

Care. Compassion. Science. It's Our Obligation.



Daiichi Sankyo Cancer Enterprise Delivering on Our Development Promises

Investors Analysts Presentation From ASCO Chicago, IL June 1st, 2018

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ASCO 2018 Highlights Cancer Enterprise Development Progress



Today's Agenda

1	2	3	4	5
DS-8201	U3-1402	Pexidartinib	Quizartinib	Cancer Enterprise
Rapid and Far-reaching Development Momentum • Mature phase 1 results across HER-2 tumors • Impact on development plan and scope • HER2 now recognized as a broader marker	HER3 ADC First in Human Debut • Key Early results	TGCT: ENLIVEN Phase 3 Study Supports Decision To Proceed to NDA Submission	Positive Survival & Benefit/Risk in R/R AML • Late Breaking / Plenary Session at EHA June 2018, Stockholm • Support decision to proceed to NDA submission	Delivering on Our Development Promises

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1

2

3

4

5

DS-8201

U3-1402

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Cancer Enterprise

Rapid and Far-reaching Development Momentum

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- Impact on development plan and scope
- HER2 now recognized as a broader marker

HER3 ADC Firs in Human Debut

Key Early results

TGCT: ENLIVEN
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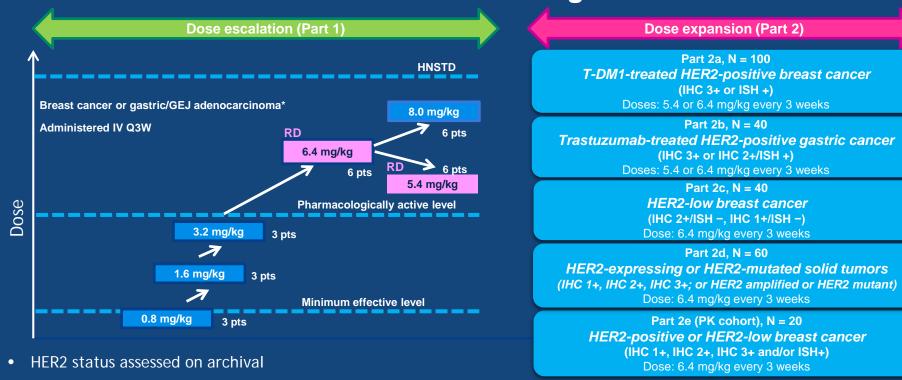
Positive Survival & Benefit/Risk in R/R AML

- Late Breaking /
 Plenary Session at
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- Support decision to proceed to NDA submission

Delivering on Our Development Promises

ADC | DS-8201: mature FTIH phase 1 results, n=241 across HER2 tumors

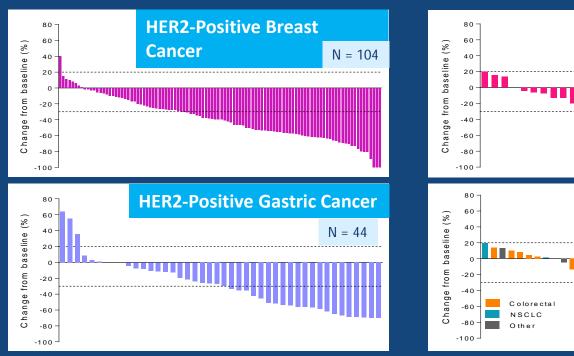
Phase 1 Trial Design

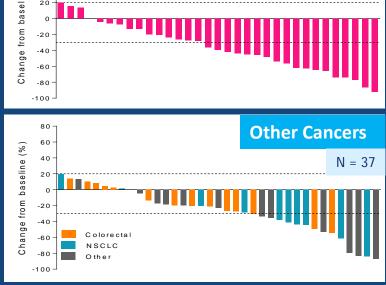


^{*} Subjects in part 1 were not required to have HER2-positive (IHC 3+ or IHC2+/ISH-positive) tumors.

FTIH: First-time in Human HER2, human epidermal growth factor receptor 2; HNSTD, highest non-severely toxic dose; IHC, immunohistochemistry; ISH, in situ hybridization; IV, intravenous; Q3W, once every 3 weeks; RD, recommended dose for dose expansion; T-DM1, trastuzumab emtansine.

ADC | DS-8201: Tumor Shrinkage by Tumor Types: (5.4 or 6.4 mg/kg)





Cancer

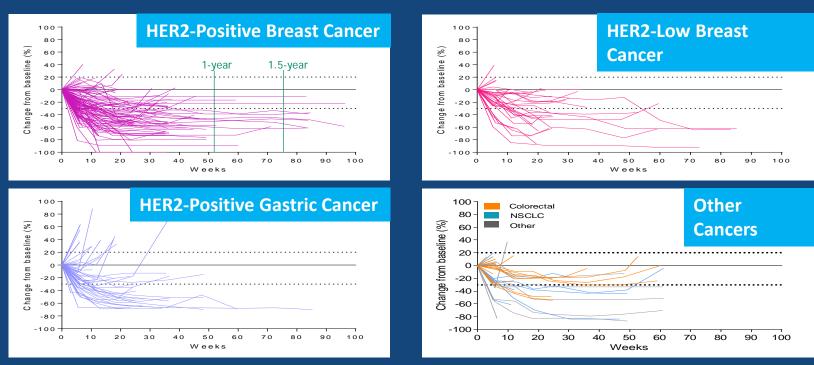
HER2-Low Breast

N = 33

- Overall, 86.3% of subjects experienced tumor shrinkage
- Confirmed ORR* in the overall population: 49.3%

Includes subjects who had ≥1 postbaseline scan. Dotted lines denote 20% increase and 30% reduction in tumor size, respectively. * Confirmed response includes subjects who had ≥2 postbaseline scans, had progressive disease, or discontinued treatment for any reason prior to second postbaseline scan. Data cutoff for this analysis is April 18, 2018.

ADC | DS-8201: Tumor Shrinkage Over Time by Tumor Type: (5.4 or 6.4 mg/kg)



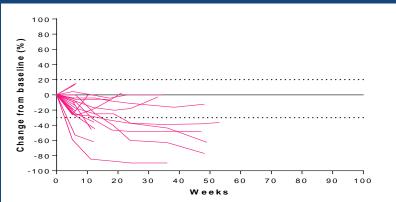
- Overall, 86.3% of subjects experienced tumor shrinkage
- 91.5% of these subjects experienced shrinkage at the time of first imaging assessment at 6 weeks

Includes subjects who had ≥1 postbaseline scan. Dotted lines denote 20% increase and 30% reduction in tumor size, respectively. Data cutoff for this analysis is April 18, 2018.

ADC | DS-8201: Activity in Breast Cancer HER2-low (by standard IHC) Redefining HER2 as a Cell Surface Target

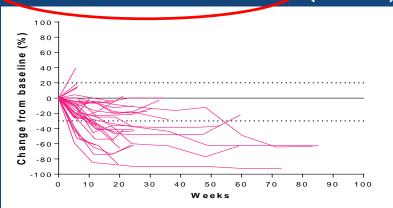
SABCS*, Dec 2017

Confirmed ORR = 31.6% (6/19)



ASCO, Jun 2018

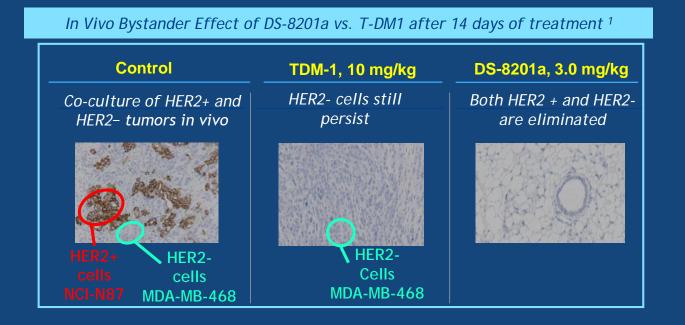
(Confirmed ORR = 50.0% (17/34))



Increase in response rate in HER2-low breast cancer over time corresponds with more mature data: continued and improved response as treatment carries on

^{*} Modi S, et al. San Antonio Breast Cancer Symposium, Dec 2017.

ADC | DS-8201: Activity in HER2 Tumors: Likely mediated through by-stander effects



1. Ogitani-Y et al. Cancer Science 2016; 107:1039-46.

Translational Science efforts underway to define HER2 selection marker

ADC | DS-8201: Efficacy Outcomes by Tumor Type (5.4 or 6.4 mg/kg)

	HER2-Positive Breast N = 111	HER2-Low Breast N = 34	HER2-Positive Gastric N = 44	Other Cancers N = 51
Confirmed ORR* % (n/N)	54.5% (54/99)	50.0% (17/34)	43.2% (19/44)	38.7% (12/31)
DCR % (n/N)	93.9% (93/99)	85.3% (29/34)	79.5% (35/44)	83.9% (26/31)
ORR in modified ITT**, % (n/N)	48.6% (54/111)	50.0% (17/34)	43.2% (19/44)	23.5% (12/51)
DOR				
Median (95% CI), months	NR	11.0 (NA)	7.0 (NA)	12.9 (2.8, 12.9)
PFS				
Median, (95% CI), months	NR	12.9 (NA)	5.6 (3.0, 8.3)	12.1 (2.7, 14.1)
Min, max	1.0, 22.2+	0.5, 19.6+	1.2, 19.6+	0.7, 14.1+

^{*} Confirmed response includes subjects who had ≥2 postbaseline scans, had progressive disease, or discontinued treatment for any reason prior to second postbaseline scan.

^{**} Modified ITT population included all subjects who received ≥1 dose of DS-8201a at either 5.4 or 6.4 mg/kg, including those subjects who were too early to assess, but are ongoing on study.

⁺ after value indicates censoring.

BC, breast cancer; CI, confidence interval; DCR, disease control rate; DOR, duration of response; GC, gastric/gastroesophageal junction cancer; HER2, human epidermal growth factor receptor 2; ITT, intent-to-treat; NA, not available; NR, not reached; ORR, overall response rate; PFS, progression-free survival. Data cutoff for this analysis is April 18, 2018.

ADC | DS-8201: Overall Safety Profile (5.4 or 6.4 mg/kg) N=241

	Overall N = 241*
Any TEAEs	238 (98.8%)
Grade ≥3 TEAEs	121 (50.2%)
Drug-related TEAEs	235 (97.5%)
Grade ≥3 drug-related TEAEs	101 (41.9%)
Serious TEAEs	50 (20.7%)
Drug-related Serious TEAEs	27 (11.2%)
TEAEs leading to treatment discontinuation	23 (9.5%)
TEAEs leading to death**	10 (4.1%)

^{*} Included all subjects who received ≥1 dose of DS-8201a at either 5.4 or 6.4 mg/kg, including those subjects who were too early to assess, but are ongoing on study.

Data cutoff for this analysis is April 18, 2018.

^{**} Cause of death included pneumonitis (4), disease progression (2), interstitial lung disease (1), lleus (1), pneumonia aspiration (1), pneumonia (1), TEAE, treatment-emergent adverse event.

ADC | DS-8201: AE of Special Interest (5.4 or 6.4 mg/kg) n=241

AEs	All grades	Grade ≥3
AST increased	47 (19.5)	2 (0.8)
ALT increased	38 (15.8)	2 (0.8)
Blood bilirubin increased	6 (2.5)	1 (0.4)
Ejection fraction decreased	2 (0.8)	0 (0.0)
Electrocardiogram QT prolonged	12 (5.0)	1 (0.4)
Interstitial lung disease	8 (3.3)	2 (0.8)
Pneumonitis	16 (6.6)	4 (1.7)
Infusion-related reactions	4 (1.7)	0 (0.0)

- Laboratory abnormalities (LFT, QTc, and LVEF) were generally low grade, and asymptomatic; DS-8201a treatment was continued in these subjects
- Events of ILD/pneumonitis including 5 fatal cases were observed
- Frequency of infusion reaction 1.7%. No serious reaction was observed

AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; ILD, interstitial lung disease; LFT, liver function tests; LVEF, left ventricular ejection fraction.

Data cutoff for this analysis is April 18, 2018.

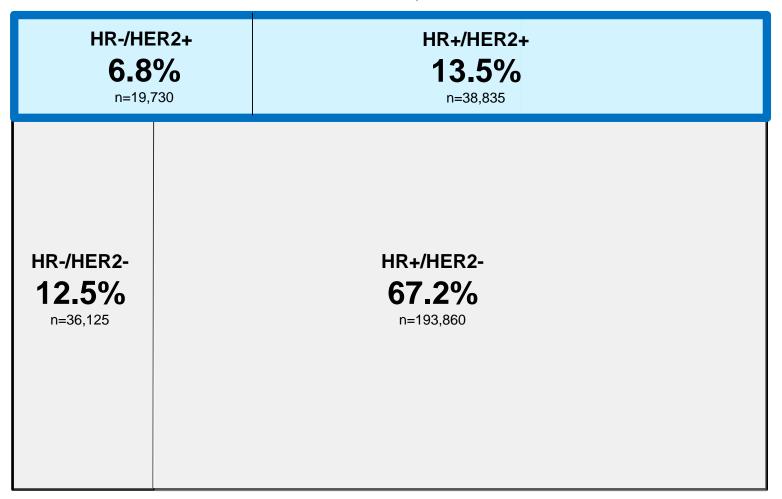
Breast Cancer Treatment Landscape 2018*





All Patients

n=288,550



^{*} Source: Decision Resources, inclusive of US, EU5, and Japan (Breast Cancer, Last updated, December 2017, CAncerMPACT (2017))

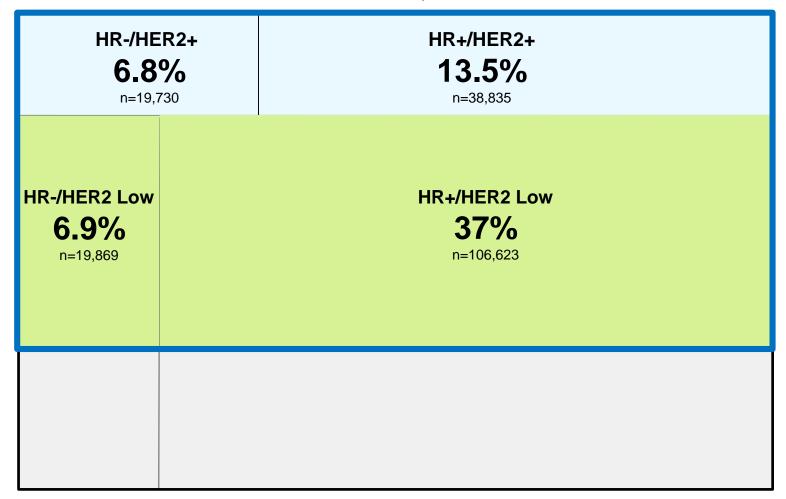
Breast Cancer Treatment Landscape 2018*



HER2+ Plus HER2 Low is ~ 64% of Total Metastatic Population

All Patients

n=288,550



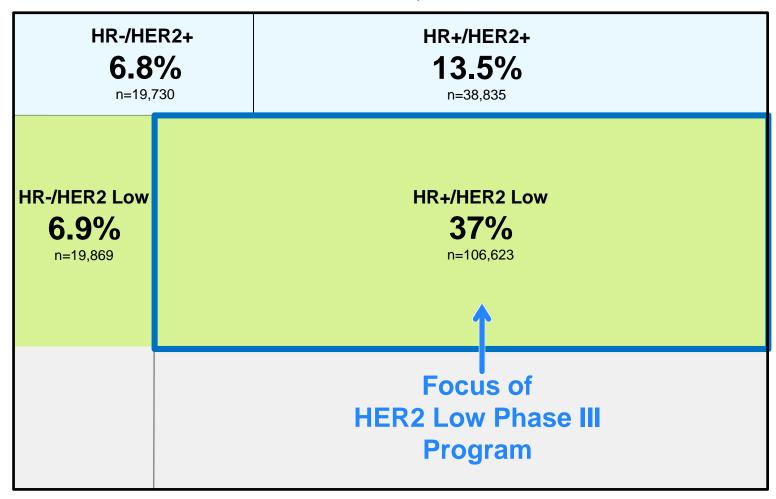
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Breast Cancer Treatment Landscape 2018*



HR+/HER2 Low is the Focus of HER2 Low Phase III Program

All Patients n=288,550

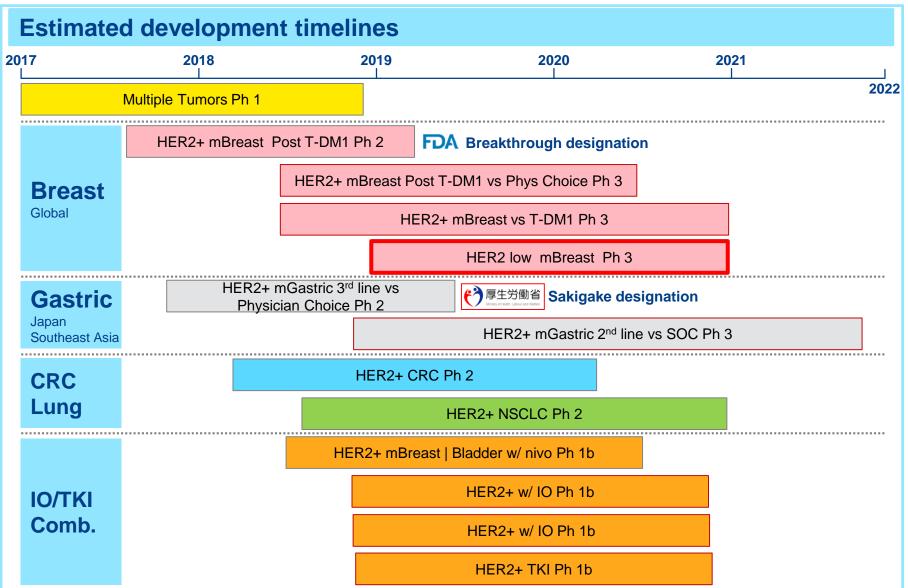


^{*} Source: Decision Resources, inclusive of US, EU5, and Japan (Breast Cancer, Last updated, December 2017, CAncerMPACT (2017))

ADC | DS-8201: Broad & Bold Development Program



Transforming "HER2 low" disease by redefining HER2 as a non-oncogenic cell surface marker



ADC | DS-8201 (trastuzumab deruxtecan) Top News



DS-8201 Flagship Asset



Focus



FDA Breakthrough Therapy **Designation (BTD)**

In patients with HER2 advanced breast cancer who have received trastuzumab, pertuzumab, and progressed after T-DM1

First agent with BTD for HER2 disease





Ongoing pivotal development

- **DESTINY-Breast01**
- **DESTINY-Gastric01**

Planned pivotal development

- Breast HER2+ post T-DM1
- Breast HER2+ vs T-DM1
- **Breast HER2 low**

- Expanding at full scale and speed into low HER2 (nononcogenic HER2) HR+ Breast Cancer
- Tracking to plan for 2020 submissions
- **Contemplating BLA in FY2019** Will not be confirmed before 4Q FY2018
- Continue drastic scaling up of production to meet revised demand

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2

3

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5

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HER3 ADC First in Human Debut

Key Early results

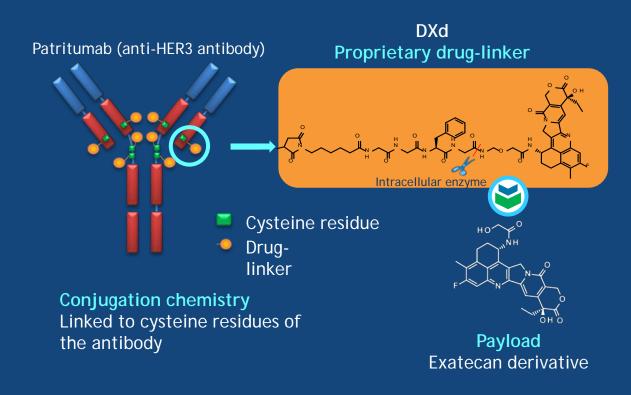
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Delivering on Our Development Promises

ADC | U3-1402: A Novel, Anti-HER3 Antibody Drug Conjugate



Critical Daiichi Sankyo DXd ADC design features

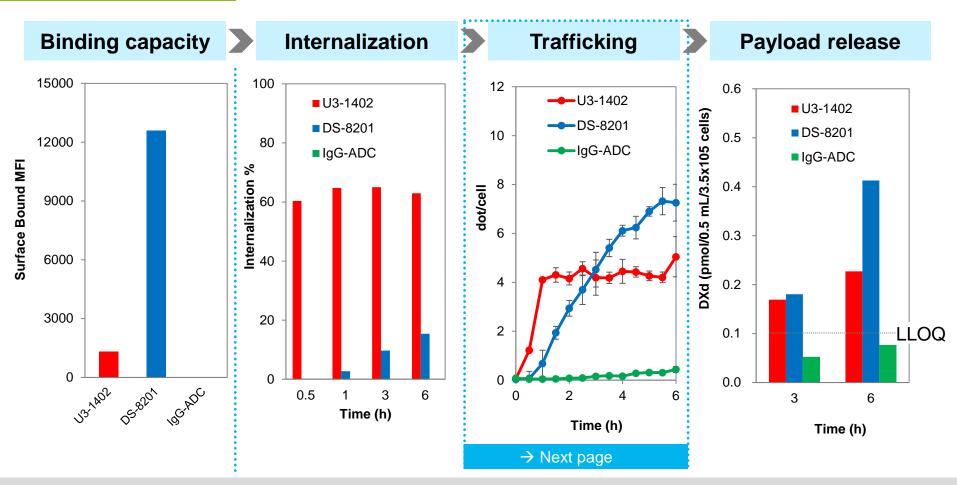
- Payload with a different MOA
- High potency of payload
- Payload with short systemic half-life
- Bystander effect
- Stable linker-payload
- Tumor-selective cleavable linker
- High drug-to-antibody ratio

U3-1402 & DS-8201: In vitro Intracellular Disposition



MDA-MB-453

HER3 and HER2 expressing Sensitive to both U3-1402 and DS-8201

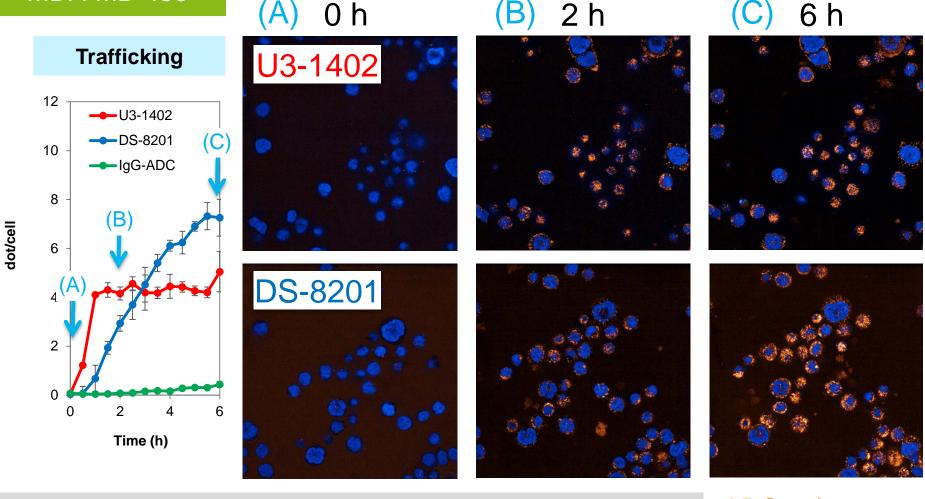


High internalization / trafficking to lysosome of U3-1402 leads to effective payload release even with low HER3 expression level

U3-1402 & DS-8201: ADC-trafficking to Lysosome





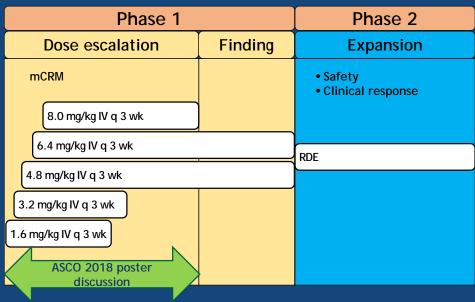


U3-1402 showed a faster time-lapse imaging trafficking to lysosomes than DS-8201, reaching a steady state at around 1 hour

ADC to lysosome Nucleus

ADC | U3-1402: Study Design

Study Design



ClinicalTrials.gov Identifier: NCT02980341

Key Eligibility Criteria

- HER3-positive (measured by IHC [2+/3+]), advanced/unresectable, or metastatic breast cancer
- Refractory to or intolerable to standard treatment, or no standard treatment is available
- ECOG PS 0-1
- Primary Objectives
 - To assess safety and tolerability of U3-1402
 - To determine MTD/RDE of U3-1402
- Secondary Objectives
 - To assess efficacy/pharmacokinetics of U3-1402
- Tumor Assessment
 - Performed by CT or MRI scans of brain, chest, abdomen, pelvis, and other disease sites, along with bone scan

mCRM = modified continuous reassessment method; RDE = recommended dose(s) for expansion.

ADC | U3-1402: Treatment-Emergent AE in ≥ 15% Patients, Dose Escalation Phase (Total N = 34)* 1/2

Preferred Term	All Grades N = 34	Grade ≥ 3
Patients with TEAEs, n (%)	33 (97)	21 (62)
Nausea	28 (82)	1 (3)
Platelet count decreased/Thrombocytopenia	23 (68)	10 (29)
Decreased appetite	21 (62)	2 (6)
Neutrophil count decreased/Neutropenia	20 (59)	9 (27)
White blood cell count decreased	18 (53)	6 (18)
Vomiting	17 (50)	0

Preferred Term	All Grades N = 34	Grade ≥ 3
Alanine aminotransferase increased	13 (38)	3 (9)
Aspartate aminotransferase increased	13 (38)	3 (9)
Anemia	13 (38)	4 (12)
Stomatitis	11 (32)	0
Diarrhea	11 (32)	2 (6)
Rash/Rash maculo-papular	10 (29)	0
Malaise	9 (27)	0
Fatigue	9 (27)	0

^{*}Analysis set: Patients who received at least one dose of U3-1402. Percentage is calculated using the number of patients in the column heading as the denominator.

TEAE = treatment-emergent adverse event. Based on April 27, 2018 data cutoff.

ADC | U3-1402: Treatment-Emergent AE in ≥ 15% Patients, Dose Escalation Phase (Total N = 34)* 2/2

Preferred Term	All Grades N = 34	Grade ≥ 3
Patients with TEAEs, n (%)	33 (97)	21 (62)
Hypoalbuminemia	8 (24)	0
Epistaxis	7 (21)	0
Blood alkaline phosphatase increased	6 (18)	0
Headache	6 (18)	0
Dry skin	5 (15)	0
Dysgeusia	5 (15)	0
Hypokalemia	5 (15)	3 (9)
Nasopharyngitis	5 (15)	0

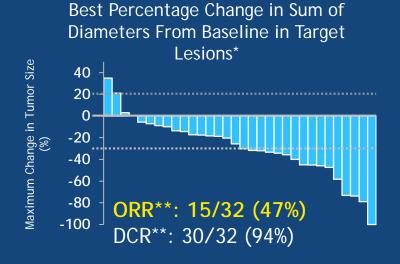
- Majority of TEAEs were Grades 1 and 2
- Toxicities have so far been manageable
- DLTs consisted of the following
 - Platelet count decreased Gr.4 (one subject at 4.8 mg/kg)
 - Platelet count decreased Gr.4 (one subject at 6.4 mg/kg)
 - Platelet count decreased Gr.4, AST increased Gr. 3, ALT increased Gr.3 (one subject at 8.0 mg/kg)
 - ALT increased Gr.3 (one subject at 8.0 mg/kg)
- MTD by mCRM method** has not been reached
- Serious AE's noted in 11 (32%) of treated patients

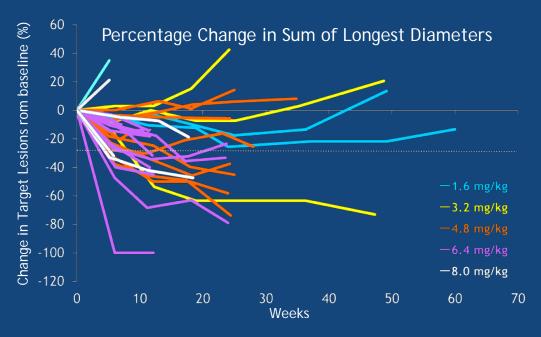
ALT = alanine transferase; AST = aspartate aminotransferase; DLT = dose limiting toxicity; Gr = grade; MTD = maximal tolerated dose; TEAE = treatment-emergent adverse event.

^{*}Analysis set: Patients who received at least one dose of U3-1402. Percentage is calculated using the number of patients in the column heading as the denominator.

^{**}Modified Continuous Reassessment (mCRM) using a Bayesian logistic regression model (BLRM) following the escalation with overdose control (EWOC) principle Based on April 27, 2018 data cutoff.

ADC | U3-1402: Activity





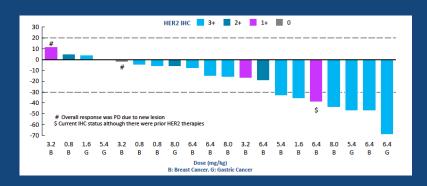
^{*}Analysis set: Efficacy evaluable patients with at least one scan. Baseline is defined as the last measurement taken before the first dose of study drug.

**Investigators assessment. For each patient, the best percent change from baseline in the sum of diameters for all target lesions is represented by a vertical bar.

DCR = disease control rate; ORR = objective response rate.

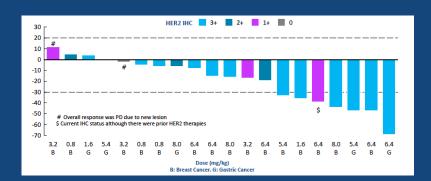
Daichi Sankyo ADC DXd Technology: HER2 & HER3 ADCs first in human testing: 2016 & 2018 data

DS-8201 late-breaking ESMO 2016 Dose escalation phase



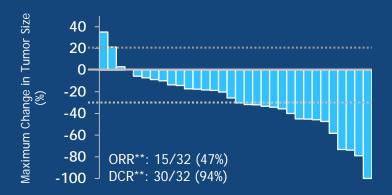
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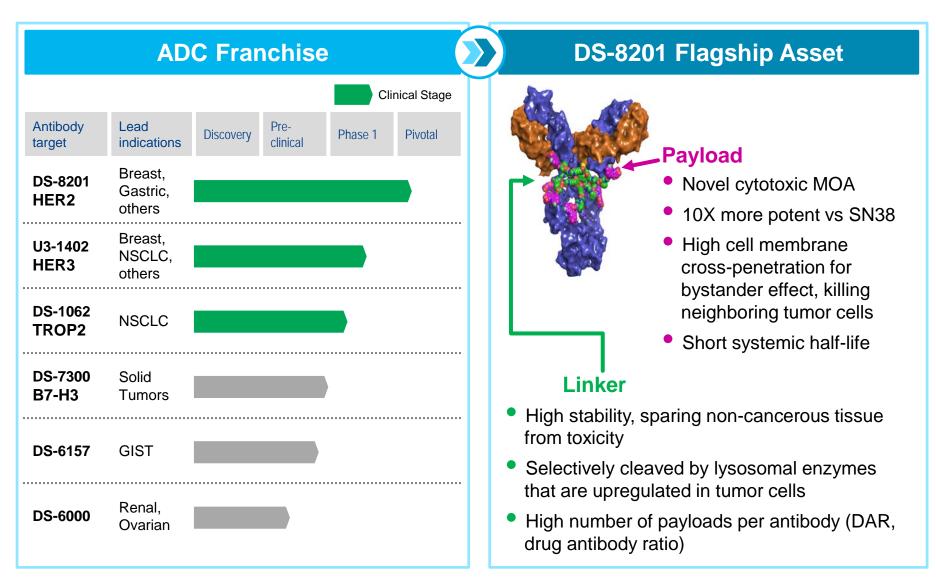
ORR:7/20 (25%)

U3-1402 ASCO 2018
Dose escalation phase



ADC | Franchise Focus and Flagship Asset





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1

2

3

4

5

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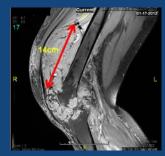
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Delivering on Our Development Promises

Pexidartinib | ENLIVEN placebo-controlled phase 3 study Background

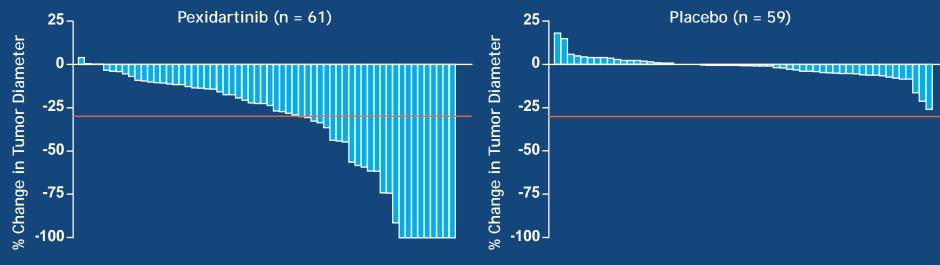
- Tenosynovial Giant Cell Tumor (TGCT) is a rare, locally aggressive, inflammatory, nonmalignant neoplasm^{1,2}
 - Occurs mainly in the synovium of joints, bursae, or tendon sheaths^{1,2}
 - Clinical features include swelling, pain, limited range of motion, and stiffness¹
- Surgical resection is standard primary treatment¹
- US prevalence ~ 17k
- No currently approved systemic therapies³⁻⁵
- 1. Staals et al. Eur J Cancer. 2016;63:34-40.
- 2. de Saint Aubain Somerhausen and van de Rijn. IARC Press. 2013;100-103.
- 3. Tap et al. *N Engl J Med*. 2015;351:1502-1512.





- 4. Cassier et al. *Cancer*. 2012:118:1649-1655.
- 5. Gelderblom et al. *Lancet Oncol*. 2018;19:639-648.

Pexidartinib | ENLIVEN Primary Endpoint: Tumor Response by RECIST



Treatment, n (%)	Complete	Partial	Stable Disease	Progressive Disease	Not Evaluable	Overall Response Rate [95% CI]
Pexidartinib n = 61	9 (15)	15 (25)	24 (39)	1 (2)	12 (20)	24 (39) [28.1, 51.9] <i>P</i> < 0.0001
Placebo n = 59	0	0	46 (78)	1 (2)	12 (20)	0 [0, 6.1]

^{*}Baseline mean sum of the longest tumor diameters was 10.1 and 10.6 cm for pexidartinib and placebo, respectively.

Pexidartinib | ENLIVEN Clinical Benefit Endpoints

Clinical Benefit Endpoints	Pretreatment Baseline Mean (SD)	Pexidartinib (95% CI)	Placebo (95% CI)	P Value
Range of motion: % normal reference	63 (23)	+15% (10.9, 19.2)	+6% (1.5, 10.9)	0.0043
PROMIS physical function scale: Function on scale of 0-100; all population average = 50	38 (6)	+4.1 (1.8, 6.3)	-0.9 (-3.0, 1.2)	0.0019
Worst stiffness: Scale of 0 (normal) - 10	6 (2)	-2.5 (-3.0, -1.9)	-0.3 (-0.9, 0.3)	< 0.0001
BPI worst pain response: Response = ≥30% improvement from baseline on scale of 0 (normal) - 10	6 (2)	31% (20.9, 43.6)	15% (8.2, 26.5)	NS

Pexidartinib | ENLIVEN Hepatotoxicity

Liver Function, n (%)	Pexidartinib Part 1 n = 61	Placebo Part 1 n = 59	Pexidartinib Crossover 800 mg/d n = 30
AST or ALT ≥ 3 × ULN	20 (33)	0	4 (13)
TBili ≥ 2 × ULN	3 (5)	0	0
TBili \geq 2X \times ULN and AST or ALT \geq 3 \times ULN	3* (5)	0	0

^{*}All were serious AEs with ALP ≥ 2.5 x ULN.

- 8 patients discontinued pexidartinib due to hepatic AEs
 - 4 cases were serious nonfatal AEs with increased bilirubin, 1 lasting
 7 months
 - All serious hepatic events emerged during the first 2 months of pexidartinib treatment

Pexidartinib: Hepatotoxicity Outside of TGCT

- Non-TGCT development program for malignant diseases (n = 637)
- Serious liver toxicity also observed
- Two most concerning cases:
 - 1 case required liver transplant (breast cancer)
 - Pexidartinib at 1200 mg/d combined with paclitaxel
 - 1 case associated with death (mucosal melanoma)
 - Pexidartinib at 1000 mg/d
- Hepatotoxicity occurred during first 2 months of pexidartinib treatment

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1

2

3

4

5

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Delivering on Our Development Promises

Quizartinib Single Agent in AML



First phase 3 trial to demonstrate improved overall survival vs. cytotoxic chemotherapy in Relapsed/Refractory *FLT3*-ITD–mutant AML

Late-breaking Submission

4. Acute myeloid leukemia - Clinical EHA-4422

QUIZARTINIB SIGNIFICANTLY PROLONGS OVERALL SURVIVAL IN PATIENTS WITH FLT3-INTERNAL TANDEM DUPLICATION-MUTATED (MUT) RELAPSED/REFRACTORY AML IN THE PHASE 3, RANDOMIZED, CONTROLLED QUANTUM-R TRIAL

Jorge E. Cortes 1, Samer Khaled², Giovanni Martinelli³, Alexander E. Perl⁴, Siddhartha Ganguly⁵, Nigel Russell⁶, Alwin Krämer⁷, Hervé Dombret³, Donna Hogge³, Brian A. Jonas¹o, Anskar Yu-Hung Leung¹¹, Priyanka Mehta¹², Pau Montesinos¹³, Markus Radsak¹⁴, Simona Sica¹⁵, Meena Arunachalam¹6, Melissa Holmes¹⁶, Ken Kobayashi¹⁶, Ruth Namuyinga¹⁶, Nanxiang Ge¹⁶, Antoine Yver¹⁶, Yufen Zhang¹⁶, Mark J. Levis¹²



- 1/3 subjects with refractory disease, 2/3 with relapse within 6 months of first line treatment
- Quizartinib significantly prolonged OS in pts with R/R FLT3-ITD mutant AML compared with cytotoxic chemotherapy
- 24% reduction in risk of death (95% CI 0.58-0.98; stratified log-rank test, 1-sided P=0.0177).
- Median OS was 27 wks (95% CI 23.1-31.3) vs. 20.4 wks (95% CI 17.3-23.7)
- Safety profile appears consistent with that observed at similar doses
- Demonstrates value of targeting the *FLT3*-ITD driver mutation with a potent and selective FLT3i.

Late-Breaking Abstract
Plenary Session
EHA meeting 16 June 2018
Stockholm, SW

ASCO 2018 Highlights Cancer Enterprise Development Progress



Today's Agenda

1

2

3

4

5

DS-8201

U3-1402

Pexidartinib

Quizartinib

Cancer Enterprise

Rapid and Far-reaching Development Momentum

- Mature phase 1 results across HER-2 tumors
- Impact on development plan and scope
- HER2 now recognized as a broader marker

HER3 ADC Firs in Human Debut

Key Early results

TGCT: ENLIVEN
Phase 3 Study
Supports
Decision To
Proceed to NDA
Submission

Positive Survival & Benefit/Risk in R/R AML

- Late Breaking /
 Plenary Session at
 EHA June 2018,
 Stockholm
- Support decision to proceed to NDA submission

Delivering on Our Development Promises

ADC Franchise





Maturing data show activity across tumors expressing HER2 as a cell surface target

Incidence in Breast Cancer

- Typical HER2 ~20%
- HER2 'low' additional ~50% of all Breast cancer cases

First U3-1402 data release mimics that of DS-8201 at ESMO 2016

- HER3 ADC is first in class; HER3 widely expressed across many tumor types (Breast, lung are lead indications for development)
- Validates portability of DXd technology



Breakthrough and AML Therapies Moving to Market





Commitment to submit NDA in 2H FY2018 First-in-class for TGCT



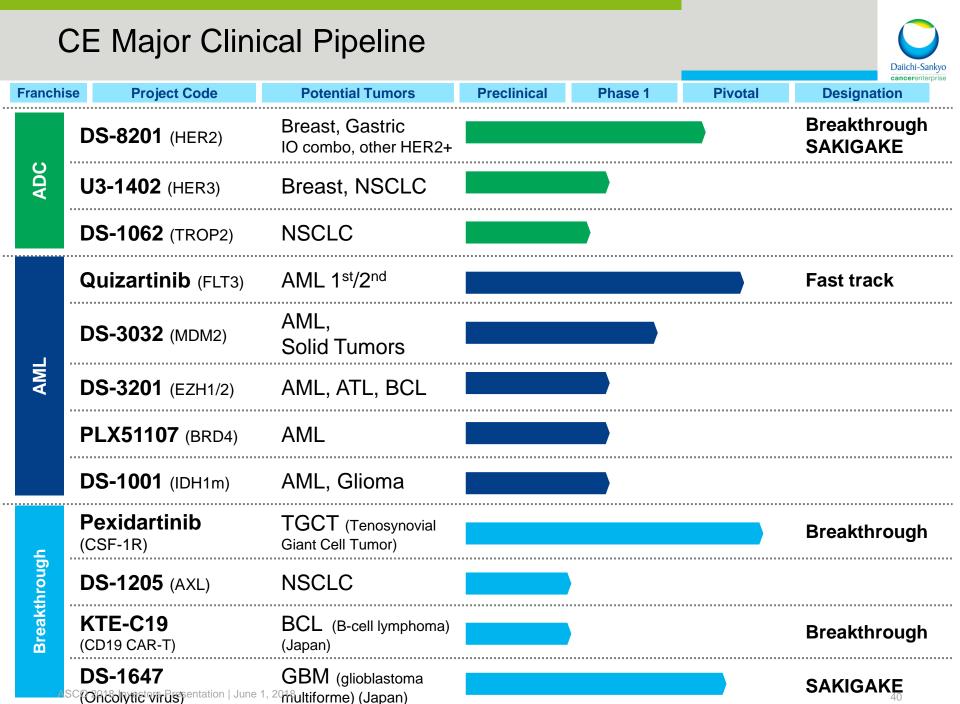


Improved overall survival in relapse/refractory AML *FLT3-*ITD compared to salvage chemotherapy

Commitment to global submission 2H FY2018

Competitive advantages

- First to show survival benefit
- First-line trial enrollment well ahead of any competing trial for selective flt3-inhibitors
- Multiple-asset AML Franchise



Cancer Enterprise | 2025 Vision "7 in 8"



By 2025, Cancer Enterprise will be a leading world-class science organization built on 3 pillars delivering 7 valuable, distinct NMEs (approved, launched, accessed)

Lead in Smart-Treatment with BIC & FIC* ADC

- Maximize existing Smart-Chemo portfolio
- Develop next generation of Smart-Chemo
- Deliver disruptive Smart-Treatments

Establish a Competitive Hematology Franchise

- Lead the FLT3 segment
- Expand beyond FLT3 segment
- Expand beyond AML

Lead with Breakthrough Science

- Deliver best-in-class
 NME or first-in-class
 disruptive** MOA NME
- Embed new technologies to magnify the value of science

3

3

7 NMEs in 8 years

A Cross-Functional Value Creation Team Changing Standard of Care (SOC) with Each NME

*BIC: Best in Class and FIC: First in Class

^{**}Disruptive: adjective meaning to radically changes an industry or business strategy, especially by creating a new market or disrupting an existing one

Cancer Enterprise | 2018 FOCUS



Deliver our Portfolio

On track to submit 3 NMEs over next 12-24 months











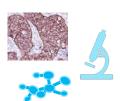
Develop our People

Attract, grow world-class talent

Translational Research Focused Enhancement

Redefining HER2 disease





Focused Research Ambition

DXd and NEXT generation ADCs

CE 2018, A Year of Delivery & Focus

A Force Today, A Leader Tomorrow





Care. Compassion. Science. It's Our Obligation.

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