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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 	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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Rapid and Far-reaching Development Momentum	HER3 ADC First in Human Debut	TGCT: ENLIVEN Phase 3 Study Supports Decision To	Positive Survival & Benefit/Risk in R/R AML	Delivering on Our Development Promises
 Mature phase 1 results across HER-2 tumors 		Proceed to NDA Submission		
 Impact on development plan and scope 				
HER2 now recognized as a broader marker				

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)



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

Includes subjects who had \geq 1 postbaseline scan. Dotted lines denote 20% increase and 30% reduction in tumor size, respectively. * Confirmed response includes subjects who had \geq 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



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. ** Cause of death included pneumonitis (4), disease progression (2), interstitial lung disease (1), Ileus (1), pneumonia aspiration (1), pneumonia (1), TEAE, treatment-emergent adverse event. Data cutoff for this analysis is April 18, 2018.

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*

HER2+ is Approximately 20% of Total Metastatic Population





* 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





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

Breast Cancer Treatment Landscape 2018* HR+/HER2 Low is the Focus of HER2 Low Phase III Program





* 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

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



Sakigake gastric cancer

DESTINY

Ongoing pivotal development

- DESTINY-Breast01
- DESTINY-Gastric01

Planned pivotal development

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

Focus

Expanding at full scale and speed into **Iow 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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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

Phase 1	Phase 2		
Dose escalation	Finding	Expansion	
mCRM		• Safety • Clinical response	
8.0 mg/kg IV q 3 wk			
6.4 mg/kg IV q 3 wk		RDF	
4.8 mg/kg IV q 3 wk			
3.2 mg/kg IV q 3 wk 1.6 mg/kg IV q 3 wk ASCO 2018 poster discussion			

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 \geq 15% Patients, Dose Escalation Phase (Total N = 34)* 1/2

Preferred Term	All Grades N = 34	Grade ≥ 3	Preferred Term	All Grades N = 34	Grade ≥ 3
Patients with TEAEs, n (%)	33 (97)	21 (62)	Alanine aminotransferase	13 (38)	3 (9)
Nausea	28 (82)	1 (3)	increased	13 (30)	3 (7)
Platelet count decreased/Thrombocytopenia	23 (68)	10 (29)	Aspartate aminotransferase increased	13 (38)	3 (9)
Decreased appetite	21 (62)	2 (6)	Anemia	13 (38)	4 (12)
Neutrophil count	· · · · · · · · · · · · · · · · · · ·		Stomatitis	11 (32)	0
decreased/Neutropenia	20 (59)	9 (27)	Diarrhea	11 (32)	2 (6)
White blood cell count	18 (53)	6 (18)	Rash/Rash maculo-papular	10 (29)	0
decreased	10 (33)		Malaise	9 (27)	0
Vomiting	17 (50)	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 \ge 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

*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.

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

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



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

DS-8201 late-breaking ESMO 2016 Dose escalation phase U3-1402 ASCO 2018 Dose escalation phase





ORR:7/20 (25%)

ADC | Franchise Focus and Flagship Asset





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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



*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% Cl)	Placebo (95% Cl)	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 \ge 2X \times ULN and AST or ALT \ge 3 \times ULN	3* (5)	0	0

*All were serious AEs with ALP \ge 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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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 Dombret⁸, Donna Hogge⁹, Brian A. Jonas¹⁰, 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. Levis¹⁷

- 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-ITDmutant 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

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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





CE Major Clinical Pipeline

Franch	ise Proiect Code	Potential Tumors	Preclinical	Phase 1	Pivotal	cancerenterprise Designation
ADC	DS-8201 (HER2)	Breast, Gastric IO combo, other HER2+				Breakthrough SAKIGAKE
	U3-1402 (HER3)	Breast, NSCLC				
	DS-1062 (TROP2)	NSCLC				
AML	Quizartinib (FLT3)	AML 1 st /2 nd				Fast track
	DS-3032 (MDM2)	AML, Solid Tumors				
	DS-3201 (EZH1/2)	AML, ATL, BCL				
	PLX51107 (BRD4)	AML				
	DS-1001 (IDH1m)	AML, Glioma				
Breakthrough	Pexidartinib (CSF-1R)	TGCT (Tenosynovial Giant Cell Tumor)				Breakthrough
	DS-1205 (AXL)	NSCLC)		
	KTE-C19 (CD19 CAR-T)	BCL (B-cell lymphoma) (Japan)				Breakthrough
	DS-1647	GBM (glioblastoma				

Daiichi-San

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)



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





CE 2018, A Year of Delivery & Focus

A Force Today, A Leader Tomorrow





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