

Passion for Innovation.
Compassion for Patients.™



DAIICHI SANKYO **-Transforming into Oncology-**

Sunao Manabe
President and COO

June 2, 2019
ASCO Investor Relations Presentation, Chicago, IL

Forward-looking Statements

Management strategies and plans, financial forecasts, future projections and policies, and R&D information that Daiichi Sankyo discloses in this material are all classified as Daiichi Sankyo's future prospects. These forward looking statements were determined by Daiichi Sankyo based on information obtained as of today with certain assumptions, premises and future forecasts, and thus, there are various inherent risks as well as uncertainties involved. As such, please note that actual results of Daiichi Sankyo may diverge materially from Daiichi Sankyo's outlook or the content of this material. Furthermore, there is no assurance that any forward-looking statements in this material will be realized. Regardless of the actual results or facts, Daiichi Sankyo is not obliged and does not have in its policy the duty to update the content of this material from the date of this material onward.

Compounds under discussion are investigational agents and are not approved by the FDA or any other regulatory agency worldwide as a treatment for indications under investigation. Efficacy and safety have not been established in areas under investigation.

Daiichi Sankyo takes reasonable care to ensure the accuracy of the content of this material, but shall not be obliged to guarantee the absolute accuracy, appropriateness, completeness and feasibility, etc. of the information described in this material. Furthermore, any information regarding companies, organizations or any other matters outside the Daiichi Sankyo Group that is described within this material has been compiled or cited using publicly available information or other information, and Daiichi Sankyo has not performed in-house inspection of the accuracy, appropriateness, completeness and feasibility, etc. of such information, and does not guarantee the accuracy thereof.

The information described in this material may be changed hereafter without notice. Accordingly, this material or the information described herein should be used at your own judgment, together with any other information you may otherwise obtain. This material does not constitute a solicitation of application to acquire or an offer to sell any security in the United States, Japan or elsewhere.

This material disclosed here is for reference purposes only. Final investment decisions should be made at your own discretion. Daiichi Sankyo assumes no responsibility for any damages resulting from the use of this material or its content, including without limitation damages related to the use of erroneous information.

Our History and the Path to Merger

Two drug discovery-oriented companies originating in Japan



With Continued Focus on Discovery...



Daiichi-Sankyo

Daiichi Sankyo has created blockbusters worldwide from the own lab

Pravastatin



Daiichi-Sankyo



Edoxaban

Olmesartan



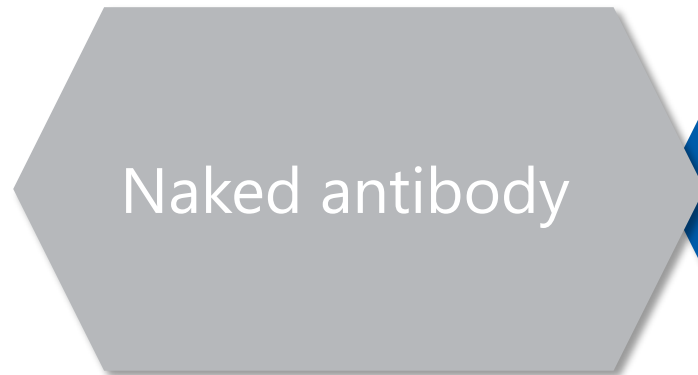
Levofloxacin



Prasugrel

Becoming a Competitive Force by Establishing Strength & Expertise in Diverse Modalities

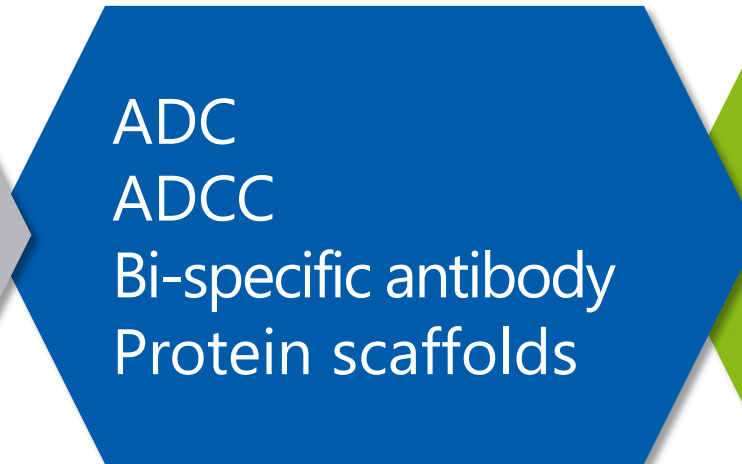
Wave 1



U3^{PHARMA}

Acquired U3 Pharma

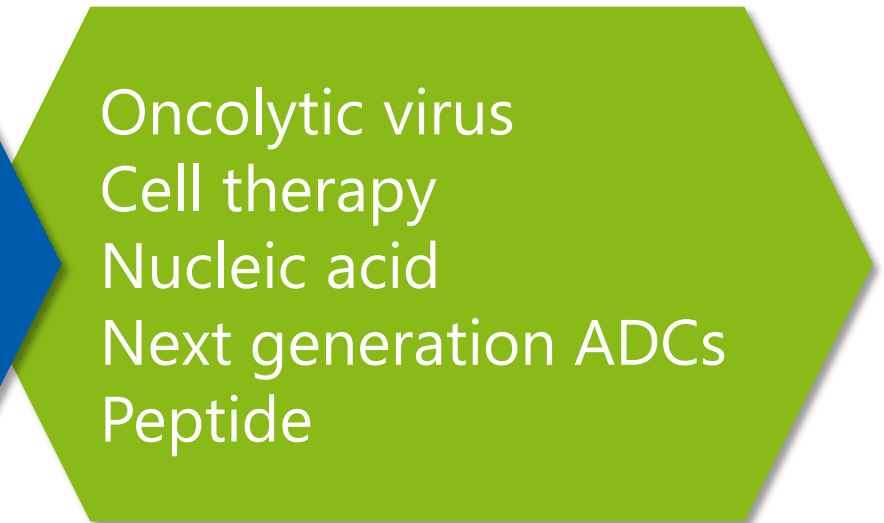
Wave 2



GLYCOTOPE
ADC Collaboration

zymeworks
Bi-specific AB Collaboration

Wave 3



University of Tokyo
G47Δ Collaboration

Kite
In-licensed Axi-Cel®


Making Progress & Realizing the 2025 Vision in Oncology









Our first global oncology product will soon launch



Exceptional Progress & Momentum in our ADC Franchise

ADC Franchise (as of June 2019)

 Clinical stage

	 Project (Target)	Target Indications	Discovery	Pre-Clinical	P1	Pivotal
1	DS-8201 (HER2)	Breast, Gastric, CRC, NSCLC				
2	U3-1402 (HER3)	NSCLC, Breast				
3	DS-1062 (TROP2)	NSCLC				
4	DS-7300 (B7-H3)	Solid tumors				
5	DS-6157 (GPR20)	GIST				
6	DS-6000 (undisclosed)	Renal, Ovarian				
7	(TA-MUC1)	Solid tumors				

CRC: colorectal cancer, NSCLC: non-small cell lung cancer, GIST: gastrointestinal stromal tumor

Phase 1 study in metastatic breast cancer 3rd line or after

ORR	PFS	DOR
59.5%	22.1m	20.7m

DS-8201 | Strategic Collaboration with AstraZeneca

Up to \$6.9 billion (¥759.0 billion) total consideration

Unique Science



AstraZeneca



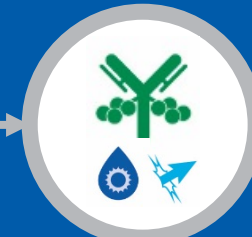
*Extensive expertise
in oncology*



Opportunities for
strategic collaboration
with excellent partner



Accelerate building in-
house oncology
business infrastructure



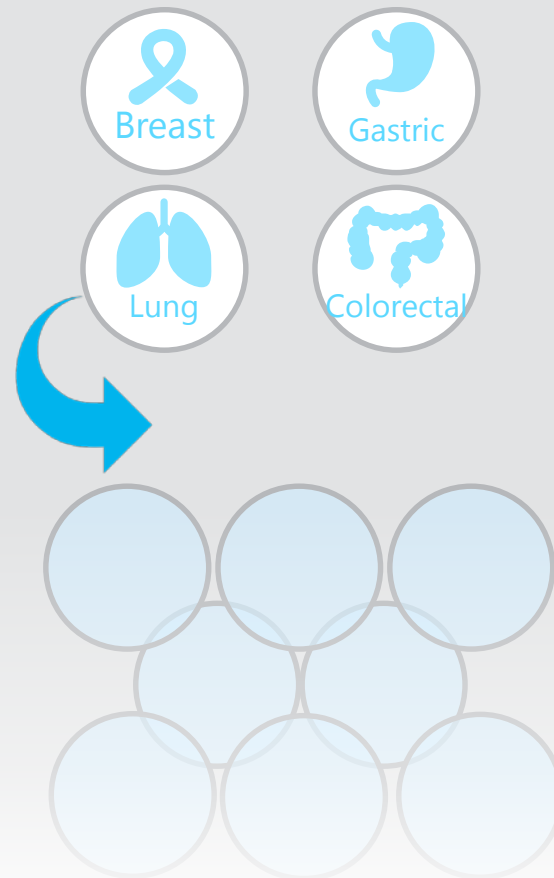
Maximize product value
for in-house oncology
products

DS-8201 | Strategic Collaboration ... Our Intent

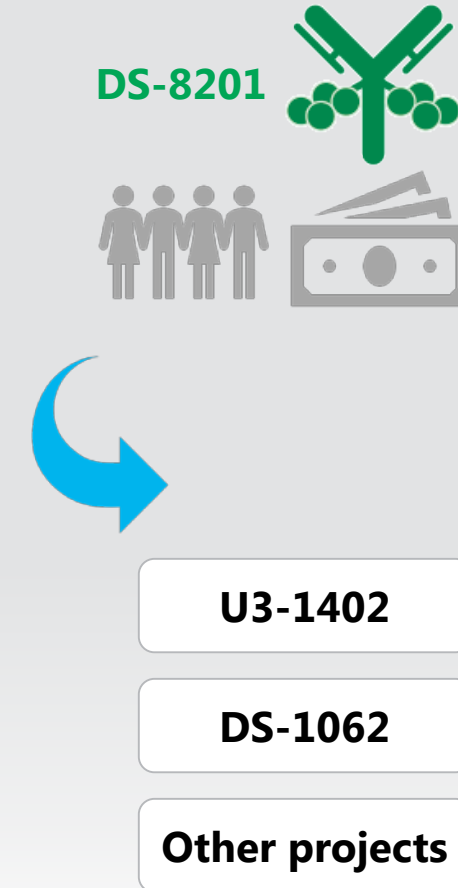
Earlier penetration
in global market



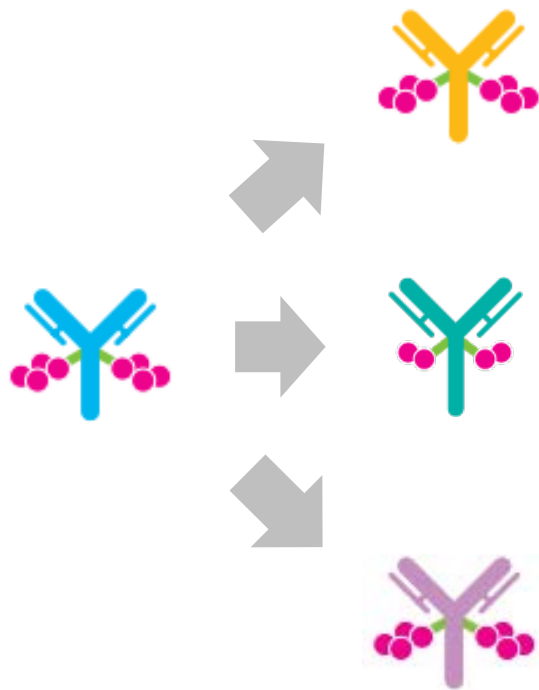
Expand indications



Optimize resources



Same drug-linker applicable to different antibodies



U3-1402 (HER3 ADC)

- P1 study ongoing in breast cancer
 - Initial data presented at ASCO 2018 and SABCS 2018
 - Very similar data to initial data of DS-8201
- P1 study ongoing in EGFRm NSCLC
 - **Initial data presented on May 31st at ASCO**

DS-1062 (TROP2 ADC)

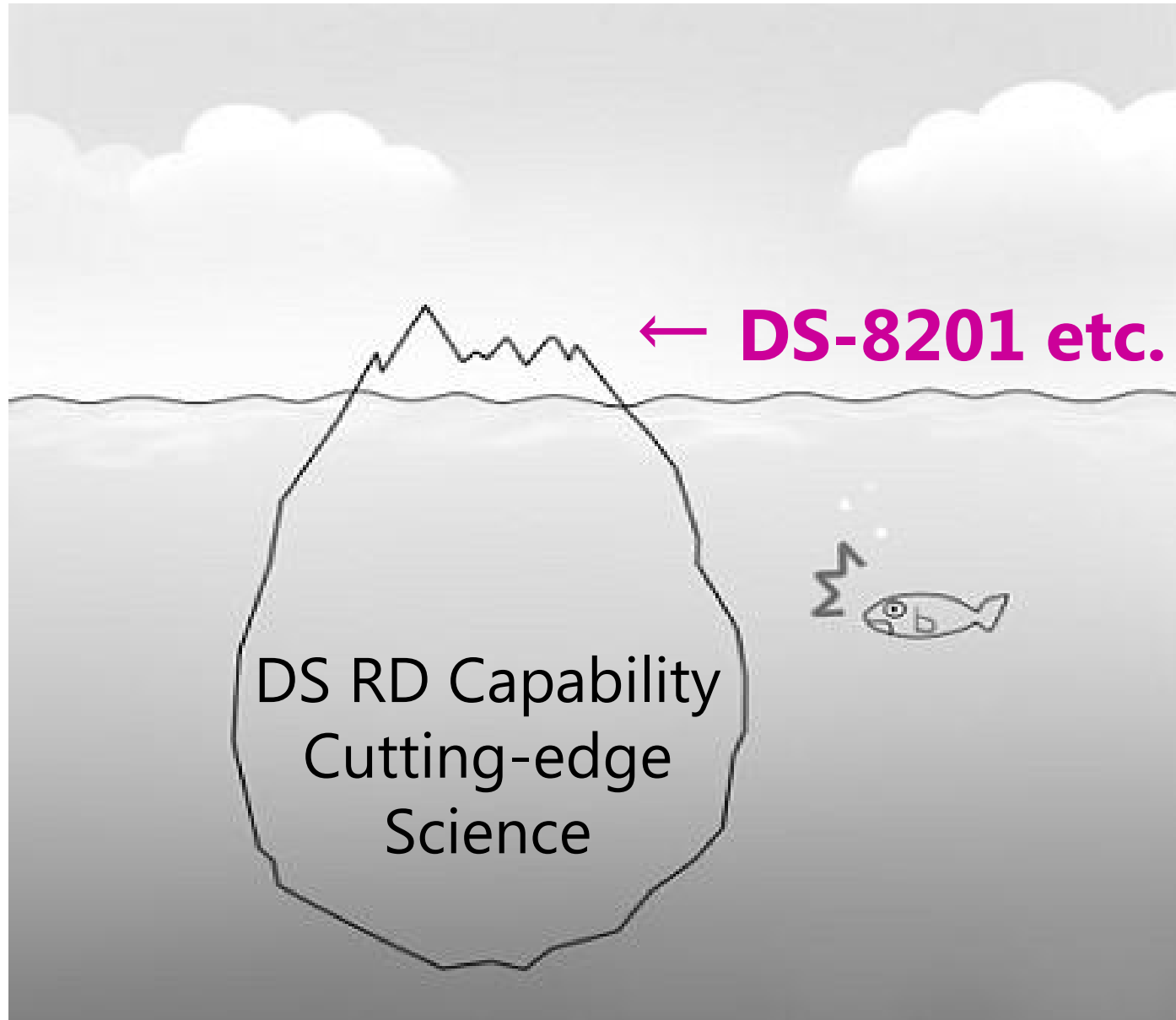
- P1 study ongoing in NSCLC
 - **Initial data presented on June 2nd at ASCO**

DS-7300 (B7-H3 ADC)

DS-6157 (GPR20 ADC)

- First-in-human P1 studies will start in FY2019

DS RD Capability





**The First Year of
DS Oncology Business**

Now is the time ...

Help More Patients!



Passion for Innovation.
Compassion for Patients.™



Daiichi-Sankyo
cancerenterprise



Daiichi Sankyo: ASCO2019 Highlights

Investors Relations Presentation
ASCO, Chicago, IL
June 2, 2019

Antoine Yver MD MSc

Exec VP & Global Head R&D Oncology
Chair Cancer Enterprise

ASCO 2019 Highlights

Cancer Enterprise Development Progress

Today's Agenda

1

DS-8201

*HER2 DXd ADC
and AZ
Collaboration*

- Accelerate and expand; do the right thing
- Breast cancer BLA acceleration to 1H FY19

2

U3-1402 &
DS-1062

*HER3 DXd ADC &
TROP2 DXd ADC*

- Data update
- Implications

3

DS-7300 &
DS-6157

*Next human-stage
DXd ADC*

- Targeting B7-H3 and GPR20
- Updates

4

Regulatory
Reviews

*ODAC and Ongoing
Reviews*

- Pexidartinib
- Quizartinib

5

Rest of the
Portfolio

*Brief Review of
Activities*

- Quizartinib: QuANTUM-First
- DS-3201 EZH1/2 inhibitor
- DS-1001 IDH1m inhibitor
- DS-3032 mdm2 inhibitor

ASCO 2019 Highlights

Cancer Enterprise Development Progress

Today's Agenda

1

DS-8201

*HER2 DXd ADC
and AZ
Collaboration*

- Accelerate and expand; do the right thing
- Breast cancer BLA acceleration to 1H FY19

2

U3-1402 &
DS-1062

*HER3 DXd ADC &
TROP2 DXd ADC*

- Data update
- Implications

3

DS-7300 &
DS-6157

*Next human-stage
DXd ADC*

- Targeting B7-H3 and GPR20
- Updates

4

Regulatory
Reviews

*ODAC and Ongoing
Reviews*

- Pexidartinib
- Quizartinib

5

Rest of the
Portfolio

*Brief Review of
Activities*

- Quizartinib: QuANTUM-First
- DS-3201 EZH1/2 inhibitor
- DS-1001 IDH1m inhibitor
- DS-3032 mdm2 inhibitor

“Accelerate, Expand, Do the Right Thing”

- ✓ All joint committees formed and actively engaged
- ✓ All ‘critical’ joint committees fully staffed and working, from within <24hrs to ~1 month of the deal (executive, development, supplies, commercial, medical affairs)
- ✓ Expect to publish on clinicaltrials.gov next wave of studies by end of FY2019
- ✓ Comprehensive updated joint development plan by RD Day (Dec. 2019)
- ✓ US BLA prep well under way (DS in lead), pre-BLA with FDA within days
 - CMC teams jointly implementing further scale up capabilities to meet revised projected demand



Preparation for BLA/NDA submissions is progressing to plan




US

**BLA submission
1H FY2019**

Estimated Review Period:
6M after filing of the
application by FDA

 Fast-track status

 Breakthrough therapy
designation



Japan

**NDA submission
2H FY2019**

Estimated Review Period:
Maximum 12M after
application



EU

**MAA submission
1H FY2020**

Estimated Review Period:
12M after application

Preparation for JNDA submission is progressing steadily



NDA submission
1H FY2020

Estimated Review Period:
6M after application

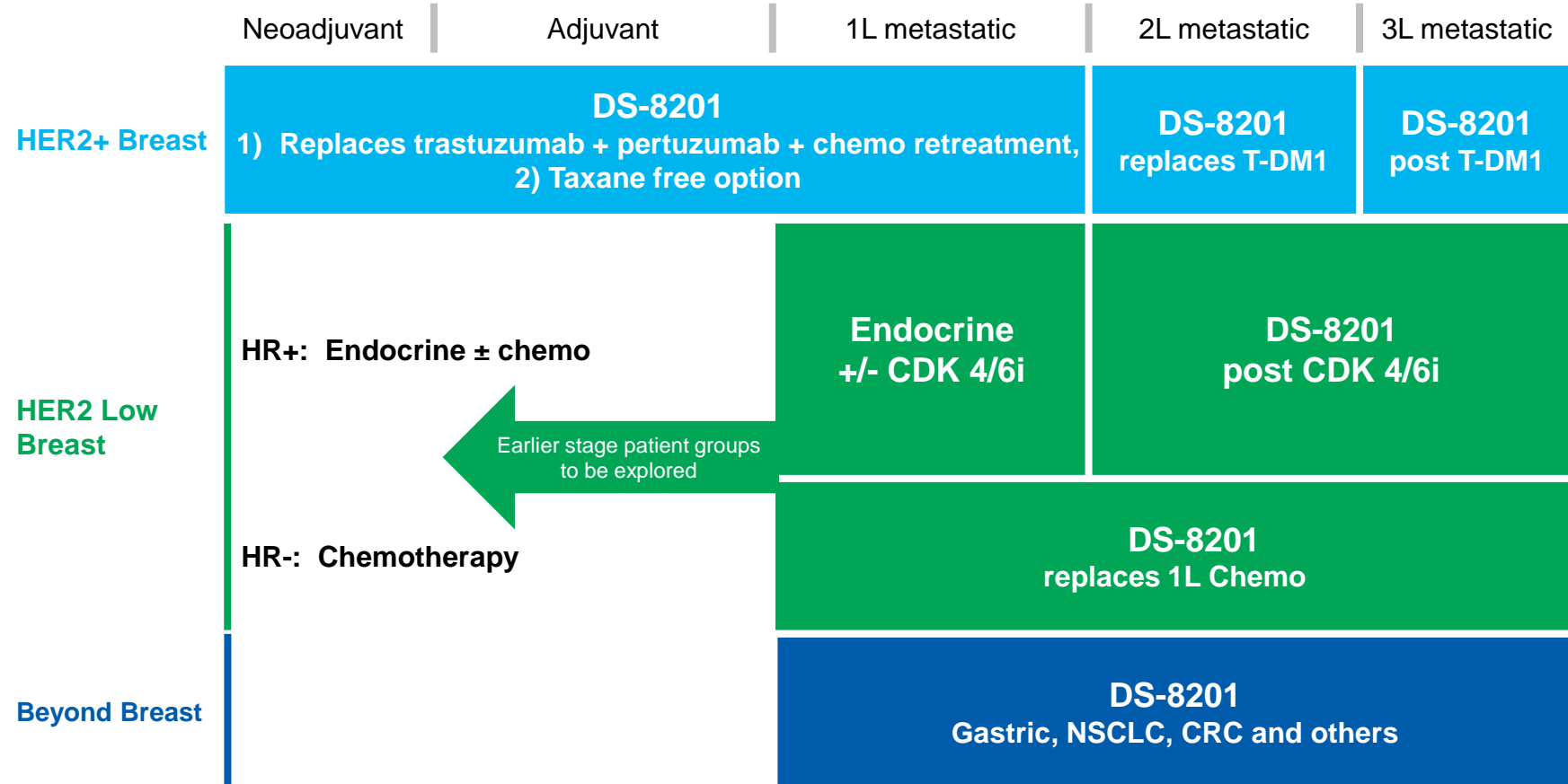
 SAKIGAKE designation

DS-8201 | Remarkable Speed in Development & Manufacturing



Less Than ~4 Years

DS-8201 | Redefining HER2 in Breast Cancer & Beyond



Characterizing the unique HER2 biology targeted by DS-8201, especially the bystander MOA, and identifying a possible tumor-agnostic signature

Published April 29, 2019 *Lancet Oncology*

Trastuzumab deruxtecan (DS-8201a) in patients with advanced HER2-positive breast cancer previously treated with trastuzumab emtansine: a dose-expansion, phase 1 study



Kenji Tamura, Junji Tsurutani, Shunji Takahashi, Hiroji Iwata, Ian E Krop, Charles Redfern, Yasuaki Sagara, Toshihiko Doi, Haeseong Park, Rashmi K Murthy, Rebecca A Redman, Takahiro Jikoh, Caleb Lee, Masahiro Sugihara, Javad Shahidi, Antoine Yver, Shanu Modi

Summary

Background Trastuzumab deruxtecan (DS-8201a) is a novel HER2-targeted antibody–drug conjugate with a humanised anti-HER2 antibody, cleavable peptide-based linker, and potent topoisomerase I inhibitor payload. A phase 1, non-randomised, open-label, multiple-dose study was done to assess the safety, tolerability, and activity of trastuzumab deruxtecan in HER2-expressing, advanced solid tumours. The dose escalation (part 1) has previously been reported and the recommended doses for expansion of 5.4 mg/kg or 6.4 mg/kg were established. In this Article, we report the safety and preliminary activity results from this phase 1 trial in all patients with HER2-positive advanced-stage breast cancer with previous trastuzumab emtansine treatment who received trastuzumab deruxtecan at the recommended doses for expansion.

Methods We did an open-label, dose-escalation and dose-expansion phase 1 trial at eight hospitals and clinics in the USA and six in Japan. Eligible patients were at least 18 years old in the USA and at least 20 years of age in Japan and had advanced solid tumours (regardless of HER2 expression in dose escalation or HER2 expression or mutation in dose expansion). The recommended doses for expansion of 5.4 mg/kg or 6.4 mg/kg trastuzumab deruxtecan were administered intravenously to patients once every 3 weeks until withdrawal of consent, unacceptable toxicity, or progressive disease. In this Article, all patients with HER2-positive advanced-stage breast cancer with previous trastuzumab emtansine treatment who received trastuzumab deruxtecan at the recommended doses for expansion were analysed together. The primary endpoints of the study were safety and preliminary activity (proportion of patients who achieved an objective response as assessed by the investigators). The activity evaluable set included all patients who received at least one dose of trastuzumab deruxtecan at the recommended doses for expansion, and for whom both baseline and post-treatment activity data were available. The safety analysis set included all patients who received at least one dose of trastuzumab deruxtecan at the recommended doses for expansion. Enrolment for patients with HER2-positive breast cancer has been completed. This trial is registered at ClinicalTrials.gov, number NCT02564900, and ClinicalTrials.jp, number JapicCT1-152978.

Findings Between Aug 28, 2015, and Aug 10, 2018, 115 of 118 patients with HER2-positive breast cancer were treated with at least one dose of trastuzumab deruxtecan at the recommended doses for expansion. All patients had at least one treatment-emergent adverse event. Frequent grade 3 or worse treatment-emergent adverse events included anaemia (19 [17%] of 115) and decreased neutrophil (16 [14%]), white blood cell (ten [9%]), and platelet (nine [8%]) counts. At least one serious treatment-emergent adverse event occurred for 22 (19%) patients. Investigators reported 20 cases of interstitial lung disease, pneumonitis, or organising pneumonia, including one grade 3 event and two treatment-related deaths due to pneumonitis. One death unrelated to study treatment was due to progressive disease. 66 (59.5%; 95% CI 49.7–68.7) of 111 patients had a confirmed objective response.

Interpretation Trastuzumab deruxtecan had a manageable safety profile and showed preliminary activity in trastuzumab emtansine-pretreated patients with HER2-positive breast cancer. These results suggest that further development in phase 2 and 3 clinical trials for HER2-positive breast cancer is warranted.

Funding Daiichi Sankyo Co. Ltd.

Copyright © 2019 Elsevier Ltd. All rights reserved.

Introduction

About 15–20% of breast cancers show HER2 over-expression or amplification, an attribute that is generally associated with aggressive disease.^{1–3} Recommended first-

line therapy for patients with metastatic HER2-positive breast cancer is dual blockade with anti-HER2 humanised monoclonal antibody therapies trastuzumab and pertuzumab, in combination with chemotherapy.^{4,5} At the

Lancet Oncol 2019

Published Online

April 29, 2019

[http://dx.doi.org/10.1016/S1473-2045\(19\)30097-X](http://dx.doi.org/10.1016/S1473-2045(19)30097-X)

See Online/Comment

[http://dx.doi.org/10.1016/S1473-2045\(19\)30088-9](http://dx.doi.org/10.1016/S1473-2045(19)30088-9)

Department of Breast and

Medical Oncology, National

Cancer Center Hospital, Tokyo,

Japan (K Tamura MD); Advanced

Cancer Translational Research

Institute, Department of

Medical Oncology, Showa

University, Tokyo, Japan

(Prof) Tsurutani MD);

Department of Medical

Oncology, Kindai University

Faculty of Medicine, Osaka,

Japan (Prof) Takahashi MD);

Department of Medical

Oncology, The Cancer Institute

Hospital of Japanese

Foundation for Cancer

Research, Tokyo, Japan

(S Takahashi MD); Department

of Breast Oncology, Aichi

Cancer Center Hospital,

Nagoya, Japan (H Iwata MD);

Department of Medical

Oncology, Dana-Farber Cancer

Institute, Boston, MA, USA

(I E Krop MD); Medical

Oncology, Sharp HealthCare,

San Diego, CA, USA

(C Redfern MD); Department of

Breast Surgery, Social Medical

Corporation Hakuhai Sakaga

Hospital, Kagoshima, Japan

(Y Sagara MD); Department of

Gastrointestinal Oncology,

National Cancer Center

Hospital East, Kashiwa, Japan

(T Doi MD); Department of

Medicine, Washington

University School of Medicine,

St Louis, MO, USA (H Park MD);

Department of Breast Medical

Oncology, University of Texas

MD Anderson Cancer Center,

Houston, TX, USA

(R K Murthy MD); Department

of Medical Oncology &

Hematology, University of

Trastuzumab deruxtecan (DS-8201a) in patients with advanced HER2-positive gastric cancer: a dose-expansion, phase 1 study



Kohji Shitara, Hiroji Iwata, Shunji Takahashi, Kenji Tamura, Haeseong Park, Shanu Modi, Junji Tsurutani, Shigenori Kadowaki, Kensei Yamaguchi, Satoru Iwasa, Kaku Saito, Yoshihiko Fujisaki, Masahiro Sugihara, Javad Shahidi, Toshihiko Doi

Summary

Background Trastuzumab deruxtecan (DS-8201a) is a novel HER2-targeted antibody–drug conjugate with a humanised anti-HER2 antibody, cleavable peptide-based linker, and topoisomerase I inhibitor payload. A phase 1, non-randomised, open-label, multiple-dose study was done to assess the safety, tolerability, and activity of trastuzumab deruxtecan in HER2-expressing advanced solid tumours. The dose escalation (part 1) has previously been reported and the recommended doses for expansion of 5.4 mg/kg or 6.4 mg/kg were established. In this Article, we report the safety and preliminary activity results from this phase 1 trial in all patients with HER2-positive gastric or gastro-oesophageal junction cancer who received trastuzumab deruxtecan at the recommended doses for expansion.

Methods This was an open-label, dose-escalation and dose-expansion phase 1 trial done at eight hospitals and clinics in the USA and six in Japan. Eligible patients were at least 18 years old in the USA and at least 20 years old in Japan and had advanced solid tumours (regardless of HER2 expression in dose escalation or HER2 expression or mutation in dose expansion). The recommended doses for expansion of 5.4 mg/kg or 6.4 mg/kg trastuzumab deruxtecan were administered intravenously to patients once every 3 weeks until withdrawal of consent, unacceptable toxicity, or progressive disease. In this Article, all patients with HER2-positive gastric or gastro-oesophageal junction cancer with previous trastuzumab treatment who received trastuzumab deruxtecan were analysed together. The primary endpoints of the study were safety and preliminary activity (proportion of patients who achieved an objective response as assessed by the investigators). The activity evaluable set included all patients who received at least one dose of trastuzumab deruxtecan at the recommended doses for expansion, and for whom both baseline and post-treatment activity data were available. The safety analysis set included all patients who received at least one dose of trastuzumab deruxtecan at the recommended doses for expansion. Enrolment for patients with gastric or gastro-oesophageal junction cancer has completed. This trial is registered at ClinicalTrials.gov, number NCT02564900, and ClinicalTrials.jp, number JapicCT1-152978.

Findings Between Aug 28, 2015, and Aug 10, 2018, 44 patients with HER2-positive gastric or gastro-oesophageal junction cancer received at least one dose of trastuzumab deruxtecan at the recommended doses for expansion. All patients had at least one treatment-emergent adverse event. The most frequent grade 3 or worse treatment-emergent adverse events included anaemia (13 [30%]) and decreases in neutrophil (nine [20%]), platelet (eight [18%]), and white blood cell (seven [16%]) counts. Serious treatment-emergent adverse events occurred in 11 (25%) patients. There were four pneumonitis cases (three grade 2 and one grade 3). There were no drug-related deaths due to treatment-emergent adverse events. 19 (43.2%; 95% CI 28.3–59.0) of 44 patients had a confirmed objective response.

Interpretation Trastuzumab deruxtecan had a manageable safety profile and showed preliminary activity in heavily pretreated patients with HER2-positive gastric or gastro-oesophageal junction cancer. These results support further investigation of trastuzumab deruxtecan for HER2-positive gastric or gastro-oesophageal junction cancer post-trastuzumab.

Funding Daiichi Sankyo Co. Ltd.

Copyright © 2019 Elsevier Ltd. All rights reserved.

Introduction

Gastric cancer is the third leading cause of cancer death worldwide.¹ In 2012, based on the International Agency for Research on Cancer GLOBOCAN estimates,¹ approximately 950 000 new cases of gastric cancer were diagnosed and 700 000 deaths occurred globally.

However, the incidence varies regionally and is generally higher in east Asia than in Europe and North America.² Around 20% of advanced gastric or gastro-oesophageal junction cancers are HER2-positive.³ In patients with these cancers, chemotherapy plus trastuzumab, a HER2-targeted monoclonal antibody, improved overall

Lancet Oncol 2019

Published Online

April 29, 2019

[http://dx.doi.org/10.1016/S1473-2045\(19\)30088-9](http://dx.doi.org/10.1016/S1473-2045(19)30088-9)

See Online/Comment

[http://dx.doi.org/10.1016/S1473-2045\(19\)30168-8](http://dx.doi.org/10.1016/S1473-2045(19)30168-8)

Department of Gastrointestinal

Oncology, National Cancer

Center Hospital East, Kashiwa,

Chiba, Japan (K Shitara MD,

T Doi MD); Department of

Breast Oncology, Aichi Cancer

Center Hospital, Nagoya, Aichi,

Japan (H Iwata MD,

S Kadowaki MD); Department of

Medical Oncology, The Cancer

Institute Hospital of Japanese

Foundation for Cancer

Research, Tokyo, Japan

(S Takahashi MD,

K Yamaguchi MD); Department

of Gastrointestinal Medical

Oncology, National Cancer

Center Hospital, Tokyo, Japan

(K Tamura MD, S Iwasa MD);

Department of Medicine,

Washington University School

of Medicine, St Louis, MO, USA

(H Park MD); Department of

Medical Oncology, Memorial

Sloan Kettering Cancer Center,

New York, NY, USA

(S Modi MD); Department of

Medical Oncology, Kindai

University Faculty of Medicine,

Osaka, Japan

(Prof) Tsurutani MD);

Department of Medical

Oncology, Advanced Cancer

Translational Research

Institute, Showa University,

Tokyo, Japan (Prof) Takahashi

MD); Department of

Research and Development

(K Saito MS, Y Fujisaki MS) and

Biostatistics and Data

Management (M Sugihara PhD),

Daiichi Sankyo Co. Ltd, Tokyo,

Japan; and Research and

Development, Daiichi Sankyo

Inc, Basking Ridge, NJ, USA

(J Shahidi MD)

Comment: Gaia Giannone, *Filippo Montemurro

Division of Medical Oncology (GG) and Multidisciplinary
Outpatient Oncology Clinic (FM), Candiolo Cancer Institute,
FPO-IRCCS, Candiolo 10060, Italy



“These findings appear even more interesting considering that all patients had to have trastuzumab emtansine-resistant disease by protocol and most of them had also progressed on pertuzumab.”

“Although based on a smaller sample size, the results in the HER2-positive gastric cancer cohort are equally meaningful. By contrast with HER2-positive breast cancer, no anti-HER2 strategy other than trastuzumab has shown efficacy in these patients, and no HER2- targeting compound is currently approved to treat trastuzumab-resistant disease.”

^aSubjects who received 5.4 or 6.4 mg/kg with ≥ 2 postbaseline scans, or who had progressive disease or discontinued treatment for any reason before second postbaseline scan. DCR, disease control rate; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; ISH, in situ hybridization; ORR, objective response rate.

HER2 Positive (IHC 3+ or IHC 2+/ISH+) Breast Cancer	
Confirmed Overall Response Rate (66/111) ^a	59.5% (95% CI 49.7 – 68.7)
Median Duration of Response	20.7 months (range not estimable)

HER2 Positive (IHC 3+ or IHC 2+/ISH+) Gastric Cancer	
Confirmed Overall Response Rate (19/44) ^a	43.2% (95% CI 28.3 – 58.0)
Median Duration of Response	7.0 months (95% CI 4.4 – 16.6)

DS-8201 | P1 Study *Lancet Oncology* Breast Cancer

	Pertuzumab + trastuzumab + docetaxel (1L) ¹	T-DM1 (1L, failed study) ²	T-DM1 (2L) ³	T-DM1 (3L+) ⁴	DS-8201 ⁵
mPFS	18.5m	14.1m	9.6m	6.2m	22.1m
DoR	20.2m	20.7m	12.6m	9.7m	20.7m
OS	56.5m	53.7m	30.9m	22.7m	NR
ORR	80%	60%	43.6%	31%	59.5%
Median prior Rx for adv. disease	0	0	1	4	7 100% prior T-DM1 88% prior pertuzumab

¹CLEOPATRA (NEJM 2012), ²MARIANNE (J Clin Oncol 2017), ³EMILIA (NEJM 2012), ⁴TH3RESA (Lancet Oncol 2017),

⁵Lancet Oncology, April 29, 2019, m: Month, NR:Not Reached

DS-8201 | P1 Study *Lancet Oncology* Gastric Cancer

	Trastuzumab + chemo (1L) ¹	Ramucirumab + chemo (2L) ²	T-DM1 (failed study; 3+L) ³	DS-8201⁴
mPFS	6.7m	4.4m	2.7m	5.6m
DoR	6.9m	4.4m	4.3m	7.0m
OS	13.8m	9.6m	7.9m	12.8m
ORR	47%	28%	21%	43.2%
Median prior LoT ⁵	0	1	1	3

¹ToGA (Lancet 2010), ²RAINBOW (Lancet Oncol. 2014), ³GATSBY (Lancet Oncol. 2017), ⁴Lancet Oncology, published April 29, 2019
m: Month, ⁵Line of Therapy

Investigator-Reported and Adjudicated Cases of ILD

- Median duration of treatment 108 days; 29.5% subjects on treatment for ≥ 180 days
 - Median time to onset of ILD 149 days

Population	Adjudication status	Grade					Total
		1	2	3	4	5	
All subjects All doses, N = 665	Investigator reported, n (%)	30 (4.5)	23 (3.5)	6 (0.9)	2 (0.3)	5 (0.8)	66 (9.9)
	Cases adjudicated, n	16	13	4	0	5	38
	Adjudicated as drug-related ILD, n	11	12	3	0	4	30

Data cutoff: October 15, 2018

- **March 2018: ILD recognized as DS-8201 risk: key actions implemented**
 - Proactive awareness of subjects thru consent, to report signs or symptoms of possible ILD
 - Active training of investigational sites on monitoring for, evaluation and treatment of suspected ILD cases

Spring 2019: Proactive “Safe Use Campaign”

“DS-8201: have you screened for and mitigated against ILD today?”

ASCO 2019 Highlights

Cancer Enterprise Development Progress

Today's Agenda

1

DS-8201

*HER2 DXd ADC
and AZ
Collaboration*

- Accelerate and expand; do the right thing
- Breast cancer BLA acceleration to 1H FY19

2

U3-1402 &
DS-1062

*HER3 DXd ADC &
TROP2 DXd ADC*

- Data update
- Implications

3

DS-7300 &
DS-6157

*Next human-stage
DXd ADC*

- Targeting B7-H3 and GPR20
- Updates

4

Regulatory
Reviews

*ODAC and Ongoing
Reviews*

- Pexidartinib
- Quizartinib


5









Rest of the
Portfolio

*Brief Review of
Activities*

- Quizartinib: QuANTUM-First
- DS-3201 EZH1/2 inhibitor
- DS-1001 IDH1m inhibitor
- DS-3032 mdm2 inhibitor

ADC Franchise

 Clinical stage

 Project (Target)	Target Indications	Discovery	Pre-Clinical	P1	Pivotal
1 DS-8201 (HER2)	Breast, Gastric, CRC, NSCLC				
2 U3-1402 (HER3)	NSCLC, Breast				
3 DS-1062 (TROP2)	NSCLC				
4 DS-7300 (B7-H3)	Solid tumors				
5 DS-6157 (GPR20)	GIST				
6 DS-6000 (undisclosed)	Renal, Ovarian				
7 (TA-MUC1)	Solid tumors				

CRC: colorectal cancer, NSCLC: non-small cell lung cancer, GIST: gastrointestinal stromal tumor

U3-1402 Phase 1 Dose Escalation and Expansion Study

Eligibility

Metastatic/unresectable EGFR-mutant NSCLC and:

- T790M-negative after progression on erlotinib, gefitinib, or afatinib; **OR**
- Progressed on osimertinib

Stable brain metastases allowed
Pretreatment tumor tissue (after progression on TKI) required for retrospective analysis of HER3 expression

Dose Escalation^a

Received ≥ 1 dose of U3-1402 IV Q3W: N = 23

6.4 mg/kg, n = 5

5.6 mg/kg, n = 6

4.8 mg/kg, n = 8

3.2 mg/kg, n = 4

Ongoing
n = 16

Discontinued^b
n = 7

Dose Expansion

Will enroll additional patients at the recommended dose for expansion

Study Objectives

Primary:
Safety and tolerability of U3-1402

Secondary:
Antitumor activity of U3-1402

Exploratory:
Biomarkers of U3-1402 antitumor activity

Data cutoff of February 25, 2019. ^aDose escalation was guided by the modified continuous reassessment method with escalation with overdose control. Additional doses may be added. ^bReasons for discontinuation included progressive disease per RECIST v1.1, n = 5; clinical progression (definitive clinical signs of disease progression, but did not meet RECIST criteria), n = 1; and adverse event, n = 1. [clinicaltrials.gov NCT03260491](https://clinicaltrials.gov/NCT03260491).

Baseline Characteristics of Patients Treated with U3-1402

Baseline clinical characteristics		Dose escalation (N = 23) ^a
Age, median (range), years		63.0 (51.0–80.0)
Sex, n (%)	Female	14 (60.9)
	Male	9 (39.1)
Race, n (%)	White	13 (56.5)
	Asian	7 (30.4)
	Black or African American	1 (4.3)
	Other	2 (8.7)
ECOG performance status, n (%)	0	9 (39.1)
	1	14 (60.9)
Prior therapies, n (%)	Any EGFR TKI	23 (100.0)
	Osimertinib ^b	21 (91.3)
	Chemotherapy	10 (43.5)

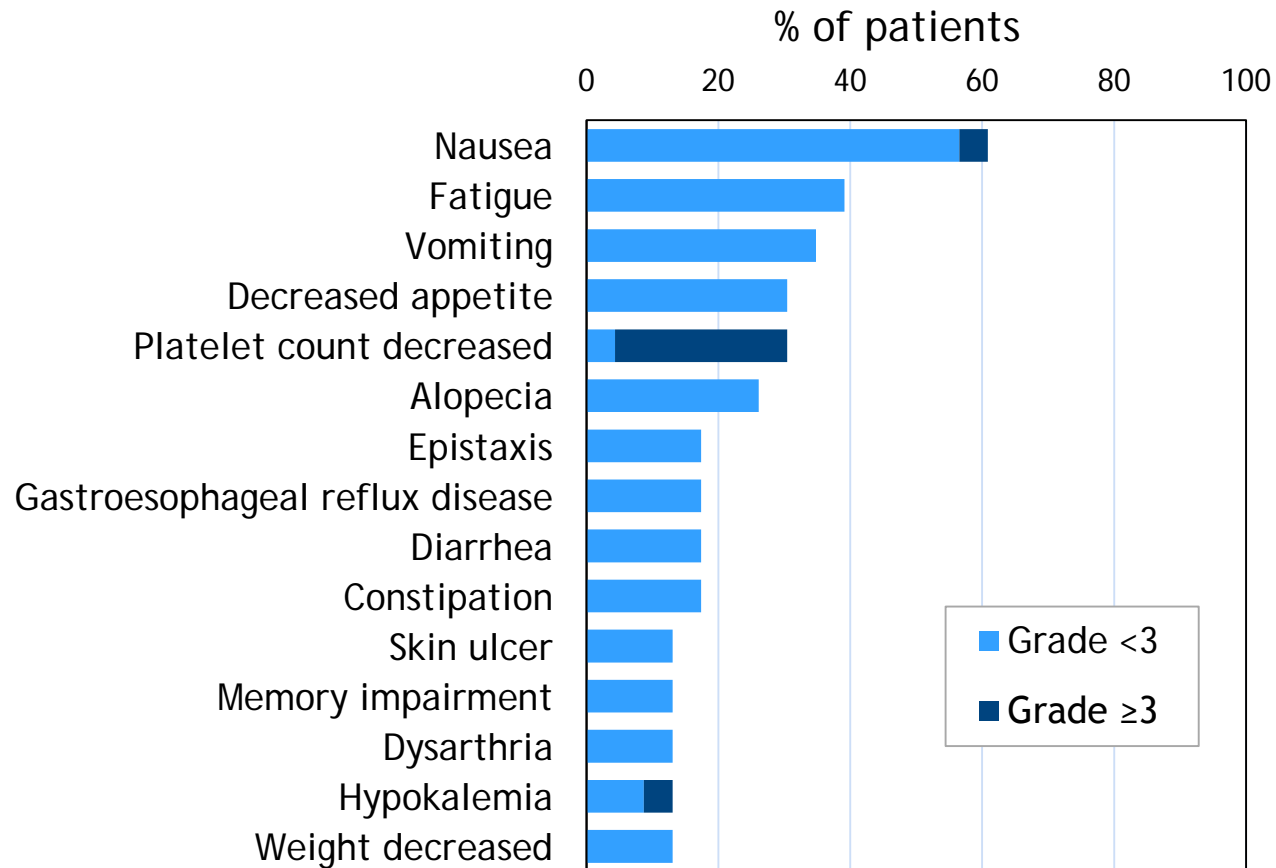
Baseline disease characteristics		Dose escalation (N = 23) ^a
Sites of metastases, n (%)	CNS ^c	14 (60.9)
	Liver	9 (39.1)
	Lung	4 (17.4)
Tumor stage, n (%)	IV	23 (100.0)
Sum of diameters of target lesions, median (range), mm		69 (20–143)

Baseline molecular characteristics		Dose escalation (N = 23) ^a
HER3 expression ^d		
Evaluable patients ^e	n/n (%)	19/19 (100.0)
Membrane H-score ^f	median (range)	193 (150–290)
<i>composite score of 0–300</i>		
EGFR mutation, ^g n (%)	Ex19del	13 (56.5)
	L858R	9 (39.1)
	L861Q	1 (4.3)

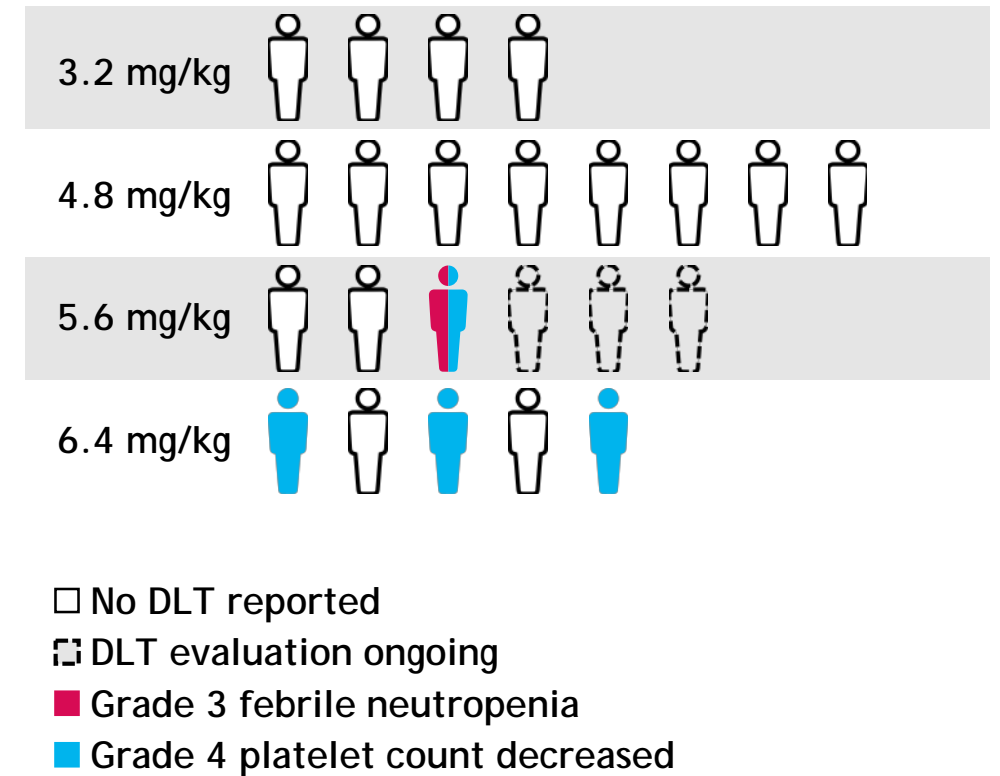
Data cutoff date of February 25, 2019. ^aSafety analysis set included all patients who received ≥1 dose of U3-1402. ^bAdditional subject with prior osimertinib reported after snapshot date, not shown. ^cIncludes brain and spinal metastases as reported by investigators. ^dBased on central analysis of tumor tissue collected prior to first dose of U3-1402. ^eIncludes patients with tumor samples that have completed retrospective analysis. ^fMembrane H-score is a composite of percentage of positively staining cells and intensity of individual cell staining. For patients with multiple H-scores, the highest number was used. ^gAs reported locally by the investigator.

TEAEs and DLTs in Patients Treated with U3-1402

Percentage of patients with TEAEs ($\geq 10\%$; N = 23)



Dose-limiting toxicities (N = 23)



Data cutoff date of February 25, 2019. TEAE analysis used the safety analysis set, which includes all patients who received ≥ 1 dose of U3-1402 (N = 23). For TEAEs in $<10\%$ of patients, there were five Grade 3 events: ALT increased n = 1; troponin increased n = 1; confusional state n = 1; hypoxia n = 1; febrile neutropenia n = 1. DLT, dose-limiting toxicity.

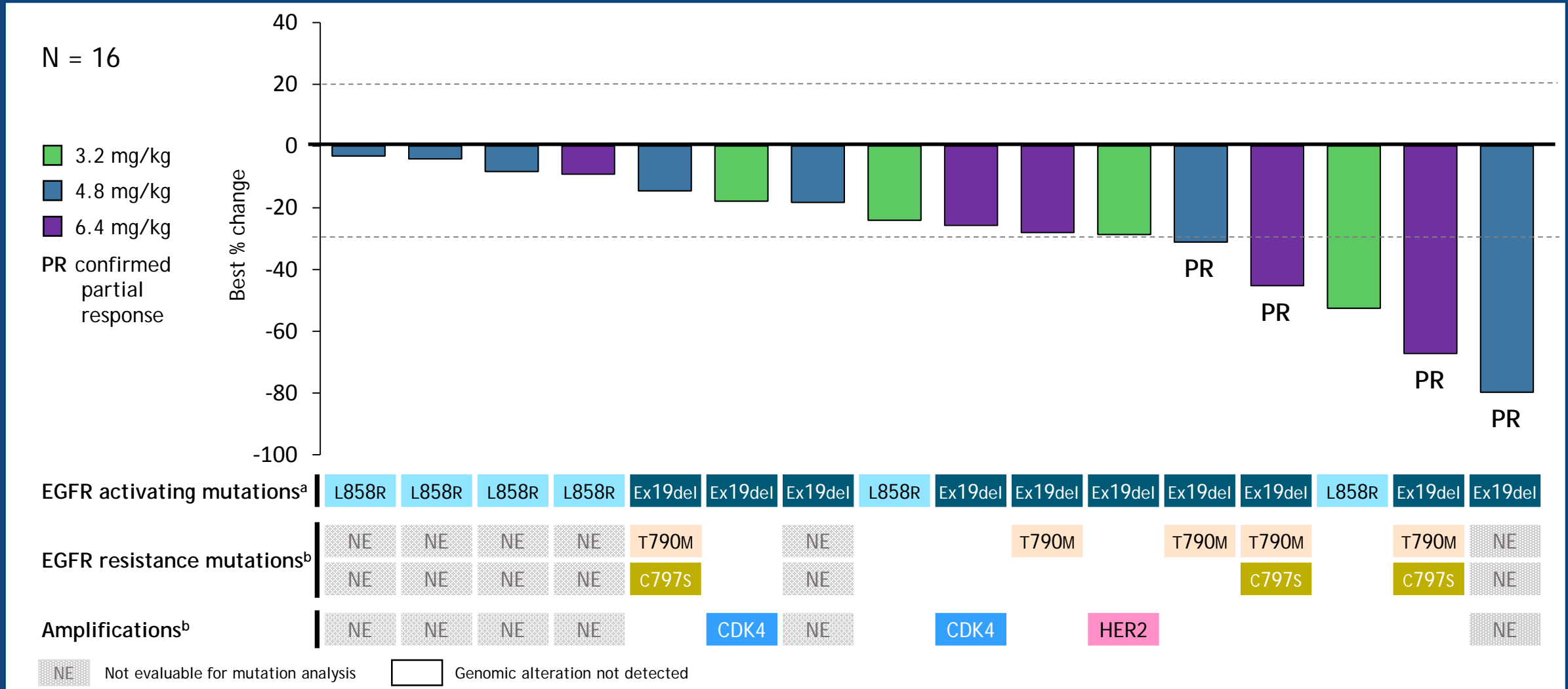
Safety Summary of Patients Treated with U3-1402

Median duration of exposure was 105 days (range: 21–336)

Summary	Dose escalation, n (%) (N = 23) ^a
TEAEs regardless of causality	23 (100.0)
Drug-related	22 (95.7)
Treatment-emergent SAEs regardless of causality	6 (26.1)
Drug-related	3 (13.0)
TEAEs leading to drug withdrawal/discontinuation	1 (4.3)
TEAEs leading to dose reduction	7 (30.4)
TEAEs leading to dose interruption	6 (26.1)
TEAEs leading to death	0

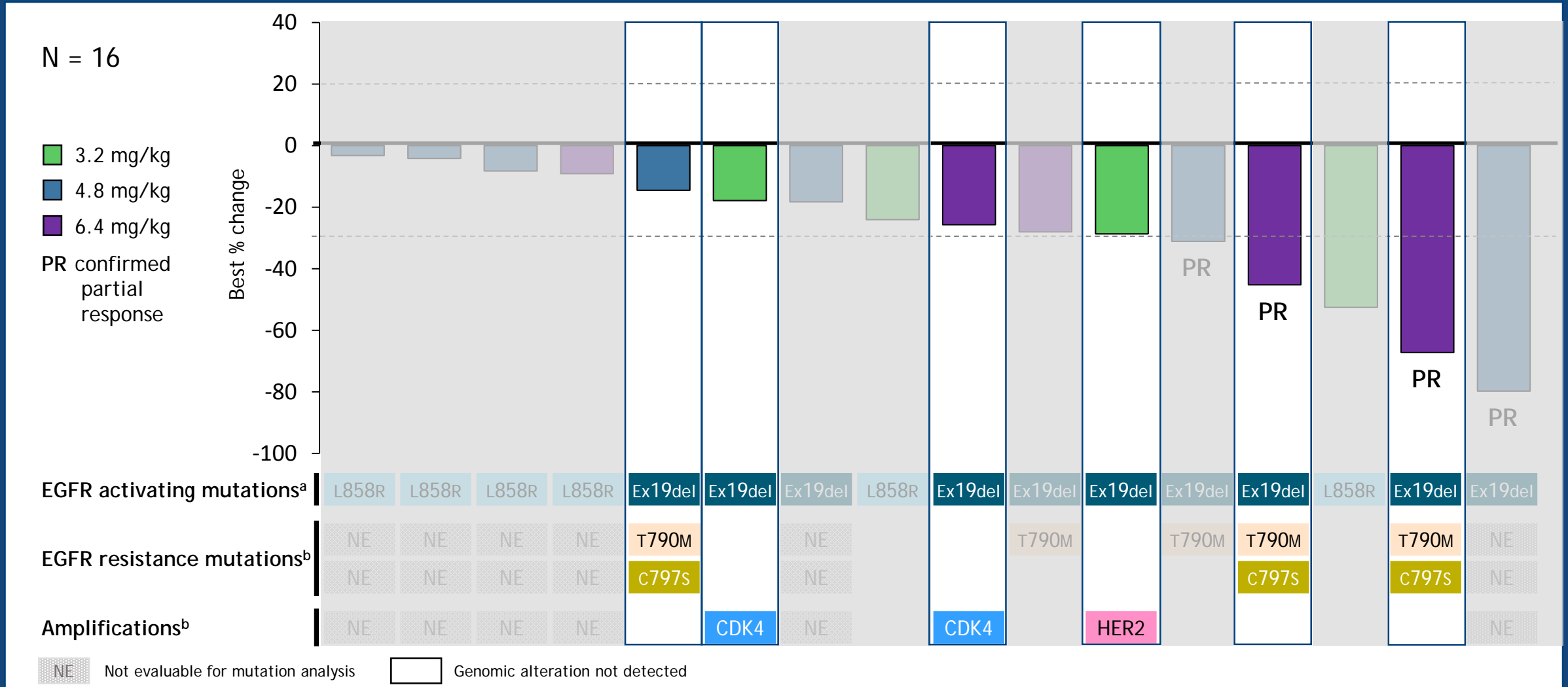
Data cutoff date of February 25, 2019. ^aSafety analysis set included all patients who received ≥1 dose of U3-1402. SAE, serious adverse event; TEAE, treatment-emergent adverse event.

U3-1402 Antitumor Activity Across Diverse EGFR-TKI Resistance Mechanisms



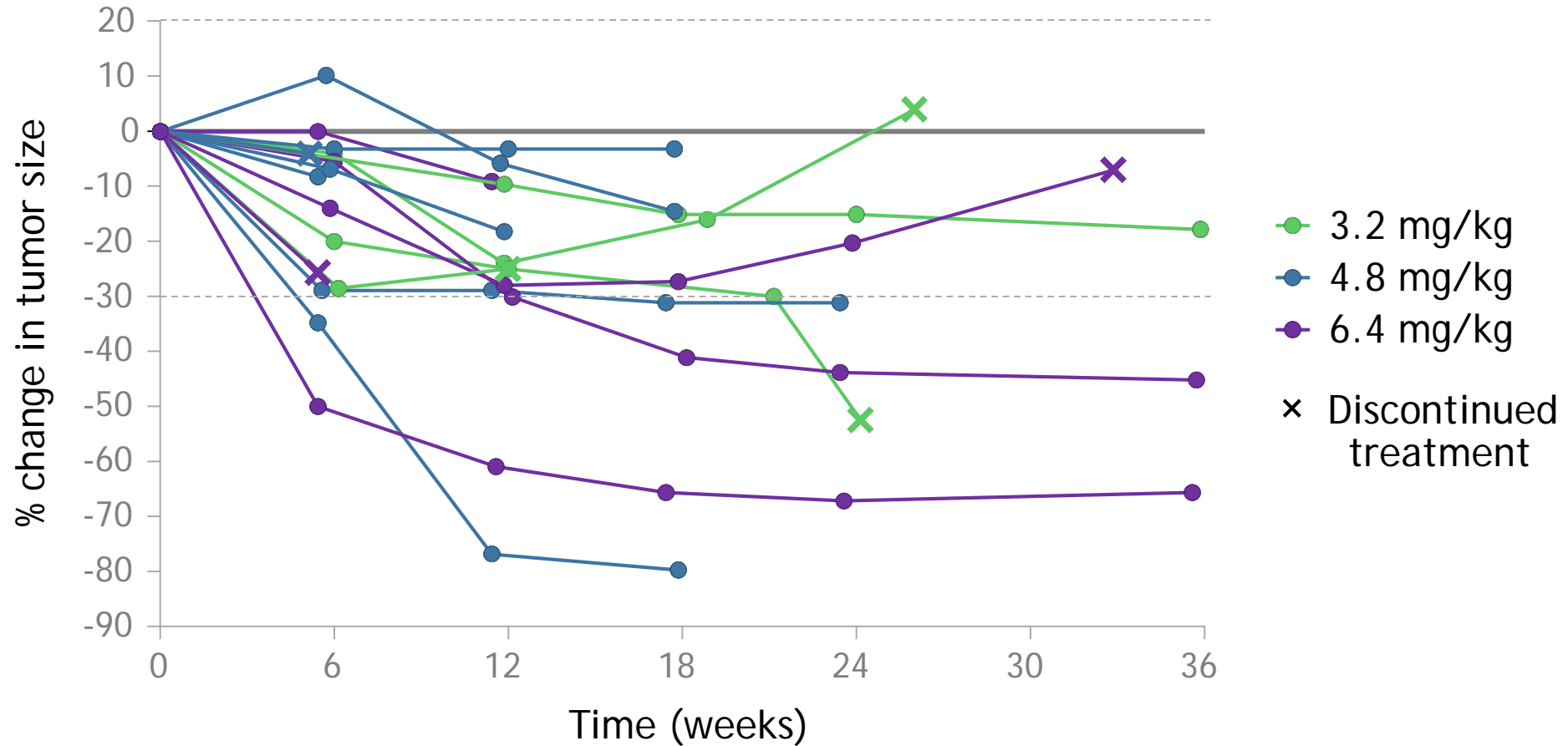
Data cutoff date of February 25, 2019. Dotted lines denote 20% increase and 30% decrease in tumor size. Sixteen patients received ≥ 1 dose of U3-1402 and had pre- and post-treatment evaluable tumor assessments. ^aLocal testing as reported by the investigator. ^bPerformed centrally using OncoPrint Comprehensive assay v3 from formalin-fixed, paraffin-embedded tumor tissue.

U3-1402 Antitumor Activity Across Diverse EGFR-TKI Resistance Mechanisms



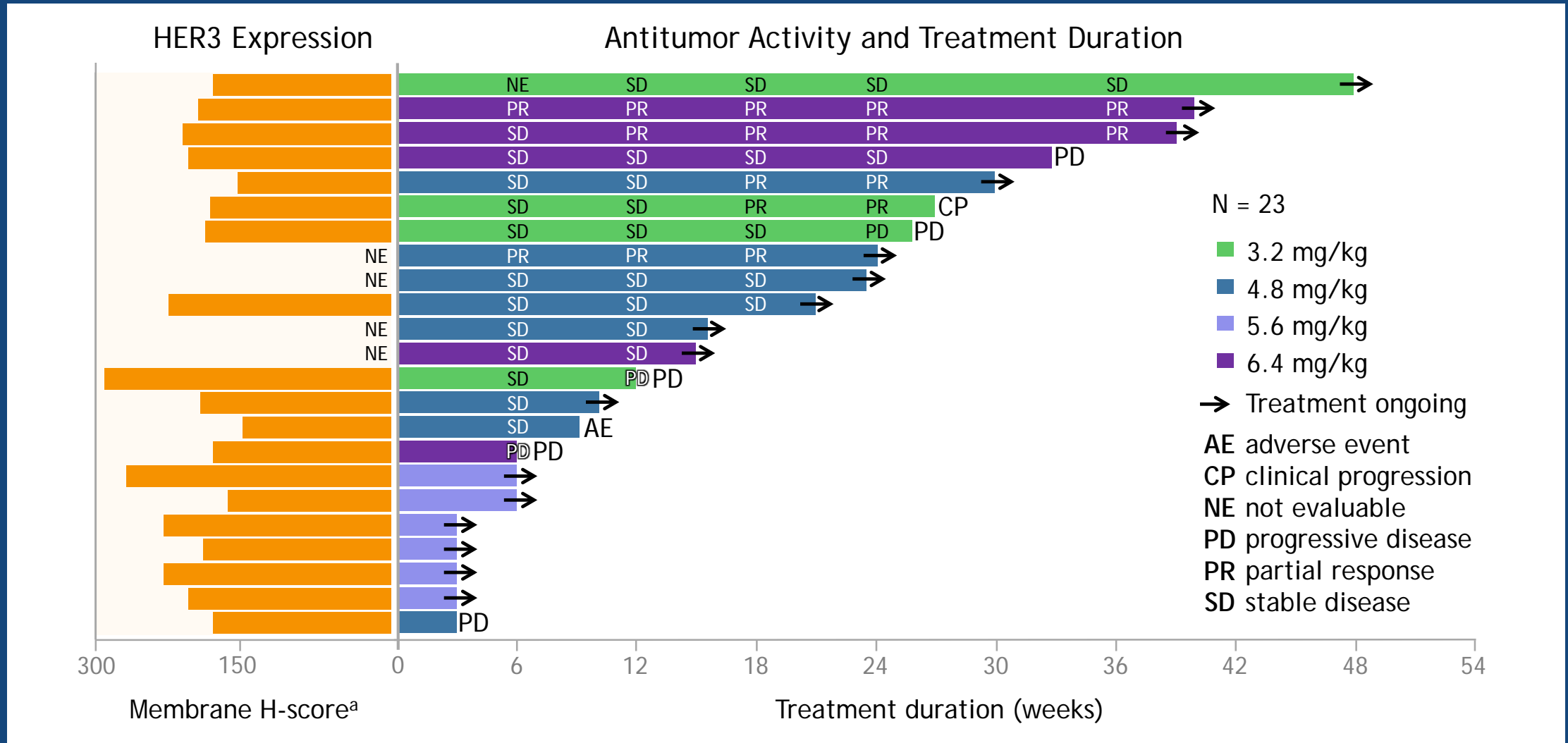
Data cutoff date of February 25, 2019. Dotted lines denote 20% increase and 30% decrease in tumor size. Sixteen patients received ≥ 1 dose of U3-1402 and had pre- and post-treatment evaluable tumor assessments.
^aLocal testing as reported by the investigator. ^bPerformed centrally using OncoPrint Comprehensive assay v3 from formalin-fixed, paraffin-embedded tumor tissue.

U3-1402 Antitumor Activity Over Time



Data cutoff date of February 25, 2019. Sixteen patients received ≥ 1 dose of U3-1402 and had pre- and post-treatment evaluable tumor assessments. Dotted lines denote 20% increase and 30% decrease from baseline in tumor size over time.

U3-1402 Treatment Duration



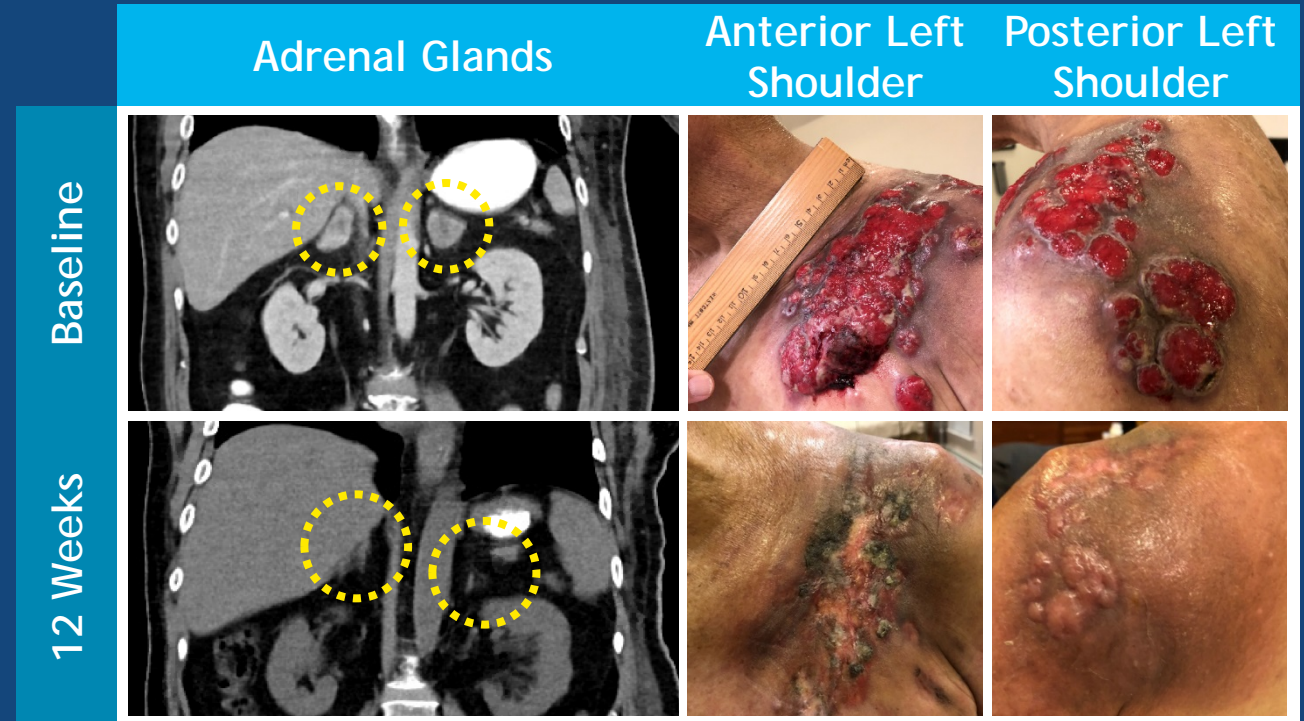
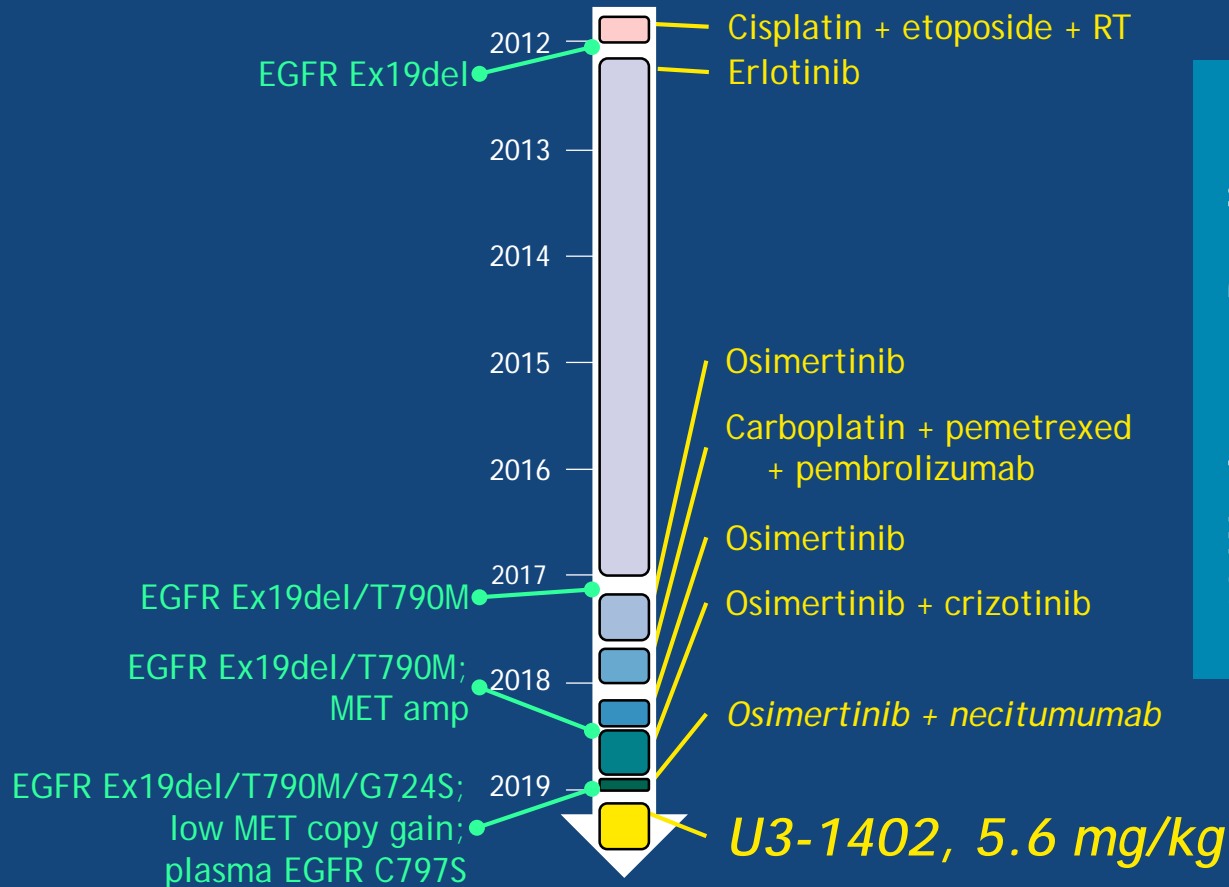
Data cutoff date of February 25, 2019. Safety analysis set included all patients who received ≥1 dose of U3-1402. ^aMembrane H-score is a composite of percentage of positively staining cells and intensity of individual cell staining. Scores range from 0–300. For patients with multiple H-scores, the highest number was used.

U3-1402 Patient Case

65-year-old male NSCLC patient

Tumor biopsy analyses:

Treatments:



Patient of Dr. Mark Awad, DFCI

Multiple development opportunities



Results confirm feasibility of a fast to market US path in **EGFRm NSCLC**



In parallel, **breast cancer** development further pursued



Prostate / colorectal expansion active planning

ASCO 2019 Highlights

Cancer Enterprise Development Progress

Today's Agenda

1

DS-8201

*HER2 DXd ADC
and AZ
Collaboration*

- Accelerate and expand; do the right thing
- Breast cancer BLA acceleration to 1H FY19

2

U3-1402 &
DS-1062

*HER3 DXd ADC &
TROP2 DXd ADC*

- Data update
- Implications

3

DS-7300 &
DS-6157

*Next human-stage
DXd ADC*

- Targeting B7-H3 and GPR20
- Updates

4

Regulatory
Reviews

*ODAC and Ongoing
Reviews*

- Pexidartinib
- Quizartinib

5

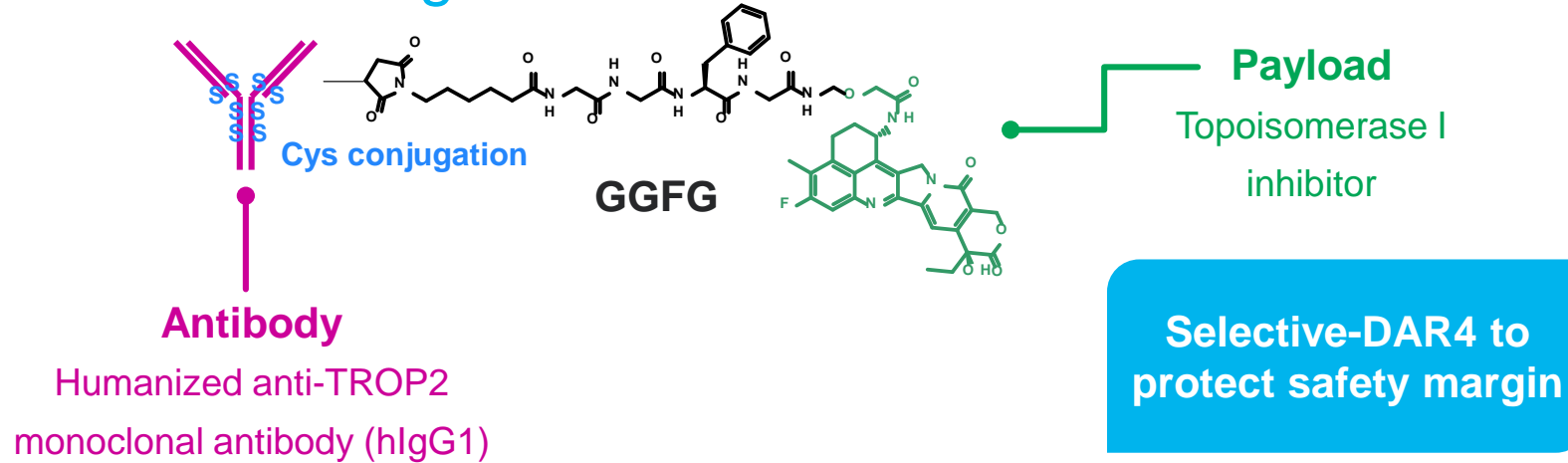
Rest of the
Portfolio

*Brief Review of
Activities*

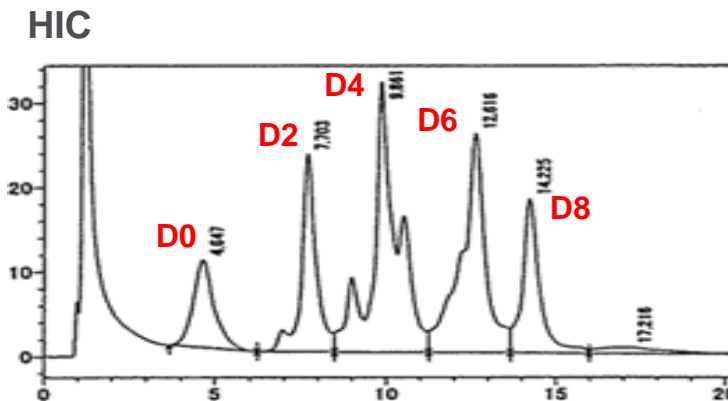
- Quizartinib: QuANTUM-First
- DS-3201 EZH1/2 inhibitor
- DS-1001 IDH1m inhibitor
- DS-3032 mdm2 inhibitor

DS-1062 | TROP2 DXd ADC with Selective DAR4

TROP2 ADC is designed to be best in class



Non-selective DAR*4

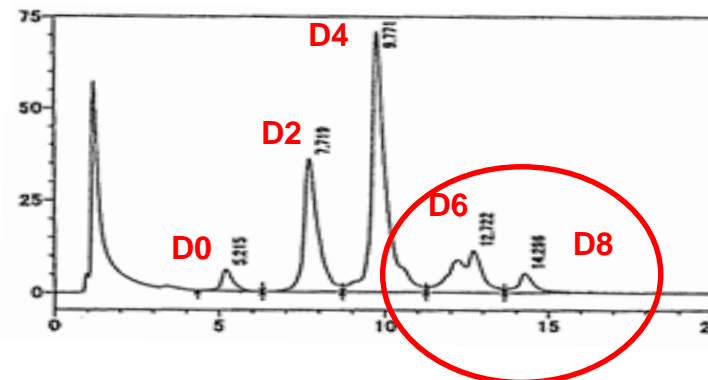


*drug-antibody ratio



Optimized
conjugation
method

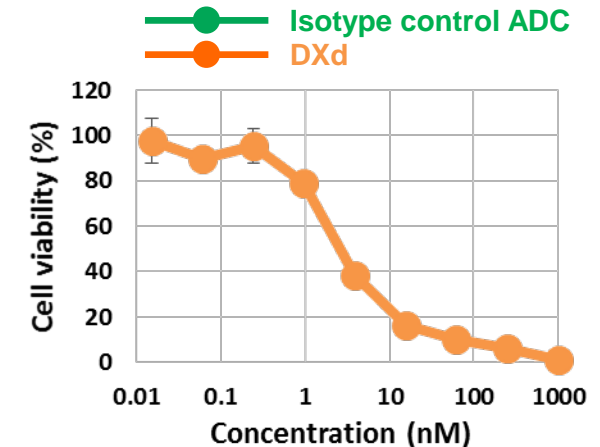
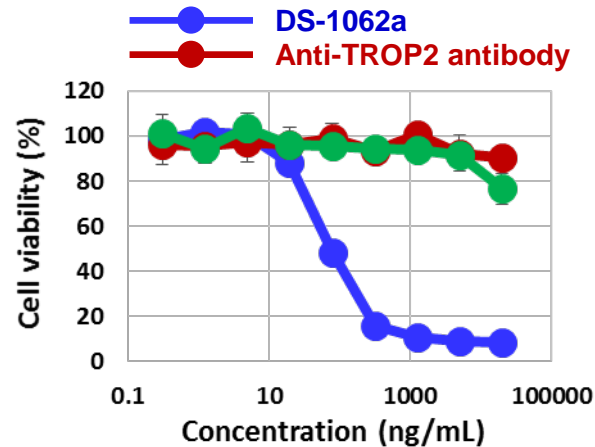
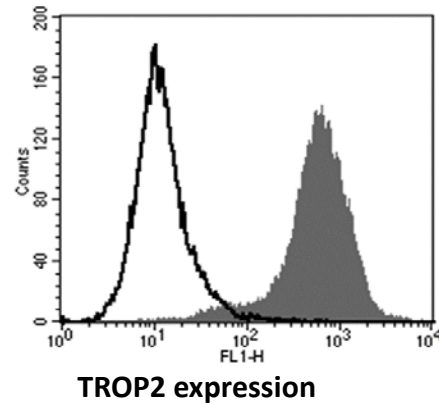
Selective DAR4



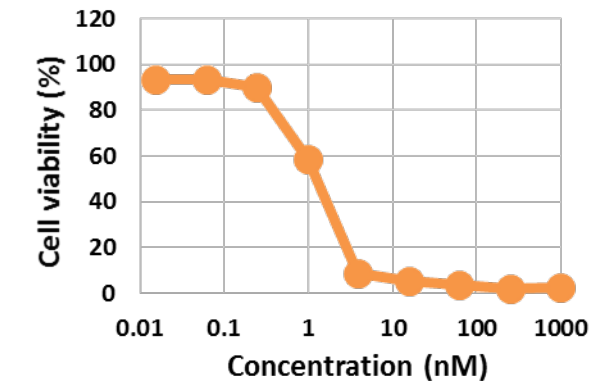
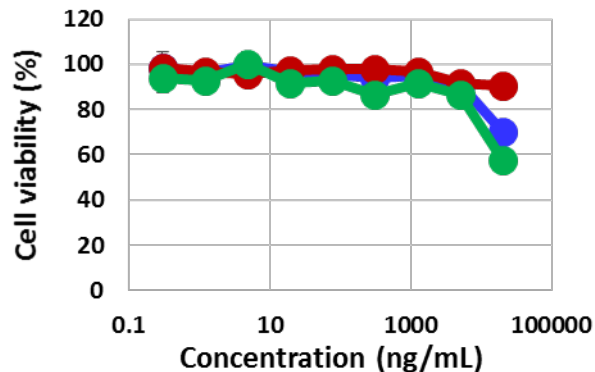
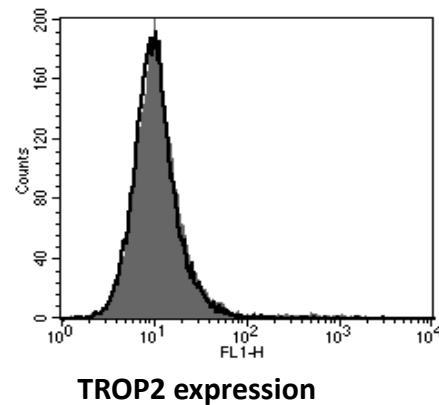
DS-1062 | *In vitro* Cell Growth Inhibitory Activity

DS-1062 demonstrated specific cell growth inhibitory activity to TROP2 positive cells, but not to TROP2-negative cells

BxPC3 (TROP2 positive)

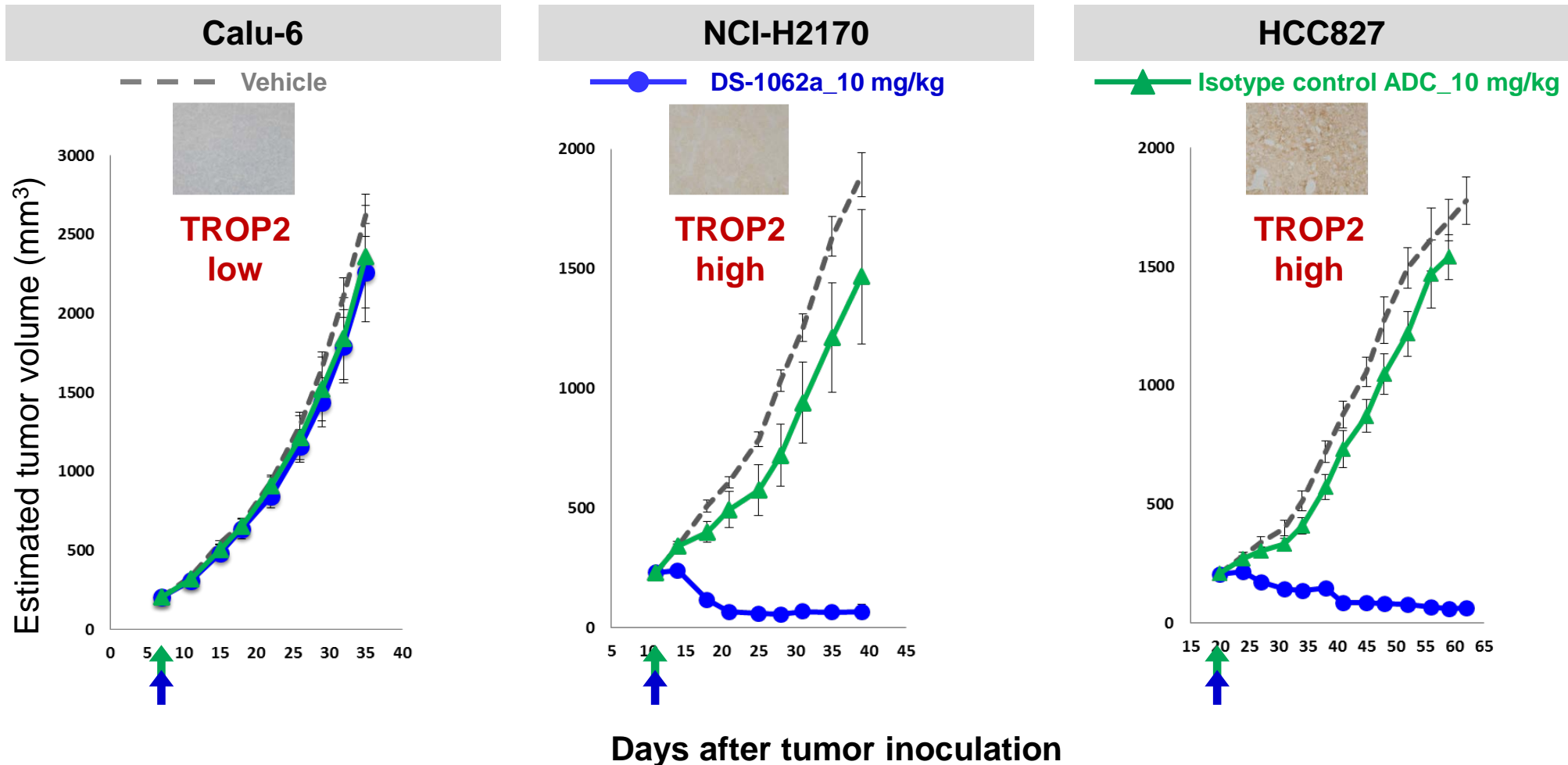


Calu-6 (TROP2 negative)



DS-1062 | Anti-Tumor Activity in Xenograft Mice Models

DS-1062 demonstrated stronger anti-tumor activity in TROP2 high tumor models compared to TROP2 low tumor models



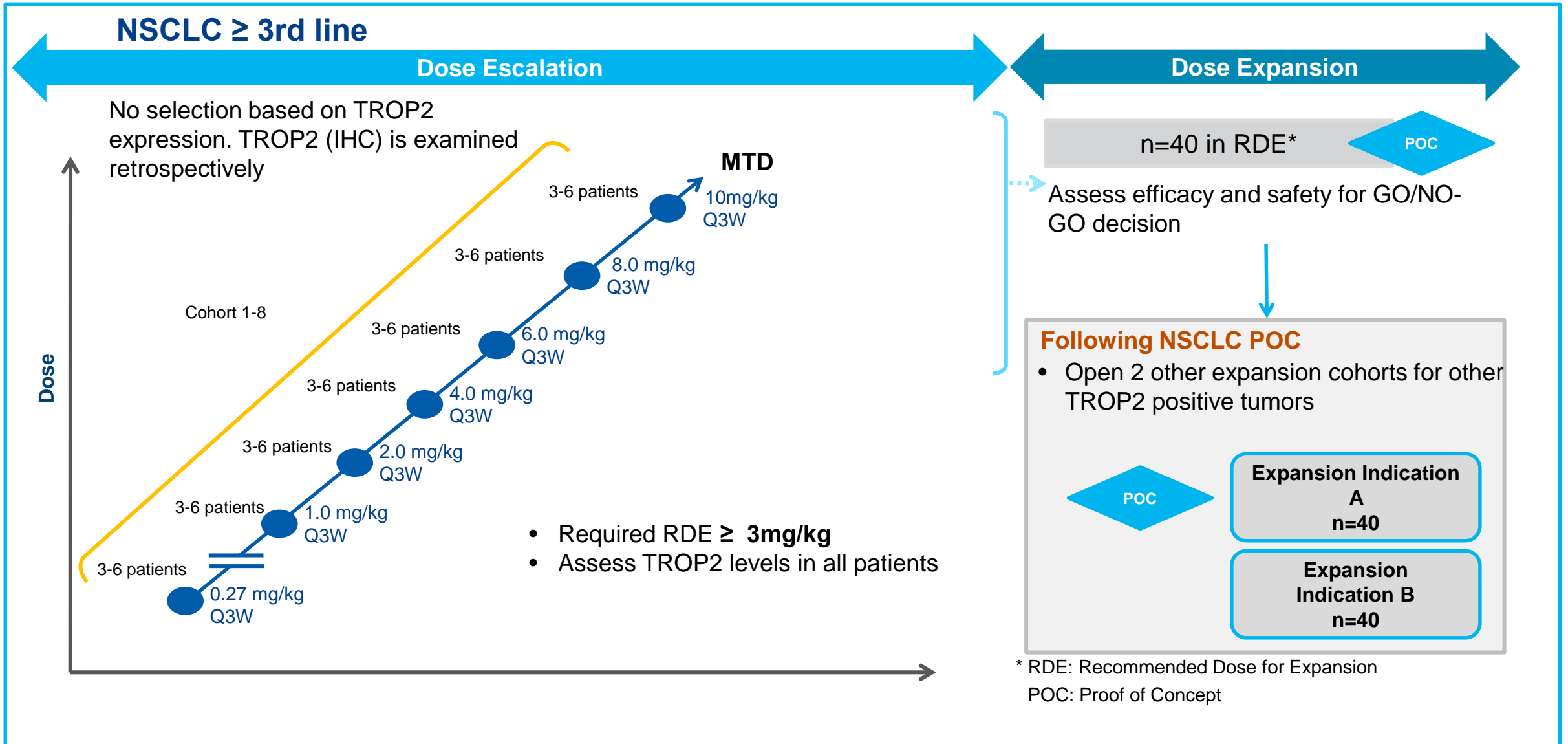
DS-1062 | Contrast with Sacituzumab Govitecan

	DS-1062 (Daiichi Sankyo)	Sacituzumab Govitecan (Immu-132/Immunomedics)
Antibody	MAAP-9001a (humanized IgG1)	hRS7 (humanized IgG1)
Payload	DXd (Topo1 inhibitor)	SN38 (Topo1 inhibitor)
DAR	4	7.6
Linker cleavage	Enzymatic	pH-dependent and enzymatic
Human PK ($T_{1/2}$)	TBD	11.7 h at 10 mg/kg dosing*
Dosing	q3w regimen	10 mg/kg at day1 and 8 of 3 weeks
Dose Limiting Toxicity in Human	TBD	Neutropenia, MTD=12mg/kg**
Stage	P1 NSCLC	P3 TNBC

* Reported in ASCO 2015 and AACR 2017; ** Clin Cancer Res; 21(17) September 1, 2015

DS-1062 | TROP2 Targeted ADC

Dose Escalation in Relapsed NSCLC



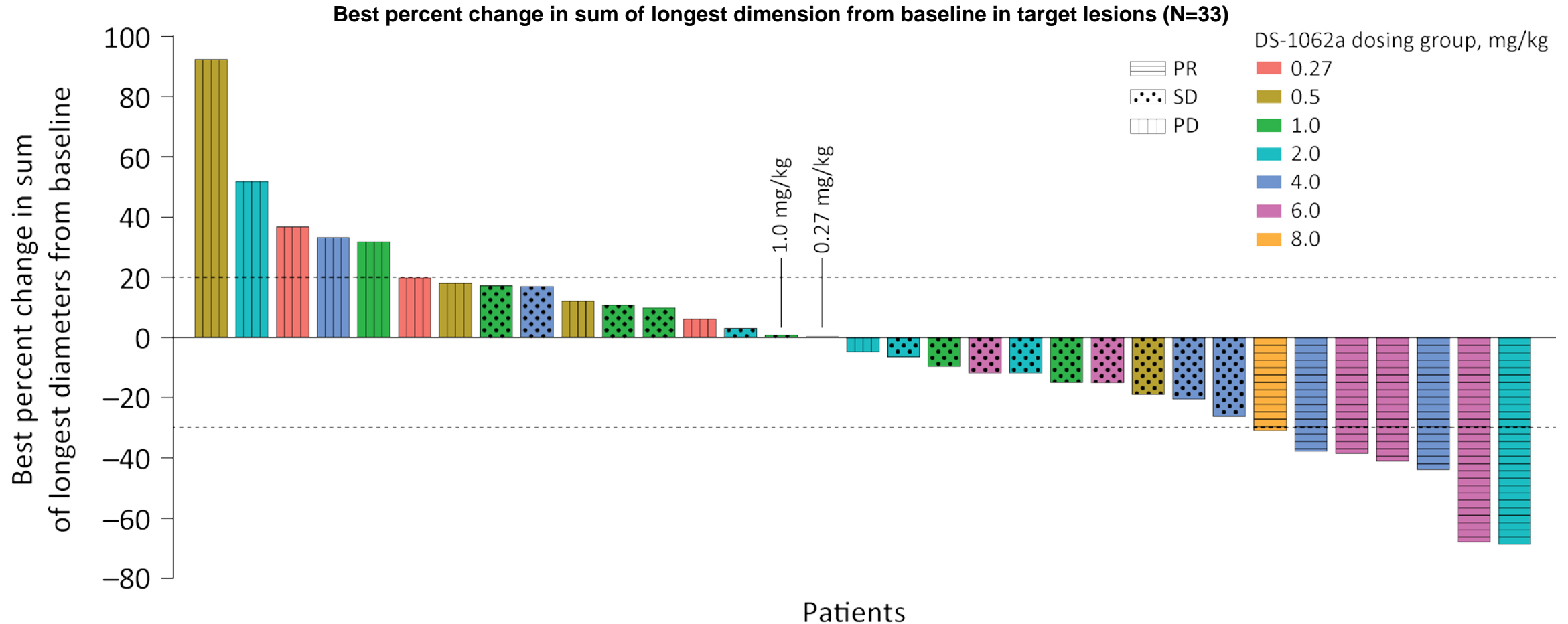
DS-1062 | TROP2 Targeted ADC: MTD Not Reached*

Safety Summary, Number of Patients with TEAEs (in ≥10% of patients), Regardless of Causality

TEAE, n (%)	N=39	
	All grades	Grade ≥3 ^{a,b}
Any TEAE	34 (87.2)	16 (41.0)
TEAE, by preferred term (in ≥10% of patients)		
Fatigue	13 (33.3)	2 (5.1)
Nausea	12 (30.8)	0
Anemia	9 (23.1)	0
Decreased appetite	9 (23.1)	0
Alopecia	8 (20.5)	0
Infusion related reaction	8 (20.5)	0
Constipation	6 (15.4)	0
Vomiting	6 (15.4)	0
Cough	5 (12.8)	0
Dyspnea	5 (12.8)	1 (2.6)
Rash	5 (12.8)	0
Diarrhea	4 (10.3)	0
Pain	4 (10.3)	1 (2.6)
Weight decreased	4 (10.3)	0

^aTEAEs include 'uncoded (all grades: n=5, 12.8%; grade ≥3, n=1, 2.6%); ^bThe majority of TEAEs were grade 3 (n=8; 20.5%), except for one grade 2 and 1 grade 5 TEAE (grade 5 sepsis; 6.0 mg/kg treatment group).
TEAE, treatment-emergent adverse event.

Objective responses emerging at >2mg/kg dose

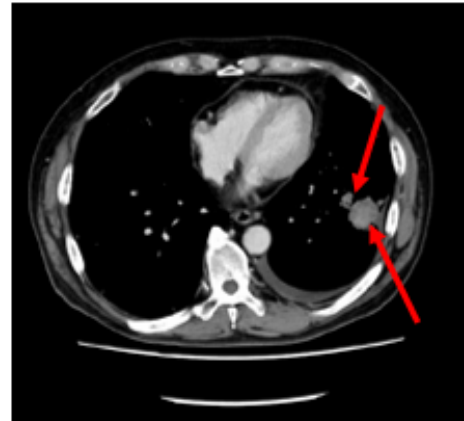


DS-1062 | TROP2 Targeted ADC

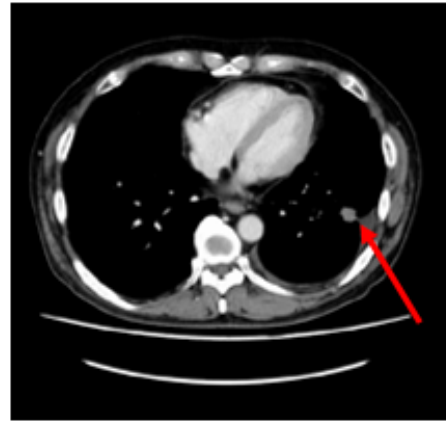
CT Scan Findings in Dose Escalation

Decrease in the number of target and nontarget lesions in a patient treated with DS-1062 2.0 mg/kg

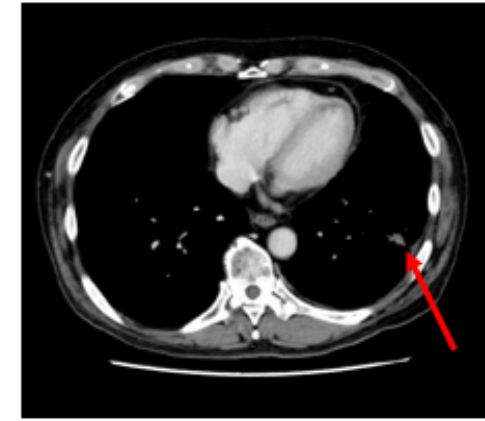
Target lesions



Baseline: Begin 2.0-mg/kg DS-1062a

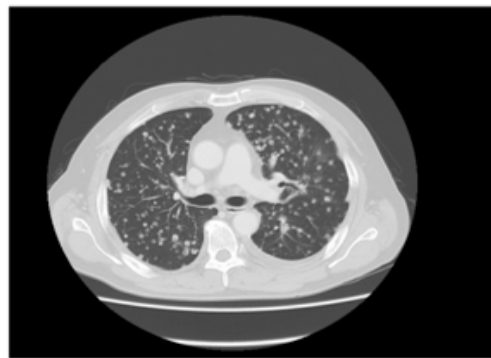


Post-Cycle 4: After 3 months of treatment
Maximum percent decrease in tumor size: 65.5%

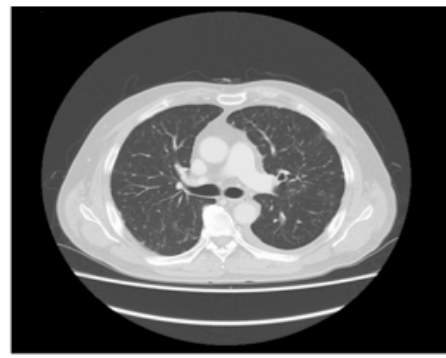


Post-Cycle 10: After 7 months of treatment
Maximum percent decrease in tumor size: 62.0%

Nontarget lesions



Baseline
Begin DS-1062a 2.0-mg/kg therapy



Post-Cycle 4
After 3 months of treatment



Post-Cycle 10
After 7 months of treatment

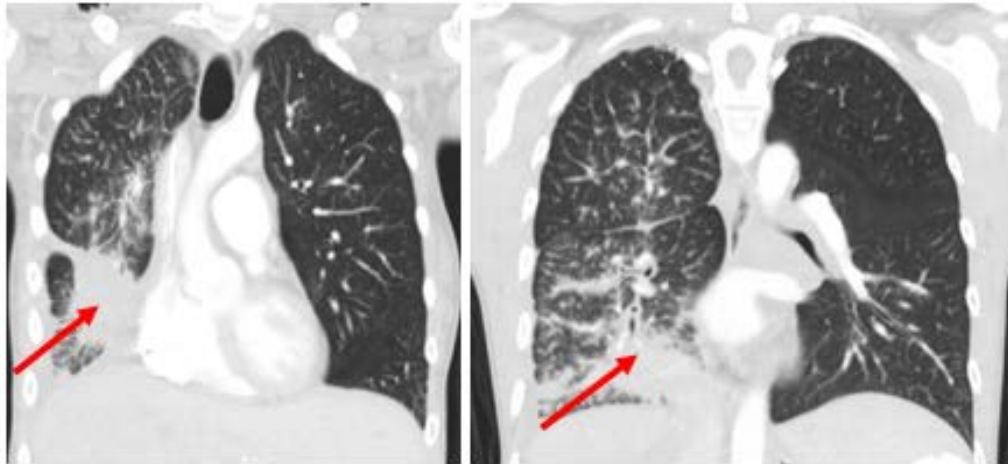
Reproduced with permission of Toshio Shimizu, MD.

ASCO 2019 Abstract #9051

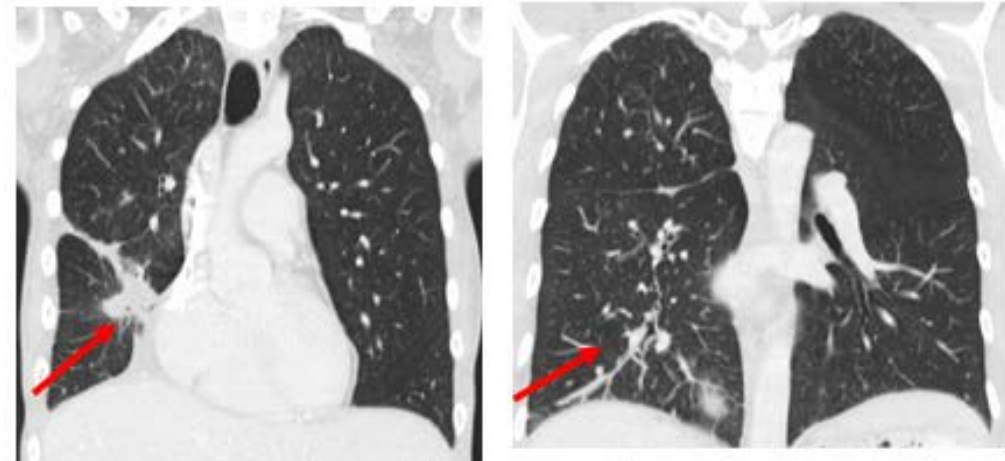
DS-1062 | TROP2 Targeted ADC

CT Scan Findings in Dose Escalation

Reduction in the size of target lesion in a patient treated with
DS-1062 4.0 mg/kg



Baseline: Begin 4.0-mg/kg DS-1062a



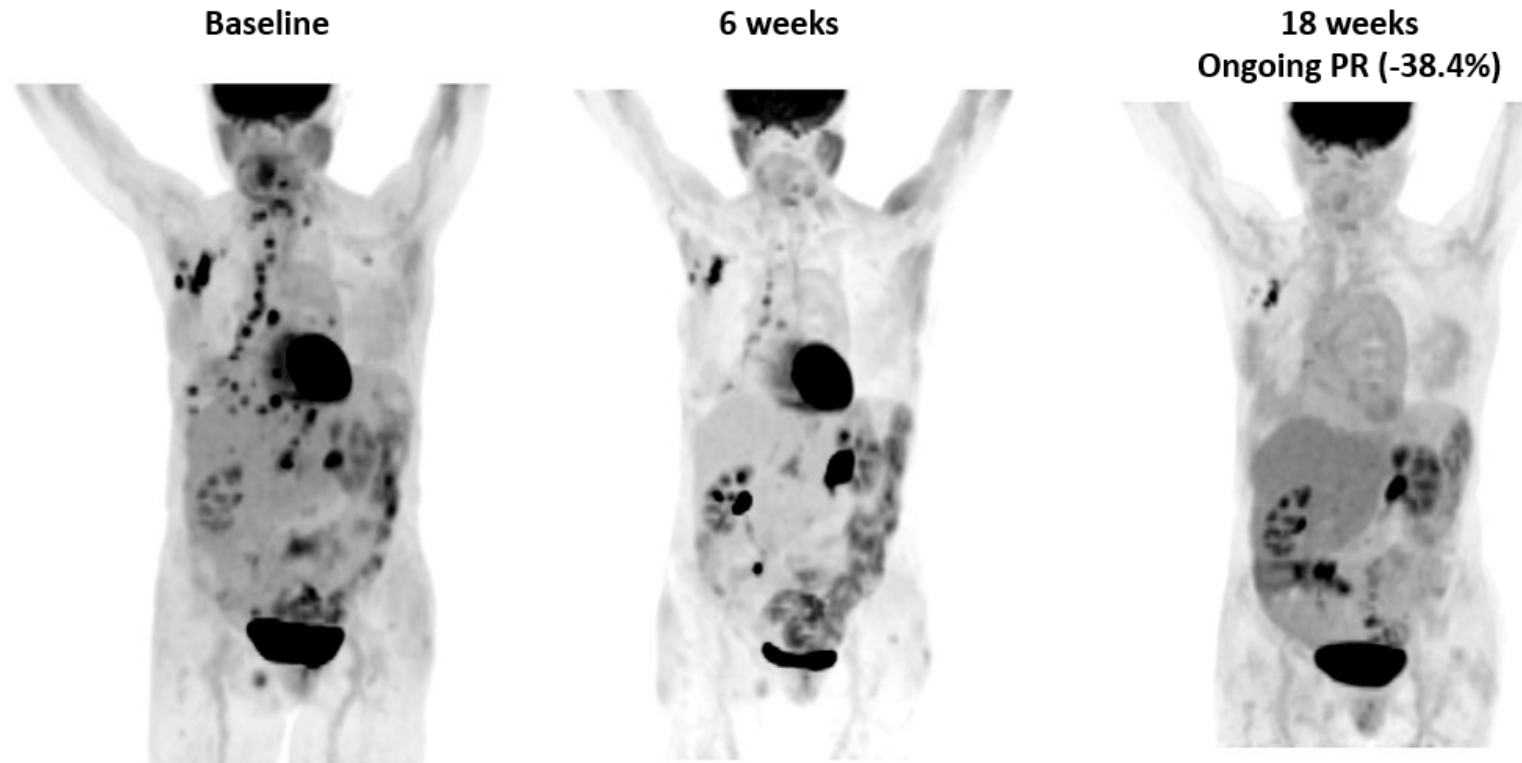
Post-Cycle 6: After 4.5 months of treatment
Maximum percent decrease in tumor size 36.6%

Reproduced with permission of Jacob Sands, MD.

DS-1062 | TROP2 Targeted ADC

CT Scan Findings in Dose Escalation

Female, age 72 years with metastatic lung adenocarcinoma, s/p platinum/pemetrexed chemotherapy and immunotherapy, on 3rd-line DS-1062 (4 mg/kg dosing cohort)

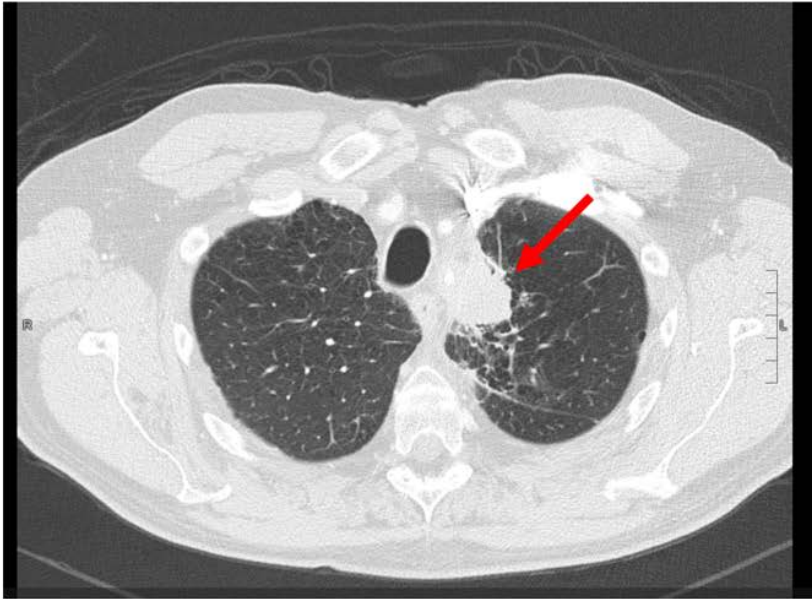


Courtesy of Dr. Rebecca Heist and Dr. Jessica Lin, MGH, Boston, USA

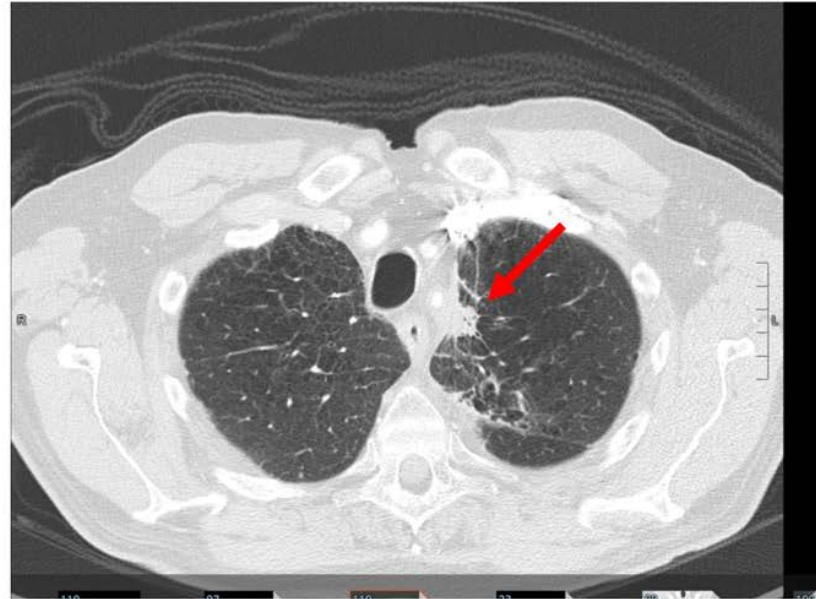
DS-1062 | TROP2 Targeted ADC

CT Scan Findings in Dose Escalation

Reduction in the size of target lesion in a patient treated with
DS-1062 8.0 mg/kg



Baseline: Begin 8.0-mg/kg DS-1062a



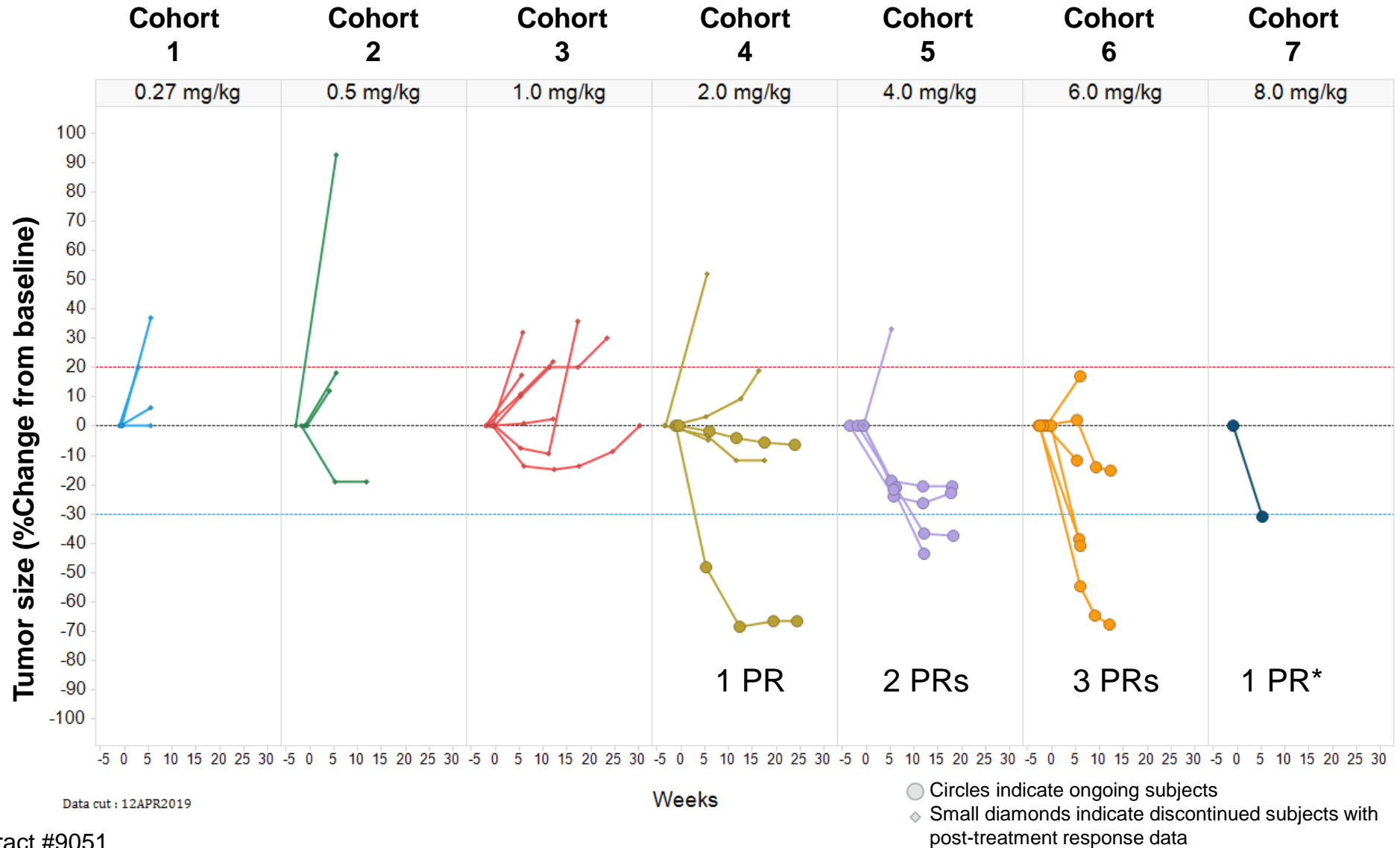
Post-Cycle 2: After 6 weeks of treatment
Maximum percent decrease in tumor size: 56%

Reproduced with permission of Alexander Spira, MD.

ASCO 2019 Abstract #9051

DS-1062 | TROP2 Targeted ADC

Dose / Effect Spider Plot (preliminary data April 12, 2019)



*3 additional PRs were confirmed after data cut-off

DS-1062 appears to have the characteristics of a “drug-to-be”



DXd portability further established



Differentiation vs IMMU-132 appears credible



Fast-to-market US path emerging

ASCO 2019 Highlights

Cancer Enterprise Development Progress

Today's Agenda

1

DS-8201

*HER2 DXd ADC
and AZ
Collaboration*

- Accelerate and expand; do the right thing
- Breast cancer BLA acceleration to 1H FY19

2

U3-1402 &
DS-1062

*HER3 DXd ADC &
TROP2 DXd ADC*

- Data update
- Implications

3

DS-7300 &
DS-6157

*Next human-stage
DXd ADC*

- Targeting B7-H3 and GPR20
- Updates

4

Regulatory
Reviews

*ODAC and Ongoing
Reviews*

- Pexidartinib
- Quizartinib

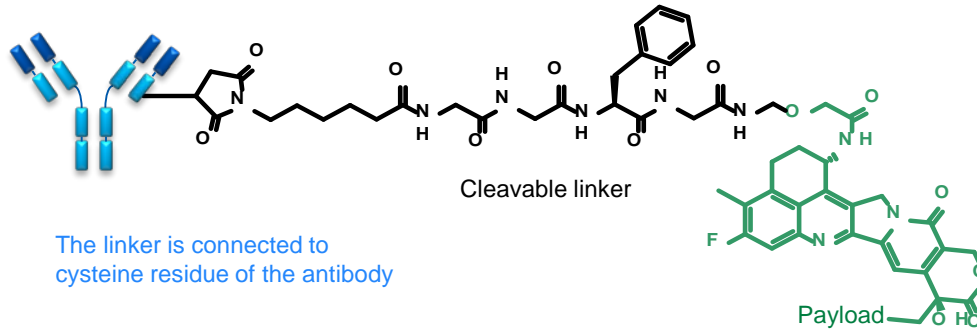
5

Rest of the
Portfolio

*Brief Review of
Activities*

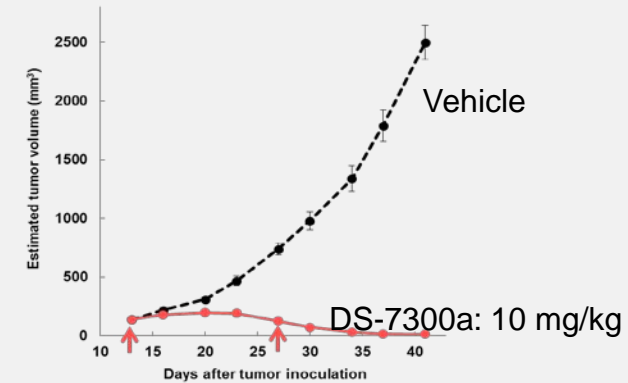
- Quizartinib: QuANTUM-First
- DS-3201 EZH1/2 inhibitor
- DS-1001 IDH1m inhibitor
- DS-3032 mdm2 inhibitor

DS-7300



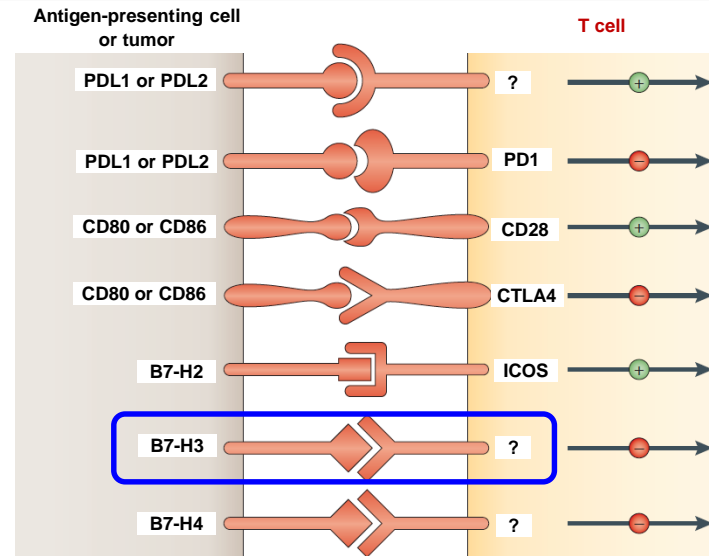
DAR4 has been used to reduce toxicity and maintain better safety margin

DS-7300 active in lung cancer xenograft model



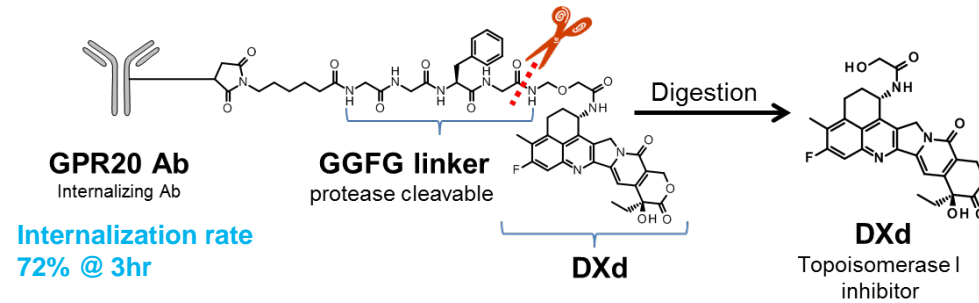
B7-H3 (CD276)

- Type I transmembrane protein belonging to B7 family, which includes immune checkpoint molecules such as CTLA-4 ligands, and PD-L1
- More highly expressed in various solid cancers, compared to normal tissues; overexpression of B7-H3 is associated with poor prognosis in some solid cancers including NSCLC and prostate cancer etc.
- Function remains to be fully elucidated



DS-6157

Drug / Antibody Ratio = 8



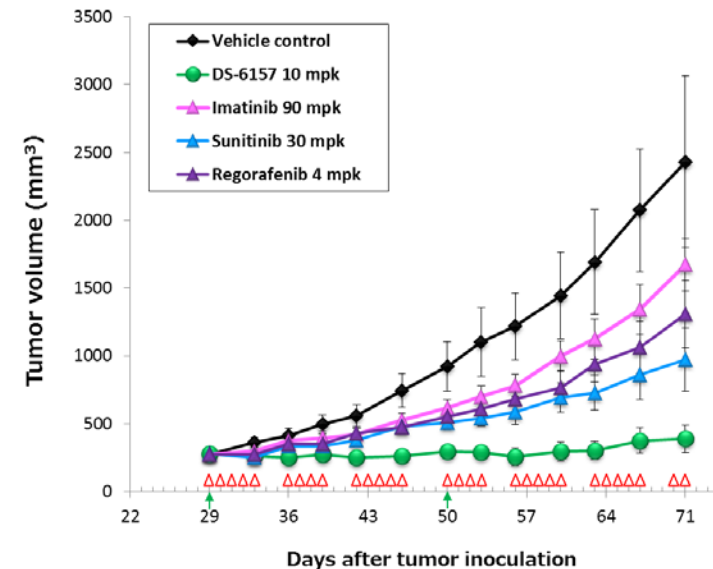
GPR20

- Orphan G Protein-Coupled Receptor (GPCR)
- GIST-specific target
- Interstitial Cells of Cajal (ICC), the cell of origin of GIST, are the only GPR20+ cells
- Function in GIST is unknown

GIST

- Three TKIs (imatinib (IM, Gleevec), sunitinib (SU), and regorafenib (RE)) have been approved
- UMNs include patients who relapse, are refractory, or intolerant to IM, with a better tolerability profile than SU and RE

Activity of DS-6157 in GIST PDX



GIST074 PDX

ileocecal metastasis of gastric GIST resected after PD during regorafenib therapy
Ex11 p.W557_K558del ; GPR20 IHC score 2

ASCO 2019 Highlights

Cancer Enterprise Development Progress

Today's Agenda

1

DS-8201

*HER2 DXd ADC
and AZ
Collaboration*

- Accelerate and expand; do the right thing
- Breast cancer BLA acceleration to 1H FY19

2

U3-1402 &
DS-1062

*HER3 DXd ADC &
TROP2 DXd ADC*

- Data update
- Implications

3

DS-7300 &
DS-6157

*Next human-stage
DXd ADC*

- Targeting B7-H3 and GPR20
- Updates

4

Regulatory
Reviews

*ODAC and Ongoing
Reviews*

- Pexidartinib
- Quizartinib

5

Rest of the
Portfolio

*Brief Review of
Activities*

- Quizartinib: QuANTUM-First
- DS-3201 EZH1/2 inhibitor
- DS-1001 IDH1m inhibitor
- DS-3032 mdm2 inhibitor

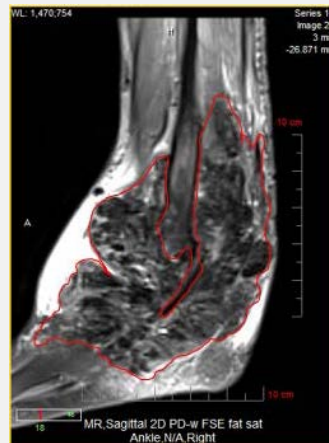
Functional improvement despite No Objective Response by RECIST

Baseline

- Mobility largely impacted
- Planning to quit work

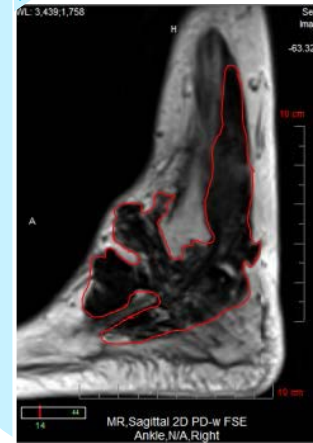


Pexidartinib



18 Months (Ongoing)

- Ankle correctly aligned
- Playing golf and tennis again



ASCO 2019: Updated Efficacy in TGCT

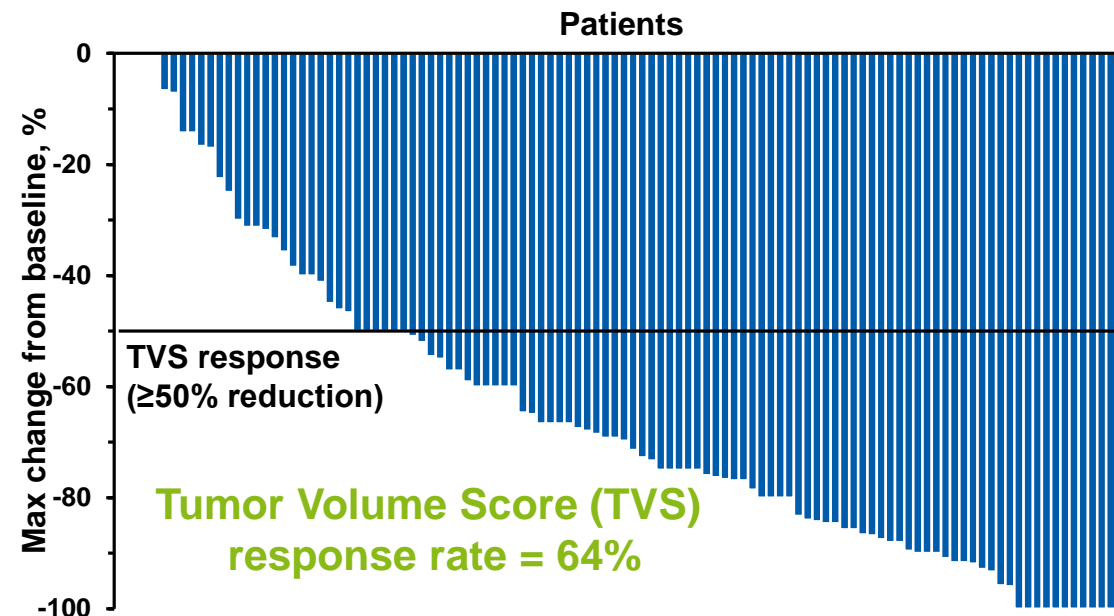
Increased and durable tumor response with continued pexidartinib treatment

ENLIVEN Primary Endpoint Results

Treatment, n (%)	Complete Response	Partial Response	Stable Disease	Progress. Disease	Not Evaluable	1° Endpoint Week 25
Pexidartinib (n=61)	9 (15)	15 (25)	24 (39)	1 (2)	12 (20)	RECIST ORR [95% CI] 24 (39%) [28.1, 51.9] P<0.0001
Placebo (n=59)	0	0	46 (78)	1 (2)	12 (20)	0 [0, 6.1]

Long-term Treatment (Updated ENLIVEN & Ph1)

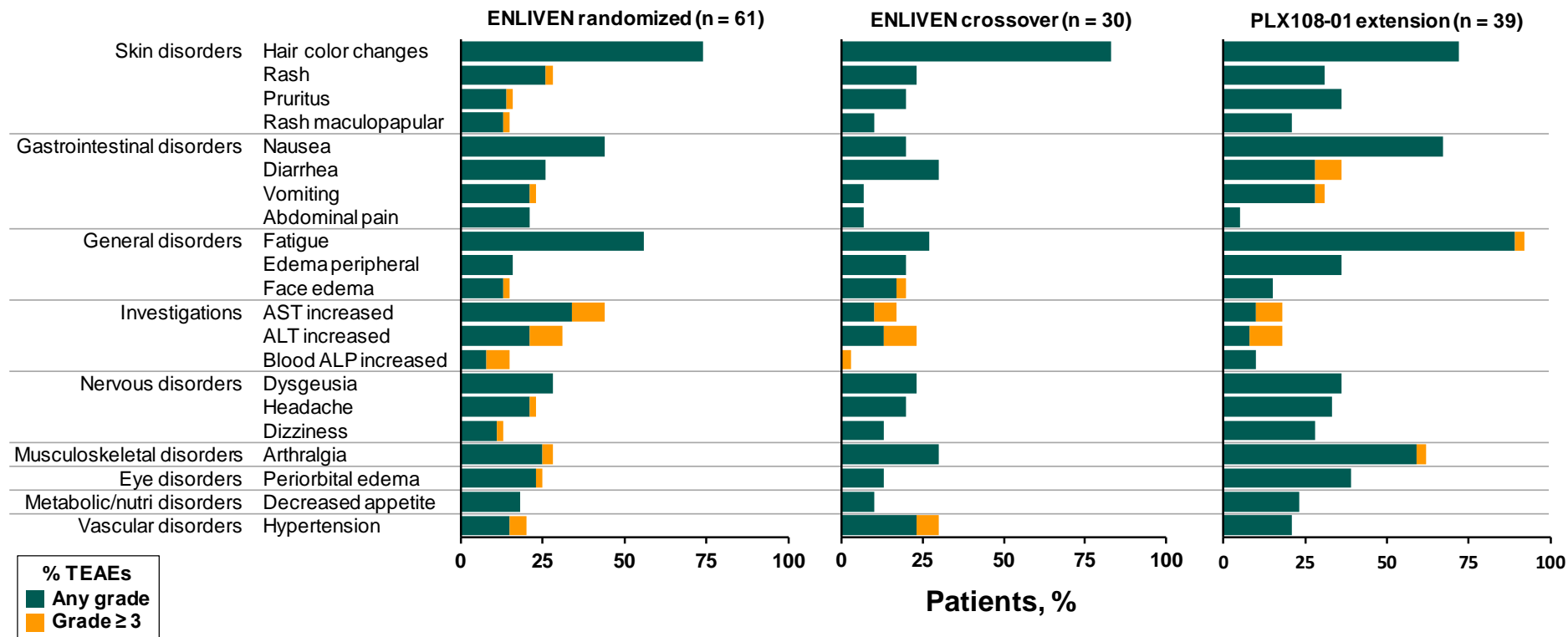
	n=130
Median treatment duration, mo (range)	17 (1-60+)
RECIST Best Overall Response (CR or PR)	70 (54%)
Median (range) RECIST Duration of Response, mo	Not Reached (2-53+)



ASCO 2019: Updated Safety in TGCT (ENLIVEN and Phase 1)

Similar safety profile and no new mixed or cholestatic hepatotoxicity

Frequency of Treatment-Emergent Adverse Events by TGCT Cohort



Long-term safety profile similar to previously reported findings

- Adverse events mostly low grade
- No new mixed or cholestatic hepatotoxicity, beyond the serious cases in the first 8 weeks of treatment

Mixed or cholestatic hepatotoxicity to date

- Rare, idiosyncratic, serious, can be fatal

- **US FDA review of NDA:** PDUFA Date of August 3, 2019
- **EU MAA submitted:** Review is ongoing



May 2019, **U.S. FDA**

Oncology Drug Advisory Committee (ODAC)

Positive ODAC Vote 80%

Does the demonstrated benefit of pexidartinib outweigh the risks of the drug in the proposed indication?

Yes

12

No

3

- US: FDA Advisory Committee complete
- Japan: Second Committee on Drugs of MHLW recommended the approval on May 30, 2019
- EU: Review proceeding per previously disclosed plans



May 2019, **U.S. FDA**

Oncology Drug Advisory Committee (ODAC)

- 8 against, 3 in favor of finding the benefit results of pivotal study QuANTUM-R outweighing the risks
- ODAC opinion not binding but considered
- FDA Review to complete by PDUFA date of August 25, 2019

ASCO 2019 Highlights

Cancer Enterprise Development Progress

Today's Agenda

1

DS-8201

*HER2 DXd ADC
and AZ
Collaboration*

- Accelerate and expand; do the right thing
- Breast cancer BLA acceleration to 1H FY19

2

U3-1402 &
DS-1062

*HER3 DXd ADC &
TROP2 DXd ADC*

- Data update
- Implications

3

DS-7300 &
DS-6157

*Next human-stage
DXd ADC*

- Targeting B7-H3 and GPR20
- Updates

4

Regulatory
Reviews

*ODAC and Ongoing
Reviews*

- Pexidartinib
- Quizartinib

5

Rest of the
Portfolio

*Brief Review of
Activities*

- Quizartinib: QuANTUM-First
- DS-3201 EZH1/2 inhibitor
- DS-1001 IDH1m inhibitor
- DS-3032 mdm2 inhibitor

AML / HEM Franchise Continues to Progress



Daiichi-Sankyo
cancerenterprise

Quizartinib

- QuANTUM-First study (Newly Diagnosed FLT3-ITD AML) continues to accrue ahead of expectations; >90% enrolled

DS-3201 EZH1/2 inhibitor

- Granted SAKIGAKE designation for PTCL in Japan in April 2019
- Small-Cell Lung Cancer (SCLC) Phase 1 study initiated

DS-1001 IDH1m inhibitor

- Phase 1 results reported at ASCO (Abstract # 2004)

DS-3032 MDM2 inhibitor (milademetan)










- Dose escalation of P1 combination studies with quizartinib and azacitidine have started

Major R&D Pipeline in Oncology (As of June 2019)

	Generic name/Project number (drug efficacy/mechanism of action)	Target Indication	Region	Stage			
				Phase 1	Phase 2	Phase 3	NDA/BLA
ADC Franchise	DS-8201 (anti-HER2 ADC)	BC (HER2 positive post T-DM1)	JP/US/EU/Asia	★			
		BC (HER2 positive vs T-DM1)	JP/US/EU/Asia				
		BC (HER2 low)	JP/US/EU/Asia				
		GC (HER2 expressing post trastuzumab)	JP/Asia	★			
		CRC	JP/US/EU				
		NSCLC	JP/US/EU				
		BC and bladder cancer (with nivolumab)	US/EU				
	U3-1402 (anti-HER3 ADC)	BC	JP/US				
		NSCLC	US				
	DS-1062 (anti-TROP2 ADC)	NSCLC	JP/US				
AML/HEM Franchise	Quizartinib/AC220 (FLT3 inhibitor)	AML (relapsed/refractory)	JP/US/EU/Asia				★
		AML (1st line)	JP/US/EU/Asia				
	DS-3032 (MDM2 inhibitor)	Solid tumor	JP/US				
		AML	JP/US				
	DS-3201 (EZH1/2 inhibitor)	PTCL	JP				★
		ATL/L	JP				
		AML, ALL	US				
		SCLC	US				
	PLX2853 (BRD4 inhibitor)	AML, solid cancer	US				
	DS-1001 (IDH1m inhibitor)	Glioma	JP				
Axi-Cel® (anti-CD19 CAR-T cells)	BCL	JP	★				
Breakthrough Science	Pexidartinib (CSF-1/KIT/FLT3 inhibitor)	TGCT	US/EU				★
	DS-1647 (G47Δ virus)	Glioblastoma multiforme	JP	★			★
	DS-1205 (AXL inhibitor)	NSCLC [with osimertinib (Asia) gefitinib (JP)]	JP/Asia				

ALL: acute lymphoblastic leukemia, AML: acute myeloid leukemia, ATL/L: adult T-cell leukemia/lymphoma, BCL: B-cell lymphoma, NSCLC: non-small cell lung cancer, PTCL: peripheral T-cell lymphoma, TGCT: tenosynovial giant cell tumor
 ★: Projects in the field of oncology which are planned for registration application based on the results of P2 studies,
 ★ designated as breakthrough therapy (FDA)/SAKIGAKE (JP)

Upcoming Milestones

DS-8201	 <p>Breast</p>  <p>DESTINY-Breast01</p>  <p>Gastric</p>  <p>DESTINY-Gastric01</p>	<p>Pivotal Phase 2 in HER2 positive mBC</p> <ul style="list-style-type: none">• US: BLA submission in 1H FY2019• JP: NDA submission in 2H FY2019• SABCS: December 2019 (planned) <p>Pivotal Phase 2 in HER2 positive mGC</p> <ul style="list-style-type: none">• JP: NDA submission 1H FY2020
Quizartinib	 <p>AML</p>  <p>QUANTUM-R</p>	<p>Relapsed/Refractory <i>FLT3</i>-ITD AML</p> <ul style="list-style-type: none">• US: FDA PDUFA August 25, 2019• JP: expecting approval in June-July 2019• EU: review on track for 2H FY2019 approval
Pexidartinib	 <p>TGCT</p>  <p>ENLIVEN</p>	<p>Tenosynovial Giant Cell Tumor</p> <ul style="list-style-type: none">• US: FDA PDUFA August 3, 2019• EU: review on track 1H FY2020
DS-1647 (G47Δ)	 <p>GBM</p>	<p>Glioblastoma multiforme</p> <ul style="list-style-type: none">• JP: NDA submission in 1H FY2019



Daiichi Sankyo, Inc.

US Launch Readiness in Oncology

Ken Keller, *President and CEO, Daiichi Sankyo, Inc.*

Four Launch Success Requirements

1

**RIGHT
DRUG**

2

**EASILY
IDENTIFIED
PATIENT
TYPE WITH
UNMET
NEED**

3

**CUSTOMER
INTIMACY**

4

**SURROUND
THE DRUG
WITH A
TAILORED
SUPPORT
SYSTEM**

We will be ready for Pexidartinib, Quizartinib, DS-8201 and beyond

1

RIGHT DRUG

- Pexidartinib demonstrated a positive overall response rate by multiple measures in the multicenter, randomized, double-blind, placebo-controlled phase 3 study (ENLIVEN)
- Cholestatic/mixed hepatotoxicity (onset in first 8 weeks, rare, idiosyncratic, serious, can be fatal)

2

EASILY IDENTIFIED PATIENT TYPE WITH UNMET NEED

- If FDA approved, pexidartinib would be the first and only treatment for patients with TGCT
- Proposed indication: Adult patients with symptomatic TGCT associated with severe morbidity or functional limitations and not amenable to improvement with surgery

3

CUSTOMER INTIMACY

HCPs have never had approved systemic therapeutic option to offer

- ~50% of US Sarcoma Centers of Excellence have managed pexidartinib TGCT patients in clinical trials
- New DSI talent of rare disease experts with 350 years combined pharmaceutical experience and ~150 years combined oncology experience

4





SURROUND THE DRUG WITH A TAILORED SUPPORT SYSTEM

- Strong support system enabling appropriate use: REMS program, patient registry, working 1:1 with specialists trained to prescribe pexidartinib
- We will link and educate orthopedic surgeons and treating physicians through multidisciplinary CME
- We plan to connect physicians and patients to Sarcoma Center of Excellence, and pexidartinib certified prescribers with simple tools

1

Right Drug: Physicians react favorably to DS-8201 profile post T-DM1

Physician Reaction to Product X (DS-8201) TPP: 3L post T-DM1 in HER2+ Breast Cancer

CATEGORY		DRIVERS TO PRESCRIBING
Efficacy		Physicians very impressed with Product X efficacy data, noting that a DOR of 12+ months and an ORR of 46% are nearly unheard of in 3L
Tolerability		Side effects associated with Product X perceived as manageable
Administration		Physicians pleased with the Q3W dosing schedule as this is expected with T-DM1
Technology		Many reacted favorably to a new ADC product

2

The “DS-8201 Patient” is Known, but has Limited Options

- DS-8201 First proposed indication HER2+ post T-DM1 mBC
- Confidence in treatment declines as few options exist after T-DM1

1L at a GLANCE	% of Patients Treated in 1L	Primary Regimen Used in 1L	Primary Driver of Choice	Physician Confidence in Treating 1L
	100%	Herceptin + Perjeta + chemotherapy	Time to Progression PFS 2-3 years	Very Confident
		Upwards of 60% Drug-treated Pt. Market Share*		

2L at a GLANCE	% of Patients Treated in 2L	Primary Regimen Used in 2L	Primary Driver of Choice	Physician Confidence in Treating 2L
	75%	Kadcyla	Response Rate 30-60%	Mixed
		Upwards of 45% Drug-treated Pt. Market Share*		

3L at a GLANCE	% of Patients Treated in 3L	Primary Regimen Used in 3L	Primary Driver of Choice	Physician Confidence in Treating 3L
	67%	No Dominant Regimen	Patient QoL	Not Confident

* FY19 mBC Situation Analysis, DS-8201a; Global Tandem Oncology Monitor (MAT Q1 2018)

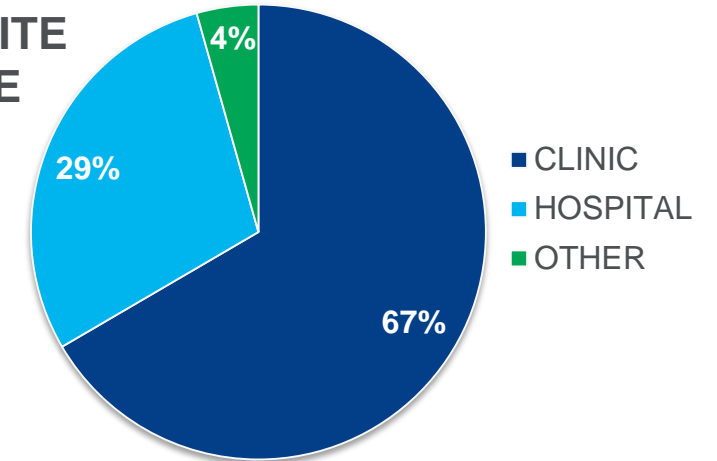
3

Customer Intimacy: We Have Existing Relationships with >90% of T-DM1 Prescribers

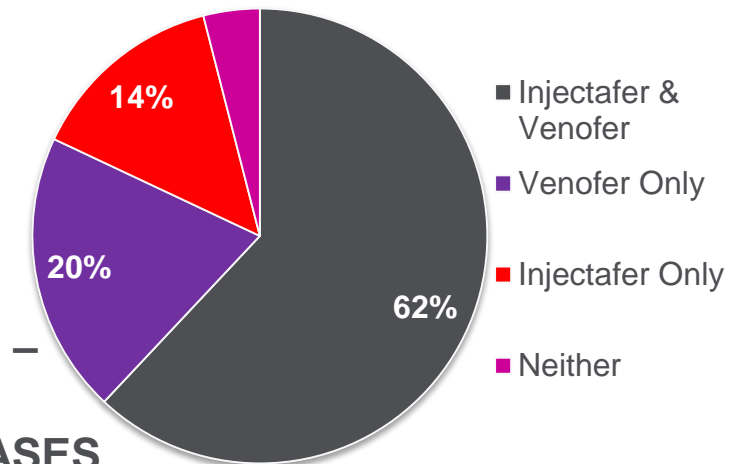


- T-DM1 is key analogue for DS-8201
- DS-8201 proposed lead indication - post T-DM1
- T-DM1 US revenue - \$400M (past 12 mo.)
- T-DM1 purchased, administered primarily in a clinic (non-hospital) setting
- Injectafer is market-leading IV iron, >75% of business is Oncology
- >90% of T-DM1 purchasers also purchase Injectafer and/or Venofer (clinic and hospital)
- Injectafer and Venofer revenue in T-DM1 purchasing accounts estimated at >\$400M
- We have deep customer knowledge that extends to Oncology GPOs

T-DM1 SITE OF CARE



TOP 100 T-DM1 CLINICS – IV IRON PURCHASES



Source: Symphony Non-Retail WAC Dollar share, 26 weeks ending 3-3-2018.

3

Customer Intimacy: Injectafer Business Provides Foundational Skills to Accelerate DS-8201 launch



	ONCOLYTIC DS-8201	INJECTAFER
Sophisticated and Total Account Sell (Utilizing HUB services and support staff)	✓	✓
Understanding Economic Models	✓	✓
ASP & Contracting Implications	✓	✓
Role of Guidelines in Treatment Decisions	✓	✓
Competitive Therapeutic Area	-/✓	✓
Buy and Bill Product	✓	✓
Infused Medication	✓	✓

We are building upon our business skills with clinical acumen...

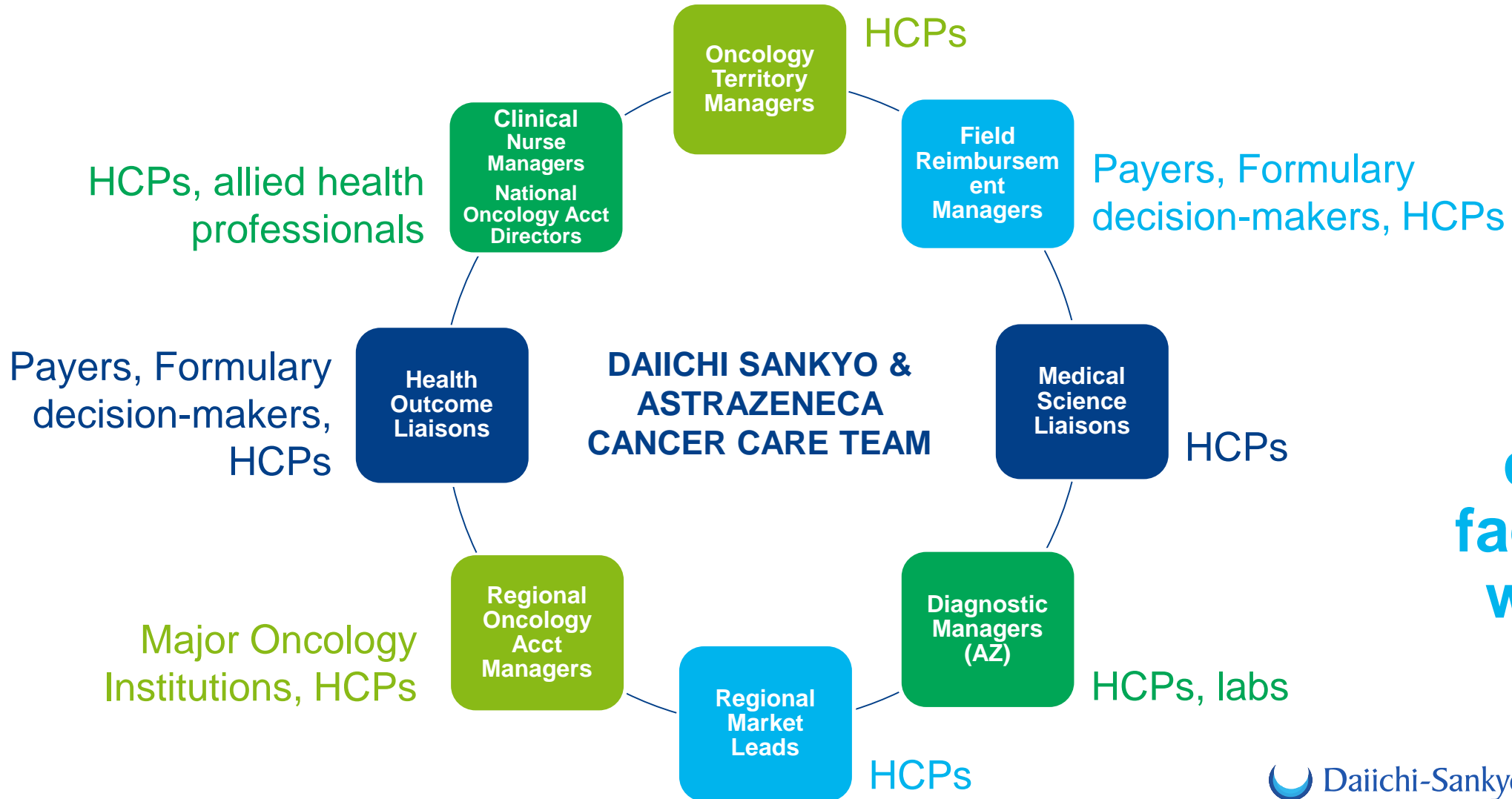
**Collaborating with AstraZeneca to extend our scope, reach and expertise
Pairing Daiichi Sankyo clinical acumen with institutional / business expertise**

**The Promise
of DS-8201
Has Drawn
Great
Interest
from High
Quality
Talent**

- Recruiting experienced commercial team **from many pharma leaders in oncology** to supplement our existing IV iron organization
- Marketing, Sales, Access and Reimbursement Senior Leaders and Medical Affairs Colleagues with **vast oncology experience** in many therapeutic categories
 - Team will be fully on board Q3 FY2019
 - Commercial launch readiness by January 2020 given BLA submission expected in 1H FY2019

4

Surround The Drug...Daiichi Sankyo & AstraZeneca Collaboration to Fully Support Rapid Adoption



400+ U.S. customer-facing roles will launch DS-8201



We Will Be Ready for Potential Early 2020 Launch

KEY INSIGHTS

- Kadcyła (T-DM1) is key analogue for DS-8201
- Patient identification is well understood – patients are “waiting”
- Future DS-8201 customers are Injectafer prescribers today
- Future DS-8201 customers are AZ customers today (synergy)
- DS & AZ Part B management capabilities provide foundation for DS-8201

ACTION

Customer mapping completed

Launch preparation for patients waiting for DS-8201 – HCPs know their patients well, treating them over time

Complete partnered commercial organization in Q3 to leverage existing customer knowledge and relationships

Create reimbursement and support services to facilitate appropriate use and access

The Four Launch Success Requirements in Place

