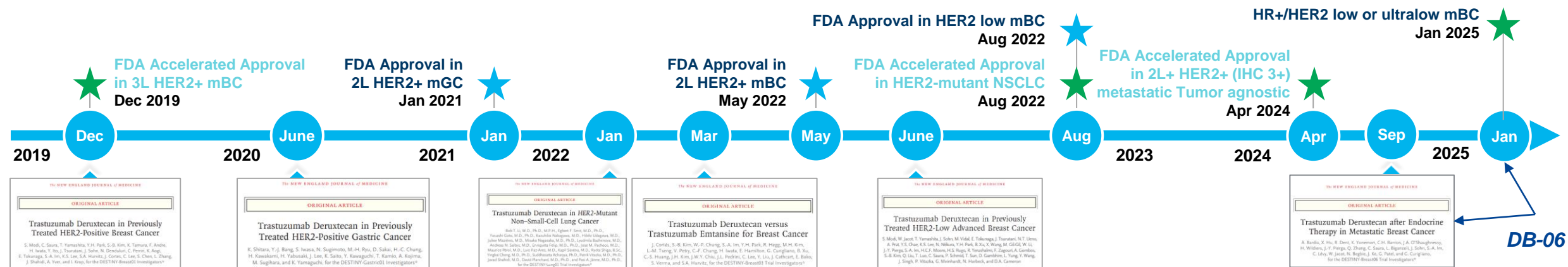
BC: breast cancer, EGFR: epidermal growth factor receptor, FY: fiscal year

HR: hormone receptor, NSCLC: non-small cell lung cancer, Non-sq: non-squamous, PD-(L)1: programmed death (ligand) 1,

TLR: top line results, TNBC: triple negative breast cancer TROP2: trophoblast cell surface antigen 2

ENHERTU[®] is a standard of care and paradigm-changing drug

The DESTINY clinical development program has yielded 8 BTD, 6 NEJM and 19 NCCN recommendations



Current NCCN Clinical Guideline Recommendations (19)*:

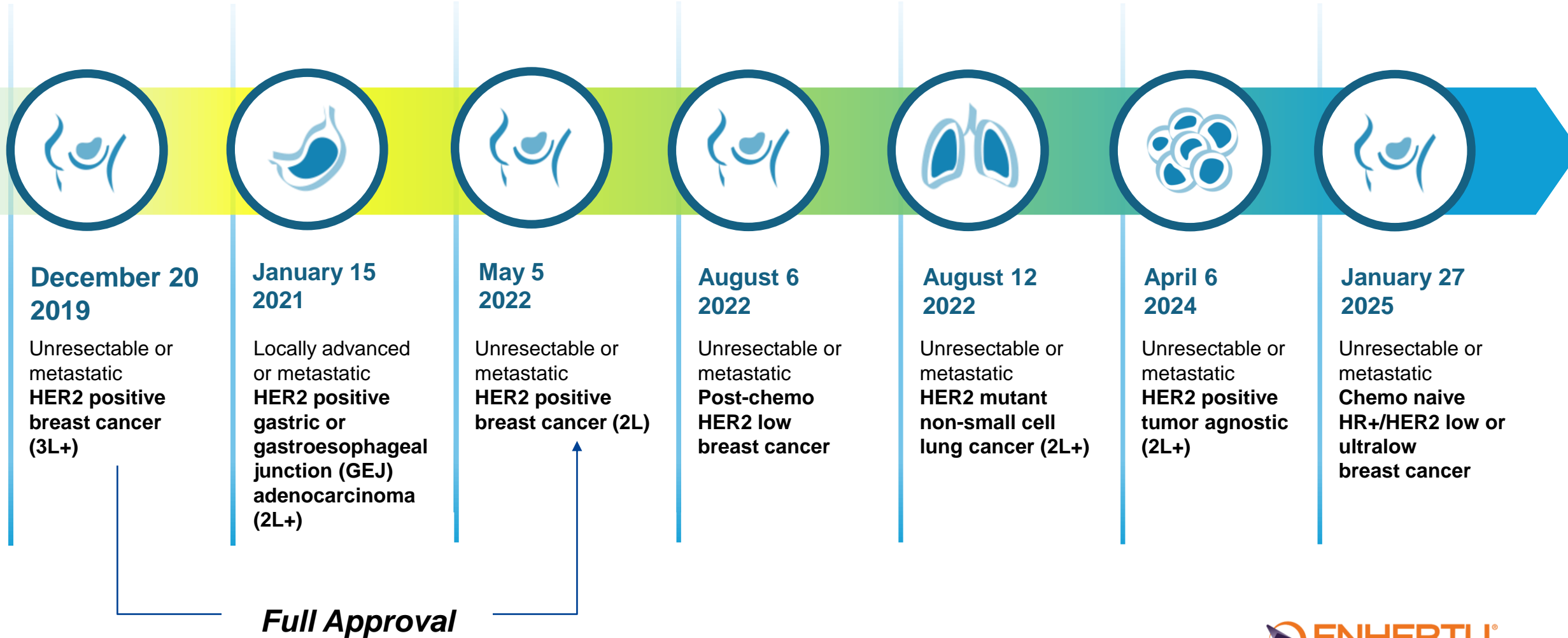
Breast	NCCN CATEGORY 1	For 2L patients with HER2 IHC 0+, 1+ or 2+/ISH negative breast cancer (HR+ and HER2- with Visceral Crisis or Endocrine Refractory)
	NCCN CATEGORY 2A	For 1L patients with no Germline BRCA1/2 mut and/or IHC HER2 0+, 1+ or 2+/ISH negative breast cancer (HR+ and HER2- with Visceral Crisis or Endocrine Refractory)
	NCCN CATEGORY 1	Second-line therapy over T-DM1 for recurrent unresectable (local or regional) or stage IV HER2+ breast cancer
	NCCN CATEGORY 2A	Treatment option for patients with brain metastasis with HER2+ breast cancer
GI	NCCN CATEGORY 2A	For 2L+ unresectable locally advanced, recurrent, or metastatic HER2+ gastric/GEJ/esophageal cancer
	NCCN CATEGORY 2A	For 2L or subsequent therapy (or initial treatment for pMMR/MSS unresectable metachronous metastases, with previously FOLFOX/CAPEOX within past 12mos) for advanced or metastatic HER2-amplified (IHC 3+) colon or rectal cancer
	NCCN CATEGORY 2A	For 2L or subsequent therapy for advanced or metastatic HER2-amplified (IHC 3+) small bowel cancer
	NCCN CATEGORY 2A	Subsequent line regimen if disease progression for HER2+ (IHC 3+) biliary tract cancers
	NCCN CATEGORY 2A	Subsequent line regimen for locally advanced/metastatic and therapy for recurrent HER2+ (IHC 3+) pancreatic cancer
GYN	NCCN CATEGORY 2A	For 2L+ HER2+ (IHC 3+ or 2+) cervical cancer

GYN (cont'd)	NCCN CATEGORY 2A	For 2L+ HER2+ (IHC 3+ or 2+) endometrial cancer
	NCCN CATEGORY 2A	Recurrence therapy for platinum-resistant HER2+ (IHC 3+ or 2+) ovarian cancer
	NCCN CATEGORY 2A	For 2L+ HER2+ (IHC 3+ or 2+) vaginal cancer
	NCCN CATEGORY 2A	For 2L+ HER2+ (IHC 3+ or 2+) vulvar cancer
Lung	NCCN CATEGORY 2A	Targeted therapy option for metastatic NSCLC with ERBB2 (HER2) mutations
	NCCN CATEGORY 2A	Subsequent therapy option for advanced or metastatic HER2+ (IHC 3+) NSCLC
Add'l Rec's	NCCN CATEGORY 2A	For subsequent line locally advanced or metastatic HER2+ (IHC 3+) bladder cancer
	NCCN CATEGORY 2A	For recurrent or metastatic HER2+ salivary gland tumors with no surgery or radiotherapy options
	NCCN CATEGORY 2B	Subsequent line regimen for HER2+ (IHC 3+) non-nasopharyngeal cancers with no satisfactory alternative treatment options
	NCCN CATEGORY 2A	For HER2+ (IHC 3+) occult primaries (adenocarcinoma and squamous cell)

Preferred Option
Useful in Certain Circumstances

*Please refer to NCCN.org for full recommendation language; content on this slide current as of February 2024
 2L: second-line. BTD: Breakthrough Designation. GEJ: gastroesophageal junction HER2: human epidermal growth factor receptor 2. IHC: immunohistochemistry. IV: intravenous. mBC: metastatic breast cancer. mGC: metastatic gastric cancer. NCCN: national comprehensive cancer network. NEJM: new England journal of medicine. NSCLC: non-small cell lung cancer. pMMR/MSS: proficient mismatch repair/microsatellite stable. T-DM1: trastuzumab emtansine.

To date, ENHERTU[®] has expanded to six indications, based on the DESTINY clinical development program



Global ENHERTU[®] net sales have exceeded 140 Bn JPY per quarter

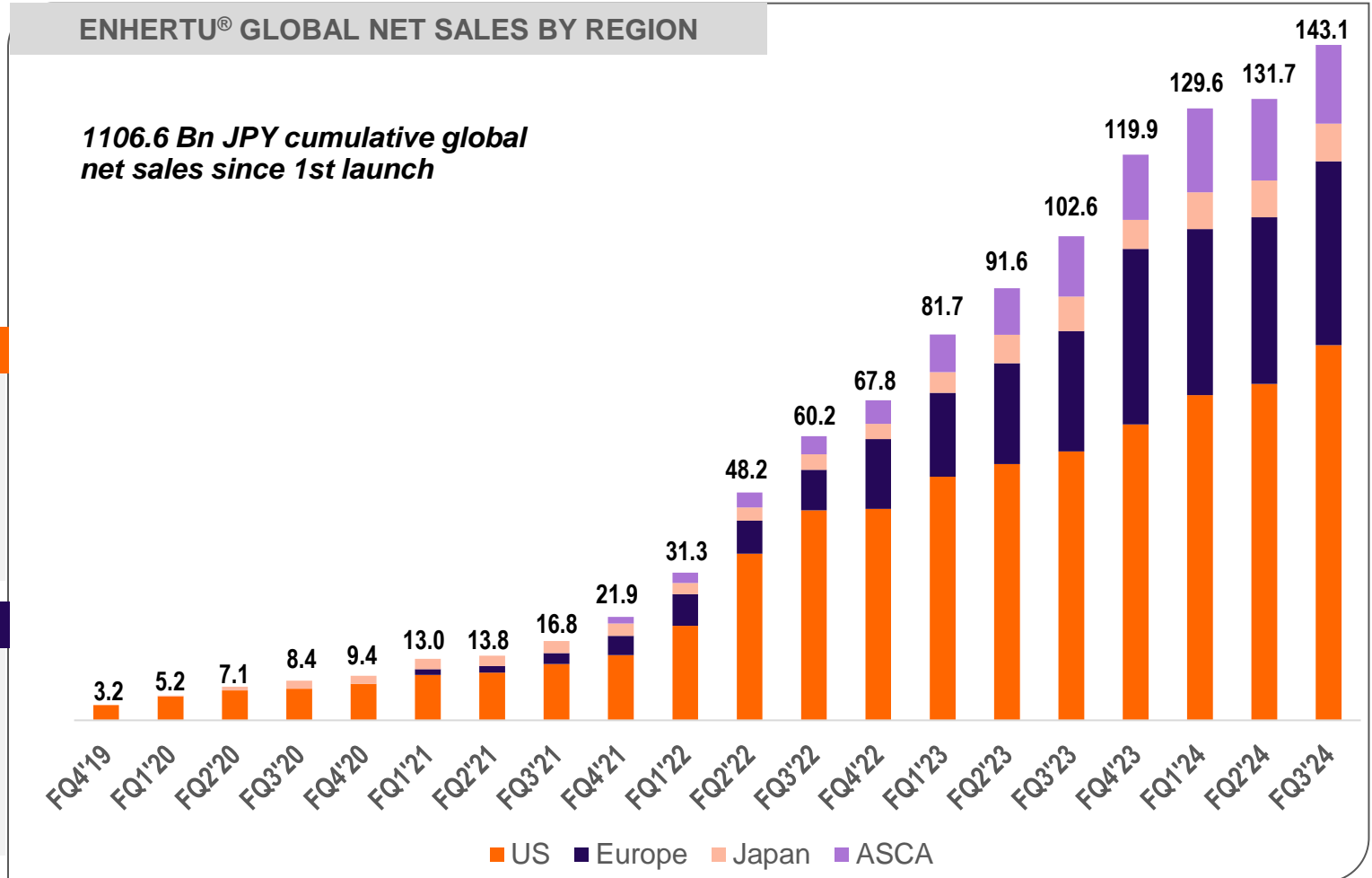
Overall, global net sales in FY2024 Q3 was 143.1 Bn JPY; **+8.7% sequential q-o-q growth** and **+39.5% vs FY2023 Q3** driven by US and Europe

US

In the US, FY2024 Q3: 79.5 Bn JPY
+11.5% vs. prior quarter;
+22.6 Bn JPY (+39.6%) vs. prior year

EU

In the EU, FY2024 Q3: 39.0 Bn JPY
+10.4% vs. prior quarter;
+13.5 Bn JPY (+52.9%) vs. prior year



*Incl. Gross profit share in AstraZeneca territory

ENHERTU®: strong global performance

>60

**countries/
regions**

Robust commercial footprint

>39%

YOY

Accelerating momentum throughout the globe and major catalysts in place for 2025-27

\$3.7B*

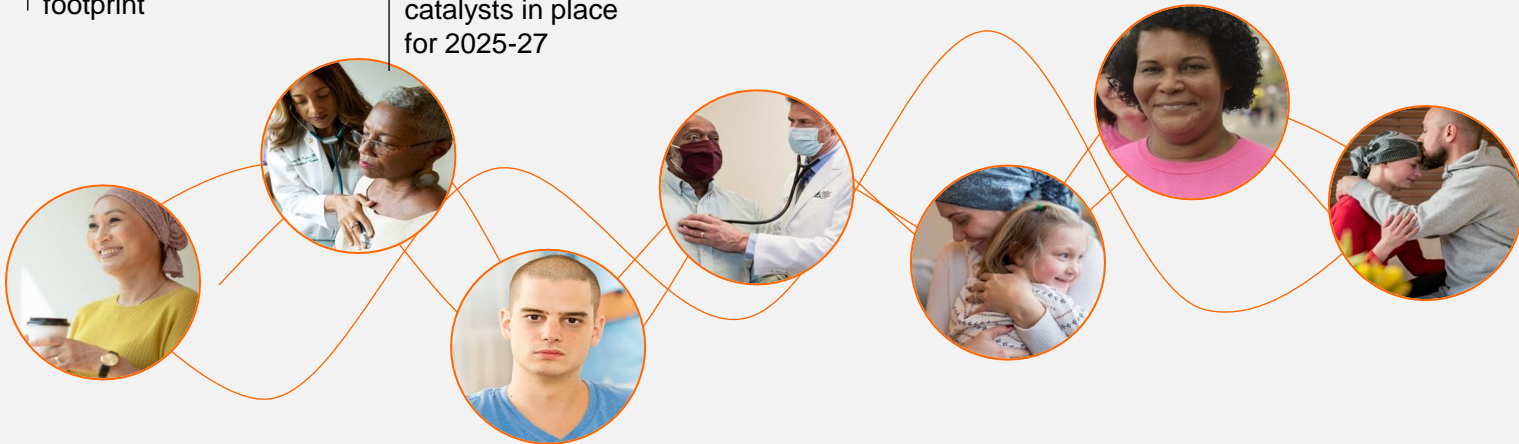
in revenue

delivered in CY 2024 with US and EU leading the way

More than
131 K

patients

across breast, lung, gastric cancer and tumor agnostic



Achieved #1 Market share
in 100% of fully launched countries**

*CY2024 Internal sales report: Global sales (Daiichi Sankyo and AstraZeneca total revenue)

**Internal market research results

*** 3L HER2+ metastatic gastric cancer is approved in Japan. There is no current 2L approval in Japan for metastatic gastric cancer

2L: second-line, HR: hormone receptor, IHC: immunohistochemistry, YOY: year over year

US APPROVAL: MAY 2022 | EU Approval: JULY 2022

2L HER2+ Metastatic Breast Cancer

JP APPROVAL: NOV 2022

US APPROVAL: AUG 2022 | EU Approval: JAN 2023

Post-chemo HER2 low Metastatic Breast Cancer

JP APPROVAL: MAR 2023

US APPROVAL: Jan 2025

Chemo naive HR+/HER2 low or ultralow Metastatic Breast Cancer

US APPROVAL: AUG 2022 | EU Approval: OCT 2023

2L+ HER2 Mutant Metastatic Lung Cancer

JP APPROVAL: AUG 2023

US APPROVAL: JAN 2021 | EU Approval: DEC 2022

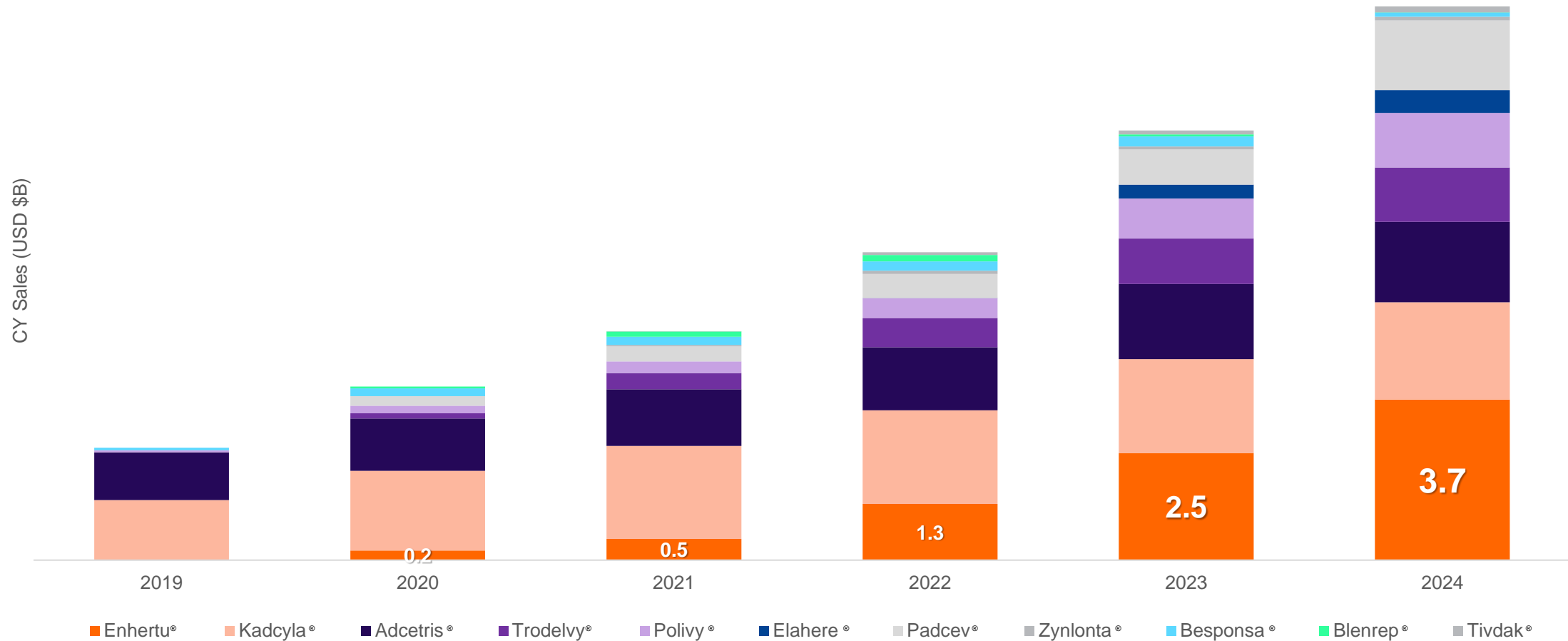
2L+ HER2+ Metastatic Gastric Cancer ***

JP APPROVAL: SEP 2020

US APPROVAL: Apr 2024

2L+ HER2+ (IHC3+) Metastatic Tumor Agnostic

ENHERTU[®] has led the way in the growing ADC market

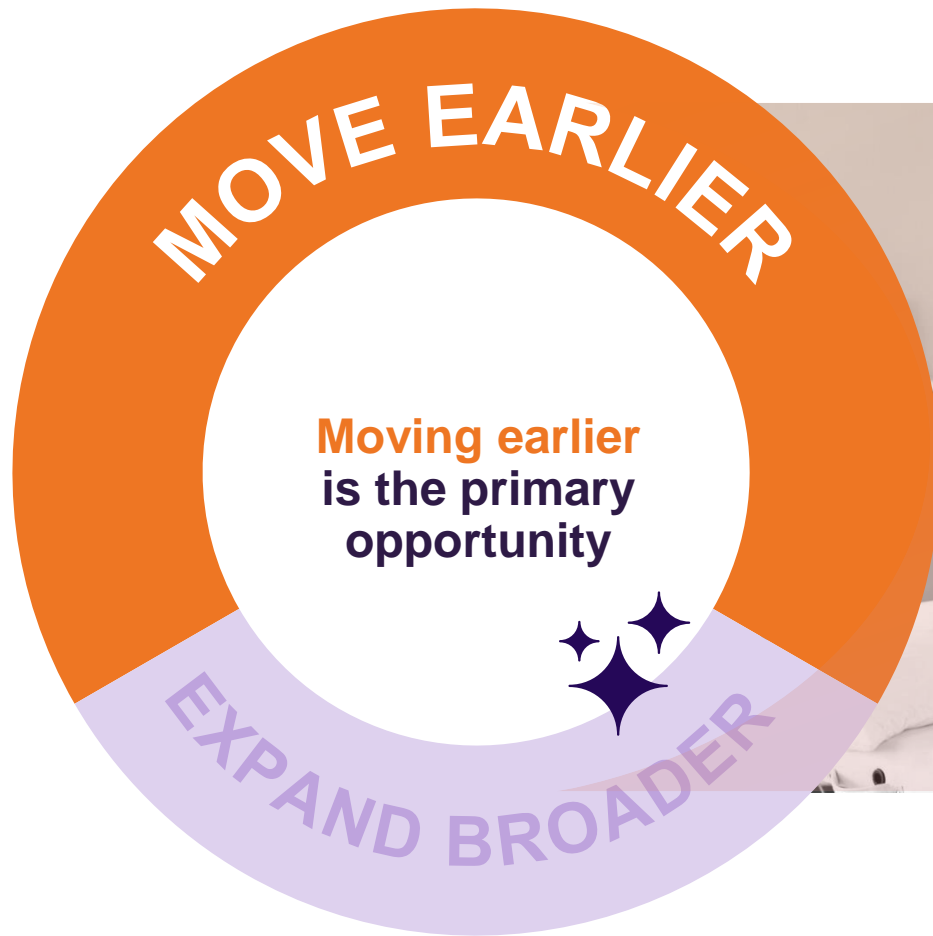


Source: Evaluate Pharma, accessed February 4, 2025

Note: Sales were converted to USD based on the currency conversion rate of the relevant year.
 ADC: antibody drug conjugate, CY: Calendar year; FY: Fiscal year
 2024 ADC revenues are analyst estimates excluding Kadcylo, Polivy which are actual reported revenue
 ENHERTU sales are based on DS internal reported revenues (Global DS+AZ total revenue)



ENHERTU[®] is at an inflection point as TLR from key clinical trials have the potential to move it earlier and broader



In the next three years, ENHERTU[®] is positioned to become the biggest breast cancer drug ever.

ENHERTU[®] is DESTINED for more as key clinical trial results and new indications seek to go earlier and broader

2025-2026 Potential New Indications

BREAST INDICATIONS

DESTINY-Breast06

HR+/HER2 low & ultralow chemo naive metastatic breast cancer

DESTINY-Breast09

HER2 positive metastatic breast cancer (1L)

DESTINY-Breast11

HER2 positive early breast cancer (neoadjuvant)

DESTINY-Breast05

HER2 positive early breast cancer (adjuvant*)

LUNG AND GASTRIC INDICATIONS

DESTINY-Gastric04

HER2 positive gastric cancer (2L)

DESTINY-Lung04

HER2 mutant metastatic NSCLC (1L)

Future Indications 2027+

DESTINY-Gastric05

HER2 positive gastric cancer (1L)

DESTINY-BTC01

HER2 positive biliary tract cancer (1L)

DESTINY-Ovarian01

HER2 positive ovarian cancer (1L)

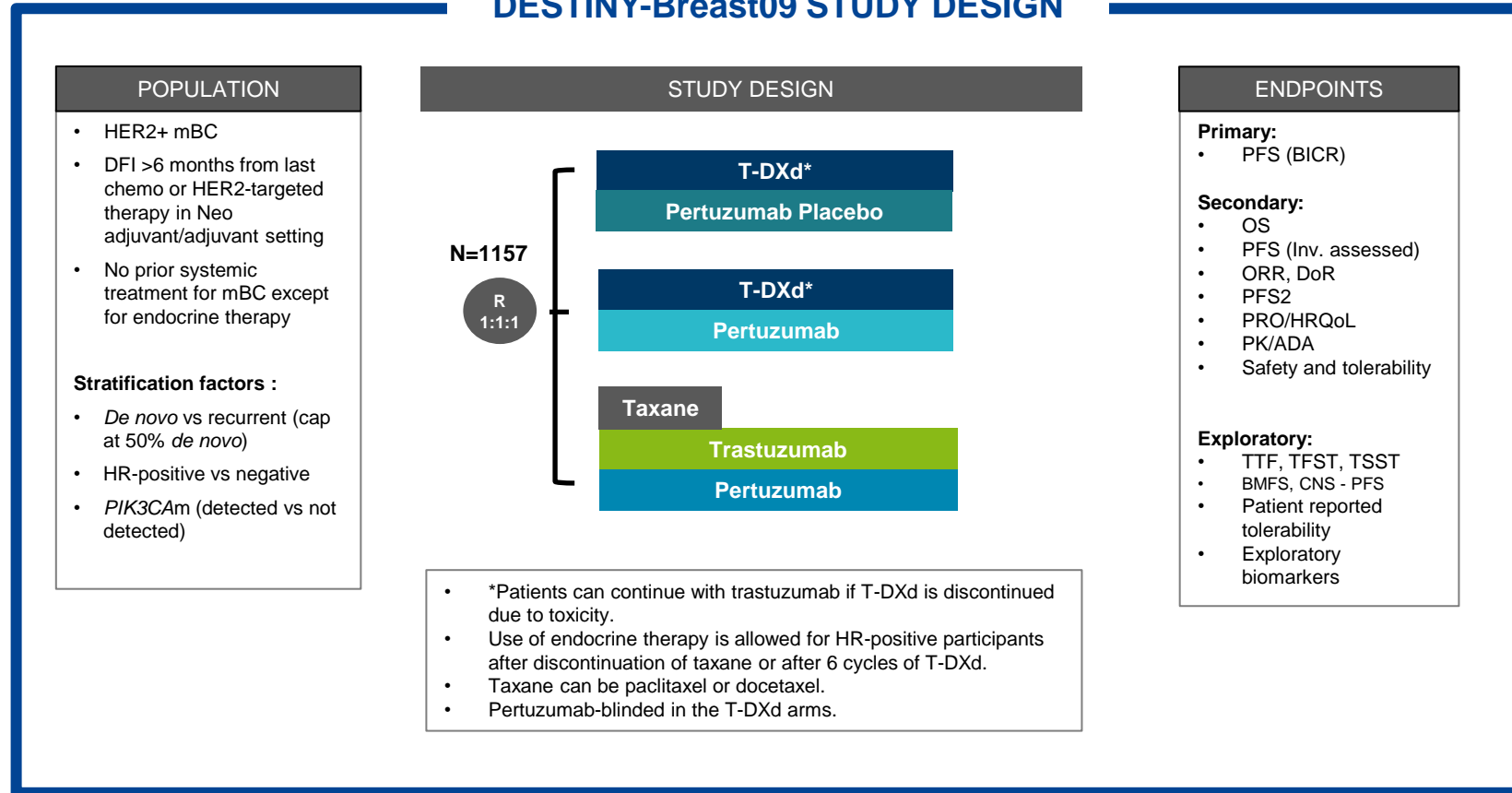
*Adjuvant therapy for patients with residual invasive disease following neoadjuvant therapy
1L: first-line, 2L: second-line, HR: hormone receptor, NSCLC: non-small cell lung cancer

DESTINY-Breast09 advances ENHERTU[®] to the first line mBC setting

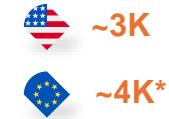
DESTINY-Breast03 results provide optimism

**Incremental to DB-01 & 03

DESTINY-Breast09 STUDY DESIGN



INCREMENTAL ELIGIBLE PATIENT POPULATION**



*Germany, France, Italy, Spain, UK

MARKET INSIGHTS

THP efficacy leaves room for improvement

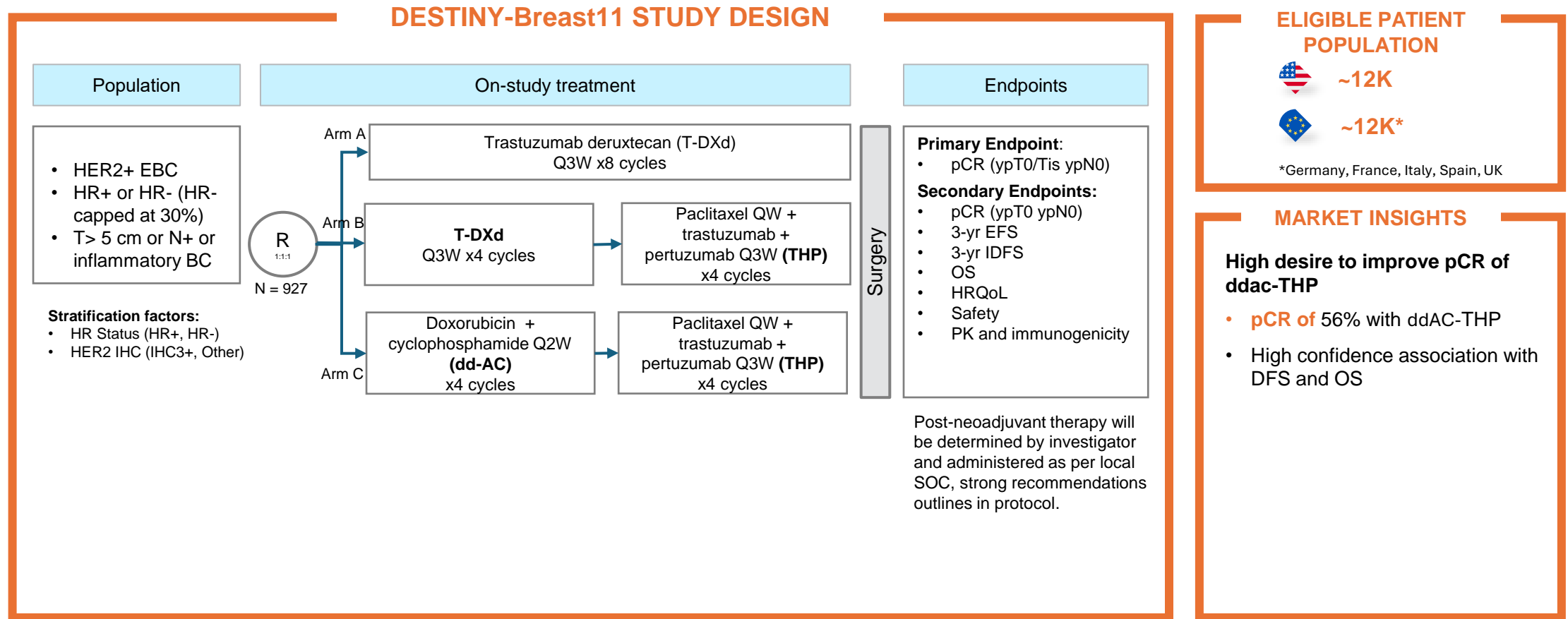
- mPFS 19m
- 12m landmark OS 65% THP
- ORR 80% THP

Real-world attrition rates across first- to third-line therapies in patients with HER2-positive metastatic breast cancer. Indicates that 29.6% of patients did not receive treatment beyond the first line

ADA: anti-drug antibody, BMFS: Brain metastasis free survival, BICR: blinded independent central review, CNS: Central nervous, DFI: Disease Free Interval, DOR: duration of response, HRQoL: Health-related quality of life, HR: Hormone receptor, mBC: metastatic breast cancer, OS: overall survival, ORR: objective response rate, PRO: Patient report outcome, PK: pharmacokinetics, PFS: progression-free survival, R: randomization, THP: Taxane+Trastuzumab+Pertuzumab, T-DXd: Trastuzumab deruxtecan, TTF: Treatment time to failure, TFST: Time to First Subsequent therapy TSST: Time to subsequent therapy

DESTINY-Breast11 and DESTINY-Breast05 advances ENHERTU[®] into the early-stage BC setting, seeking to cure more patients

Neo Adj HER2+ eBC: first launch in curative intent setting & earliest opportunity for use

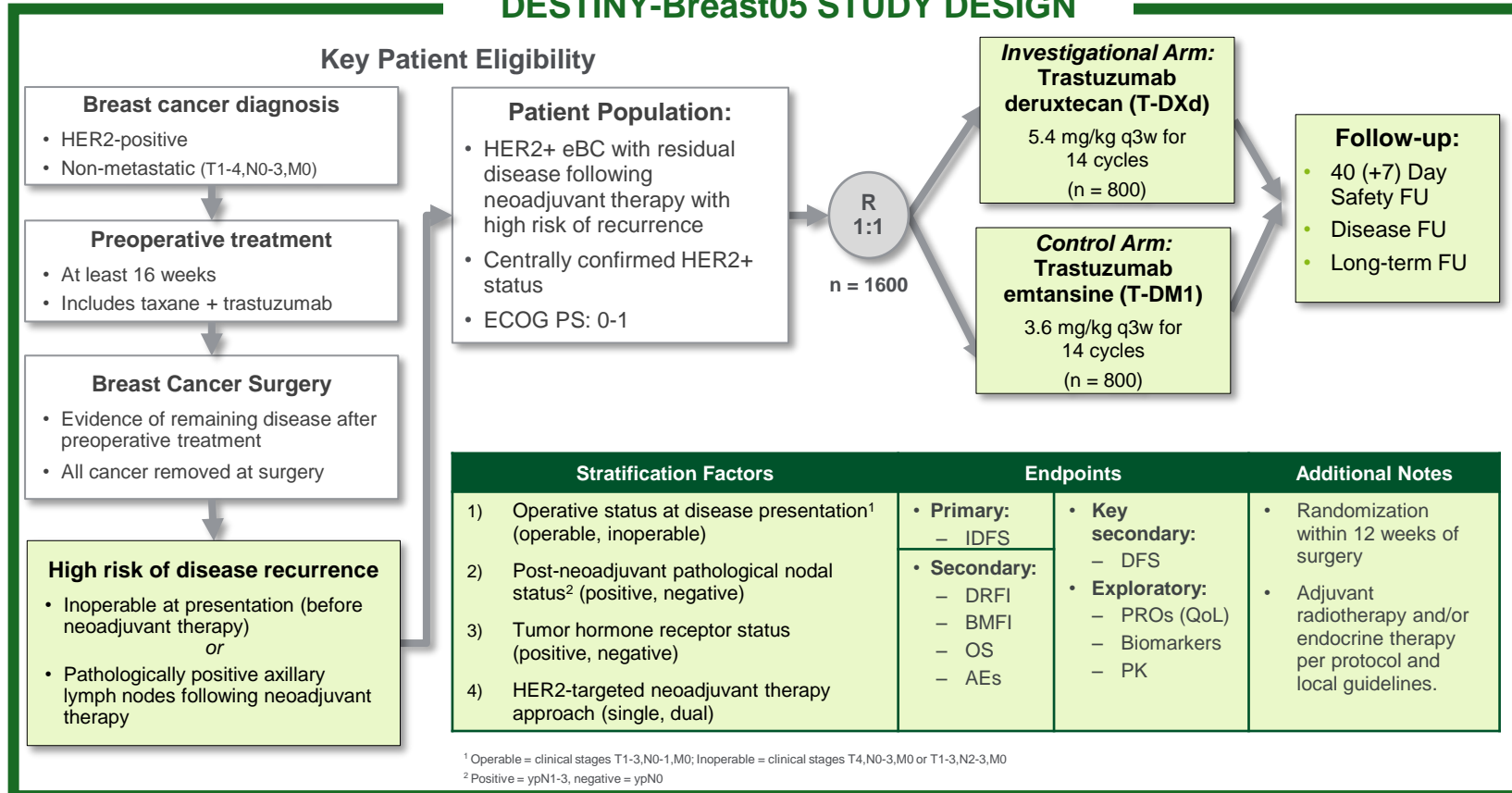


DFS: Disease-free survival, eBC: early breast cancer; EFS: Even-free survival; IDFS: Invasive disease-free survival; HRQoL: Health-related quality of life, OS: Overall survival; pCR; Pathologic complete response, PK: pharmacokinetics; R: randomization; THP: Taxane+Trastuzumab+Pertuzumab;

DESTINY-Breast05 and DESTINY-Breast11 advances ENHERTU[®] into the early-stage BC setting, seeking to cure more patients

Adjuvant* HER2+ eBC: notable next step in the BC treatment journey, with competitor (Kadcyla[®])

DESTINY-Breast05 STUDY DESIGN



ELIGIBLE PATIENT POPULATION

~4K
 ~4K*

*Germany, France, Italy, Spain, UK

MARKET INSIGHT

Efficacy improvement is desired

- **3-year IDFS rate is 83% T-DM1**
- Previous HTH clinical trials versus T-DM1 is encouraging
- Selecting for higher risk patients


*Adjuvant therapy for patients with residual invasive disease following neoadjuvant therapy

AE: adverse event; BMFI: Brain metastases-free interval; DFS: Disease-free survival; DRFI: Distant recurrence-free interval; eBC: early breast cancer; ECOG PS: Eastern Cooperative Oncology Group performance status; FU: follow-up; HER2: Human epidermal growth factor receptor 2; IDFS: Invasive disease-free survival; OS: Overall survival; PK: pharmacokinetics; PRO: patient reported outcome; QoL: quality of life R=randomization

Expanding oncology portfolio: DATROWAY[®] expected approvals and pivotal data in 2025

Breast

NSCLC

Approval / Expected approval	Expected TLR
<p>TROPION-Breast01</p> <p>HR+ and HER2 low or negative metastatic breast cancer (2L/3L) </p> <ul style="list-style-type: none"> • US: Approval on January 17, 2025 • JP: Approval on December 27, 2024 • EU: Recommended for approval by CHMP • Eligible patients^{**}: 2L HR+/HER2- mBC ~42k* 	<p>TROPION-Breast02</p> <p>TNBC, PD-1/PD-L1 ineligible (1L)</p> <ul style="list-style-type: none"> • DATROWAY[®] versus chemotherapy • Expected TLR timing: FY2025 H1 • Eligible patients^{**}: ~14k
<p>TROPION-Lung05</p> <p>EGFR mutated, previously treated (incl. EGFR directed therapy) (2L+)</p> <ul style="list-style-type: none"> • FDA has accepted a new application and granted Priority Review and Breakthrough Therapy Designation • PDUFA date: July 12, 2025 • Eligible patients^{***} ~3K+ (US) 	<p>AVANZAR</p> <p>Non-AGA, Durvalumab combo (1L)</p> <ul style="list-style-type: none"> • DATROWAY[®] + durvalumab + carboplatin versus pembrolizumab + histology-specific platinum-based chemotherapy • Expected TLR timing: CY2025 H2 • Eligible patients^{**}: ~56k^{****}

*Not considering overlapping with ENHERTU eligible patients' population(DB-04/DB-06)

**US, Germany, France, Italy, Spain, UK, JP

***US only. There is potential for additional upside in patient eligibility from recently approved TKI+CTx regimens, such as FLAURA2 in the future if 1L use grows significantly

****NSQ (Non-Squamous) TROP2 Positive

AGA: actionable genomic alterations, CY: calendar year, CHMP: Committee for Medicinal Products for Human Use, EGFR: epidermal growth factor receptor, FDA: Food and Drug Administration, HR: hormone receptor, NSCLC: non-small cell lung cancer, PD-(L)1: programmed death (ligand) 1, TLR: topline results, TNBC: triple negative breast cancer, TROP2: trophoblast cell surface antigen-2

Potential for nine launches with ~3X increase in patient opportunity in 2025-2026

2025-2026 Potential
New Indications

BREAST INDICATIONS

DESTINY-Breast06

HR+/HER2 low & ultralow chemo naïve metastatic breast cancer

DESTINY-Breast09

HER2 positive metastatic breast cancer (1L)

DESTINY-Breast11

HER2 positive early breast cancer (neoadjuvant)

DESTINY-Breast05

HER2 positive early breast cancer (adjuvant*)

TROPION-Breast01

HR+ and HER2 low or negative metastatic breast cancer (2L/3L)

TROPION-Breast02

TNBC, PD-1/PD-L1 ineligible (1L)

LUNG AND GASTRIC INDICATIONS

DESTINY-Gastric04

HER2 positive gastric cancer (2L)

DESTINY-Lung04

HER2 mutated metastatic NSCLC (1L)

TROPION-Lung05

EGFR mutated, previously treated (incl. EGFR directed therapy) (2L/3L)

*Adjuvant therapy for patients with residual invasive disease following neoadjuvant therapy
EGFR: epidermal growth factor receptor, HR: hormone receptor, NSCLC: non-small cell lung cancer, PD-(L)1: programmed death (ligand) 1, TNBC: triple negative breast cancer,



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- Held various leadership roles with increasing responsibility across marketing, market access and business analytics



US OBD possesses comprehensive commercial & medical capabilities across five core functions, highlighted by large customer-facing teams

Customer-facing teams account for ~70% of US OBD headcount

MEDICAL AFFAIRS

- Medical Science Liaisons
- Medical Value Liaisons
- Medical Diagnostics
- Medical Education & Information
- HEOR

BUSINESS OPERATIONS

- Market Research & Data Analytics
- Sales Operations
- Training – All Customer Facing Roles
- Training – Leadership Development



SALES

- Field Sales – Oncology Breast
- Field Sales – Oncology Lung
- Field Sales – Oncology Hematology

MARKETING

- Regional Marketing Liaisons
- Product / Brand Teams
- Omni-Channel Marketing

MARKET ACCESS

- Account Managers
- Field Reimbursement Managers
- Oncology Nurse Educators
- National Account Managers
- Strategic Value & Access Marketing
- Strategic Contracting & Pricing

ENHERTU[®] revenue growth continues in the US

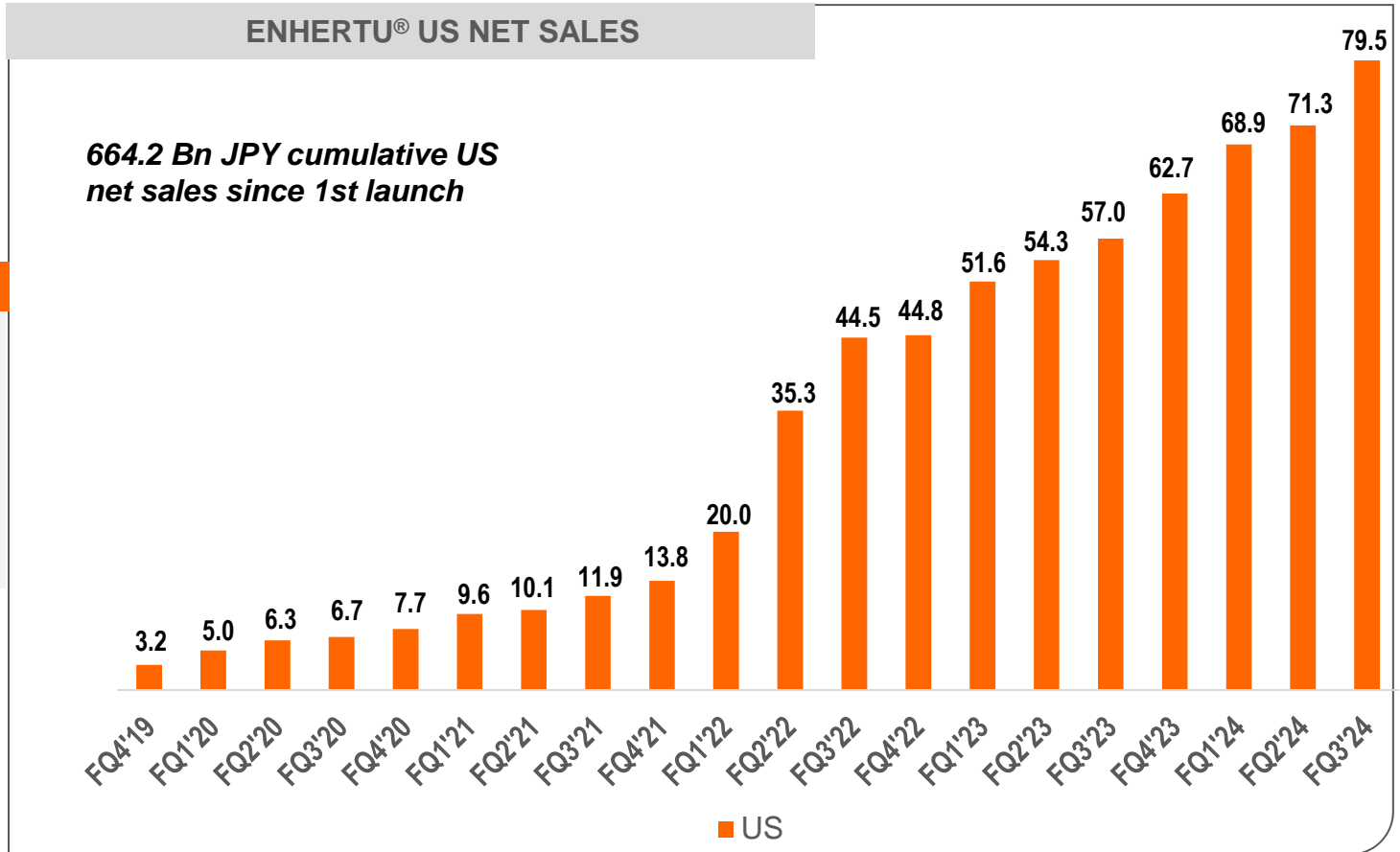
US net sales exceeded 79 Bn JPY in FY Q3 '24

ENHERTU[®] US NET SALES

664.2 Bn JPY cumulative US net sales since 1st launch

US

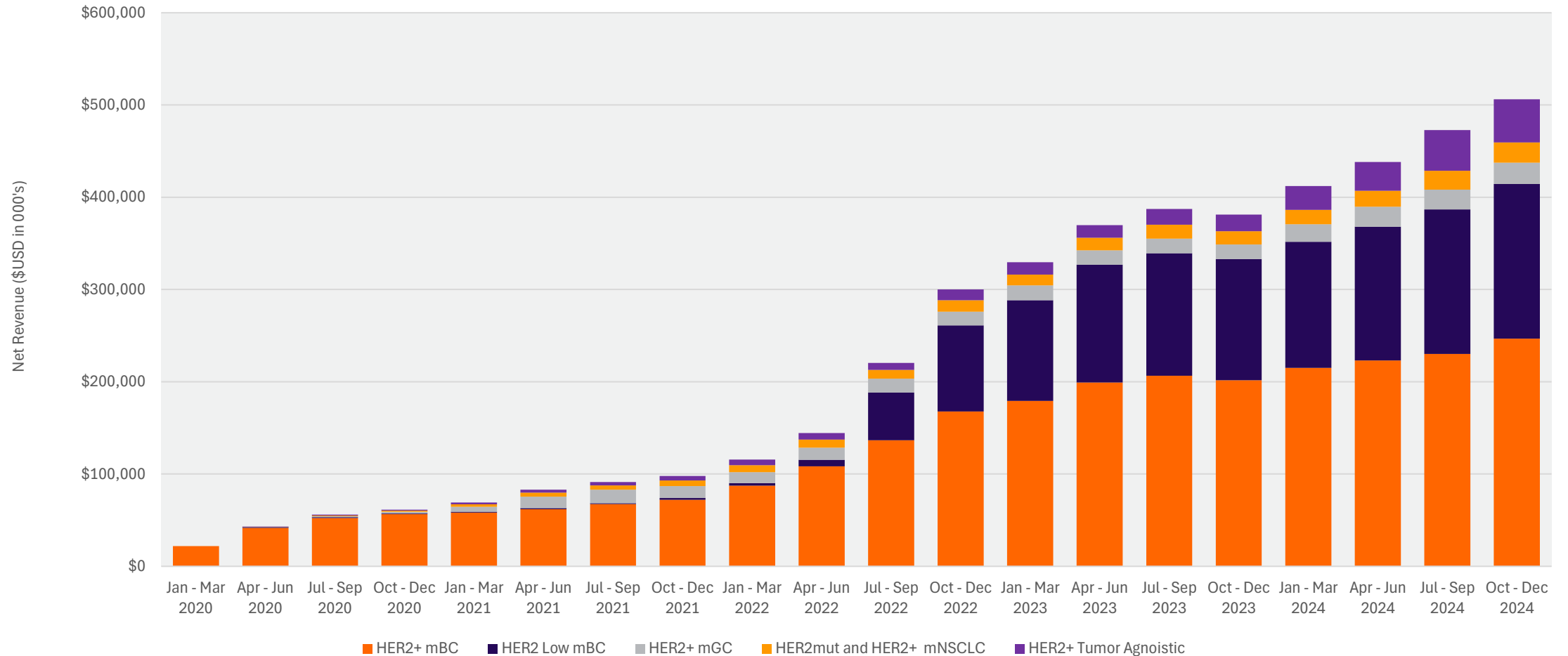
Overall, US net sales in FY2024 Q3 was 79.5 Bn JPY;
+11.5% sequential q-o-q growth
+22.6 Bn JPY (+39.6%) vs FY2023 Q3



*DS External reported sales
 Bn: billion, FQ: fiscal quarter, FY: fiscal year, JPY: Japanese Yen, q-o-q: quarter over quarter

ENHERTU[®] – US revenue split over time (launch – December 2024)

Although breast indications make up ~85% of the total Net Revenue for ENHERTU[®], non-breast indications continue to expand treatment and revenue opportunities for the brand



Growth opportunities remain within ENHERTU[®] current indications



HER2+ mBC

Achieved

ENHERTU[®] is currently the dominant market leader (Market share>60%) for 2L HER2+ mBC in US

FY2024 Q3 vs FY2024 Q2: **+9.5%***
 FY2024 Q3 vs FY2023 Q3: **+24.9%***

Opportunities

- Cement magnitude of benefit, particularly among low DB-03 users and across patient types (including HR+/HER2+ patients)
- Increase confidence in benefit/risk profile through further education on AE identification & management



HR+/HER2 low mBC

Achieved

ENHERTU[®] has become the market leader (Market share>50%) in the post chemo setting

FY2024 Q3 vs FY2024 Q2: **+9.4%***
 FY2024 Q3 vs FY2023 Q3: **+30.3%***

Opportunities

- Pivot to DB-06 at FDA approval in early Q1'CY25 driving pre-chemo use
- Displace chemo (IV & oral) and expand to a broader population with HER2-ultralow



Tumor Agnostic

Achieved

ENHERTU[®] is approved in the US, and has achieved a high market share in HER2+ IHC tested patients

FY2024 Q3 vs FY2024 Q2: **+8.9%***
 FY2024 Q3 vs FY2023 Q3: **+166.4%***

Opportunities

- Increase awareness of the HER2+ indication and improve IHC testing rates from current levels of ~30% to become a new standard of care
- There is still room to grow market share even in the HER2+ IHC tested patients

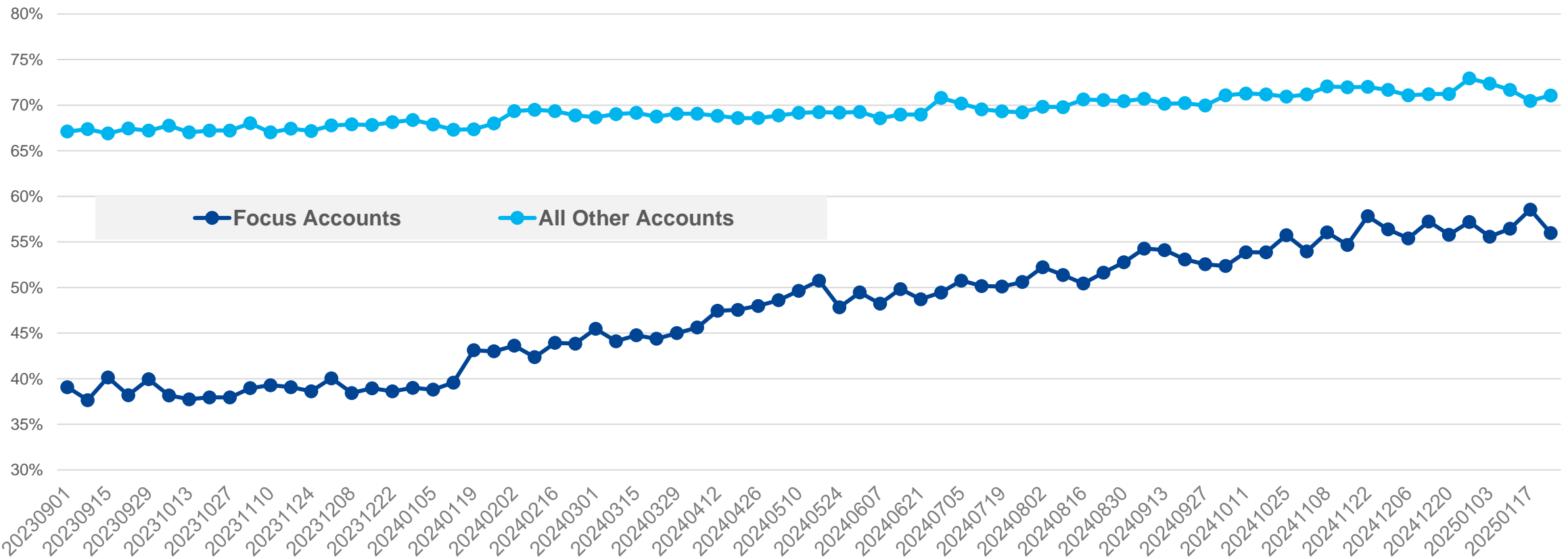
*Sales revenue (USD)

HCP: health care provider, HER2: human epidermal growth factor receptor 2, IHC: immunohistochemistry, mBC: metastatic breast cancer,

Slow adopters continue to increase utilization as evidence and experience grows

- Focus accounts have grown share (relative to Kadcyła®) from 40% to 55%-60% over the past 12 months

ENHERTU® Market Share (vs Kadcyła®) - Focus Accounts vs All Other



Source: Internal database – Patient market share of ENHERTU® vs Kadcyła®
wk: week

ENHERTU® *NOT TODAY* DTC Campaign

***NOT TODAY* connects ENHERTU® to people living with mBC, reflecting their truth.**

...And as the cultural pendulum swings towards authenticity and away from the warrior mentality, *NOT TODAY* follows suit, empowering women to **take back what cancer has stolen from them.**

For certain adults with HER2-positive metastatic breast cancer (mBC)

Sure, HER2-positive metastatic breast cancer will try to take it all. But

NOT TODAY

See how ENHERTU delivered results in adults with HER2-positive mBC who have received a prior anti-HER2 breast cancer treatment

[Learn more >](#)

Important Safety Information ^

What is the most important information I should know about ENHERTU?
ENHERTU can cause serious side effects, including:
Lung problems that may be severe, life-threatening or that may lead to death. If you develop lung problems your healthcare provider may treat you with corticosteroid medicines. Tell your healthcare provider right away if you get

What is ENHERTU?
ENHERTU is a prescription medicine used to treat adults who have:
• Human epidermal growth factor receptor 2 (HER2)-

NOW APPROVED

For certain adults with HR+, HER2-low or HR+, HER2-ultralow, metastatic breast cancer (mBC) who received prior endocrine treatment in the metastatic setting

Sure, HER2-low and HR+, HER2-ultralow metastatic breast cancer will try to take it all. But

NOT TODAY

Previously diagnosed with HER2-negative metastatic breast cancer (mBC)? You may actually have low levels of HER2

[Learn more >](#)

Important Safety Information ^

What is the most important information I should know about ENHERTU?
ENHERTU can cause serious side effects, including:

What is ENHERTU?
ENHERTU is a prescription medicine used to treat adults who have:

Response to treatment

Initial results (May 2021)

In the first assessment, more people had their tumors shrink with ENHERTU than with ado-trastuzumab emtansine†§

Overall response

83% with ENHERTU & 36% with ado-trastuzumab emtansine

Important Safety Information ^

What is the most important information I should know about ENHERTU?
ENHERTU can cause serious side effects, including:

What is ENHERTU?
ENHERTU is a prescription medicine used to treat

In adults with HR+, HER2-low or HR+, HER2-ultralow, mBC who received prior hormone treatment in the metastatic setting

Median progression-free survival

ENHERTU helped people live longer without their cancer growing or spreading compared to chemotherapy*†

13.2 months with ENHERTU & 8.1 months with chemotherapy

Important Safety Information ^

What is the most important information I should know about ENHERTU?
ENHERTU can cause serious side effects, including:

What is ENHERTU?
ENHERTU is a prescription medicine used to treat adults who have:

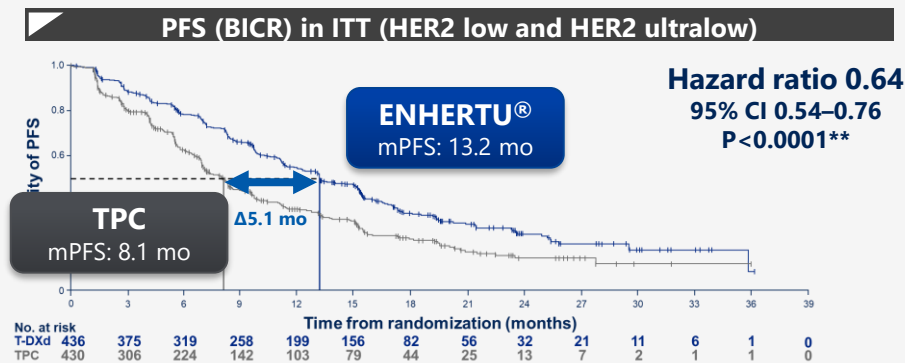
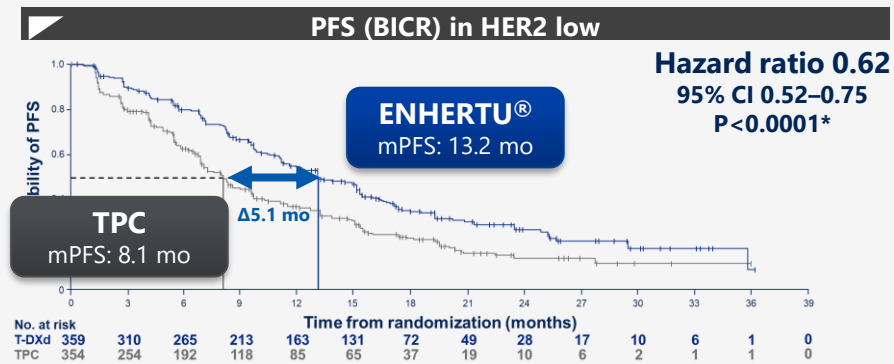
ENHERTU®: HR+/HER2 low or HER2 ultralow, chemo naive opportunity



- There remains unmet need in HR+ / HER2 low breast cancer for patients who progress after ≥ 1 endocrine-based therapy
- There were previously no targeted therapies specifically approved for patients with HER2 ultralow expression.
- ENHERTU® is now the first targeted therapy approved to treat HER2 ultralow expressing patients, following FDA approval of DESTINY-Breast06

DESTINY-Breast06 Study

- The primary endpoints is PFS (BICR) in HER2 low
- TLR was obtained in 2024



- Statistically significant and clinically meaningful PFS benefit vs. chemotherapy
- Consistent results in HER2-ultralow mBC
- No new safety signals were identified
- Major market patient opportunity of ~ 18k*



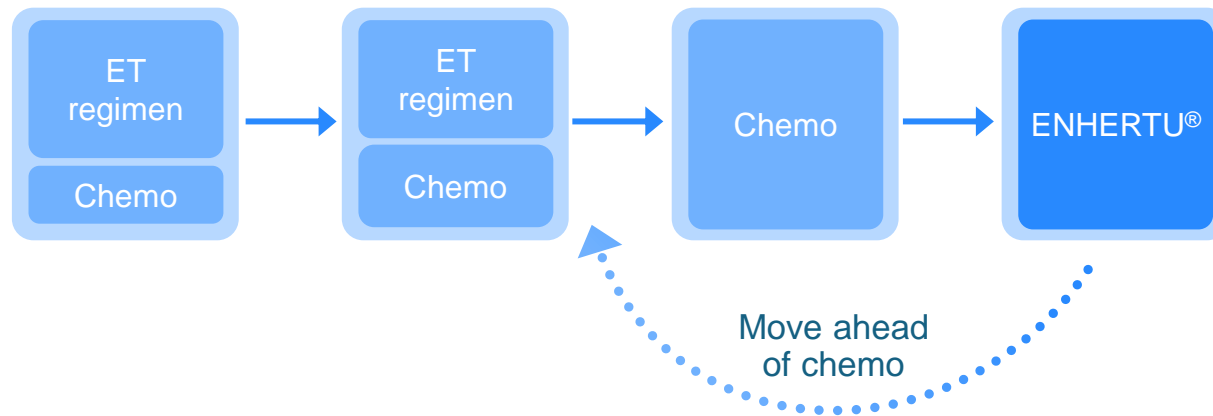
*US+Germany+France+Italy+Spain+UK+JP

BICR: blinded independent central review, CI: confidence interval, HR: hazard ratio, ICC: investigator's choice of chemotherapy, PFS: progression-free survival, OS: overall survival, Q3W: once every three weeks, TLR: topline results

DESTINY-Breast06 was designed to move ENHERTU® **earlier** in the treatment paradigm and further **broaden** the eligible patient population

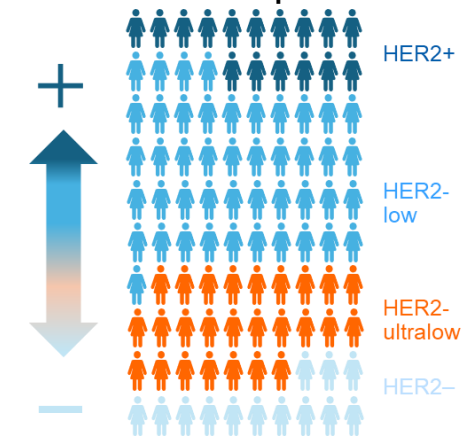
EARLIER

HER2 low in post-ET population



BROADER

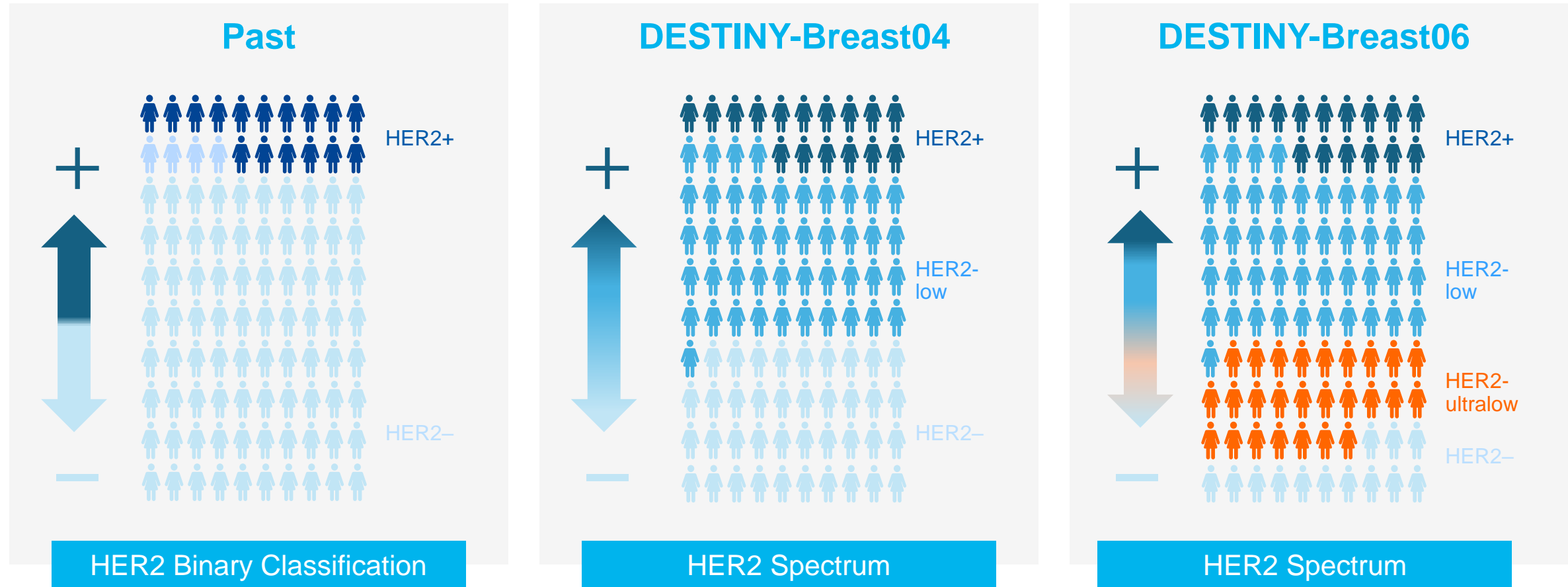
HER2 ultralow further broadening the HER2 spectrum



New classification defined as IHC 0 with membrane staining

With the DB-06 approval ~90% of all mBC patients will be eligible for ENHERTU®

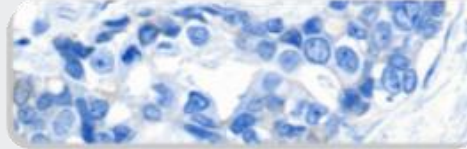
ENHERTU[®] HER2 low and ultralow indication expands the patients we can help



Defined as IHC 0 with membrane staining, ultralow is new to the HER2 spectrum

HER2 ultralow patients are not identified on reports today; ONCs will need to drive re-evaluation of existing patients with IHC 0 results

Current Reporting Recommendation



HER2
IHC
Score
0

HER2 Status
Negative

IHC 0 with membrane staining “**score**” is not **distinctly recognized** by CAP Biomarker Templates or ASCO-CAP guidelines

ANTICIPATED ID PROCESS



ONCs
to contact PATH if IHC 0

Ordering



PATH/Lab
determines re-evaluation approach

Re-Evaluation



PATH/Lab
reports result

Reporting

Call-to-Action

(if majority pts treated earlier)



Ask your PATH to re-evaluate IHC 0 results to identify any membrane staining

HER2 IHC testing in solid tumors website

“HER2Know” has expanded its website to include content on HER2 in tumors beyond breast cancer

- Testing for HER2 can inform patient care in breast and gastric cancer, among other tumor types.
- With recent clinical advancements, consistency of HER2 IHC assessment in solid tumors across the full spectrum of expression is of paramount importance.
- “HER2Know” provides a collection of clinical cases, tools to assess your HER2 IHC scoring consistency, and a range of educational resources to help you refine your approach to HER2 IHC scoring.

Breast Cancer

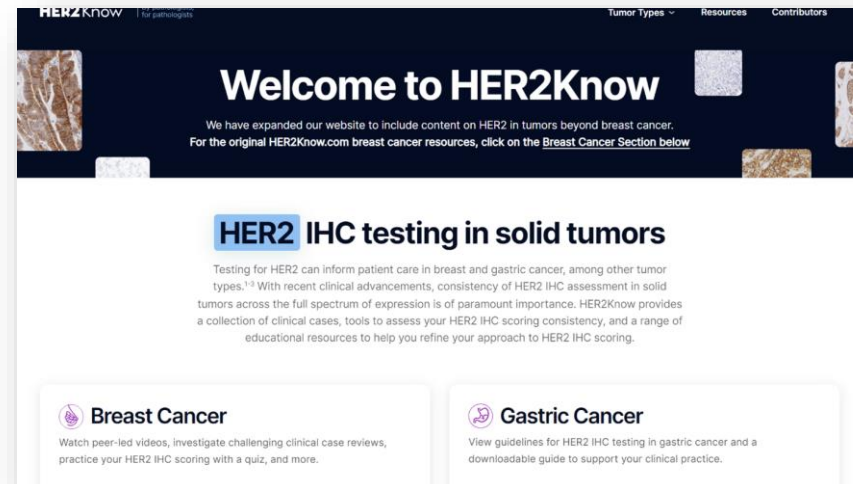


Watch peer-led videos, investigate challenging clinical case reviews, practice your HER2 IHC scoring with a quiz, and more.

Gastric Cancer



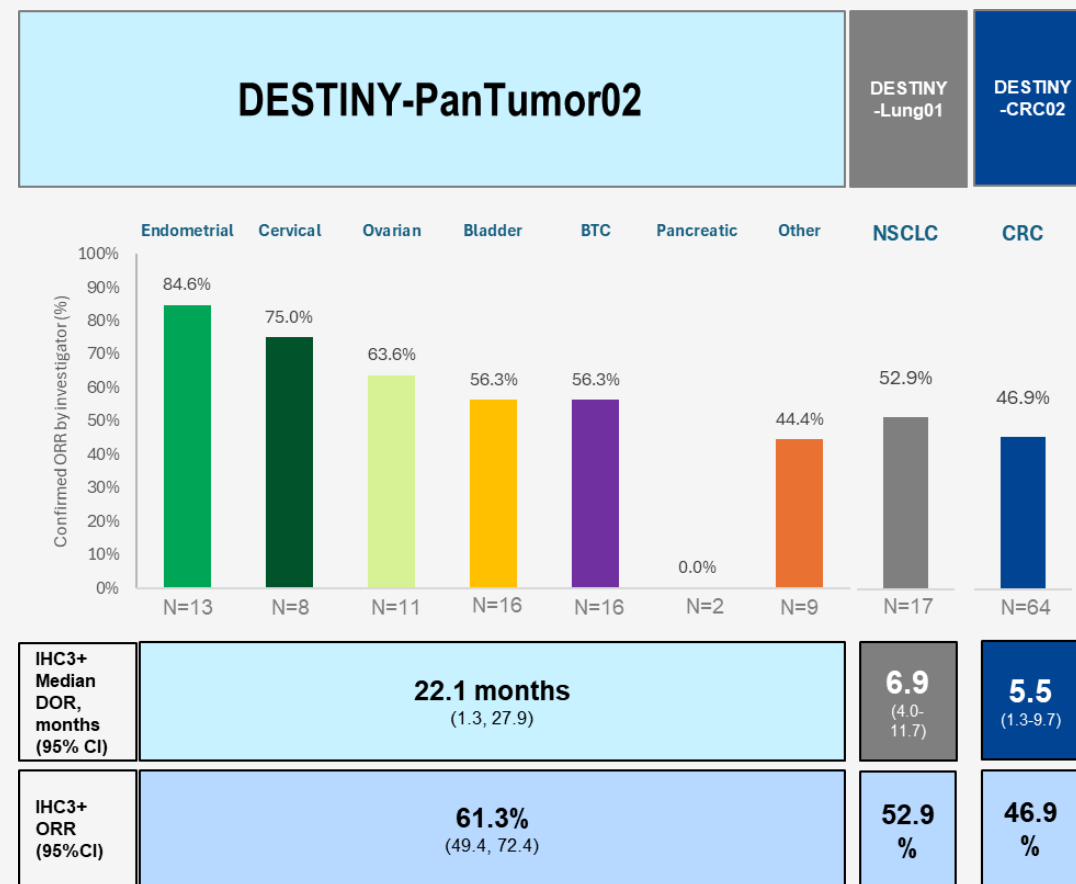
View guidelines for HER2 IHC testing in gastric cancer and a downloadable guide to support your clinical practice.



ENHERTU®: HER2 positive tumor agnostic opportunity



- There were previously no approved HER2-directed therapies particularly for those who have progressed on or are refractory to standard of care therapies, and unmet need for effective therapies for certain HER2 positive solid tumors
- ENHERTU® is now the first approved HER2-directed therapy for certain HER2 expressing solid tumors after achieving FDA approval in the HER2+ Tumor Agnostic Indication



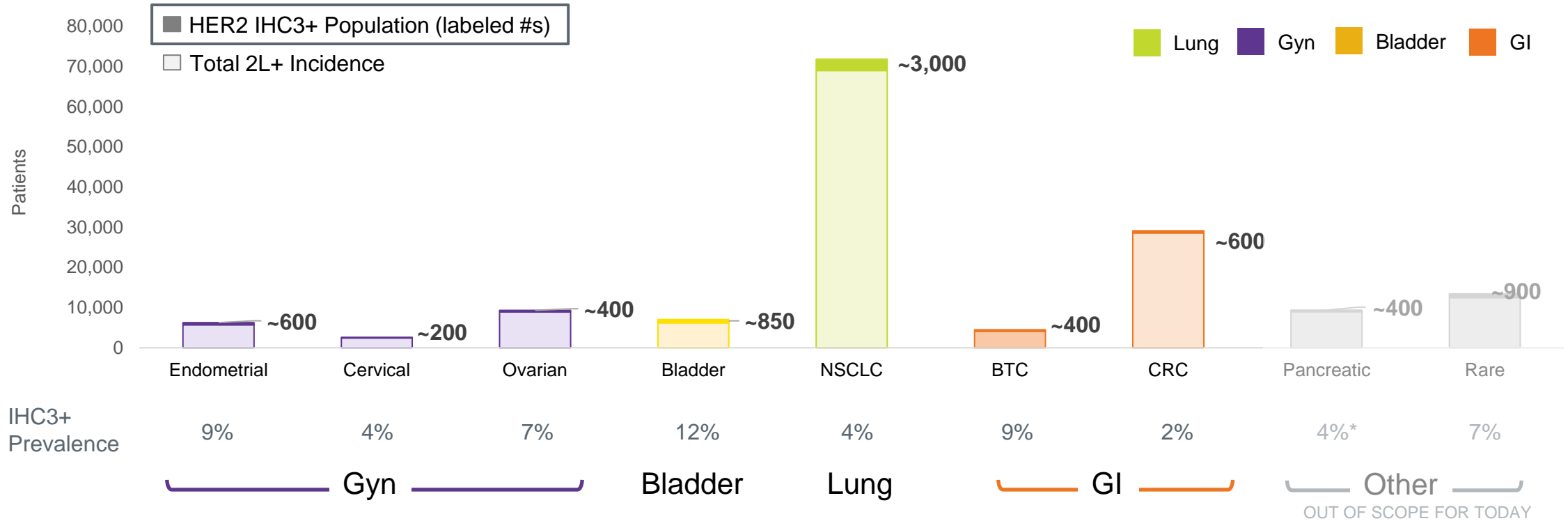
- Showed the pre-specified target for objective response rate (ORR) and demonstrated durable response across multiple HER2 positive advanced solid tumors in heavily pretreated patients
- No new safety signals were identified
- Major market patient opportunity of ~ 17k*

*US+Germany+France+Italy+Spain+UK+JP

CI: confidence interval, FDA: Food and Drug Administration HR: hazard ratio, ORR: overall response rate, OS: overall survival, PFS: progression-free survival, Q3W: once every three weeks, TLR: topline results

Tumor agnostic opportunity is sizable with ~6,000 addressable HER2+ (IHC3+) patients across tumor types in the US

Significant opportunity for ENHERTU® in HER2+ (IHC3+) patients across tumors



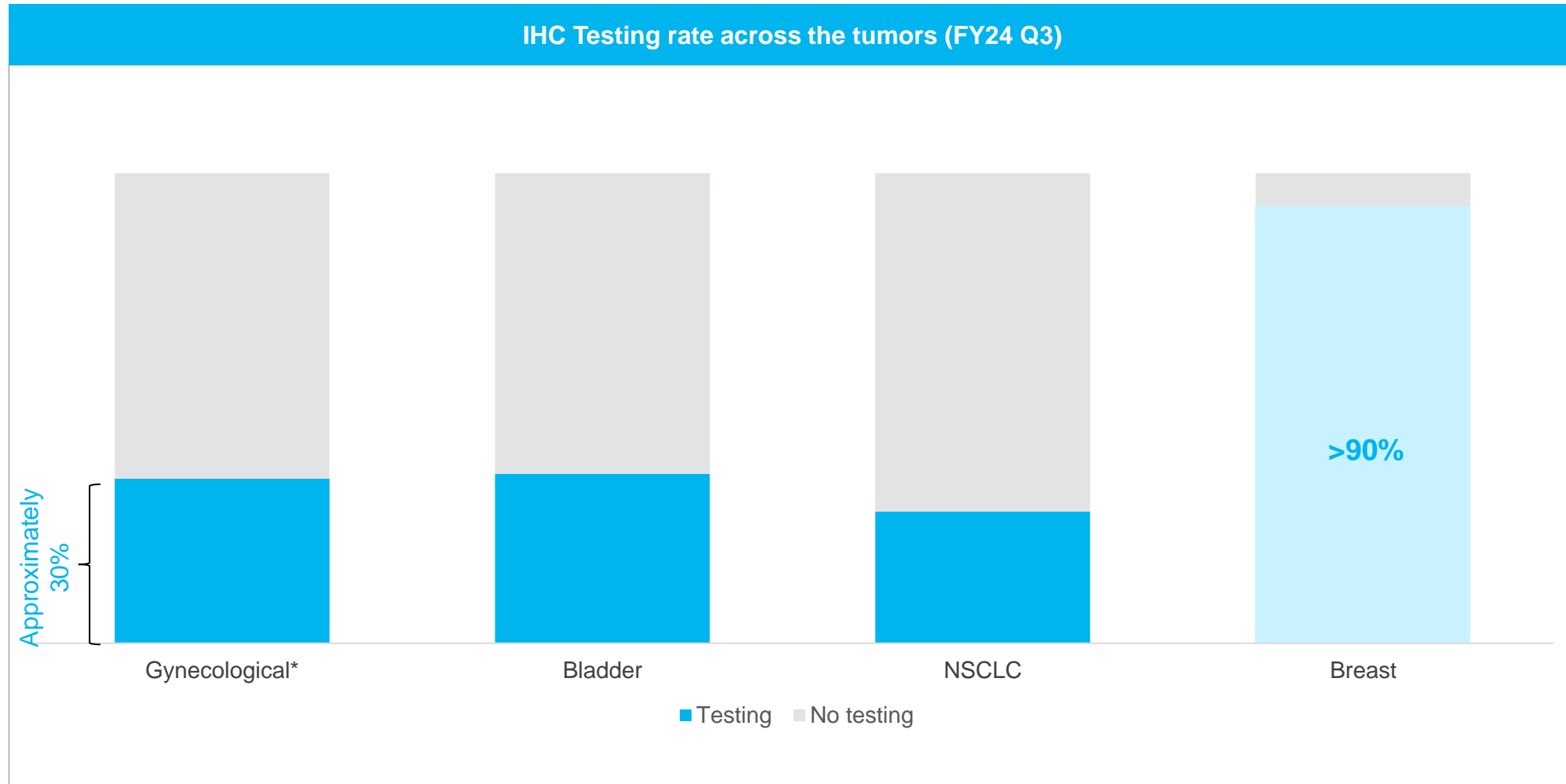
5-year survival across these tumors ranges from 2% to 25%, highlighting unmet need for improved treatment options

*IHC3+ prevalence in pancreatic ~1%-7%, assumed average of 4% for chart

Source: SEER_May2023

BTC: biliary tract cancer, CRC: colorectal cancer, GI: gastrointestinal, Gyn: gynecological, IHC: immunohistochemistry, NSCLC: non-small cell lung cancer

IHC testing rates for tumor agnostic remain low and patients do not have the opportunity to be prescribed ENHERTU®

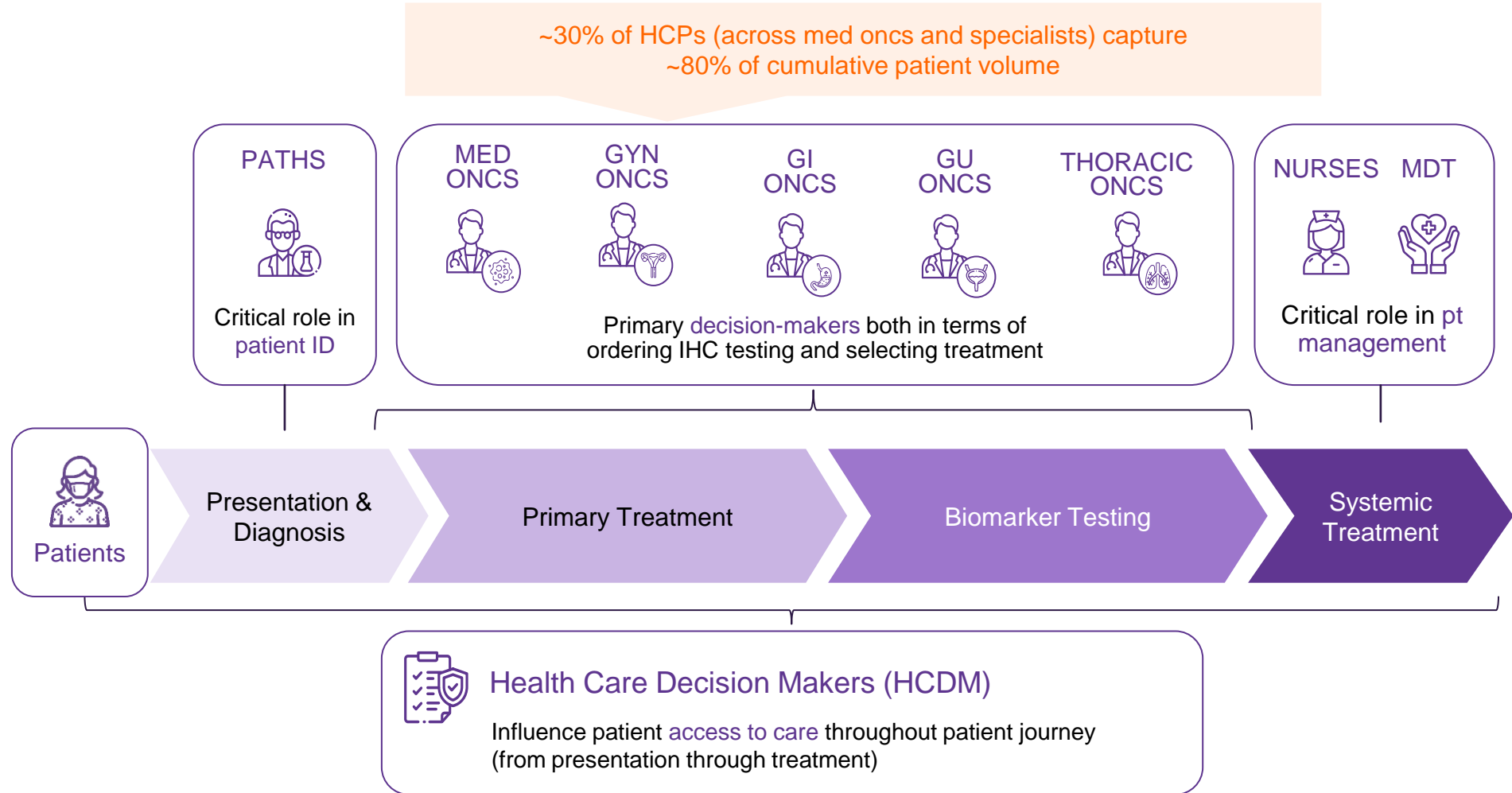


*Unweighted average of Endometrial, Cervical, Ovarian
 Testing data is from Diagnostics National Test Rate,
 FY: fiscal year, IHC: immunohistochemistry, NSCLC: non-small cell lung cancer, Q: quarter, TA: Tumor Agnostic,

ENHERTU[®] tumor agnostic HCP targeting requires differentiated engagement due to the variety of stakeholders involved across tumors

Tumor agnostic environment is complicated by the wide variety of stakeholders involved in managing a dispersed patient population

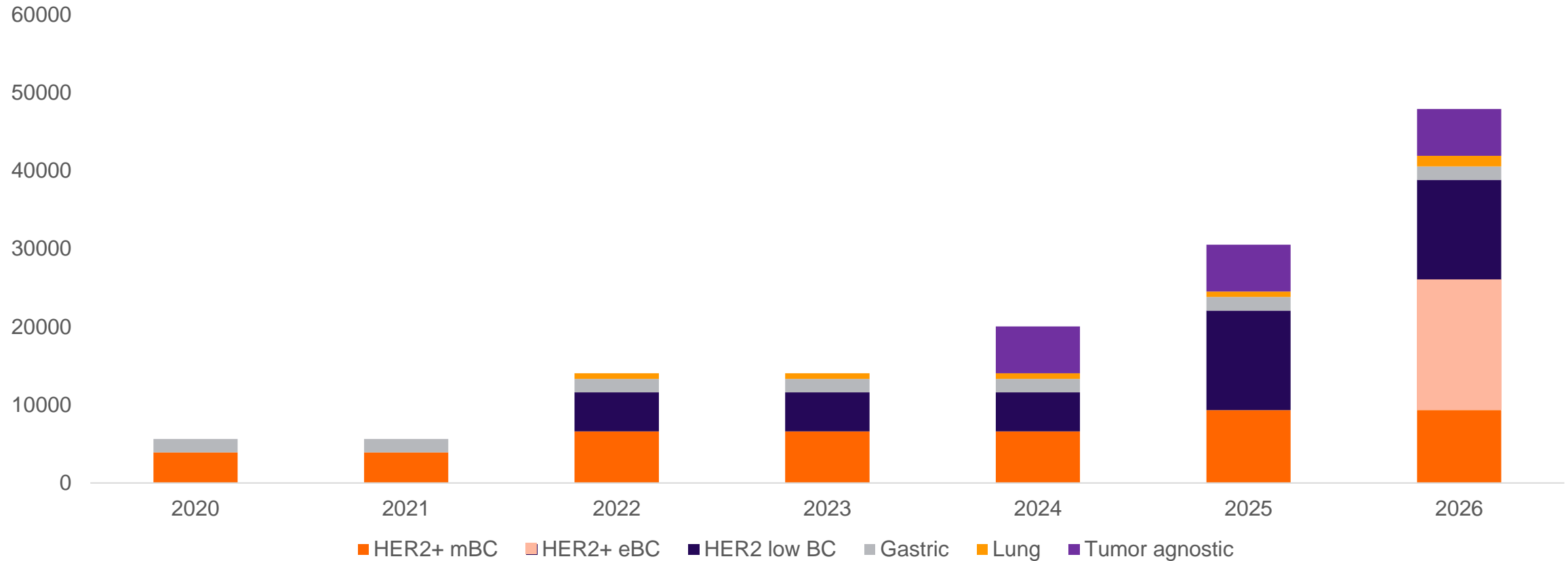
The number of tumors with this indication will require mobilization of different teams across the alliance



GI: gastrointestinal, GU: genitourinary, GYN: gynecological, HCP: health care provider, ID: identification, IHC: immunohistochemistry, MDT: multidisciplinary team, ONC: oncologist, pt: patient, TA: Tumor Agnostic, Sources: DS Analysis based on Symphony data

The eligible patient opportunity in the US expands ~2x by 2026

ELIGIBLE OPPORTUNITY FOR ENHERTU® (US)*



Calendar Year
 BC: breast cancer, eBC: early breast cancer; mBC: metastatic breast cancer
 Eligible Patients are based on internal estimates

DATROWAY[®]: 2L/3L HR+/HER2 negative breast cancer opportunity



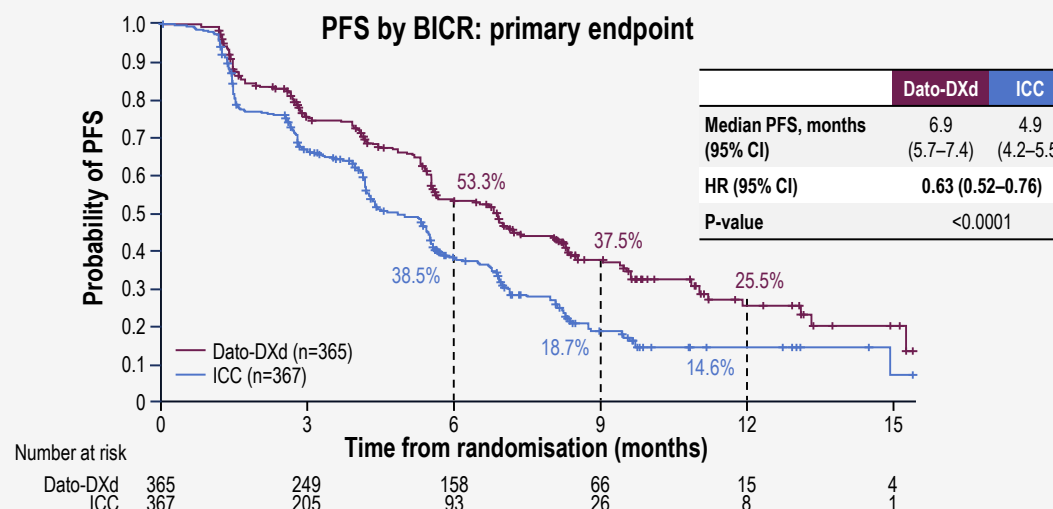
- There remains unmet need in HR+ / HER2 low or negative breast cancer for patients who progress on and are not suitable for endocrine therapy and were previously treated with 1-2 prior line(s) of chemotherapy
- DATROWAY[®] is now approved for HR+ HER2 low or negative breast cancer patients who have received prior endocrine-based therapy and chemotherapy

TROPION-Breast01 Study

- The dual primary endpoints are PFS and OS
- TLR was obtained in September 2023
- **Us: FDA Approval on January 17, 2025**
- **JP: Approval on December 27, 2024**
- **EU: Recommend for approval by CHMP**

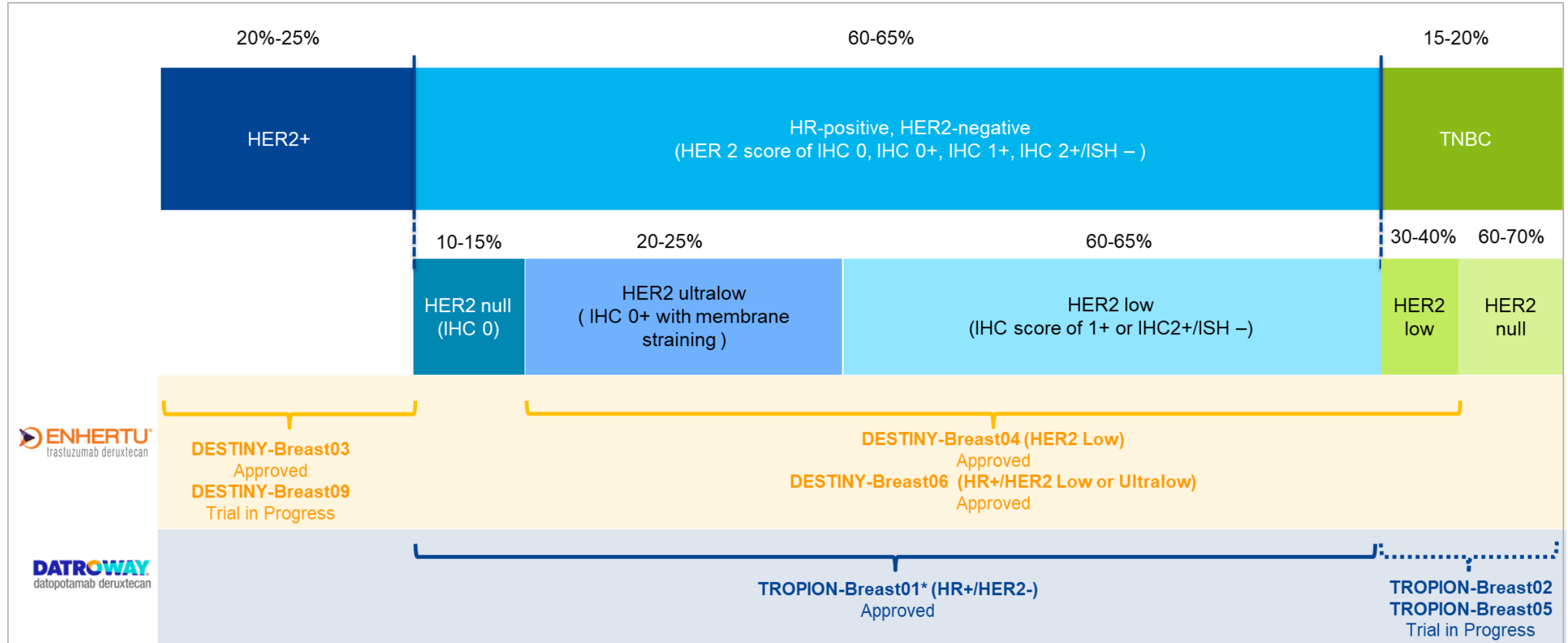


- Statistically significant and clinically meaningful efficacy (PFS) vs. chemotherapy
- Convenient Q3W dosing schedule
- Stomatitis/oral mucositis was effectively managed with dose reductions/delay
- No grade 4 or 5 ILD events



DS oncology franchise can provide benefit to nine out of 10 mBC patients

Potential indications for DATROWAY® in TNBC could reach 100% of mBC in near future



*TROPION-Breast01 indication: HR+/HER2- (IHC0, 1+ or 2+/ISH-) mBC
 mBC: metastatic breast cancer, HR: hormone receptor, IHC: immunohistochemistry, ISH: in situ hybridization, TNBC: triple negative breast cancer

DATROWAY[®]: EGFR mutated, previously treated NSCLC Opportunity



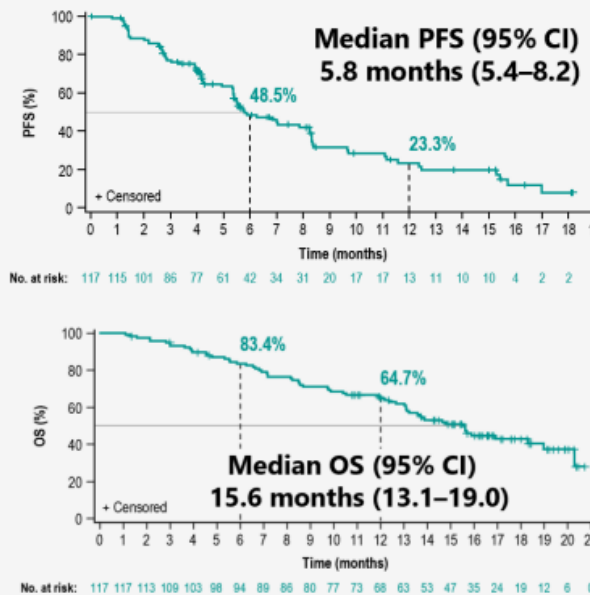
- There is an unmet need for effective therapies in EGFRm NSCLC following disease progression on TKI treatments (2L+)
- BLA* will be a Priority Review and has received Breakthrough Therapy Designation, allowing for an expedited regulatory review.
- 2L+ EGFRm NSCLC will represent DATROWAY[®] first approval in mNSCLC

Pooled Analysis of TROPION-Lung05 and TROPION-Lung01

- Primary endpoints: ORR (TL05), PFS and OS (TL01)
- **BLA for Accelerated Approval submitted to FDA in Nov 2024**
- **Granted Breakthrough Therapy Designation in Dec 2024**
- **Expected approval: FY2025 H1 (US) (PDUFA date: July 12, 2025)**

**Basis for Accelerated Approval:
ORR of 42.7%**

PFS and OS in the EGFRm Pool (N=117)



- Robust clinical data with ORR 42.7%, mDOR 7.0 months, mPFS 5.8 months, and mOS 15.6 months**
- Outcomes for patients with prior Osimertinib were similar to the overall pooled population
- Stomatitis/oral mucositis was effectively managed with dose reductions/delay
- The most common ocular surface event was dry eye (grade 1 or 2)
- No grade 4 or 5 ILD events
- US patient opportunity of ~3k+***

*Biologics license application **Pooled analysis of TL01 and TL05 ***US only. There is potential for additional upside in patient eligibility from recently approved TKI+CTx regimens, such as FLAURA2 in the future if 1L use grows significantly
 BICR: blinded independent central review; BLA: biologics license application, CI: confidence interval; EGFR: epidermal growth factor receptor, FDA: food and drug administration, HR, hazard ratio; ICC, investigator's choice of chemotherapy; ILD: interstitial lung disease, mDOR: median duration of response, NSCLC: non-small cell lung cancer, ORR: overall response rate, OS: overall survival; PDUFA: prescription drug user fee act, PFS: progression-free survival; Q3W: once every three weeks; TLR: topline results, TKI: tyrosine kinase inhibitor, TRAE: treated related adverse events

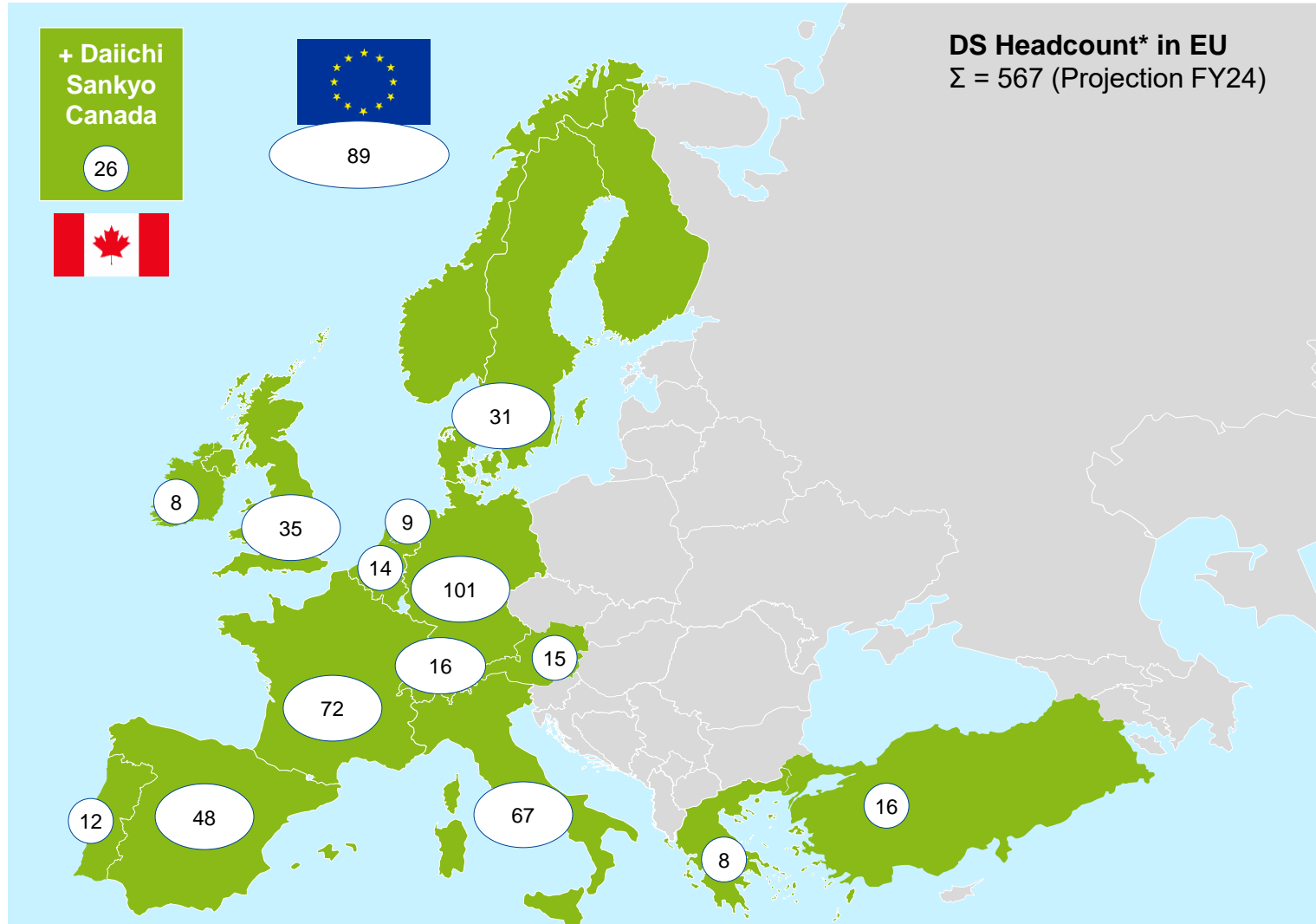
Markus Kosch

*Head, EU Oncology Business Division,
Daiichi Sankyo Europe*

- Joined Daiichi Sankyo in 2021
- Leads European and Canada oncology business at Daiichi Sankyo governing 18 countries
- Boarded physician in internal medicine, practiced in nephrology and oncology at the University Hospital in Münster until 2005 where he still teaches
- Over 20 years' experience in pharmaceutical industry in senior global, regional and country leadership roles at Wyeth and Pfizer
- Launched medicines in lung, GI cancers, hematology and breast including Palbociclib across Europe
- Board Member of the EFPIA (European Association of Pharmaceutical Industry)



EU OBD as mature organization with investment in key capabilities and right resourcing to support asset and indication launches across 18 markets



Mature and professionalized organization across HQ and 18 markets

Regional and local **investment in key capabilities** including Governmental Affairs, Patient Advocacy, OVAP, Training and Learning, etc.

Right resourcing to support new asset and indication launches

*Headcounts for EU Oncology Business Division

DSCA: Daiichi Sankyo Canada, EUKAN: Europe & Canada, HQ: headquarters, OBD: Oncology Business Division, OVAP: Oncology Value, Access, and Pricing

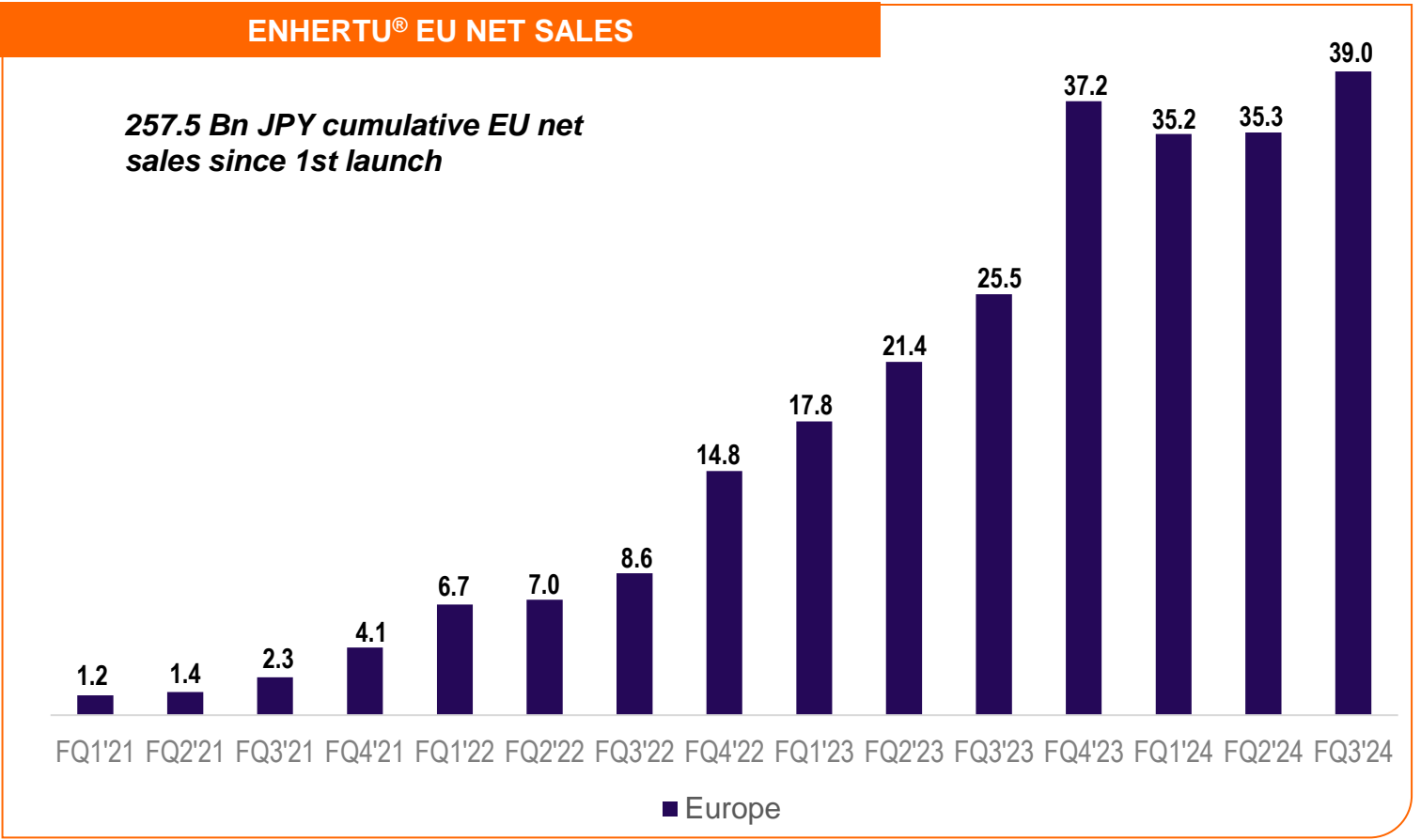
EU region has realized significant ENHERTU[®] revenue growth

EU net sales have exceeded 39 Bn JPY per quarter

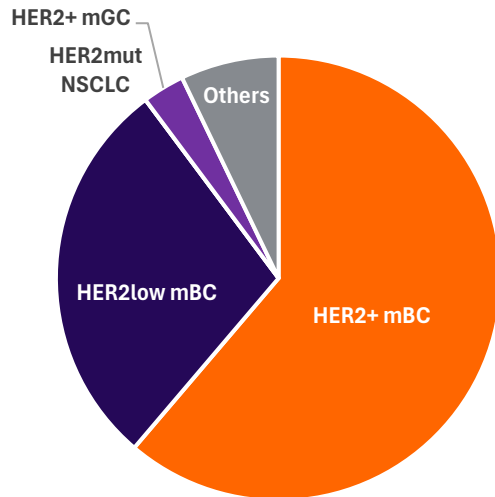
Overall, EU net sales in FY2024 Q3 was 39.0 Bn JPY;
+10.4% sequential q-o-q growth
+13.5 Bn JPY (+52.9%) vs FY2023 Q3

EU ENHERTU[®] EU NET SALES

257.5 Bn JPY cumulative EU net sales since 1st launch



Revenues by Indication

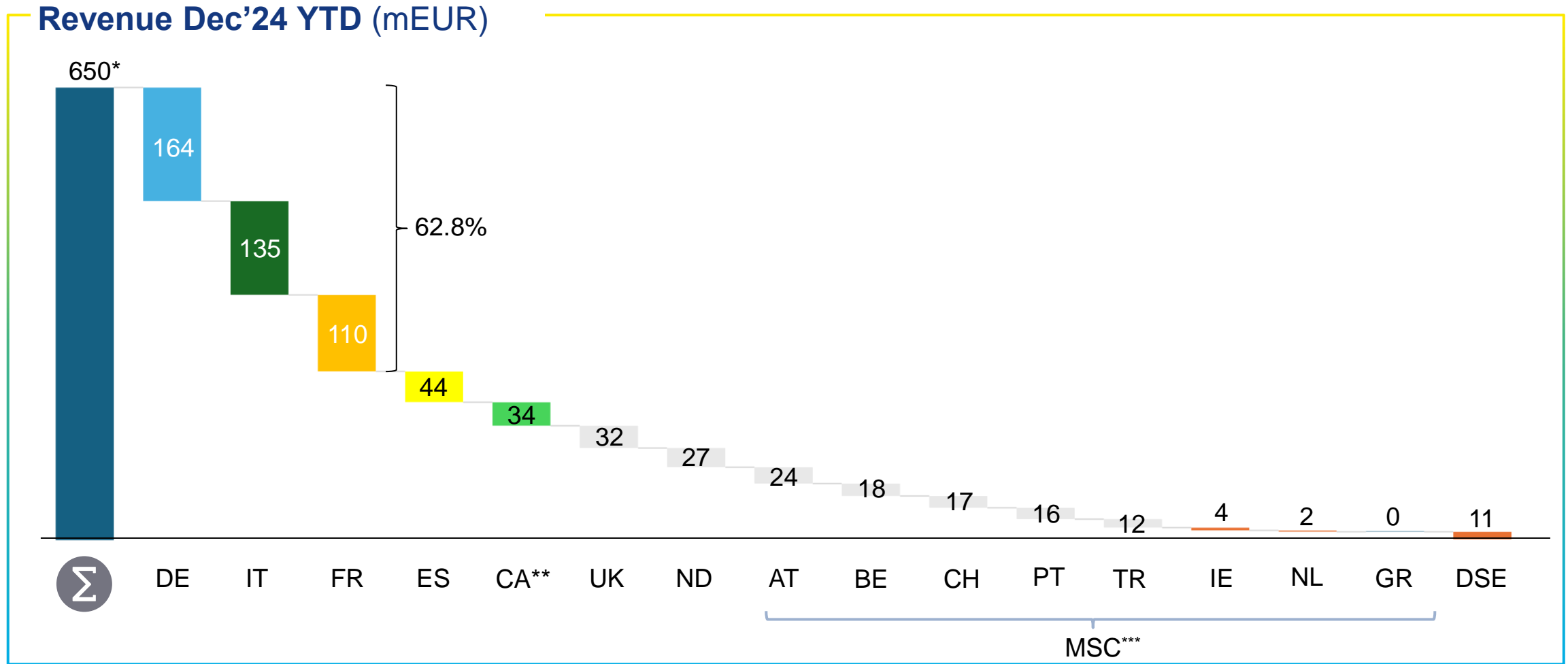


*Financial results reference data

Bn: billion, FQ: fiscal quarter, FY: fiscal year, mBC: metastatic breast cancer, mGC: metastatic gastric cancer, NSCLC: non-small cell lung cancer, JPY: Japanese Yen, q-o-q: quarter over quarter

Germany, Italy and France contribute >60% of year-to-date overall revenue

YTD Performance: revenue realized per country

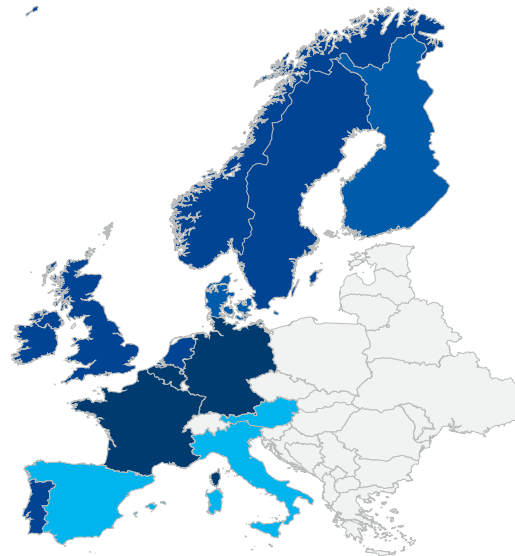


















*DaiichiSankyo booked revenue countries+Canada **CA: AZ booked revenue country

***MSC = Mid-sized countries including Austria, Switzerland, Turkey, Greece, Belgium, Portugal, Ireland, Netherlands

AT: Austria, BE: Belgium, CA: Canada, CH: Switzerland, DE: Germany, ES: Spain, FR: France, GR: Greece, IE: Ireland, IT: Italy, NL: Netherlands, ND: Nordics, PT: Portugal, TR: Turkey, UK: United Kingdom, YTD: year to date

One key difference between US and EU is the solid chain-link between regulatory approval and HTA and reimbursement decisions on country level



Archetypes based on commonalities in key decision-drivers	Description	Key Characteristics	Countries
Clinical Value-based Markets	Government dictates reimbursement based on clinical outcomes versus available products.	<ul style="list-style-type: none"> Strong focus on clinical attributes – H2H comparison preferred Comparator selection important Indirect treatment comparison (ITC) not always accepted – especially in Germany 	 France  Germany  Belgium  Luxembourg
Cost-effectiveness Markets	Government dictates reimbursement policy based on the value of improved outcomes over displaced treatment.	<ul style="list-style-type: none"> Product price is an integral part of the cost-effectiveness model Clinical value needs to be in line with product price Surrogate endpoints tend to be sufficient or can be leveraged 	 England  Portugal  Finland  Scotland  Sweden  Denmark  Ireland  Norway  The Netherlands
Budget Impact-driven Markets	Affordability of drugs is a key driver for access. In these markets decision making is typically devolved to a regional level.	<ul style="list-style-type: none"> Decision driven by new treatment's impact on current healthcare budget vs. SoC Regional payer engagement is important to facilitate formulary inclusions 	 Italy  Spain  Austria

EMA approval does not automatically imply reimbursement across all European markets and typically comes later than FDA approval in the US

At a country level, HTA and reimbursement decisions are typically made following regulatory approval

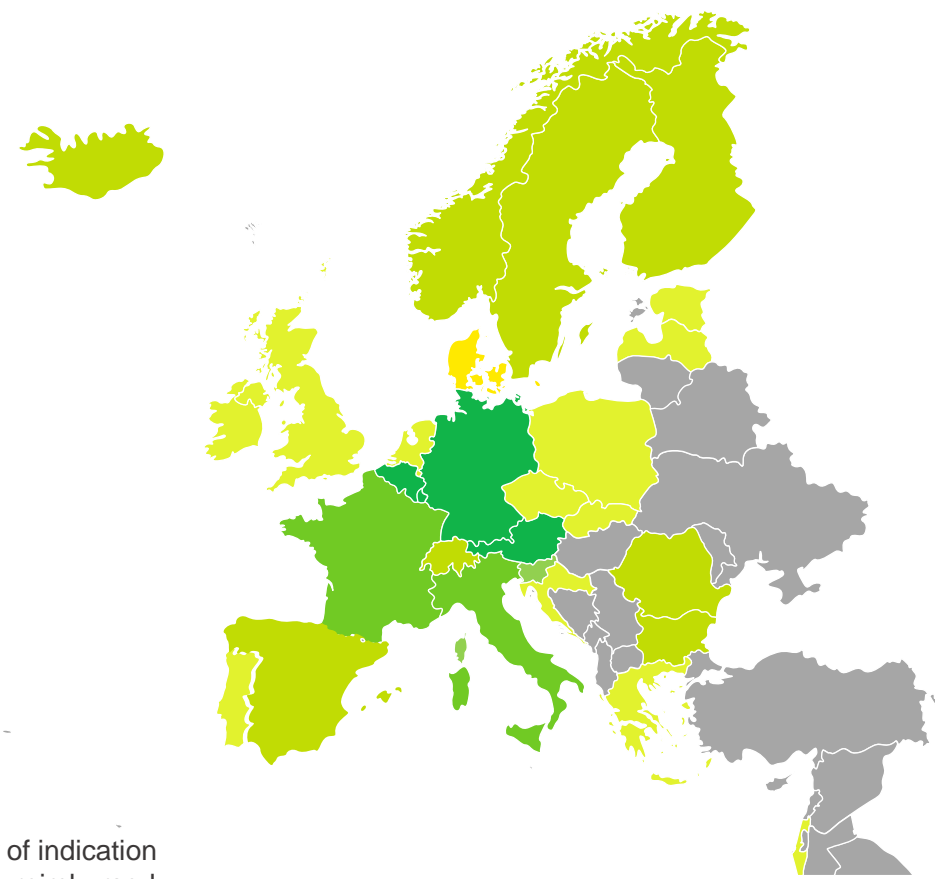
Each country in Europe makes decisions based on different aspects which can be split into 3 archetypes i.e., clinical value, cost-effectiveness, budget impact

Therapeutic options are typically more limited than in the US

To date, 50+ national reimbursement successes for ENHERTU[®] have been achieved across markets and indications



50+ national reimbursements



**HER2+
mBC 2L+
DB-03**



**HER2 low
DB-04**



**Gastric
DG-01/02**



**Lung
DL-01/02**



DB04 in AP and GC in 3L+

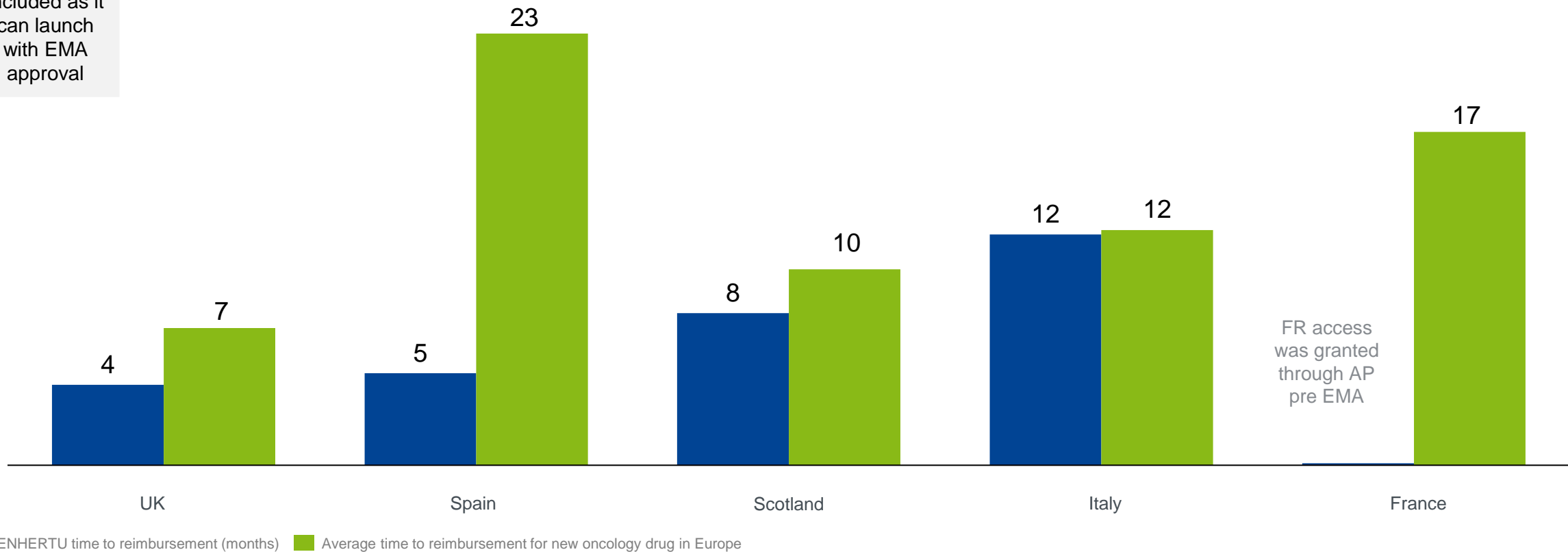
Number of indication currently reimbursed



ENHERTU[®] achieved record time to reimbursement for DESTINY-Breast03 with DS OVAP teams leading on pricing and access

HER2+ mBC 2L+ availability to patients versus industry oncology average (months)

Note:
Germany not included as it can launch with EMA approval



NB: The median time to availability is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list). DE has been excluded as reimbursement is automatically granted post EMA approval
 Sources: Internal Tracker; EFPIA Patients WAIT Indicator 2023;
 AP: accelerated approval, EMA: European Medicines Agency, DE: Germany, FR: France, OVAP: Oncology value, access, and pricing

Key growth opportunities in FY25 remain in ENHERTU[®] current indications as well as upcoming indication expansions



HER2+ mBC

Achieved

ENHERTU[®] is currently the dominant market leader (>70%) for 2L HER2+ mBC in most countries

Opportunities

- Maximum DB-03 effort to drive 2L HER2+ BC penetration, reach 70+% new patient share across the region
- Reinforce patient management of ILD through real world data and education in some countries



HR+/HER2low mBC

Achieved

ENHERTU[®] has become the market leader in several key countries in the post chemo setting

Opportunities

- 2L - 4L HER2 low mBC approximately 30%-40% market share in EU.
- Launch ENHERTU[®] in HER2 low mBC segment (DB-04) in remaining EUCAN markets and achieve broad penetration in all launched markets;
- DB-06 is filed in Europe with the goal for eventual approval and move earlier and go broader (HER2 ultralow) in the future



Tumor Agnostic

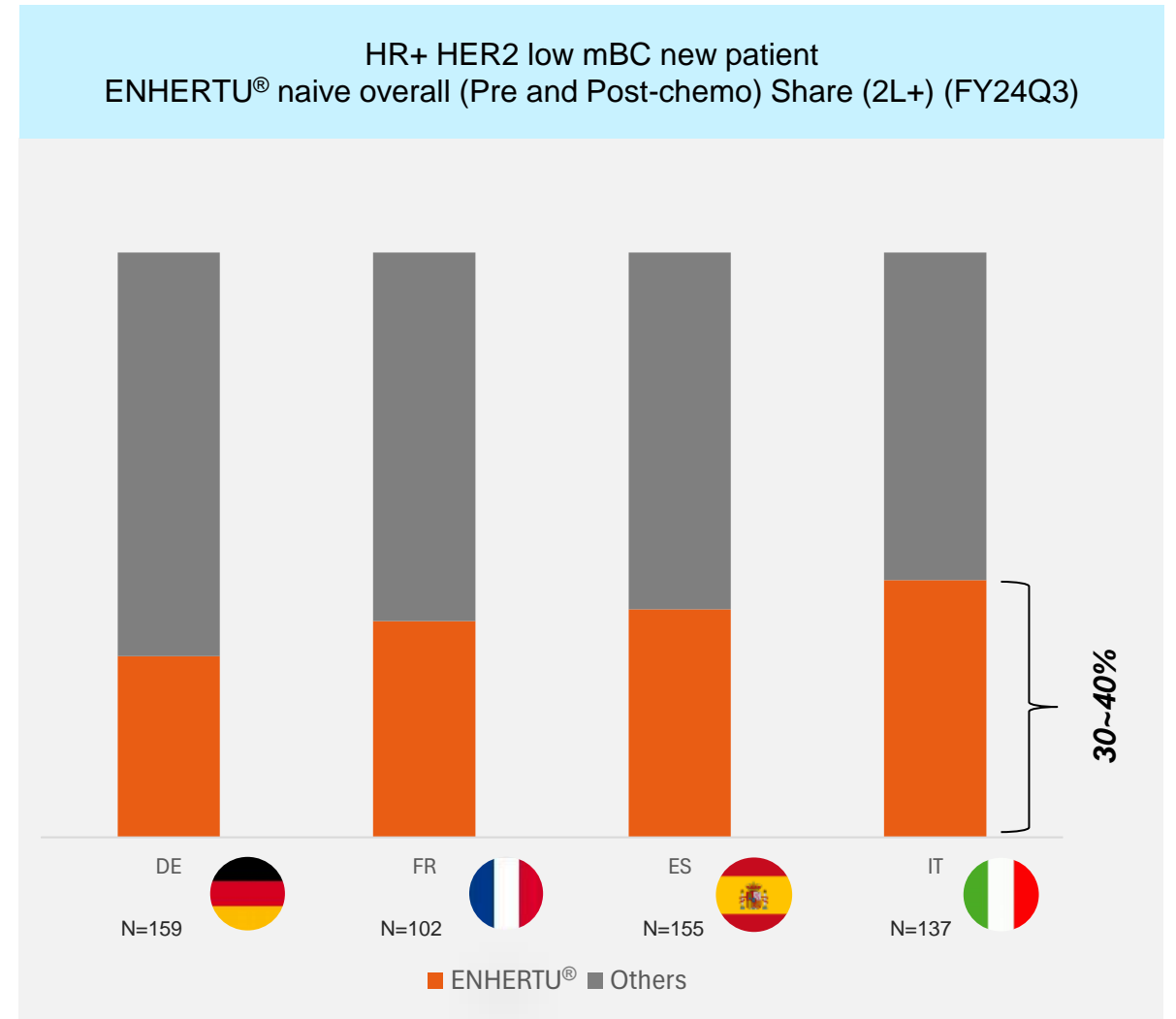
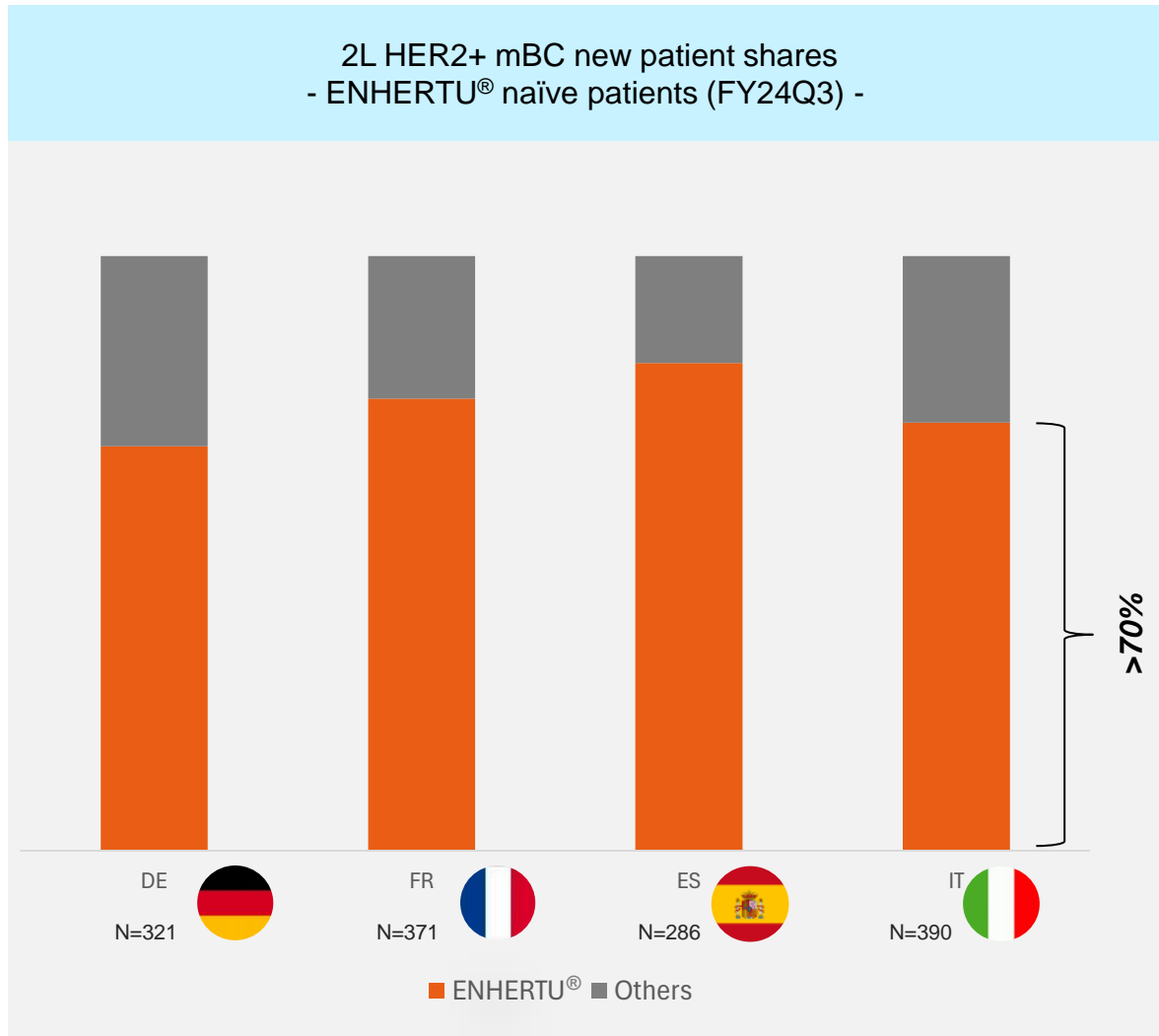
Achieved

ENHERTU[®] is approved in the US, and has achieved a high market share in HER2+ IHC tested patients

Opportunities

- Opportunity for ENHERTU[®] tumor agnostic indication is under evaluation in EUCAN

HER2+ 2L mBC shares in key EU markets, ambition to continue growth; early launch countries show strong uptake in HER2 low segment






















Source: Internal market research results FYQ3'24
 DE: Germany, ES: Spain, FR: France, IT: Italy, mBC: metastatic breast cancer,

EU is in earlier stage of launches versus US

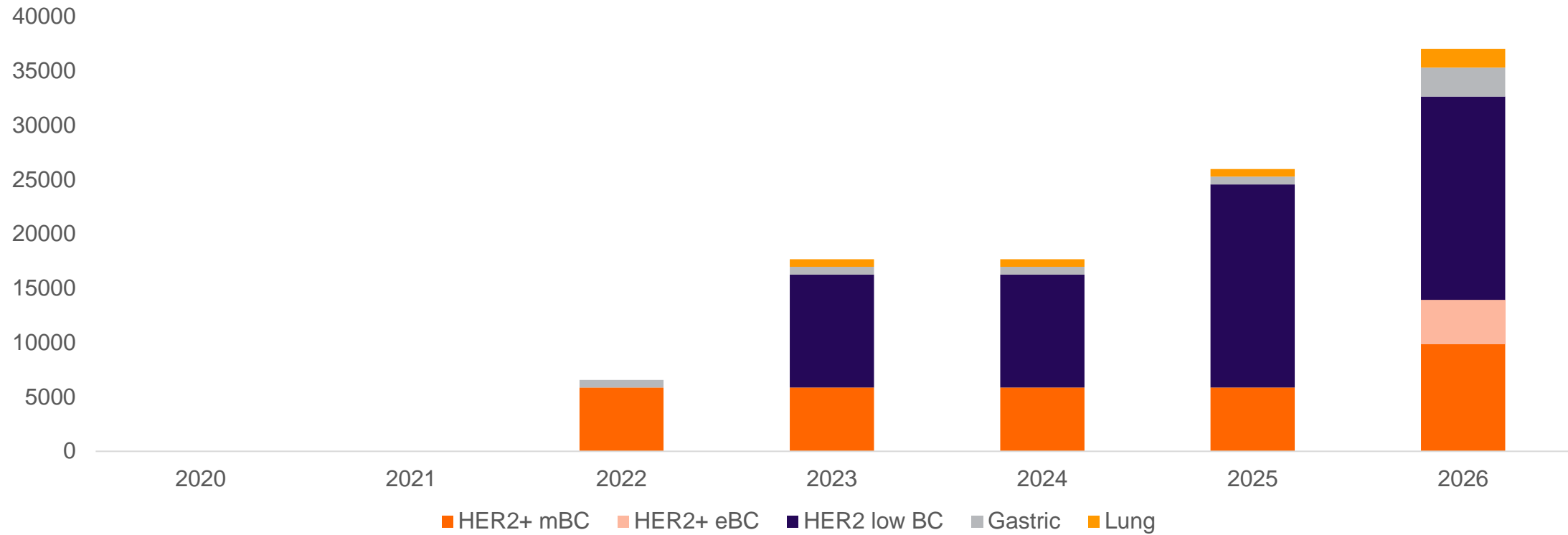
Official commercial reimbursement status

Example: Germany, France, Italy, Spain, UK

CY	2022		2023		2024		2025
	1H	2H	1H	2H	1H	2H	1H
FDA Regulatory approval	 DB-03	 DB-04					 DB-06
EMA Regulatory approval	 DB-03		 DB-04				<u>DB-06</u> The filing was accepted and working with regulatory authority throughout the review process
	 DB-03						
	 DB-03		 DB-04				
					 DB-03		 DB-04
			 DB-03		 DB-04		
		 DB-03				 DB-04	

The eligible patient opportunity in the EU for ENHERTU[®] will grow to >37k in 2026


ELIGIBLE OPPORTUNITY FOR ENHERTU[®] (EU)*



Calendar Year
 *France, Germany, Italy, Spain, UK
 BC: breast cancer; eBC: early breast cancer, mBC: metastatic breast cancer

DATROWAY[®] received a positive CHMP opinion in January; expected approval will further drive growth momentum in FY2025

DATROWAY[®] in Breast Cancer (TROPION-Breast01)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 January 2025
EMA/CHMP/28954/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Datroway²
datopotamab deruxtecan

On 30 January 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Datroway, intended for the treatment of breast cancer. The applicant for this medicinal product is Daiichi Sankyo Europe GmbH.

The full indication is:

Datroway as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative breast cancer who have received endocrine therapy and at least one line of chemotherapy in the advanced setting (see section 5.1).

DATROWAY
datopotamab deruxtecan

DATROWAY[®] first launches expected with TROPION-Breast01 in FY25 with *full launch strategy under assessment*

Passion for Innovation.
Compassion for Patients.™



Closing remarks

We are entering a catalyst rich period

INDICATION	TRIAL	CURRENT STANDARD OF CARE	OPPORTUNITY** IN MAJOR MARKETS***
HR+/HER2 low and ultralow chemo naïve mBC	DESTINY-Breast06	chemotherapy	~ 18k
HER2+ 1L mBC	DESTINY-Breast09	THP	~ 8k
HER2+ High Risk Adjuvant BC	DESTINY-Breast05	Kadcyla® Trastuzumab + pertuzumab ± chemotherapy	~ 10k
HER2mut 1L NSCLC	DESTINY-Lung04	IO combo IO mono IO + chemotherapy	~ 2k
HER2+ BC Neoadjuvant	DESTINY-Breast11	TCHP	~ 27k
HER2+ 2L mGC	DESTINY-Gastric04*	ENHERTU® Ramucirumab ± chemotherapy IO	~ 3k

*For confirmatory approval in Europe and approvals in Japan and China

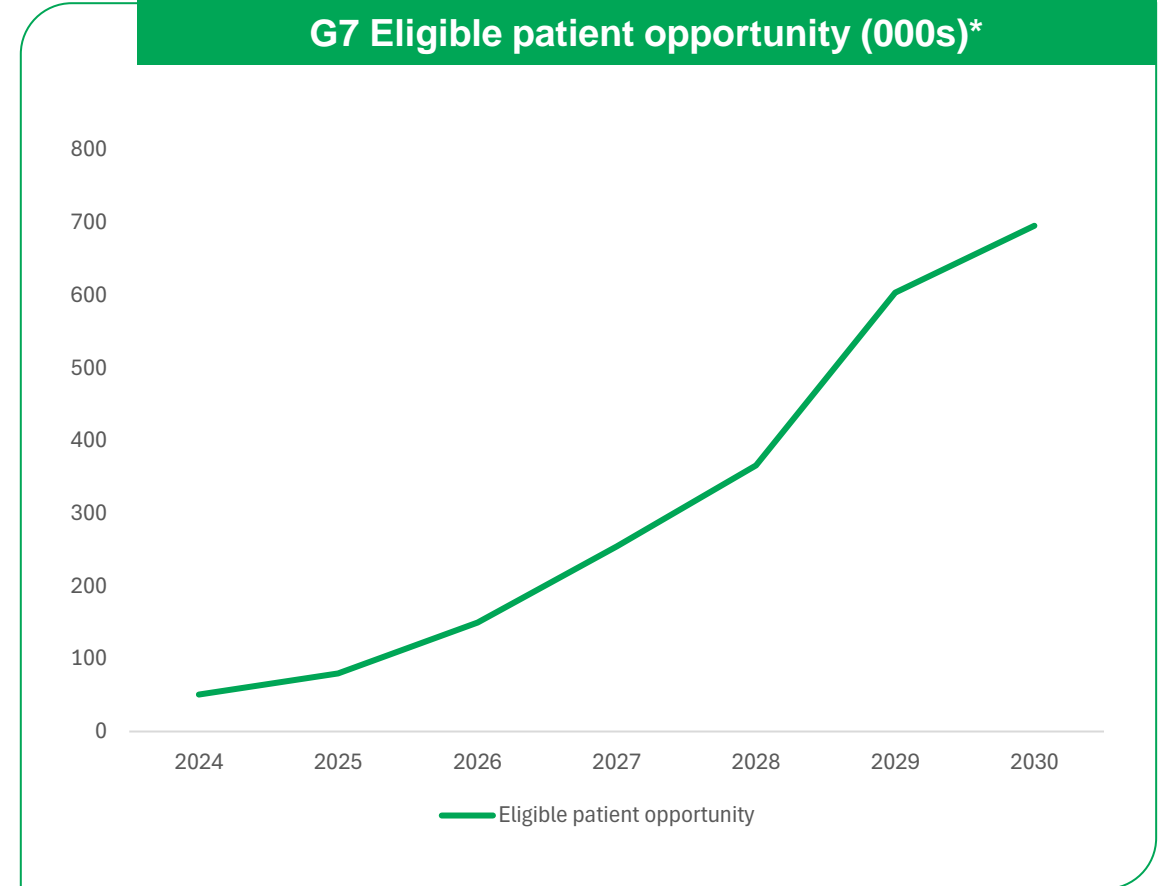
**DB-06, DB-09, DL-04, DG-04 is incremental eligible patient opportunities to current indications

*** US, France, Germany, Italy, Spain, UK, Japan

ET: endocrine therapy, HR: hormone receptor, IO: immuno-oncology therapy, mGC: metastatic gastric cancer, mBC: metastatic breast cancer, NSCLC: non-small cell lung cancer, THP: docetaxel + trastuzumab + pertuzumab, TCHP: carboplatin + docetaxel + trastuzumab + pertuzumab

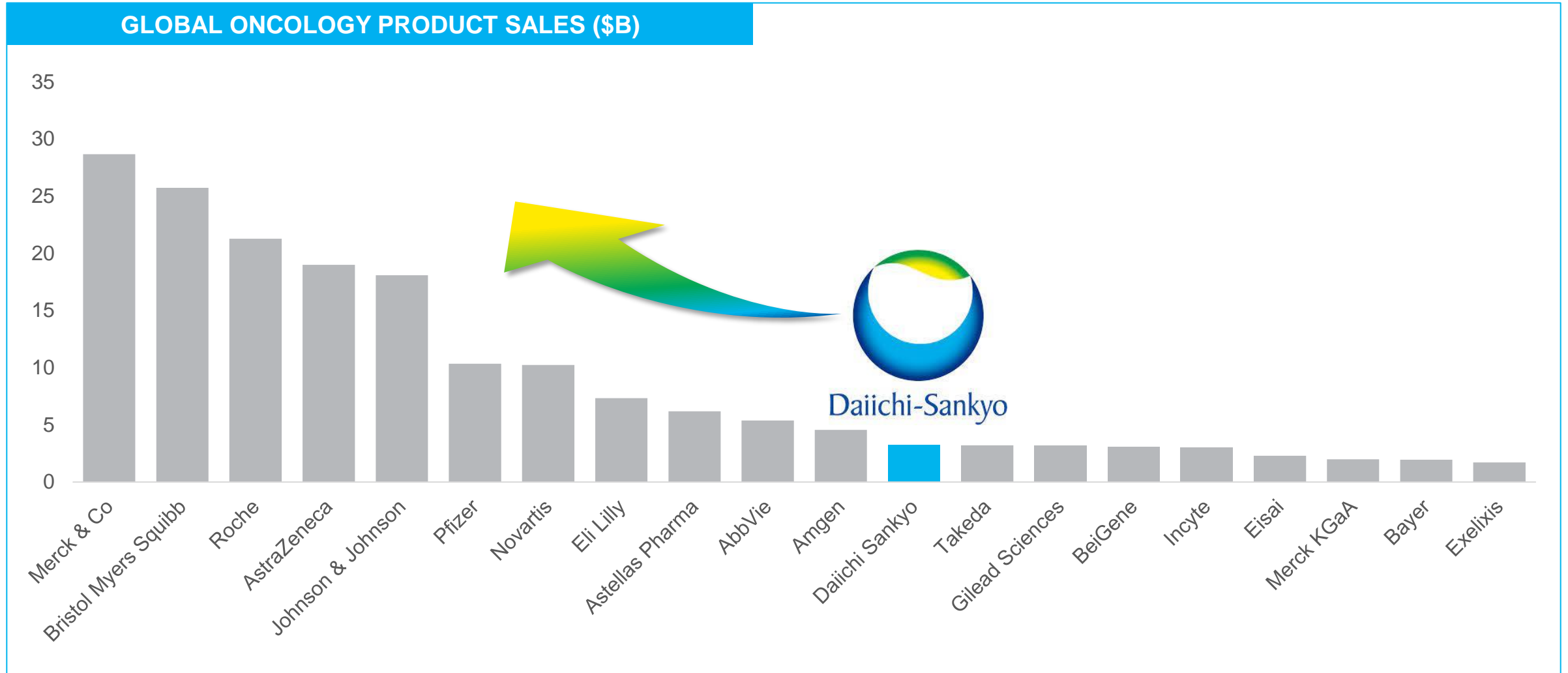
By 2030, Daiichi Sankyo's intent is to have five marketed ADCs in over 30 indications; opportunity to help ~700K patients

2025-2026 Plan	2030 Aspiration	
2 Approved ADCs in 7 indications <ul style="list-style-type: none"> • ENHERTU® • DATROWAY® • Grow from 7 to 13 indications • >3x increased opportunity to benefit patients 	5 Approved ADCs <ul style="list-style-type: none"> • ENHERTU® • DATROWAY® • HER3-DXd • I-DXd • R-DXd 	>30 Approved Indications <ul style="list-style-type: none"> • Early-stage BC • Metastatic BC • NSCLC • SCLC • Gastric cancer • Ovarian cancer • Other



*US, France, Germany, Italy, Spain, UK, Japan
 ADC: antibody drug conjugate, BC: breast cancer, , DXd: deruxtecan, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer

Daiichi Sankyo remains highly confident we will reach and exceed our goal to be a top 10 oncology company



Source: EvaluatePharma, accessed November 21, 2024

*MAT = Moving Annual Total (MAT Sept 2024 refers to October 2023 – September 2024 period)

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