Daiichi-Sankyo cancerenterprise

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

Conference Call
Highlight from ASCO 2017

DAIICHI SANKYO CO., LTD

Antoine Yver
Global Head of Daiichi Sankyo Cancer Enterprise

June 6, 2017 (JST)

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Today's Agenda

1. Opening remark
2. Cancer Enterprise
3. Key highlight from ASCO 2017
4. Q&A

We are on a journey to build a world-class oncology engine

Slide from R&D Day Dec 2016

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Past

- Daiichi Sankyo has a **history of strong science and innovation**
- In April 2016, we shared our **2025 vision –** to become a **Global Pharma Innovator with a Competitive Advantage in Oncology**

Present

- In process of launching **Cancer Enterprise** and **accelerating our most promising assets**
- Today, we are excited to **share our vision and progress to date**

Future

- Cancer Enterprise is on track to support Daiichi Sankyo **5-Year Business Plan**
  - FY2020: 40+ Bn JPY
  - FY2025: ~300 Bn JPY
- We will **deliver our portfolio for patients** and our **2025 vision**

Cancer Enterprise key messages (1/2)

Slide from R&D Day Dec 2016

- **DS-8201: Flagship asset,** HER2 ADC, key to Daiichi Sankyo strength in oncology
  - Broad opportunity
  - Partnership implications
- **Emerging franchises**
  - Acute Myeloid Leukemia **(AML)**
  - Antibody Drug Conjugate **(ADC)** technology

Cancer Enterprise key messages (2/2)

Slide from R&D Day Dec 2016

- Powerful **research engines**
  - Japan research labs, combining chemistry and biology expertise
  - Plexxikon discovery platform, enabling efficient candidate identification
- **Strategic investments** in enhanced capabilities
  - Align capabilities to aspirations
  - Strategic BD&L

Cancer Enterprise two emerging franchises

Slide from R&D Day Dec 2016

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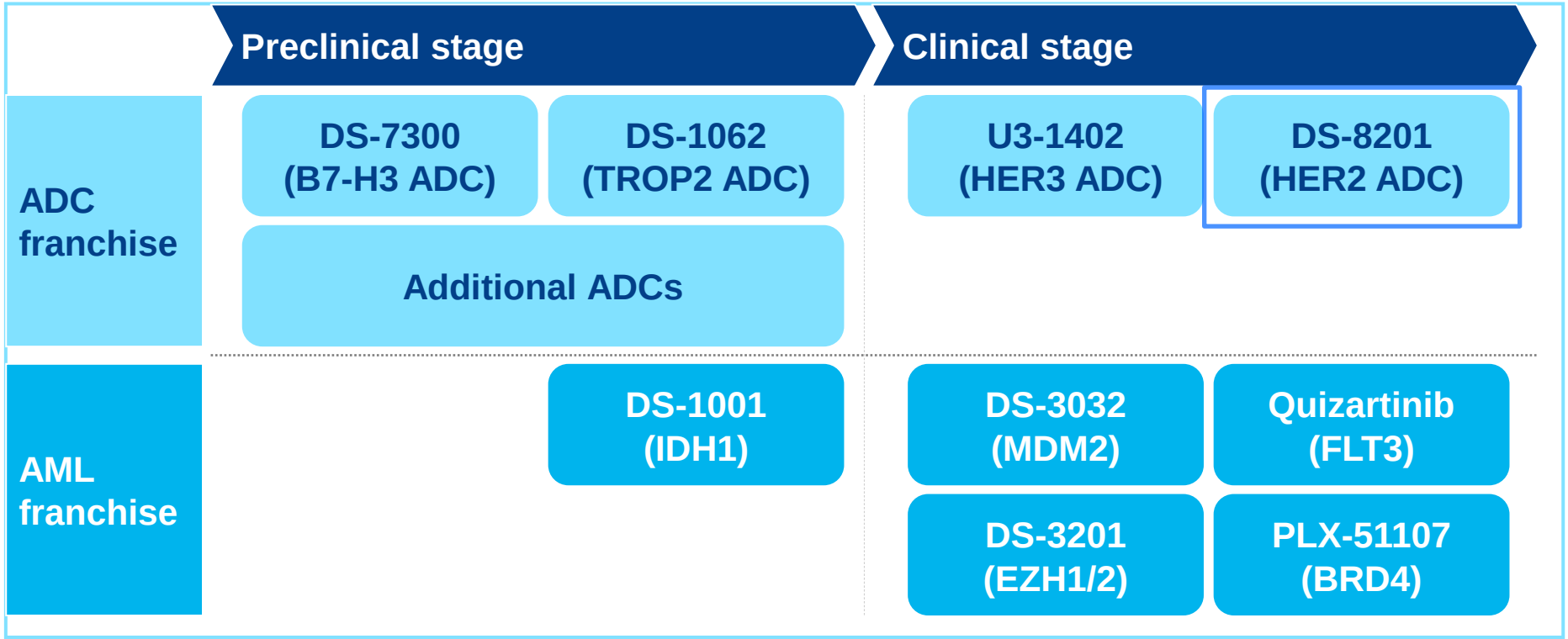

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Single agent activity of DS-8201a, a HER2-targeting antibody-drug conjugate, in heavily pretreated HER2 expressing solid tumors (Abstract No: 108)

Toshihiko Doi[1], Hiroji Iwata[2], Junji Tsurutani[3], Shunji Takahashi[4], Haeseong Park[5], Charles H. Redfern[6], Kohei Shitara[1], Chikako Shimizu[7], Hiroya Taniguchi[2], Tsutomu Iwasa[3], Shinichiro Taira[4], Albert C. Lockhart[5], Jennifer M. Fisher[6], Takahiro Jikoh[8], Yoshihiko Fujisaki[8], Caleb Lee[9], Antoine Yver[9], Kenji Tamura[7]

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PRESENTED AT: ASCO ANNUAL MEETING '17 | #ASCO17

Disclosure

- Toshihiko Doi - Consulting or Advisory Role; Amgen, Chugai Pharma, Daiichi Sankyo, Kyowa Hakko Kirin, Lilly Japan, MSD, Nippon Boehringer Ingelheim, Novartis. Research Funding; Astellas Pharma, Bayer, Boehringer Ingelheim, Celgene, Chugai Pharma, Daiichi Sankyo, Janssen, Kyowa Hakko Kirin, Lilly Japan, Merck Serono, MSD, Novartis, Pfizer, Sumitomo Group, Taiho Pharmaceutical, Takeda.
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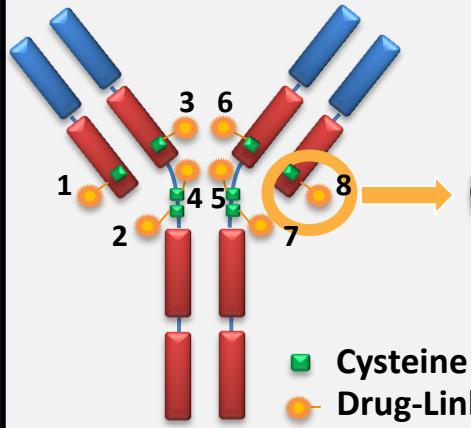
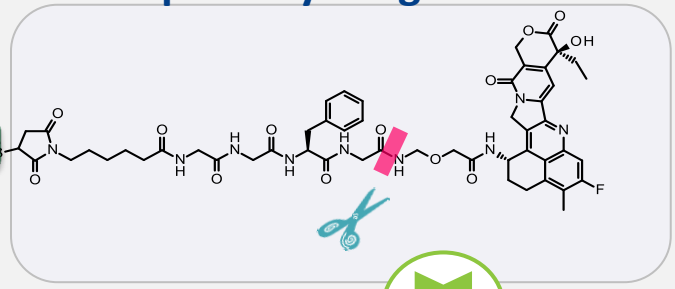
DS-8201a

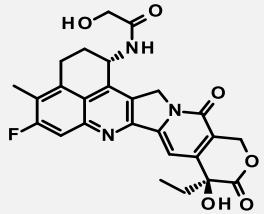


Proprietary drug-linker



Conjugation chemistry

Cysteine linked, at sites of interchain disulfide bonds



Payload (DXd)

Exatecan derivative

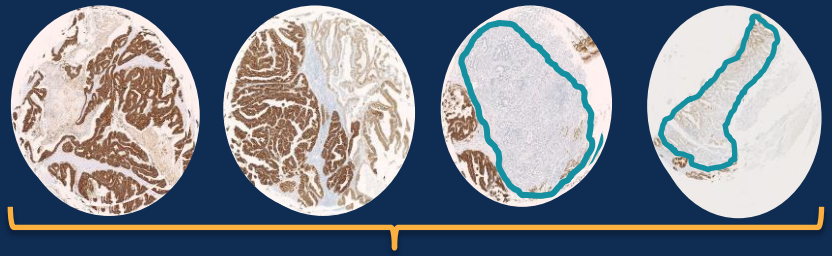
- Novel payload
- High potency
- Bystander effect
- Short systemic half-life payload
- Stable linker-payload
- Tumor selective cleavable-linker
- High drug-to-antibody ratio

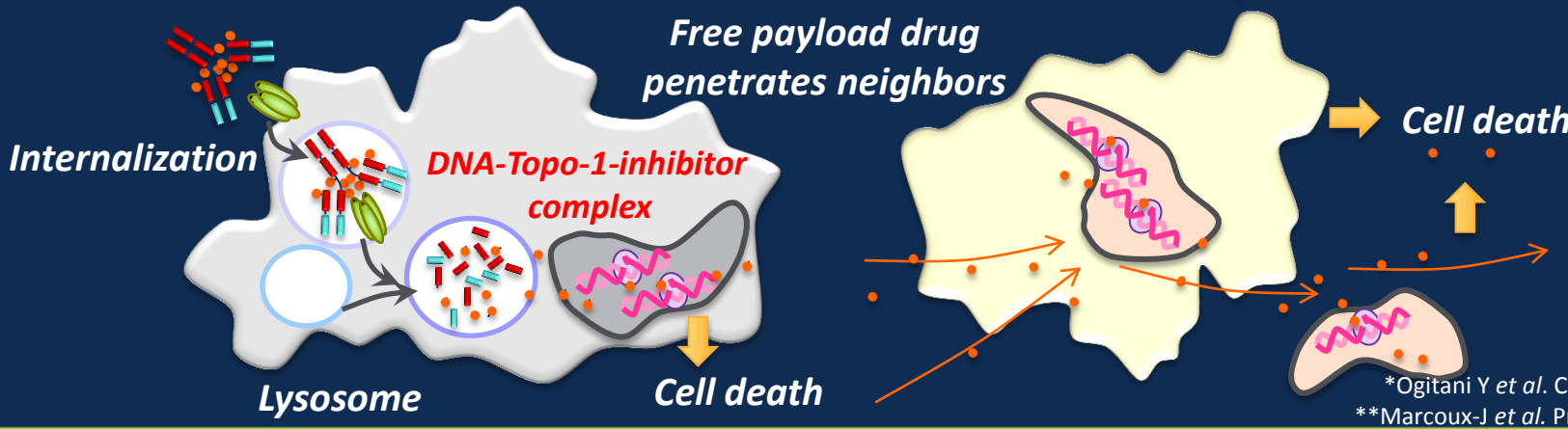
MoA of DS-8201a

	DS-8201a	T-DM1
Antibody	Anti-HER2 Ab	Trastuzumab
MOA	Topoisomerase I Bystander effect*	Tubulin
Drug-to-antibody ratio	7-8	3.5**

Heterogeneity of IHC staining in gastric cancer

All cases classify into HER2 score 3+





*Ogitani Y *et al*. Cancer Sci. 2016

**Marcoux-J *et al.* Protein Sci. 2015

Presented by: Toshihiko Doi

Ph1 Evaluation & Key eligibility criteria

Endpoint

DLT, Safety and tolerability, Efficacy, PK

Key inclusion criteria

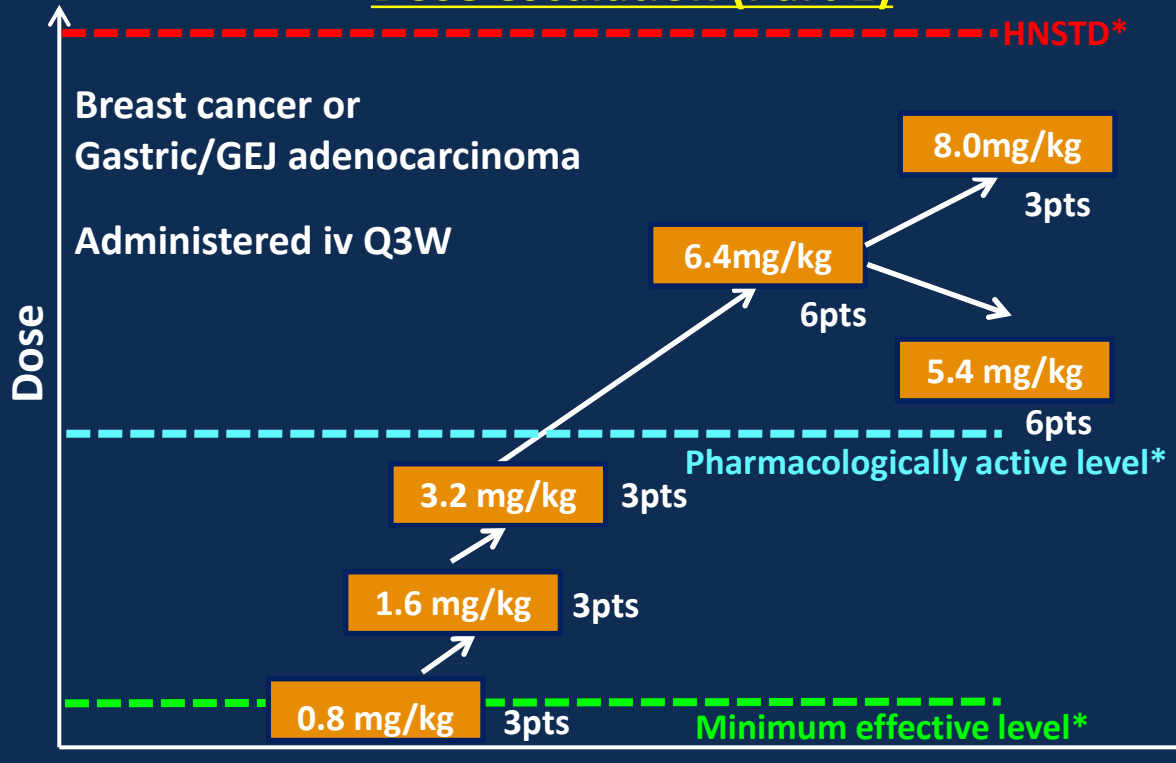
- ECOG PS 0-1
- LVEF ≥ 50%
- Adequate organ function including platelet ≥ 100,000 /mm^3, Hb ≥ 8.5 g/dL, ANC 1,500/mm^3

Definition of key DLT criteria

- Gr4 neutrophil count decreased lasting > 7days
- Gr4 anemia
- Gr4 platelet count decreased or Gr≥3 platelet count decreased lasting > 7days
- Gr4 AST or ALT increased
- Gr≥3 non-hematologic, non-hepatic major organ toxicities including symptomatic CHF, LVEF decline to < 40% or 20 % drop from baseline

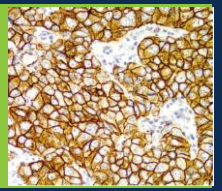
Ph1 Dose escalation and expansion

Dose escalation (Part 1)

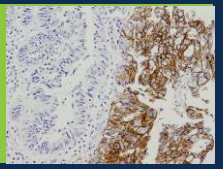


Dose expansion (Part 2)

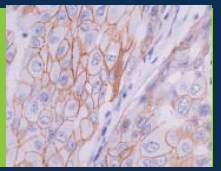
Part 2-a
HER2 positive
T-DM1 pretreated BC



Part 2-b
HER2 positive
Trastuzumab pretreated GC



Part 2-c
HER2 low BC
(IHC 2+/ISH -, IHC 1+/ISH -)



Part 2-d
HER2 expressing solid tumors except BC or GC (IHC, FISH, NGS etc.)

* Estimated based on preclinical models

Demographics (Part 1+Part 2, 5.4 + 6.4 mg/kg, N=134)

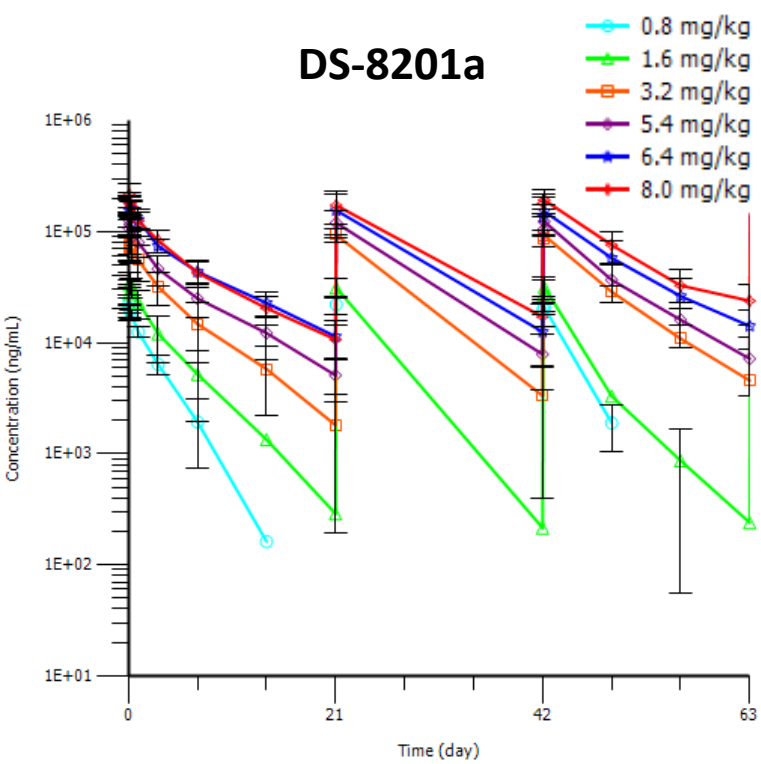
Breast cancer (N=64)	
HER2 status	
HER2 Positive	83%
HER2 Low	17%
# of prior regimen	
Median: 5.0	
Tumor size (Median: 5.1 cm)	
≤ 5cm	49%
5 – 10 cm	32%
≥ 10 cm	19%

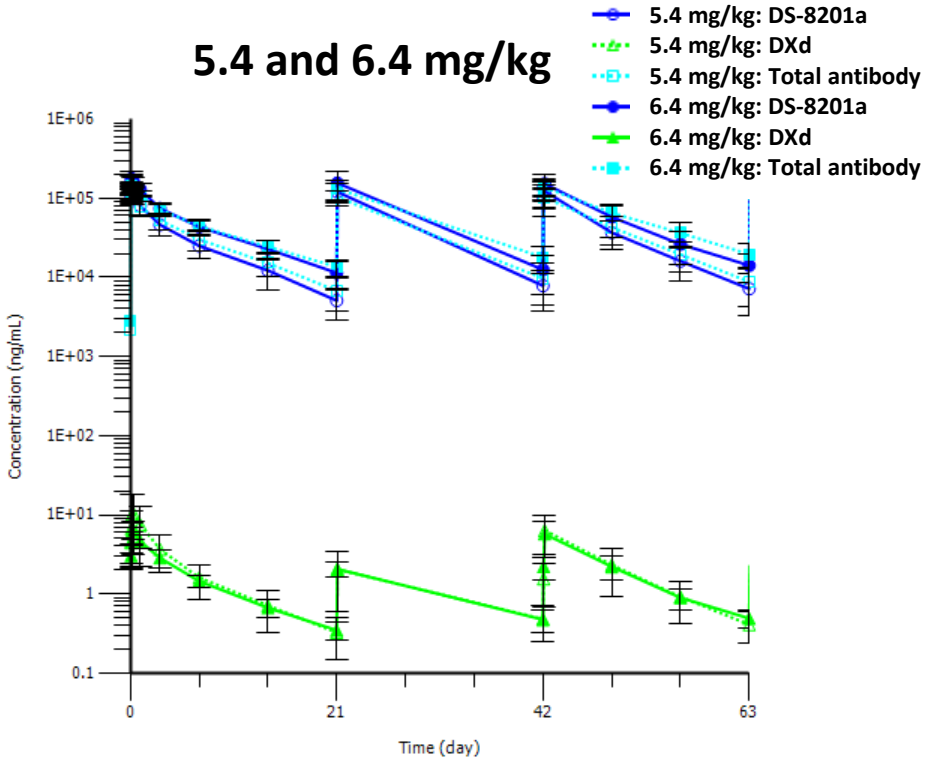
Gastric cancer (N=44)	
HER2 status	
HER2 Positive	98%
HER2 Low	2%
# of prior regimen	
Median: 3.0	
Tumor size (Median: 4.7 cm)	
≤ 5cm	54%
5 – 10 cm	17%
≥ 10 cm	29%

Others (N=26)	
# of prior regimen	
Median: 3.0	
Tumor size (Median: 7.2 cm)	
≤ 5cm	35%
5 – 10 cm	30%
≥ 10 cm	35%

Analysis set: Enrolled patients at 5.4 and 6.4 mg/kg
Data cutoff on 11-May-2017

Pharmacokinetics





Analysis set: PK evaluable patients in Part1
Data cutoff on 11-May-2017

TEAE, any grade, >20% (No DLT observed)

Preferred Term (N=133)	Grade 1 (%)	Grade 2 (%)	Grade 3 (%)	Grade 4 (%)	All (%)
Hematologic					
Platelet count decreased	13.5	9.0	8.3	3.8	34.6
Anaemia	3.0	12.0	14.3	1.5	30.8
Neutrophil count decreased	0.8	9.8	12.0	3.0	25.6
White blood cell count decreased	0.8	12.8	9.0	1.5	24.1
Gastrointestinal disorders					
Nausea	51.9	13.5	1.5	0.0	66.9
Decreased appetite	33.8	20.3	3.8	0.0	57.9
Vomiting	31.6	3.8	1.5	0.0	36.8
Diarrhoea	19.5	5.3	0.8	0.0	25.6
Constipation	18.8	3.0	0.0	0.0	21.8
Others					
Alopecia	21.1	6.0	0.0	0.0	27.1
Malaise	18.0	4.5	0.8	0.0	24.1

Any Grade 3/4 – 43.6%

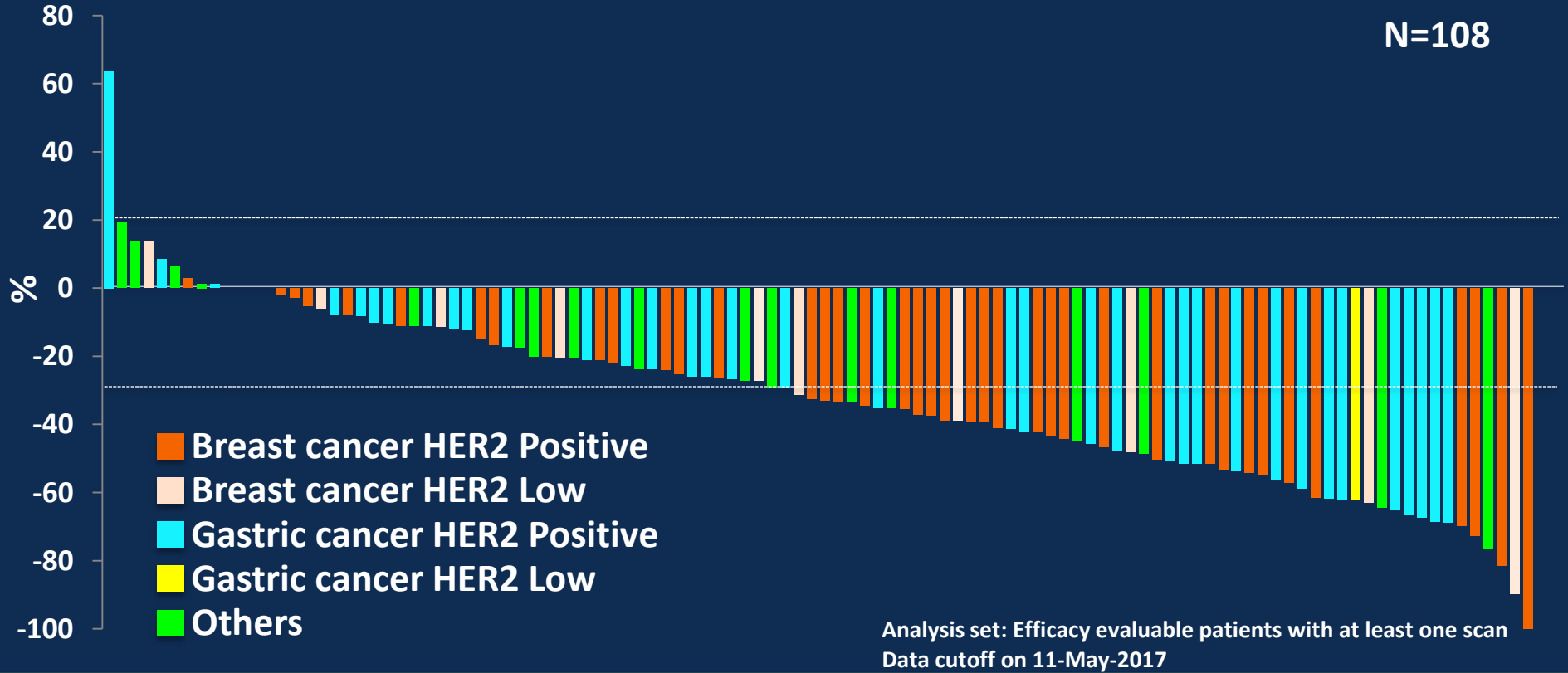
Analysis set: Safety evaluable patients who received at least one dose of DS-8201a
Data cutoff on 11-May-2017

Confirmed overall response rate (5.4+6.4 mg/kg)

	ORR n (%)	DCR n (%)
Total	39/97 (40.2)	89/97 (91.8)
Breast Cancer	19/45 (42.2)	44/45 (97.8)
BC Prior T-DM1	16/35 (45.7)	35/35 (100.0)
BC Prior T-DM1+Pertuzumab	14/30 (46.7)	30/30 (100.0)
Gastric Cancer	16/36 (44.4)	32/36 (88.9)
GC Prior CPT-11	8/18 (44.4)	17/18 (94.4)

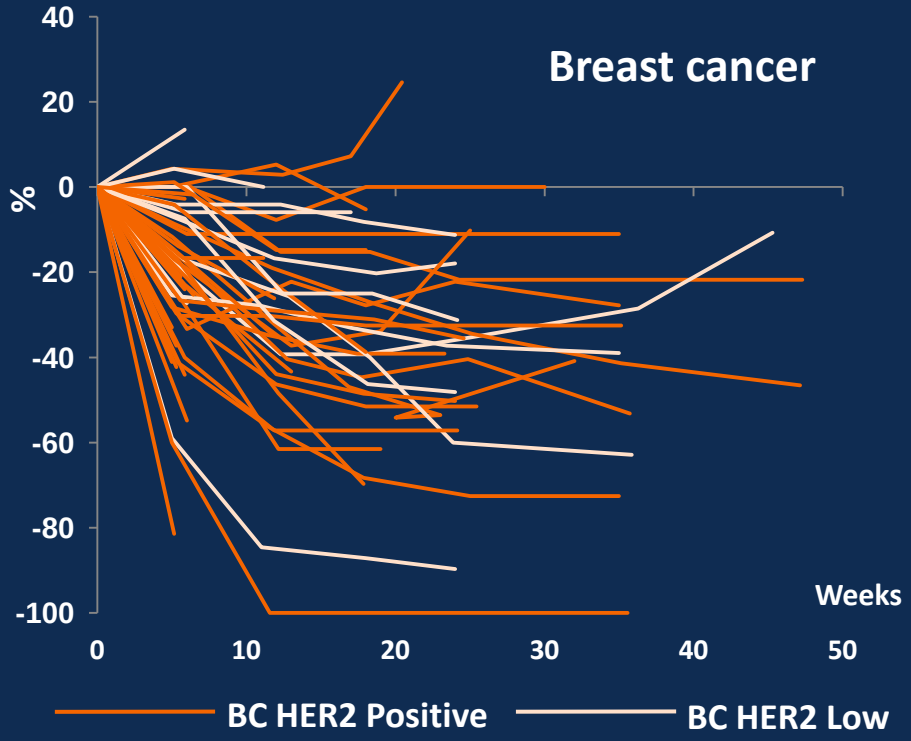
Analysis set: Efficacy evaluable patients for confirmed overall response
Data cutoff on 11-May-2017

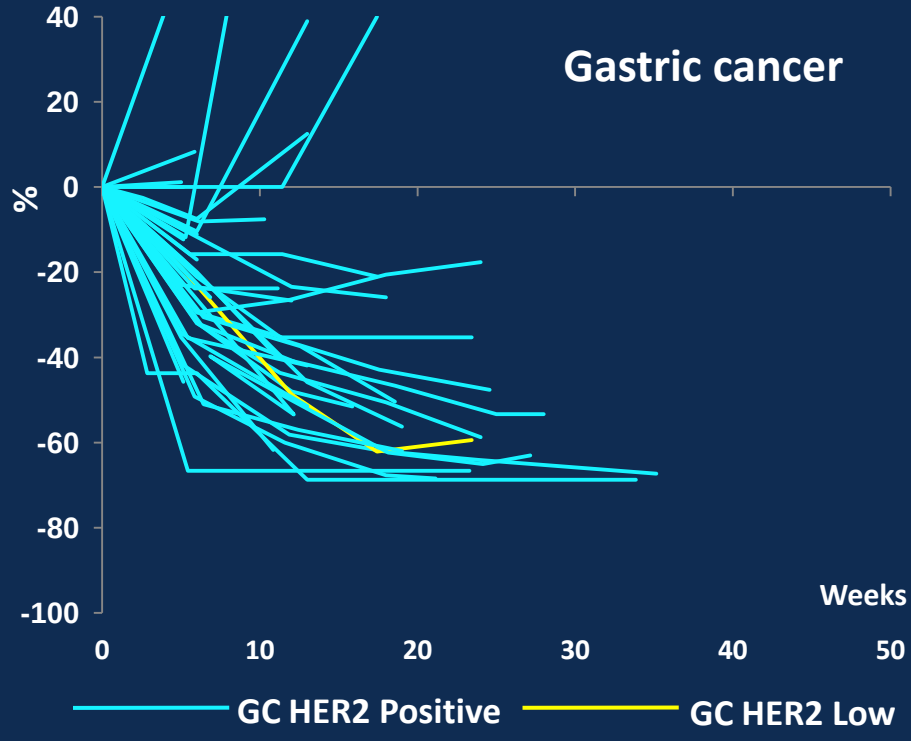
Tumor size: best % change from baseline (5.4+6.4 mg/kg)



Analysis set: Efficacy evaluable patients with at least one scan
Data cutoff on 11-May-2017

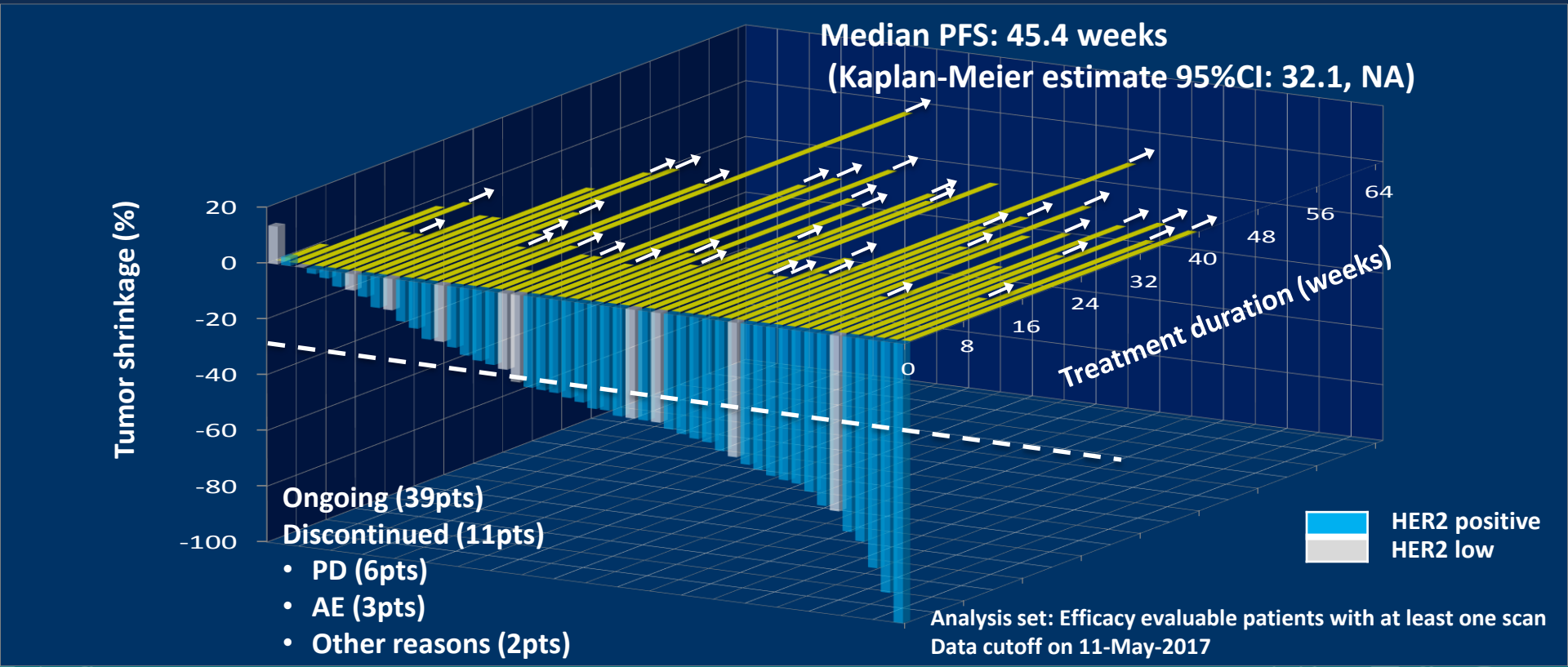
Tumor size: % Change from baseline (5.4 + 6.4 mg/kg)



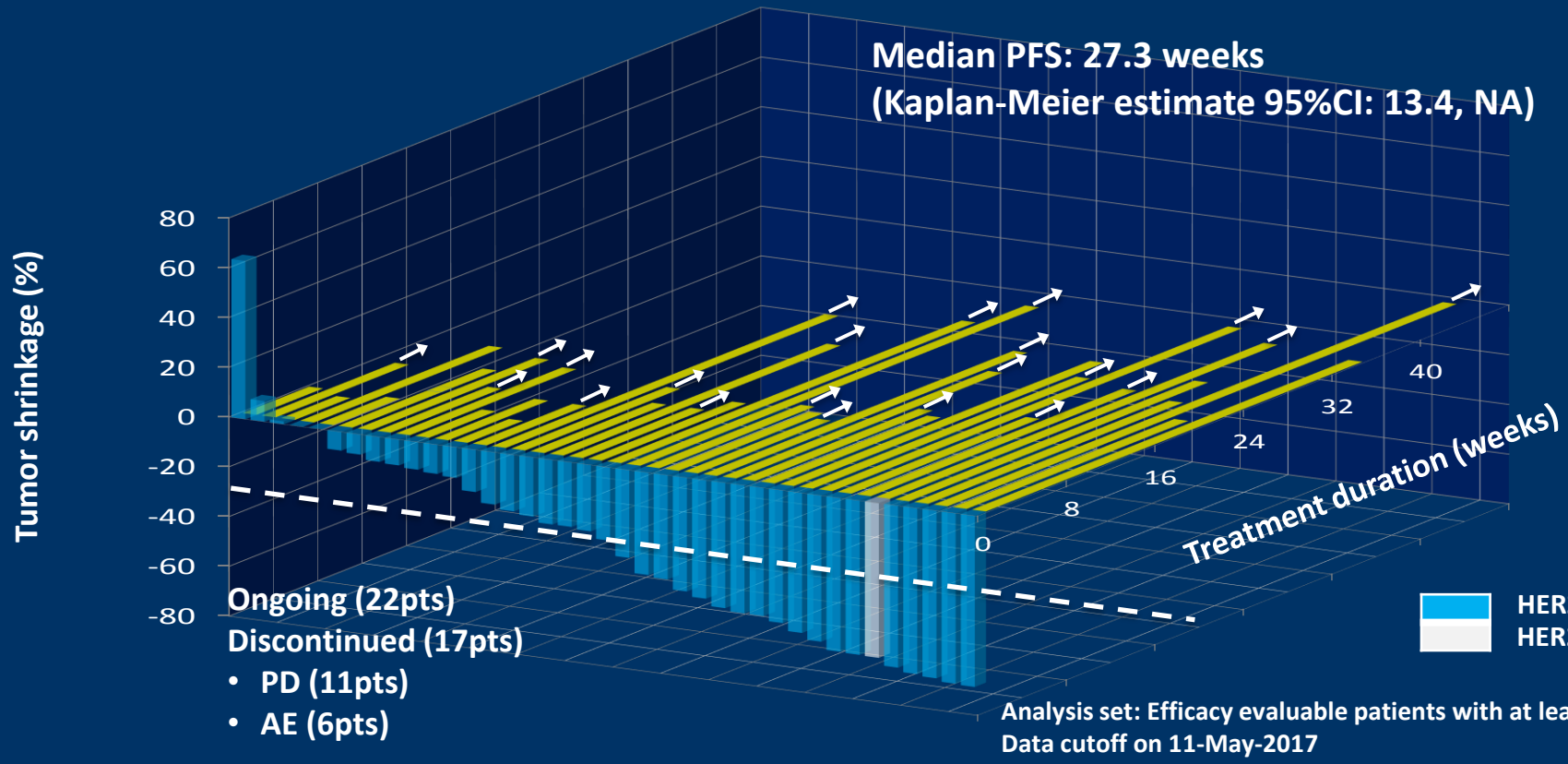


Analysis set: Efficacy evaluable patients with at least one scan
Data cutoff on 11-May-2017

Response and treatment duration (Breast cancer, 5.4 + 6.4 mg/kg)



Response and treatment duration (Gastric cancer, 5.4 + 6.4 mg/kg)



Conclusions

- Preliminary results in first in human Phase 1 trial, DS-8201a demonstrated promising antitumor activity and favorable safety profile
  - For HER2 + Breast cancer pts pretreated with T-DM1 and pertuzumab, ORR was 46.7 %
  - For HER2 + Gastric cancer pts pretreated with trastuzumab, ORR was 44.4%.
  - No DLT was observed and MTD was not reached
  - DS-8201a had few Gr 3 or more AEs or unexpected events, with low risk of cardiac toxicities
- Based on these preliminary results, Phase 2 trials are planned in pts with HER2 + GC and BC

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Q&A

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