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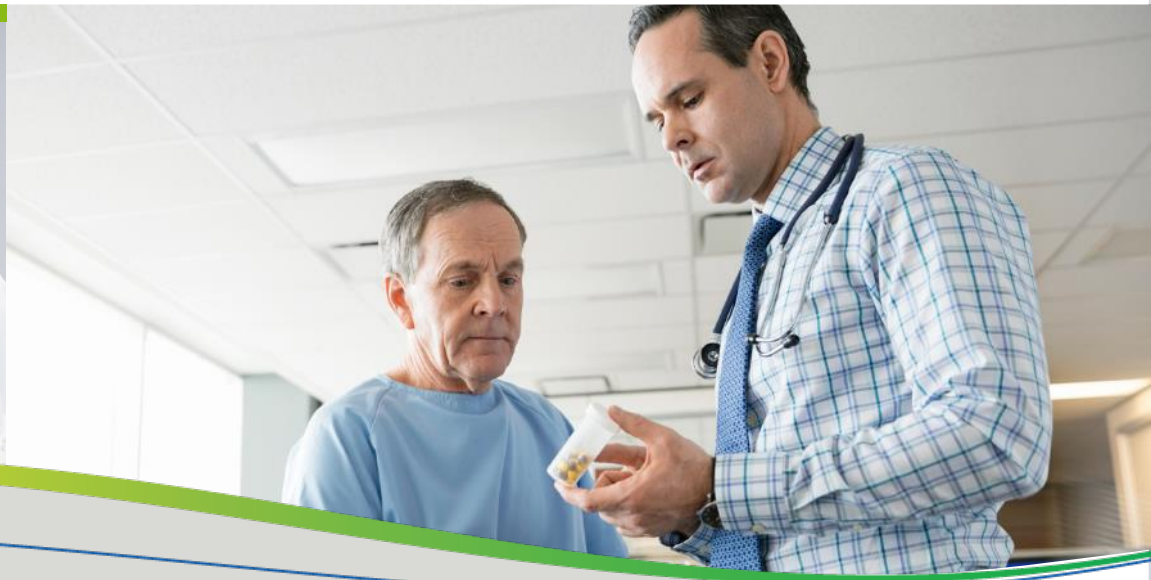

UBS Conference Call Series

Daiichi Sankyo Cancer Enterprise

Sept. 27, 2018

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Global Head of Oncology R&D and Chair, Cancer Enterprise

Forward-Looking Statements

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Topics for Today's Call

- NDA/BLA Submissions
- Regulatory designations
- Core development program major updates
- Recap of data: HER2m NSCLC at WCLC
- Partnership
- Next Data Points until RD Day Dec. 12, 2018

NDA/BLA Submissions

Confirming tracking to plan for quizartinib and pexidartinib NDA submissions, DS-8201 BLA planning

- **Quizartinib**: NDA planned 2H FY2018 based on Quantum-R results presented at EHA 2018
  - Benefiting from US FDA BTD
  - Rolling US submission
  - EU and JP are in Tier 1 submission plan
- **Pexidartinib**: NDA planned 2H FY2018 based on ENLIVEN published at ASCO2018 & overall product benefit/risk profile
  - Benefiting from US FDA BTD
  - Rolling US submission
  - EU is in Tier 1 submission plan
  - Asia plan to be further refined
- **DS-8201**: tracking to plan for BLA submission in FY2020 (base case) or FY2019 (upside case)
  - BLA submission plan will be clarified by March 2019

NDA/BLA Submissions: Tracking to Establish a Record

No single Oncology Company has submitted three NDA/BLA for first-in-class or best-in-class in 12 months or less in the past 30 years: we recognize the challenge!

- Roche/Genentech 2011
  1. Vemurafenib for melanoma
  2. Pertuzumab for breast cancer
  3. Vismodegib for basal cell carcinoma
- Novartis 2016
  1. Midostaurin for 1st line AML
  2. Ribociclib for breast cancer
  3. Lutathera peptide nucleotide for NET
- AstraZeneca 2015
  1. Olaparib for ovarian cancer
  2. Osimertinib EGFRm lung cancer
  3. Gefitinib US re-introduction for lung cancer

Regulatory Designations

2 Achieved for Quizartinib since ASCO 2018

Passion for Innovation.
Compassion for Patients.℠

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Press Release

FDA Grants Breakthrough Therapy Designation to Daiichi Sankyo's FLT3 Inhibitor Quizartinib for Relapsed/Refractory *FLT3*-ITD AML

- Quizartinib has received FDA Breakthrough Therapy designation in patients with relapsed/refractory *FLT3*-ITD AML, a very aggressive form of the disease associated with poor prognosis
- Significant unmet medical need exists in relapsed/refractory AML, as available treatment options are limited and there are no approved targeted therapies for patients with relapsed/refractory *FLT3*-ITD AML
- Third Breakthrough Therapy designation granted by FDA for a compound in the oncology pipeline of Daiichi Sankyo, reinforcing the company's commitment to transforming science into value for patients with cancer

Tokyo, Munich and Basking Ridge, NJ – (August 1, 2018) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to quizartinib, an investigational FLT3 inhibitor, for the treatment of adult patients with relapsed/refractory *FLT3*-ITD acute myeloid leukemia (AML).

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Press Release

Daiichi Sankyo's FLT3 Inhibitor Quizartinib Receives Orphan Drug Designation from Japanese MHLW for *FLT3*-Mutated AML

- Orphan drug designation in Japan for quizartinib follows recent Breakthrough Therapy designation received from the U.S. Food and Drug Administration (FDA)
- Significant unmet medical need exists for AML in Japan with no approved targeted therapies for patients with *FLT3*-ITD AML, a very aggressive form of the disease associated with poor prognosis
- Quizartinib is the first FLT3 inhibitor to demonstrate a survival benefit in a randomized, phase 3 study in patients with relapsed/refractory *FLT3*-ITD AML

Tokyo, Munich and Basking Ridge, NJ – (September 11, 2018) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) announced that quizartinib, an investigational FLT3 inhibitor, has been granted Orphan Drug designation by the Japan Ministry of Health, Labour and Welfare (MHLW) for the treatment of *FLT3*-mutated acute myeloid leukemia (AML).

Across Cancer Enterprise Portfolio

FDA Breakthrough Therapy Designation

- DS-8201 (post T-DM1 breast cancer)
- Quizartinib (R/R *FLT3*-ITD AML)
- Pexidartinib (TCGT)

SAKIGAGE Designation

- DS-8201 (post trastuzumab gastric cancer)
- DS-1647 (glioblastoma)

Orphan Drug Designation

- Quizartinib (Japan, US, EU)
- Pexidartinib (US, EU)
- DS-1647 (Japan)

Core Development Program Major Updates

Focusing only on top assets,

DS-8201

- Pivotal study breast cancer enrollment complete on plan (DESTINY-Breast 01)
- Two separate phase 3 studies are under way (DESTINY-Breast 02 & 03): breast cancer, post T-DM1 and vs. T-DM1
- Breast cancer phase 3 in HER2 low well on track to begin early 2019, following extensive regulatory consultations
  - ✓ Designated as ”the single most important study for DS Cancer Enterprise”
- US NCI CTEP collaboration

U3-1402

- MTD not reached; in dose expansion in mBC and dose escalation in NSCLC – EGFRm

Quizartinib

- QUANTUM-FIRST study (1st line AML add-on design pivotal phase 3) well on track

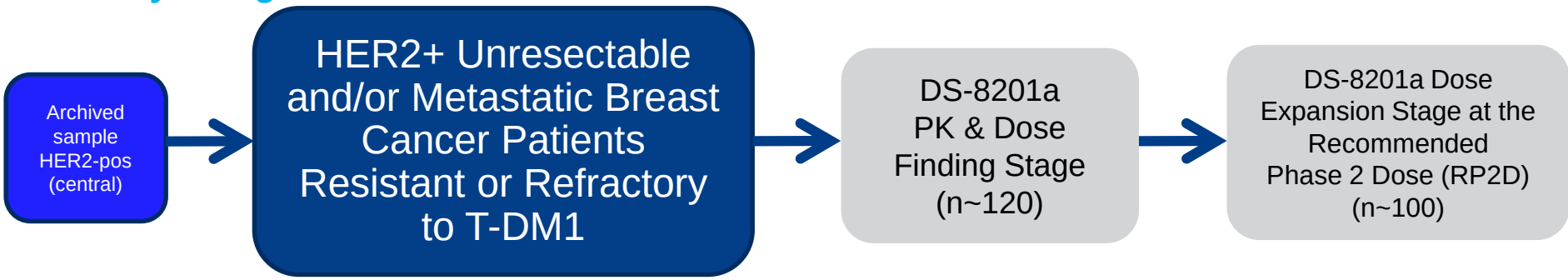
Pivotal P2 Study of DS-8201

DESTINY-Breast01

DS-8201a in Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Breast Cancer

A Phase 2, Multicenter, Open-Label Study of DS-8201a, an Anti-HER2-Antibody Drug Conjugate (ADC) for HER2 Positive, Unresectable and/or Metastatic Breast Cancer Patients Previously Treated with Ado-Trastuzumab Emtansine (T-DM1)

Study Design:



Primary Endpoint: Objective Response Rate (ORR), based on RECIST v1.1

Secondary Endpoints:

- Overall Survival (OS)
- Clinical Benefit Rate (CBR)
- Disease Control Rate (DCR)
- Progression Free Survival (PFS)
- Duration of Response (DoR)

ClinicalTrials.gov Identifier: NCT03248492

P3 Study of DS-8201 vs. Investigator's Choice

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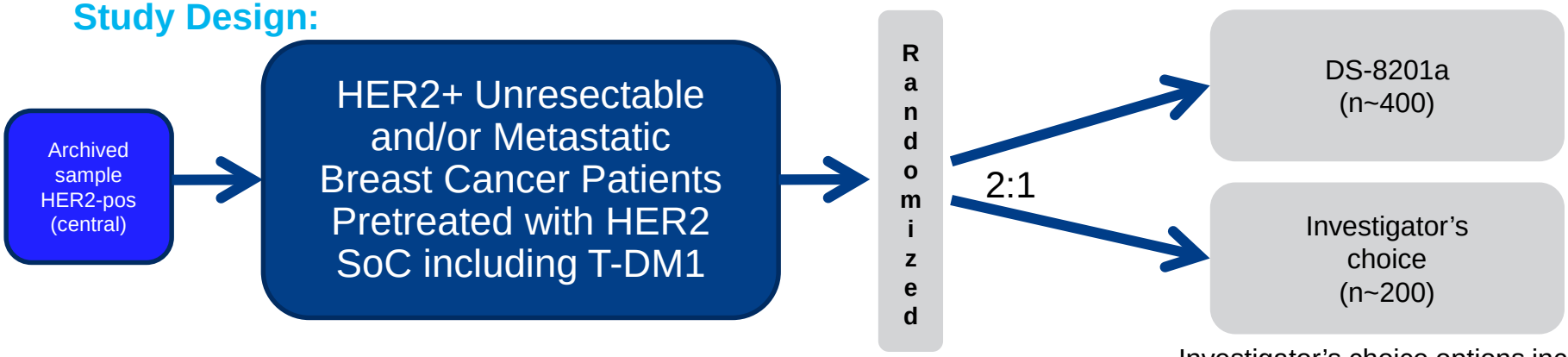
DESTINY-Breast02

DS-8201a in Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Breast Cancer

A Phase 3, Multicenter, Randomized, Open-Label, Active-Controlled Trial of DS 8201a, an Anti-HER2-Antibody Drug Conjugate (ADC), Versus Treatment of Investigator's Choice for HER2-Positive, Unresectable and/or Metastatic Breast Cancer Patients Pretreated with Prior Standard of Care (SoC) HER2 Therapies, Including Ado-Trastuzumab Emtansine (T-DM1)

Study Design:



Primary Endpoint: Progression Free Survival (PFS)

Investigator's choice options include:
- trastuzumab+capecitabine
- lapatinib+capecitabine

Secondary Endpoints:
- Overall Survival (OS)
- Objective Response Rate (ORR)
- Duration of Response (DoR)
- Pharmacokinetics (PK)
- Safety
- Clinical Benefit Rate (CBR)

ClinicalTrials.gov Identifier: NCT03523585

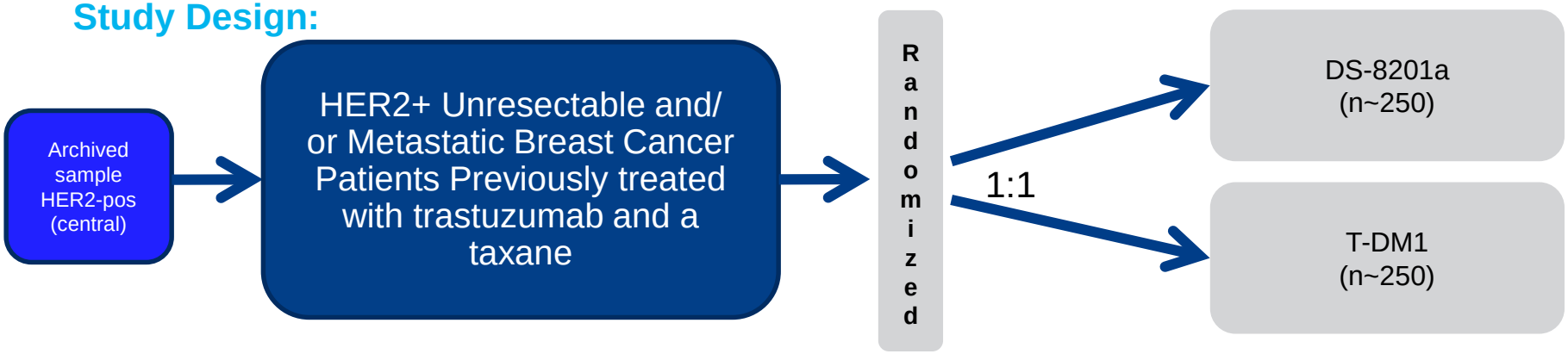
P3 Study of DS-8201 vs. T-DM1

DESTINY-Breast03

DS-8201a in Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Breast Cancer

A Phase 3, multicenter, randomized, open-label, Active controlled study of Ds-8201a, an Anti-HEr2-Antibody Drug conjugate, versus Ado-trastuzumab Emtansine (t-Dm1) for HEr2-Positive, unresectable and/or metastatic breast cancer Patients Previously treated with trastuzumab and a taxane

Study Design:



Primary Endpoint: Progression Free Survival (PFS)

Secondary Endpoints:

- Overall Survival (OS)
- Objective Response Rate (ORR)
- Duration of Response (DoR)
- Pharmacokinetics (PK)
- Safety
- Clinical Benefit Rate (CBR)

ClinicalTrials.gov Identifier: NCT03529110

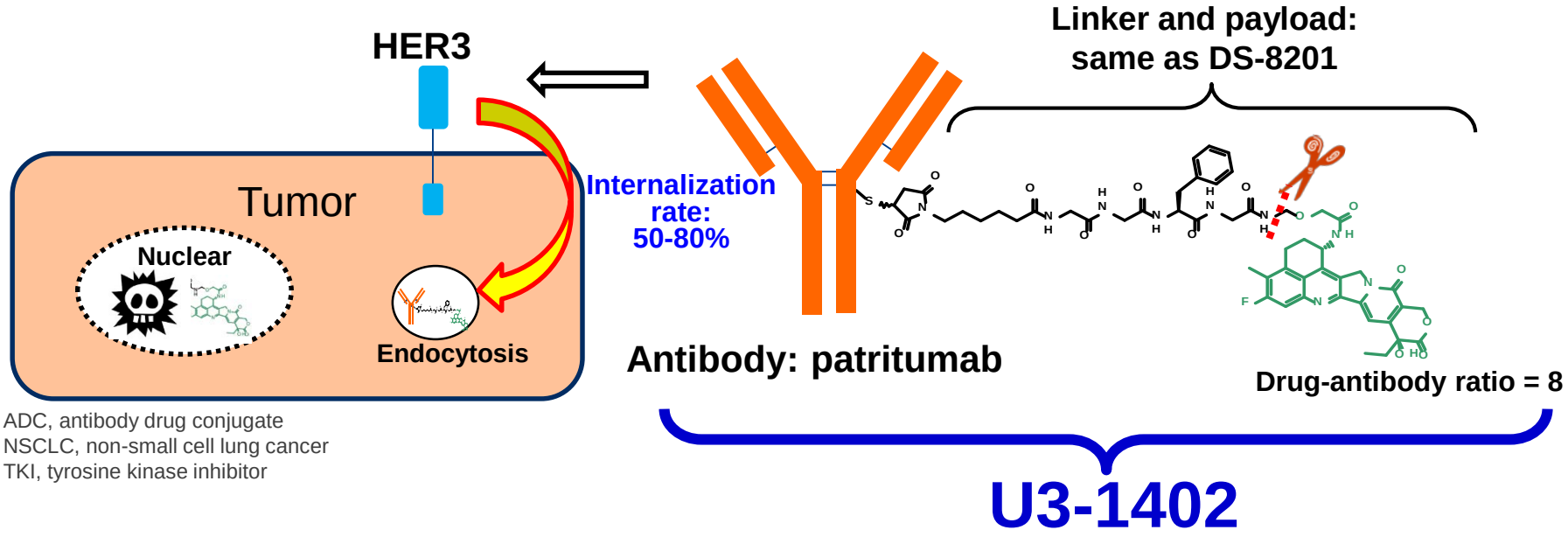
U3-1402: Potential First-in-Class HER3-Targeting ADC

Breast Cancer Phase 1/2 Trial (JP/US)

- Three-part open-label study in patients with HER3-positive metastatic/unresectable breast cancer refractory or intolerant to standard treatment

NSCLC Phase 1 Study (US/EU)

- Open-label study in patients with metastatic /unresectable EGFR-mutated NSCLC whose disease has progressed while taking an EGFR TKI, including patients with:
  - Disease progression during treatment with erlotinib, gefitinib, or afatinib and whose tumors tested negative for the T790M mutation
  - Disease progression during treatment with osimertinib regardless of T790M status



ADC, antibody drug conjugate
NSCLC, non-small cell lung cancer
TKI, tyrosine kinase inhibitor

QuANTUM-First Pivotal P3 1st Line Study of Quizartinib

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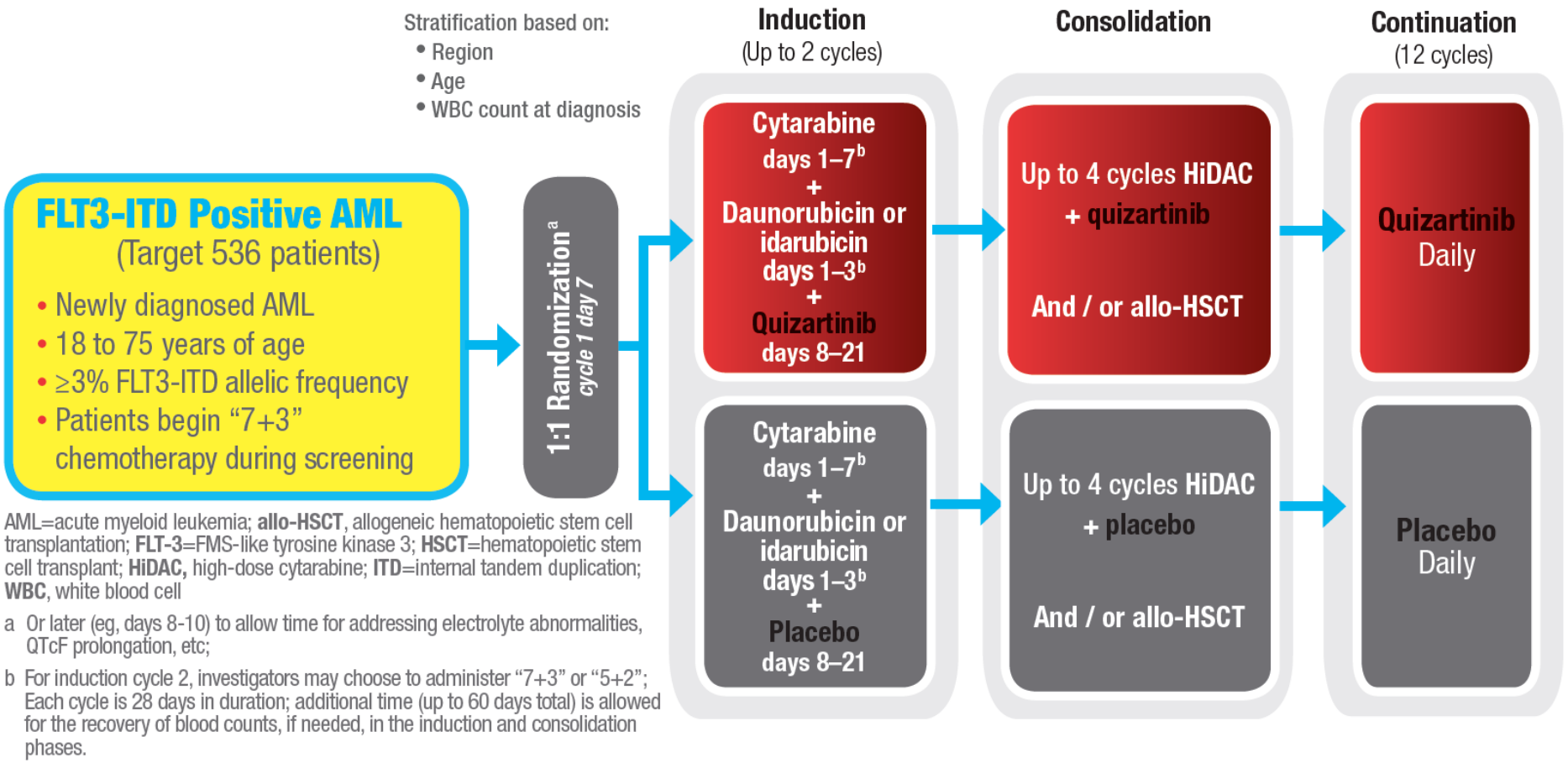


AML=acute myeloid leukemia; **allo-HSCT**, allogeneic hematopoietic stem cell transplantation; **FLT-3**=FMS-like tyrosine kinase 3; **HSCT**=hematopoietic stem cell transplant; **HiDAC,** high-dose cytarabine; **ITD**=internal tandem duplication; **WBC**, white blood cell

a Or later (eg, days 8-10) to allow time for addressing electrolyte abnormalities, QTcF prolongation, etc;

b For induction cycle 2, investigators may choose to administer "7+3" or "5+2"; Each cycle is 28 days in duration; additional time (up to 60 days total) is allowed for the recovery of blood counts, if needed, in the induction and consolidation phases.

Primary Endpoint: Event-free Survival (EFS)

Secondary Endpoints:

- Overall Survival (OS)
- Complete Remission (CR) Rate
- Composite Complete Remission (CRc) Rate
- CR with no evidence of minimal residual disease (MRD)

Location: North America, Europe, Asia/Other Regions | **ClinicalTrials.gov Identifier:** NCT02668653

DS-8201 WCLC Oral Presentation

Demographics and Baseline Characteristics

	NSCLC (N = 18)
Age, median (range), years	58.0 (23.0–83.0)
ECOG performance status 0, n (%)	4 (22.2)
ECOG performance status 1, n (%)	14 (77.8)
HER2-mutated, n (%)	11 (61.1)
Exon 20 insertions	8 (44.4)
Transmembrane domain mutation (G660D)	2 (11.1)
Extracellular domain mutation (S310F)	1 (5.6)
Missing/not examined HER2-mutated status, n (%)	7 (38.9)
Prior cancer regimens, median (range)	3.0 (1.0–10.0)
Sum of tumor diameters, median (range), cm	7.3 (2.0–17.0)

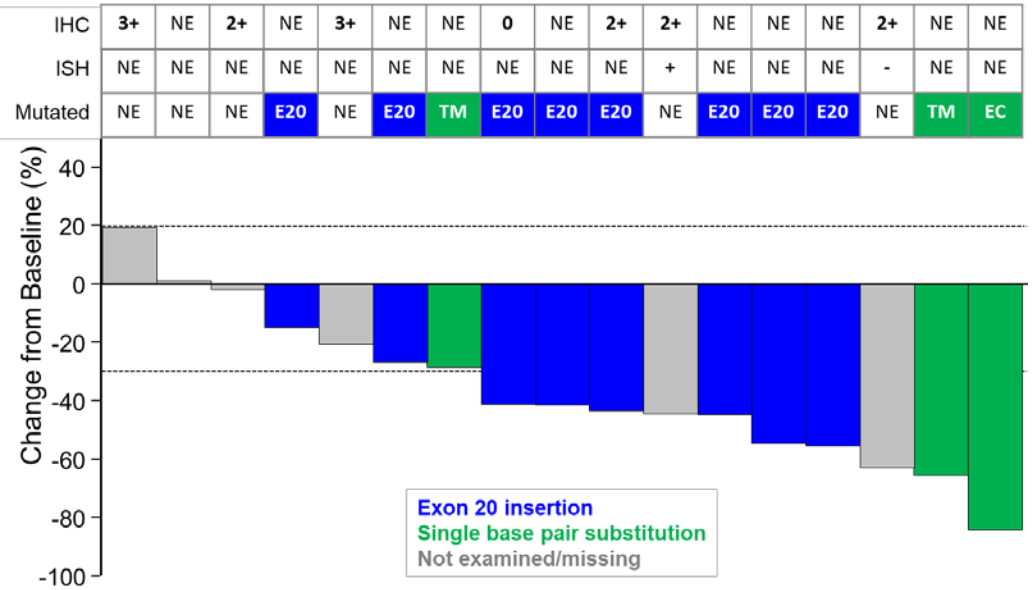
Data cutoff, August 10, 2018.
ECOG, Eastern Cooperative Oncology Group; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; NSCLC, non-small cell lung cancer.

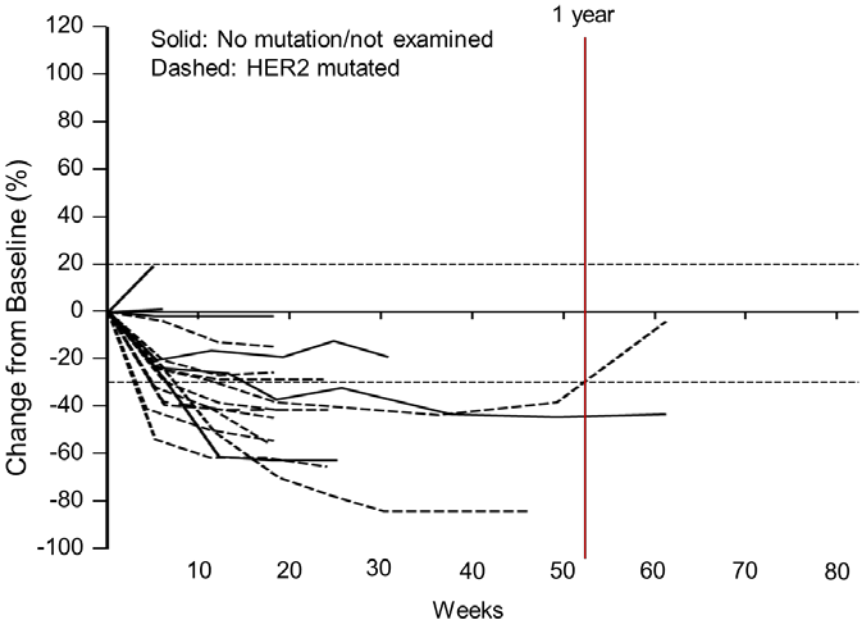
Efficacy Outcomes (Efficacy Evaluable Subjects)

	Confirmed[a] ORR, % (n/N)	Confirmed[a] DCR, % (n/N)	DOR, median (range), months	TTR, median (range), months	PFS, median (range), months
HER2-expressing or HER2-mutated NSCLC N = 18	58.8% (10/17)	88.2% (15/17)	9.9 (0.0+, 11.5)	1.4 (1.0, 4.2)	14.1 (0.9, 14.1)
HER2-mutated NSCLC n = 11	72.7% (8/11)	100% (11/11)	11.5 (0.03+, 11.5)	1.4 (1.0, 4.2)	14.1 (4.0+, 14.1)

Data cutoff, August 10, 2018.
[a]CR/PR confirmation includes subjects who had ≥2 postbaseline scans, had progressive disease, or discontinued treatment for any reason prior to second postbaseline scan.
+ after value indicates censoring.
CR, complete response; DCR, disease control rate; DOR, duration of response; HER2, human epidermal growth factor receptor 2; NSCLC, non-small cell lung cancer; ORR, objective response rate; PFS, progression-free survival; PR, partial response; TTR, time to response.

Tumor Shrinkage by HER2 Status

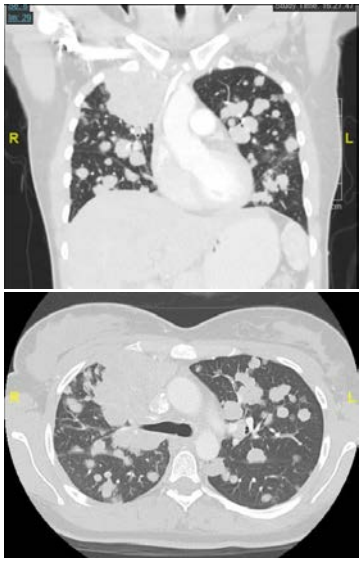




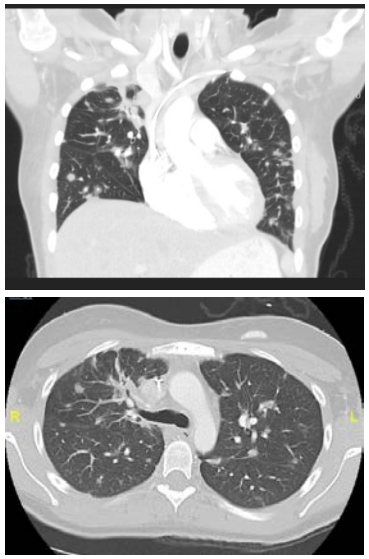
Data cutoff, August 10, 2018.
IHC by local laboratory testing.
E20, exon 20 insertion; EC, single base pair substitution at extracellular domain; IHC, immunohistochemistry; ISH, in situ hybridization; NSCLC, non-small cell lung cancer; NE, not examined or missing; TM, single base pair substitution in transmembrane domain.

Example CT Image from Responder to trastuzumab deruxtecan

- **Demographics**
  - Female 23 years of age
  - Nonsmoker
  - History of type 1 diabetes
- **January 2017:** Presented with cough and shortness of breath
  - Diagnosis: Stage IV, nonsquamous NSCLC
  - Genotype: HER2 12 base pair exon 20 insertion (presumed YVMA)
  - Treatment: Carbo/Pem; 1 cycle
- **February–June 2017:** Switched to Carbo/Nab-paclitaxel due to LFT elevations
  - Best response: SD
- **September–December 2017:** Switched to Carbo/Pem due to progression
  - Four cycles
  - Best response: SD
  - Last scan with slight increase in disease
  - Recommended HER2-targeted therapy; came to DFCI
- **February 2018:** Started [fam-] trastuzumab deruxtecan
  - Symptomatic with cough and dyspnea on exertion
  - Status: PR (confirmed)
  - Tumor shrinkage: −45%



February 2018 – baseline



May 2018 – C5D1

Images courtesy of Dr. Pasi Jänne. Special thanks to Dr. Pasi Jänne and Dr. Ian Krop of DFCI.
Carbo, carboplatin; CT, computed tomography; DFCI, Dana-Farber Cancer Institute; HER2, human epidermal growth factor 2; IV, intravenous; LFT, liver function test; NSCLC, non-small-cell lung cancer; Pem, pemetrexed; PR, partial response; SD, stable disease.

Frequent TEAEs (≥20%)

	All tumor types; 5.4 or 6.4 mg/kg[a] (N = 259)		NSCLC (N = 18)	
	Any Grade, n (%)	Grade ≥3, n (%)	Any Grade, n (%)	Grade ≥3, n (%)
Nausea	192 (74.1)	9 (3.5)	9 (50.0)	1 (5.6)
Decreased appetite	147 (56.8)	12 (4.6)	9 (50.0)	1 (5.6)
Vomiting	113 (43.6)	6 (2.3)	7 (38.9)	0
Anemia	98 (37.8)	50 (19.3)	2 (11.1)	0
Alopecia	97 (37.5)	0	9 (50.0)	0
Fatigue	88 (34.0)	6 (2.3)	8 (44.4)	0
Diarrhea	87 (33.6)	6 (2.3)	3 (16.7)	0
Constipation	85 (32.8)	2 (0.8)	4 (22.2)	0
Platelet count decreased	73 (28.2)	27 (10.4)	2 (11.1)	1 (5.6)
Neutrophil count decreased	66 (25.5)	40 (15.4)	2 (11.1)	2 (11.1)
White blood cell count decreased	66 (25.5)	32 (12.4)	2 (11.1)	1 (5.6)
Malaise	58 (22.4)	1 (0.4)	2 (11.1)	1 (5.6)
Pyrexia	53 (20.5)	2 (0.8)	0	0
Aspartate aminotransferase increased	53 (20.5)	4 (1.5)	1 (5.6)	0

- The median (range) duration of treatment for NSCLC subjects was 5.5 (0.69–14.19) months
- Adverse events were generally of low grade and most frequent AEs were GI or hematologic in nature

Data cutoff, August 10, 2018. A subject was counted once if the same AE was reported more than once.
[a]All subjects from Part 1 and Part 2 receiving ≥1 dose of trastuzumab deruxtecan 5.4 mg/kg or 6.4 mg/kg regardless of tumor type.
AE, adverse event; GI, gastrointestinal; NSCLC, non-small cell lung cancer; TEAE, treatment-emergent adverse event.

Adverse Events of Special Interest

	All tumor types; 5.4 or 6.4 mg/kg[a] (N = 259)		NSCLC (N = 18)	
	Any Grade, n (%)	Grade ≥3, n (%)	Any Grade, n (%)	Grade ≥3, n (%)
AST increased	53 (20.5)	4 (1.5)	1 (5.6)	0
ALT increased	40 (15.4)	2 (0.8)	0	0
Blood bilirubin increased	6 (2.3)	1 (0.4)	0	0
Ejection fraction decreased	2 (0.8)	0	0	0
Electrocardiogram QT prolonged	13 (5.0)	1 (0.4)	0	0
Interstitial lung disease	10 (3.9)	2 (0.8)	1 (5.6)	0
Pneumonitis	22 (8.5)	6 (2.3)	1 (5.6)	1 (5.6)
Infusion-related reactions	4 (1.5)	0	0	0

- Observed laboratory abnormalities (eg, LFT, QTc, and LVEF) were generally low grade and asymptomatic
  - [fam-] trastuzumab deruxtecan treatment was continued in these subjects with laboratory abnormalities
- The frequency of infusion reactions was low and no serious reactions have been reported to date
- There were 5 fatal cases of ILD/pneumonitis observed in the overall population (all tumor types); 1 in the NSCLC subgroup
- The grade 5 pneumonitis case in NSCLC was adjudicated as unrelated to the study drug by an independent adjudication committee

Data cutoff, August 10, 2018.
[a]All subjects from Part 1 and Part 2 receiving ≥1 dose of trastuzumab deruxtecan 5.4 mg/kg or 6.4 mg/kg regardless of tumor type.
ALT, alanine aminotransferase; AST, aspartate aminotransferase; ILD, interstitial lung disease; LFT, liver function tests; LVEF, left ventricular ejection fraction; NSCLC, non-small cell lung cancer; QTc, QT interval corrected for heart rate.

Partnerships

2 Achieved for Investigational ADC Franchise

Daiichi-Sankyo GLYCOTOPE

Press Release

Daiichi Sankyo Enters Worldwide Licensing Agreement with Glycotope for Gatipotuzumab Antibody Drug Conjugate

Tokyo, Berlin, Basking Ridge, NJ – (July 30, 2018) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) and Glycotope GmbH (hereafter, Glycotope) have entered into an exclusive worldwide licensing agreement to develop an antibody drug conjugate (ADC) by combining Daiichi Sankyo's proprietary ADC technology with Glycotope's investigational tumor-associated TA-MUC1 antibody gatipotuzumab (formerly PankoMab-GEX®), building on a previous 2017 option agreement.

Glycotope In-License

- Combines DS proprietary ADC technology with Glycotope's investigational tumor-associated TA-MUC1 antibody gatipotuzumab (formerly PankoMab-GEX®)
- 7th novel ADC

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Press Release

Daiichi Sankyo Announces Clinical Research Collaboration to Evaluate DS-8201 in Combination with KEYTRUDA® (pembrolizumab) in HER2 Expressing Breast and HER2 Expressing or HER2 Mutant Lung Cancers

Tokyo and Basking Ridge, NJ – (September 20, 2018) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) announced that it has entered into a clinical trial collaboration agreement with a subsidiary of Merck & Co., Inc., Kenilworth, New Jersey, U.S.A., known as MSD outside the United States and Canada, to evaluate the combination of Daiichi Sankyo's investigational HER2 targeting antibody drug conjugate DS-8201 and KEYTRUDA® (pembrolizumab) in HER2 expressing advanced/metastatic breast and HER2 expressing or HER2 mutant non-small cell lung cancers (NSCLC).

Merck Collaboration

- Clinical trial collaboration to evaluate DS-8201 in combination with pembrolizumab
  - HER2 expressing advanced/metastatic breast cancer
  - HER2 expressing or HER2 mutant NSCLC
- 2nd immuno-therapy combination study with DS-8201

Next Data Points until RD Day Dec. 12, 2018

Oct 2018: European Society for Medical Oncology (ESMO)

DS-8201 Ph1 CRC update

Dec 2018: San Antonio Breast Cancer Symposium (SABCS)

DS-8201 Ph1 BC update

U3-1402 Ph1 BC update

Dec 2018: American Society of Hematology (ASH)

AML Franchise: Multiple abstracts submitted, including Quizartinib QuANTUM-R

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