Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

R&D Day 2019

DAIICHI SANKYO CO., LTD.

Sunao Manabe
President and CEO

December 17, 2019@Tokyo
December 19, 2019@New York

Forward-Looking Statements

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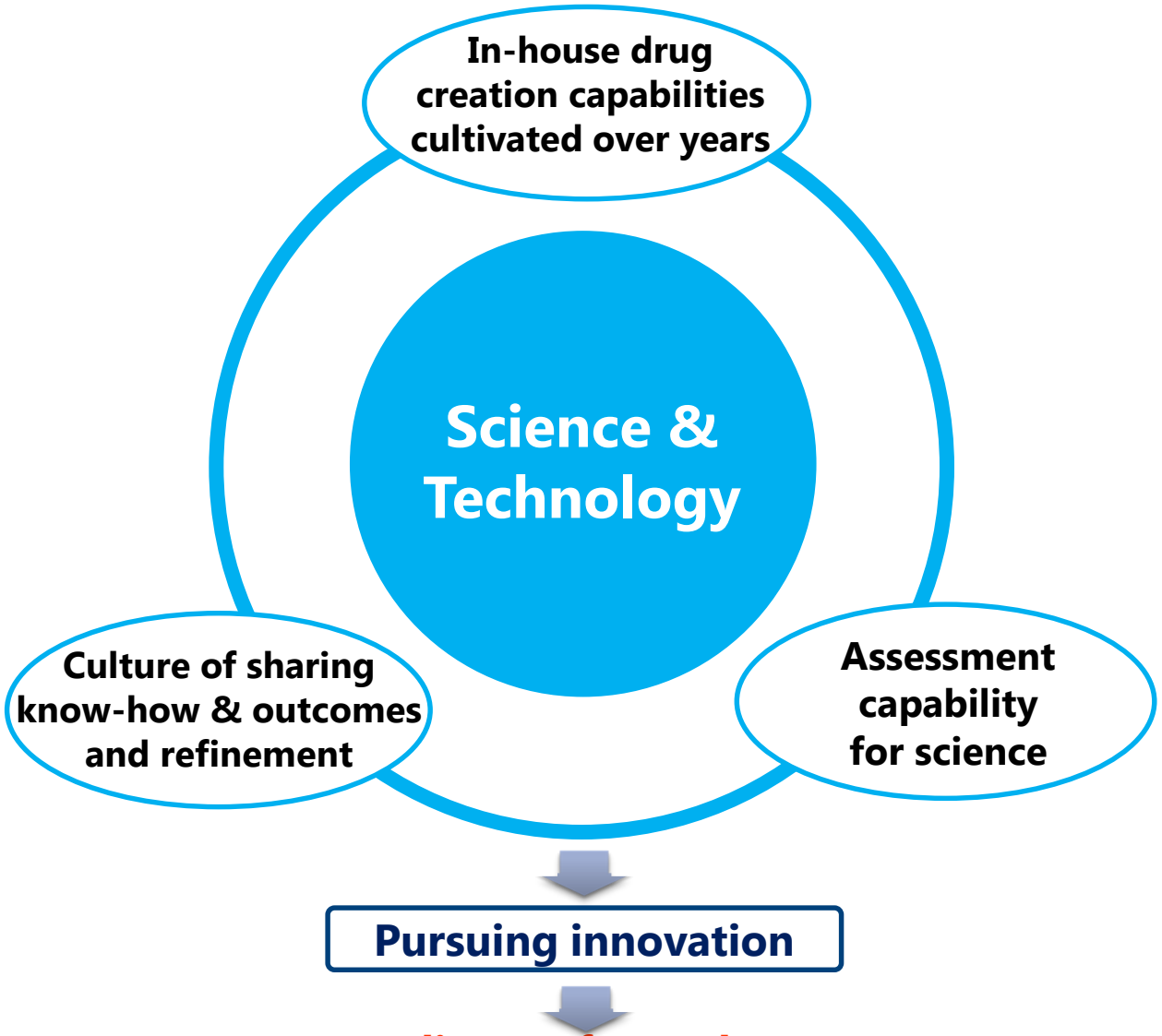
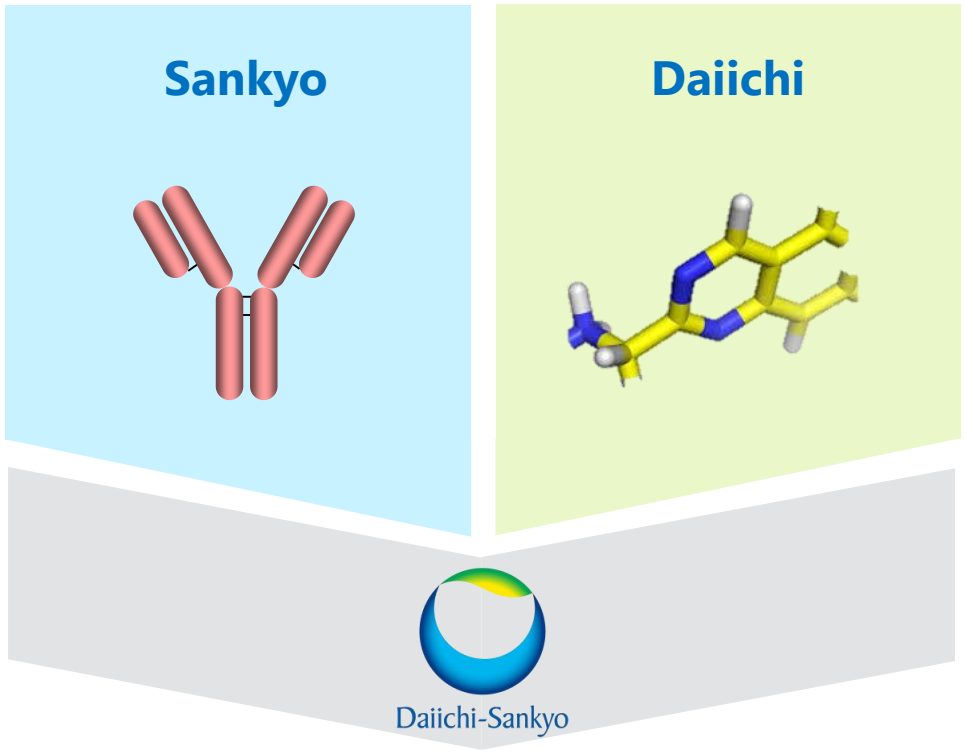
Daiichi Sankyo's R&D – Where We Are



- **Strength of Daiichi Sankyo's R&D**
  - Science & technology of combined organizations
- **Sources of science & technology**
  - In-house drug creation capabilities cultivated through innovative pharmaceuticals research & development for more than 100 years
  - Culture in which individual researchers share their know-how & acquired outcomes and making improvements from there
  - Excellent assessment capability for science

Creation of DXd-ADC Assets



- Focusing on science & technology
- Pursuing Innovation
- Created DXd-ADC assets with expectations for high competitiveness

CEO's Mission: (1) Realization of 2025 Vision

Daiichi-Sankyo

◆ Deliver DXd-ADC assets to as many patients, and as quickly as possible

Delivering DXd-ADC assets

- ◆ **Enhancement of global development & commercial capabilities**

- ◆ **Expand Investments**
  - ➢ **R&D investments primary focused on 3 ADCs**

DS-8201 DS-1062 U3-1402

  - ➢ **Additional Capital expenditures 100.0 Bn JPY or more for CMC and manufacturing**

As many patients as possible
As quickly as possible

Establish position as global No.1 ADC company

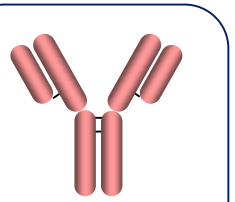
Realize 2025 Vision "Global Pharma Innovator with Competitive Advantage in Oncology"

CEO's Mission: (2) Strive for Sustainable Growth

Create assets Beyond DXd-ADC

Creation of Beyond DXd-ADC assets

- Utilize Daiichi Sankyo's competitive new modalities and technology, expand drug creation technology platform
- Identify competitive assets by reliable assessment capabilities and allocate management resources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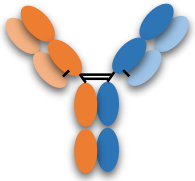
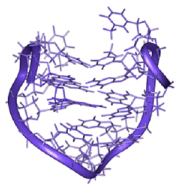
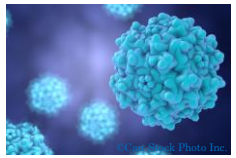
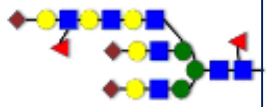
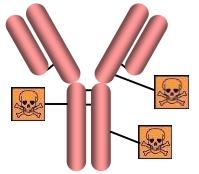
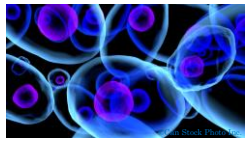

Bispecific


MED & ENA Nucleotide


Gene Therapy


Sugar chain modification


Next Generation ADC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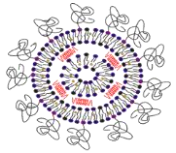
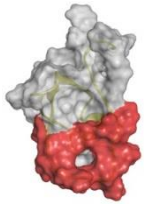

LNP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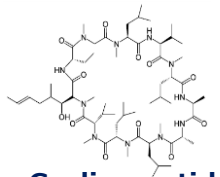
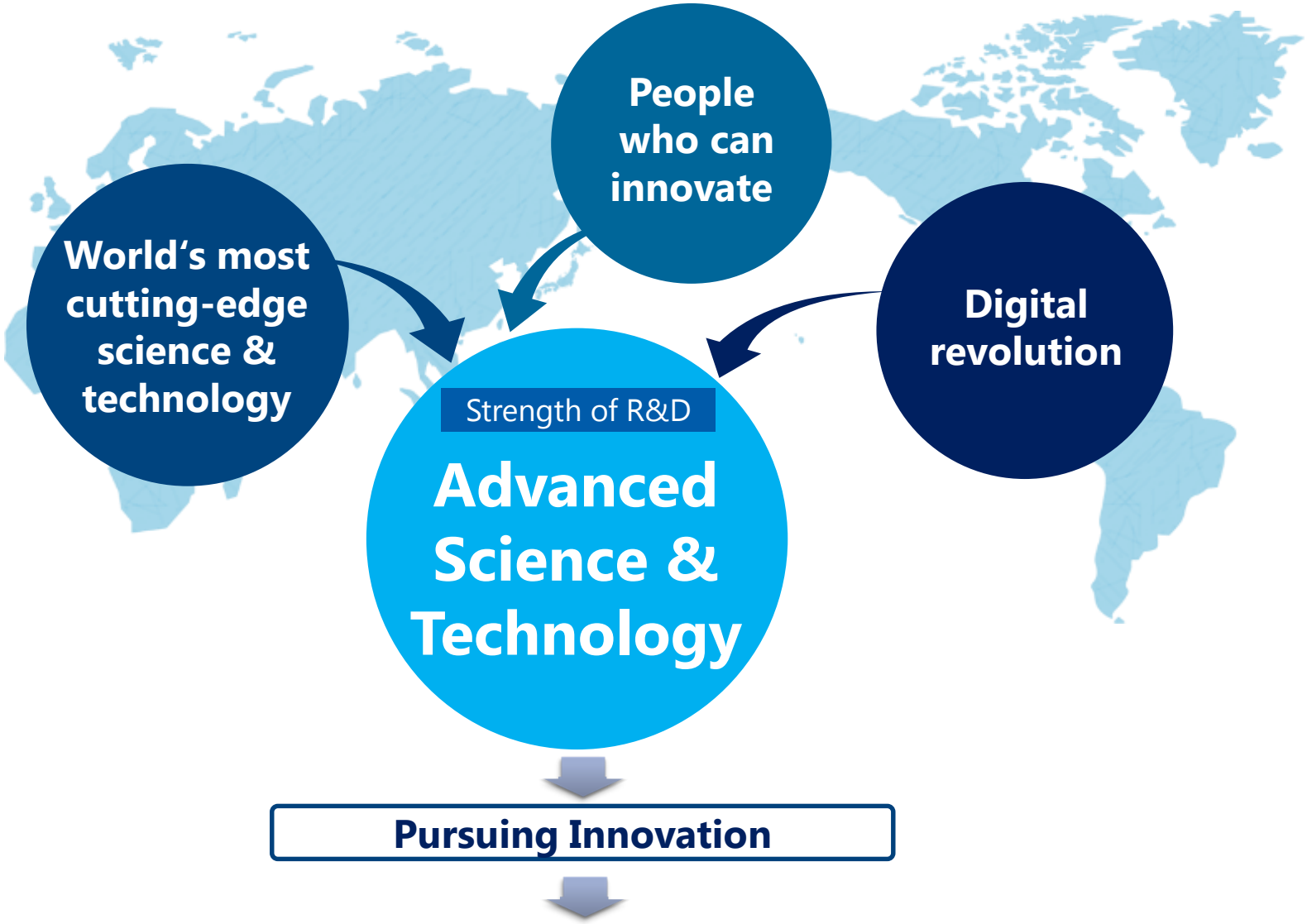

Cyclic peptide Peptide drug

Apply Daiichi Sankyo's new modalities and technologies to delivering new drugs that are not limited to specific therapeutic areas

Key Areas for Further Growth



- Acquire world's most cutting-edge science & technology necessary for global expansion
- Hire and develop the people who can innovate from all over the world
- Taking advantage of digital revolution
  （AI, Big Data, IoT etc.）
- Improve the company's science & technology

Delivery of new drugs with significant contribution for patients

Renew Mid-to-Long-Term Vision

- **In parallel with the next 5-year business plan development, mid-to-long-term vision beyond 2025 will be established**

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Compassion for Patients.™

Daiichi-Sankyo

R&D Strategy

Junichi Koga, PhD
Global Head of R&D

Progress as Planned

CE 2025 Vision

- ADC Franchise: 3
- AML Franchise: 3
- Breakthrough Science: 1

Deliver 7 NMEs in 8 years

- Quizartinib approved in JP
- Pexidartinib approved in US

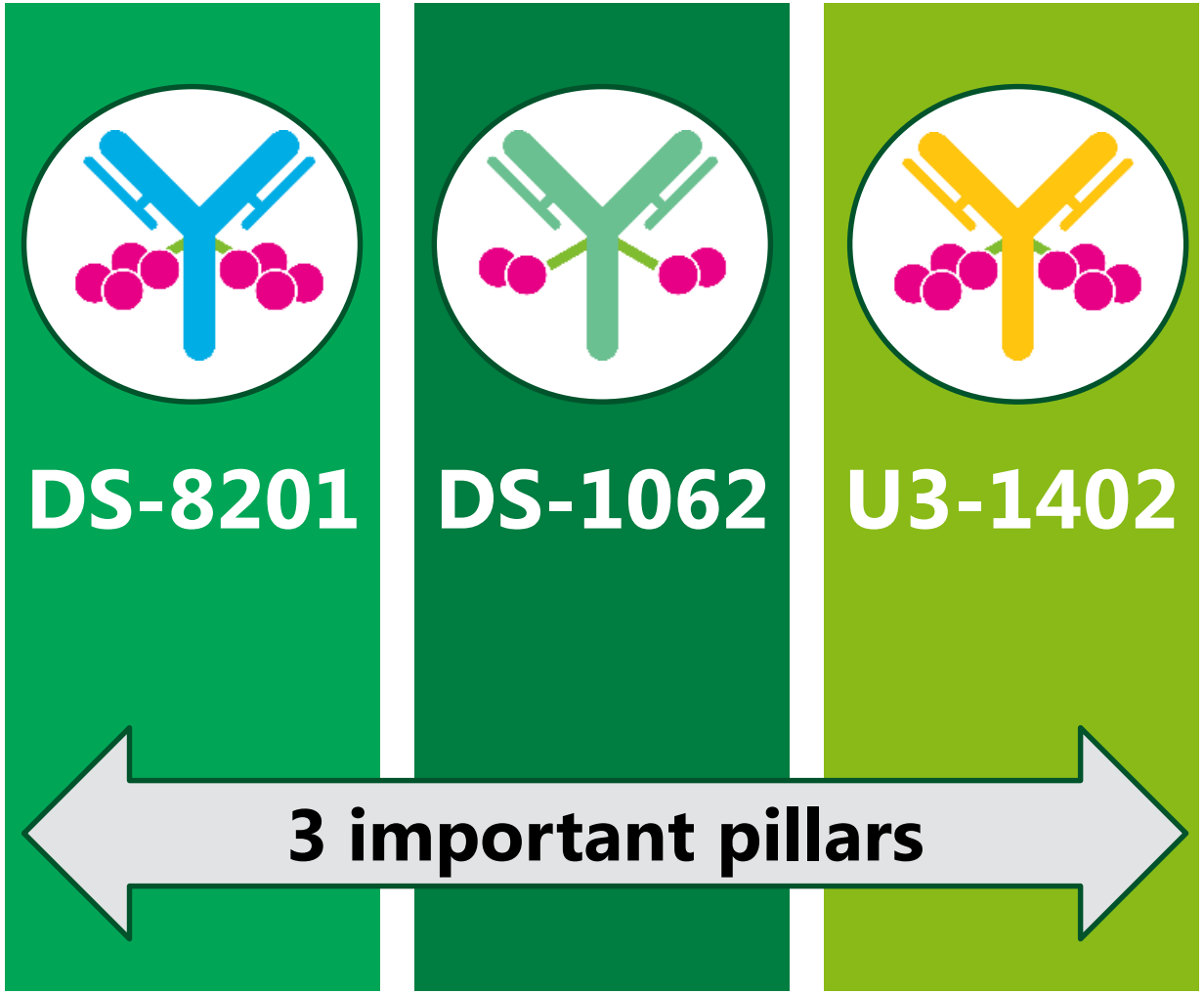
SM 2025 Vision

Maximize near-term revenue	Grow future franchises
2 NMEs in 2018-20	3 NMEs 2021-25

- Mirogabalin approved in JP
- Esaxerenone approved in JP

R&D Now Built on 3 Pillars

- The potential of 3 ADCs has increased enough to create a pillar from each of them
- Prioritize investments and resource allocation to 3 ADC projects



New R&D Strategy: 3 and Alpha

3 lead ADCs

DS-8201: maximize value with co-development partnership with AZ

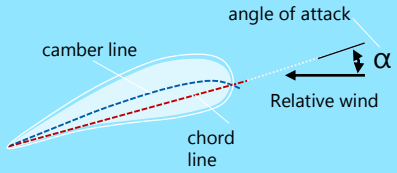
DS-1062: Substantial opportunities across multiple indications

U3-1402: fast to market

Science-informed precision medicine:
three ADCs based on the unique biology of DXd technology and the vector/receptor

Alpha

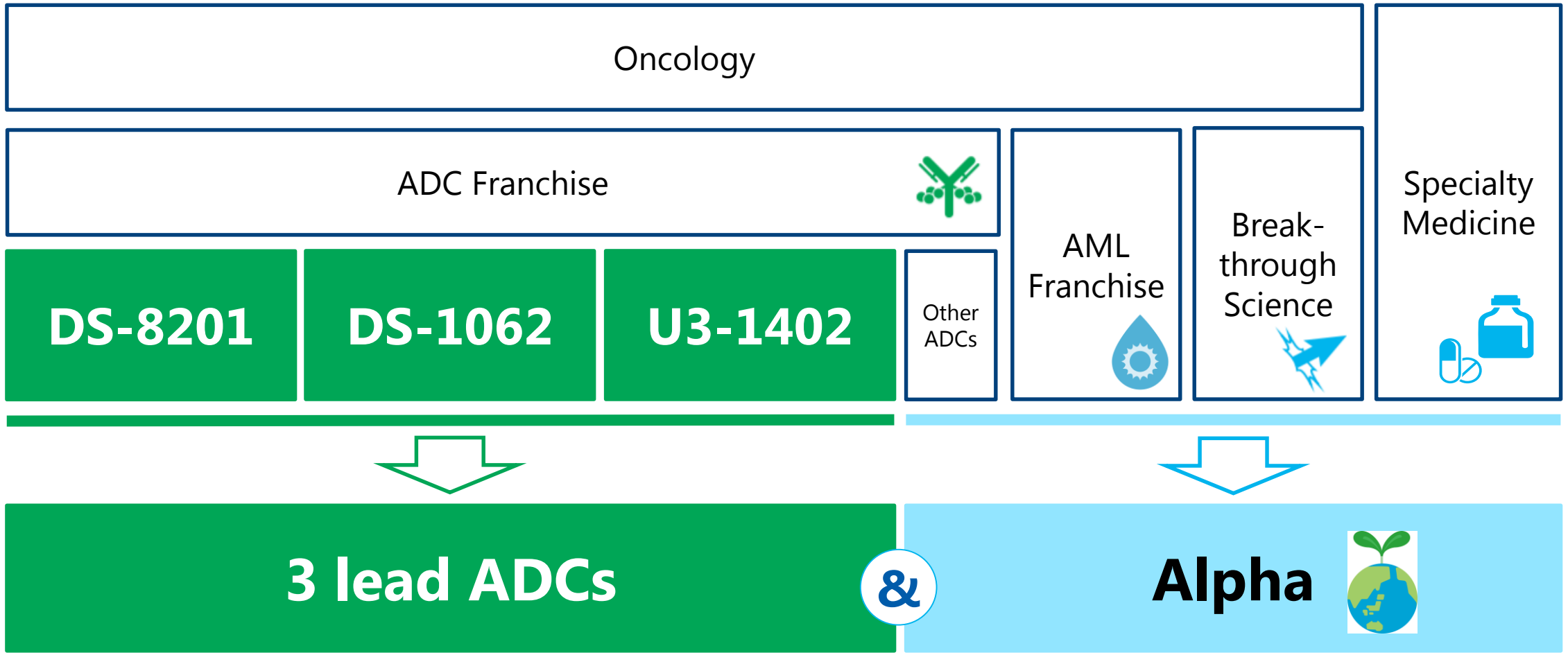
Alpha = angle of attack and speed of elevation



Alpha = Performance far exceeding benchmark index

Alpha= **the cutting edge and power of true innovation delivering drugs changing SOC**

Categorization of 3 and Alpha



- **Timely and flexible resource allocation**
- **Seamless collaboration among organizations in order to further combinatorial innovation**

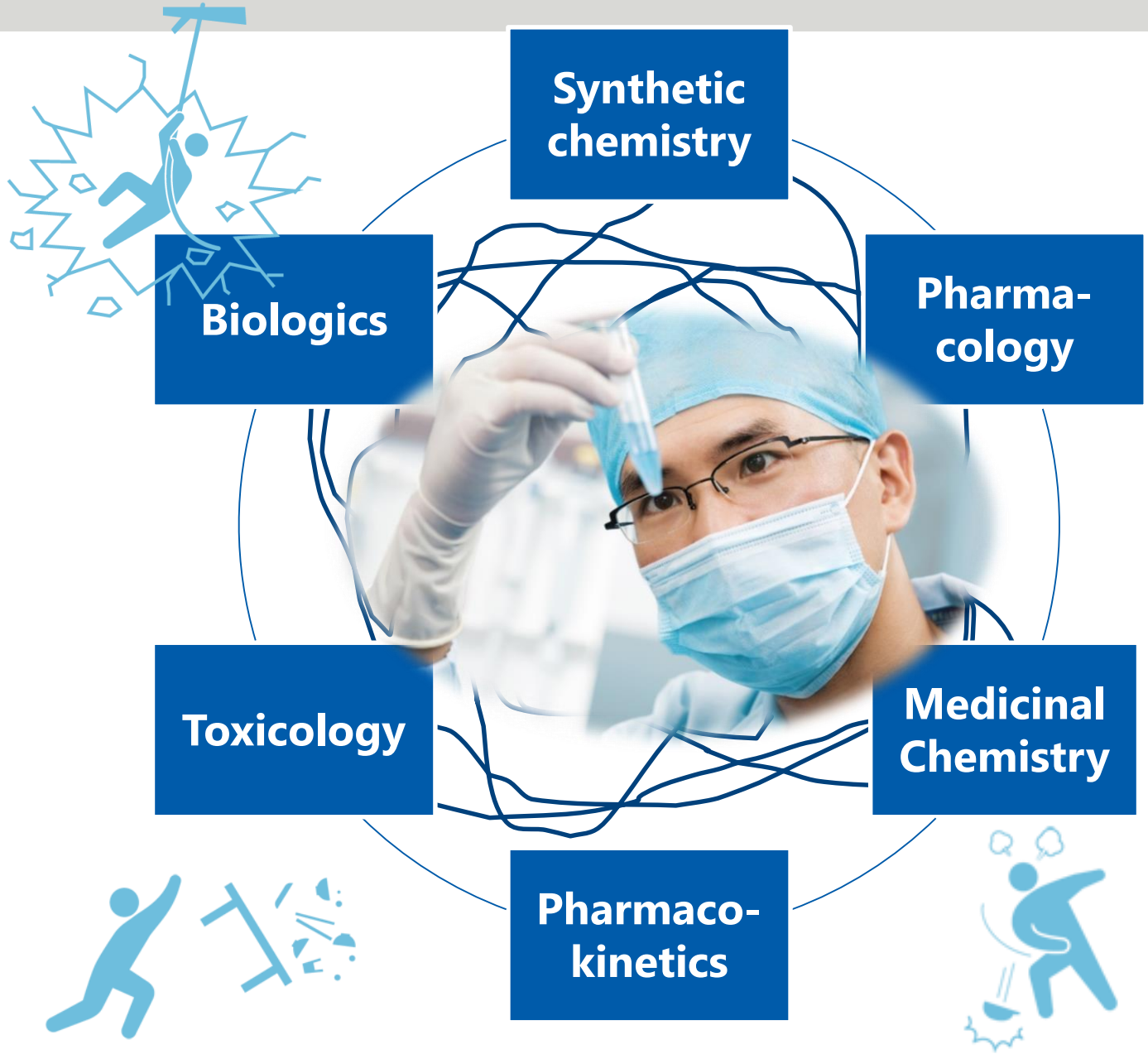
Daiichi Sankyo Focus on Drugs Changing SOC

Drugs Changing SOC

- **First-in-class drugs** having disruptive MOA
- Target others cannot deliver

- **Best-in-class drugs** improved through medicinal chemistry and biology to meet unmet medical needs

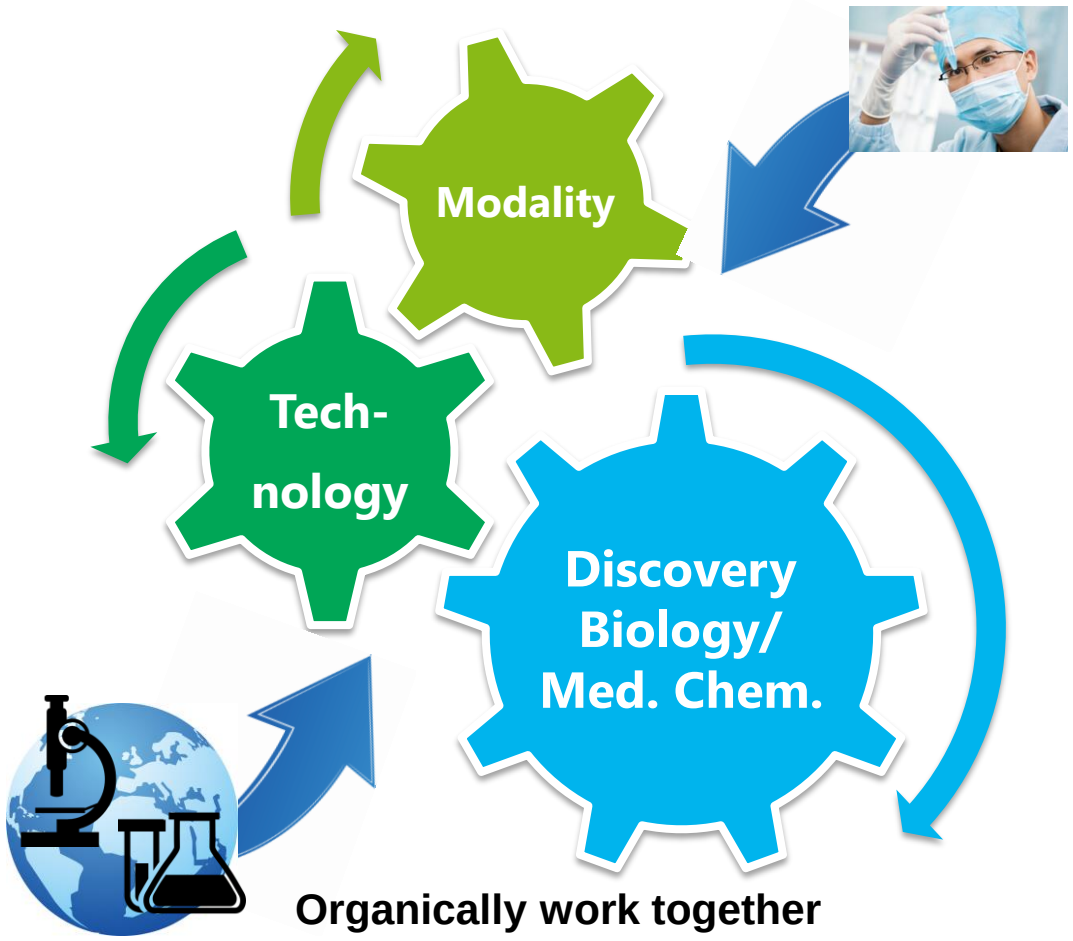
Daiichi Sankyo Researchers



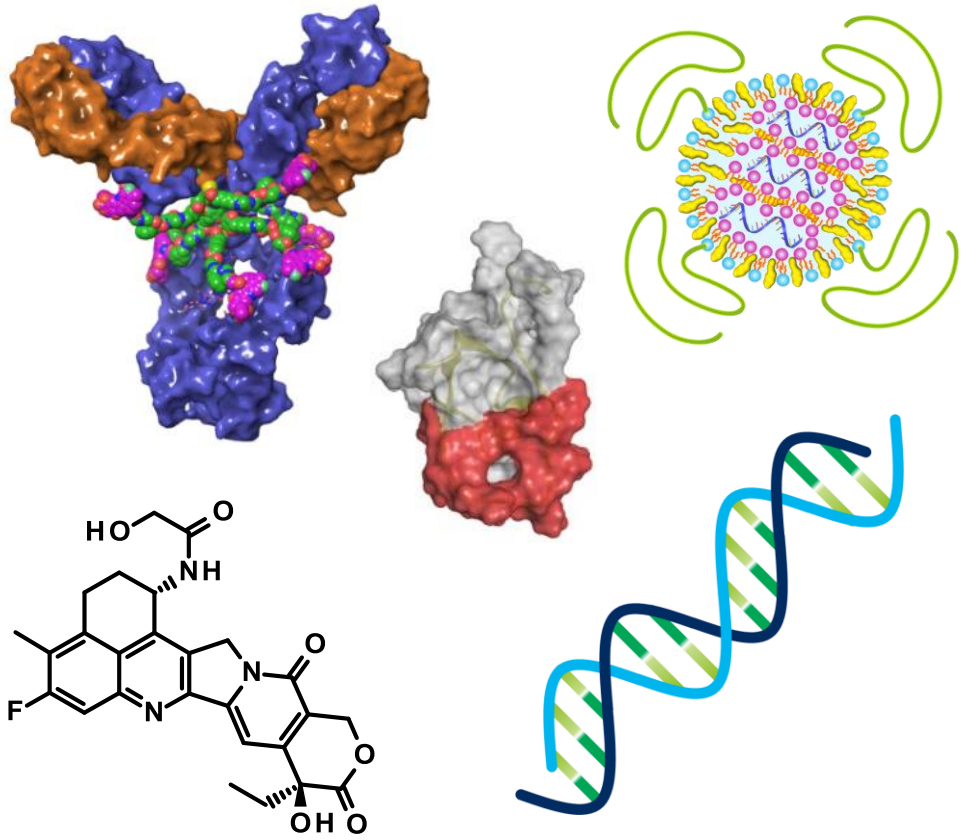
- Excellent junior scientists have been recruited and developed in a wide range of areas
- Resilience mindset is respected among scientists
- Disruptive thinking and approach are encouraged
- Constructive working environment regardless of expertise and hierarchy

Daiichi Sankyo's Unique Science & Technology

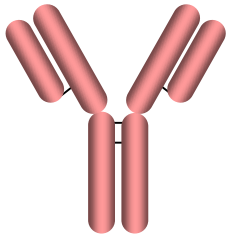
Outstanding medicinal chemistry, antibody engineering & discovery biology



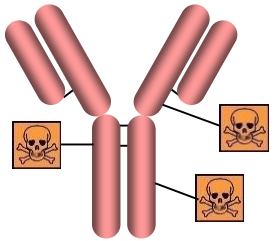
Discovery of drugs changing SOC



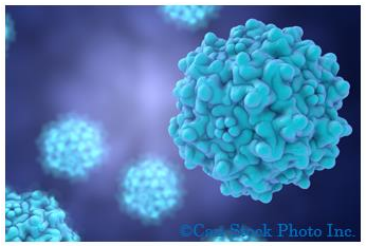
Technology Portfolio in Daiichi Sankyo



Antibody



Next Generation ADC



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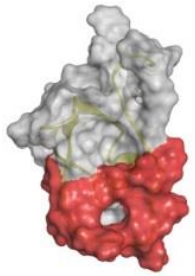

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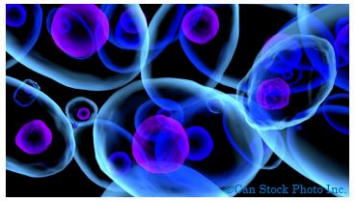


Cell Therapy

Oncology

Genetic/ Orphan Disease

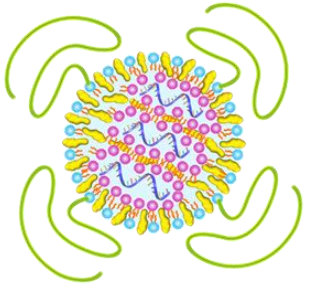
Inflammation/ Immunology

Cardio-renal diseases

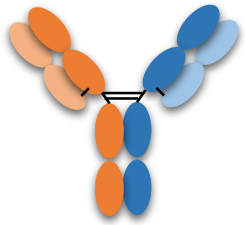
Neurology/ Neuroscience

Vaccine

MED & ENA Nucleotide



LNP/mRNA



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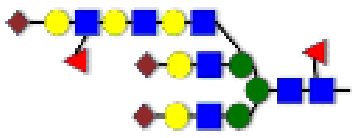

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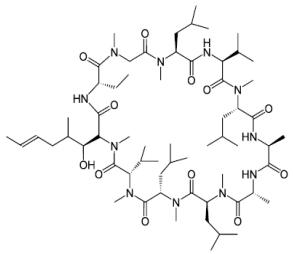
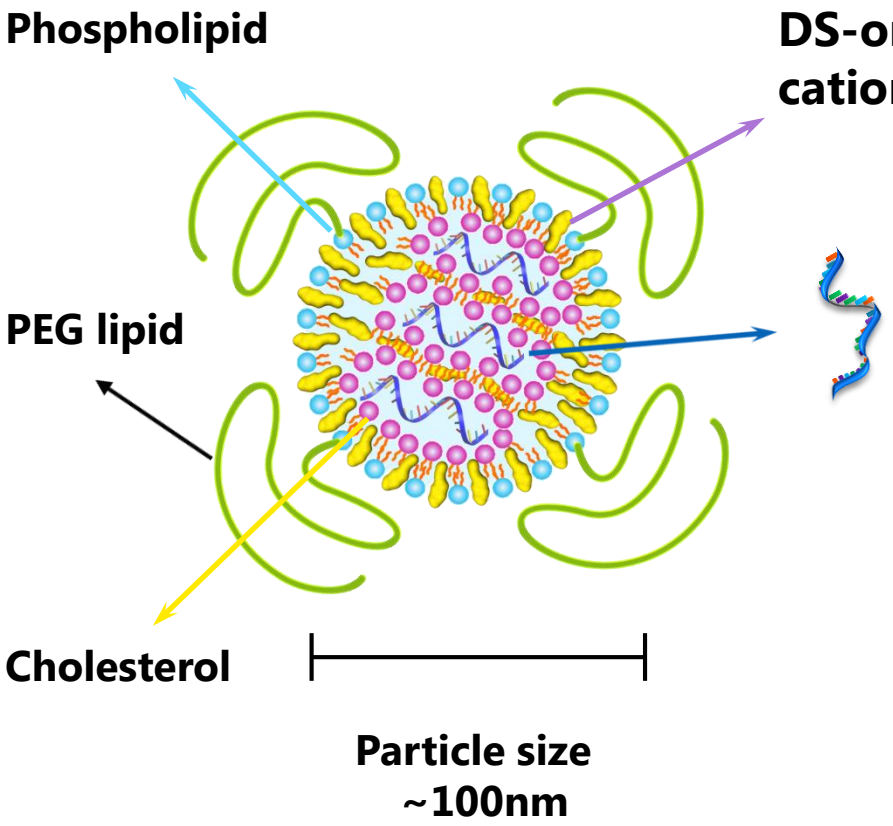


Cyclic peptide Peptide drug

DS-Original Lipid Nanoparticle (LNP)



Nucleic acids

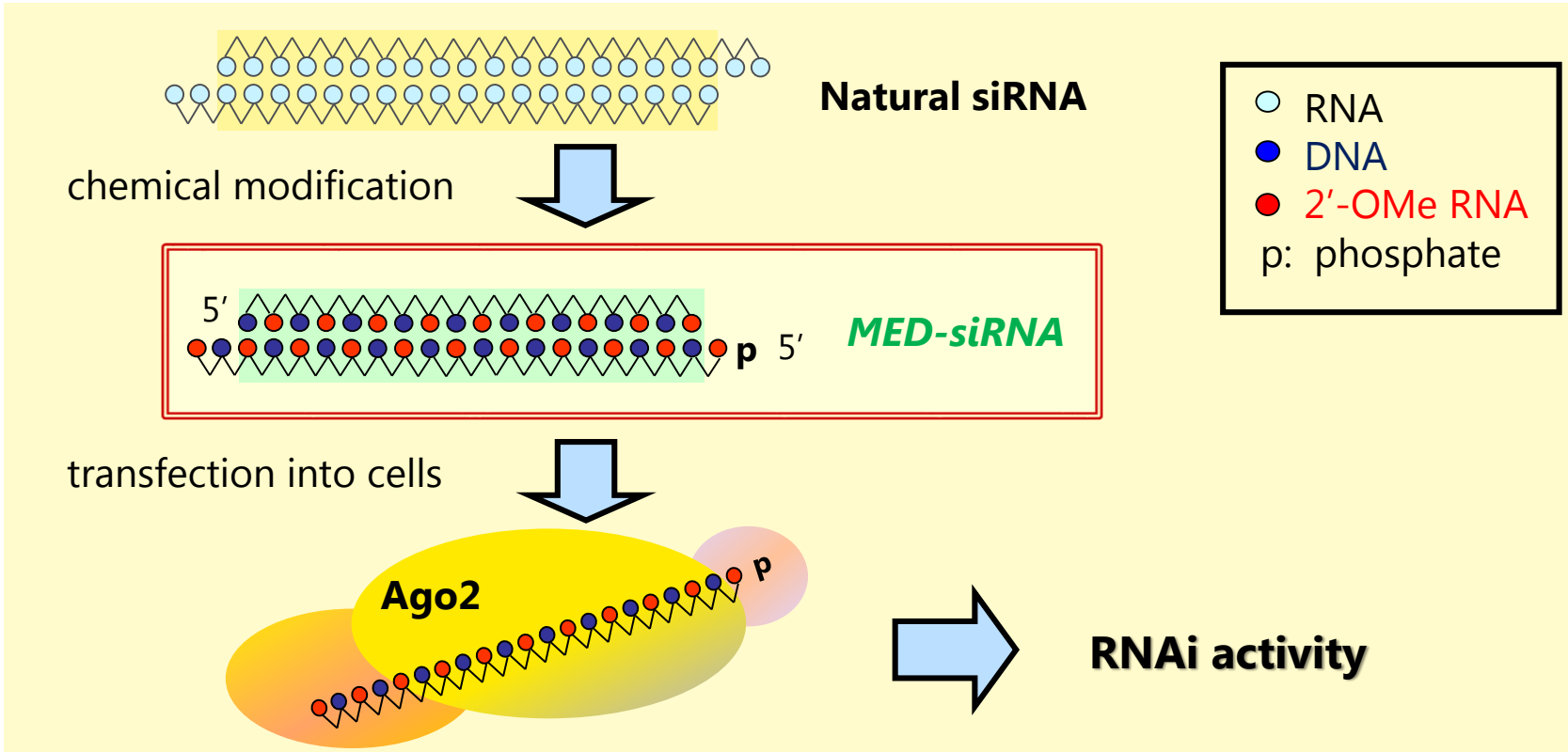
single- or double-strand DNA and RNA, modified oligonucleotides
(e.g. MED-siRNA, mRNA)

Therapeutic application research (cancer, genetic disease etc.) are on-going.

- **Efficient encapsulation of nucleic acids**
- **High nucleic acid delivery ability**
- **Wide safety margin due to metabolizable cationic lipid**
- **Suitable to clinical development**

DS-Original Small Interfering RNA: *MED-siRNA*

MED-siRNA* modified with alternately combined *2′-O-methyl RNA* and *DNA

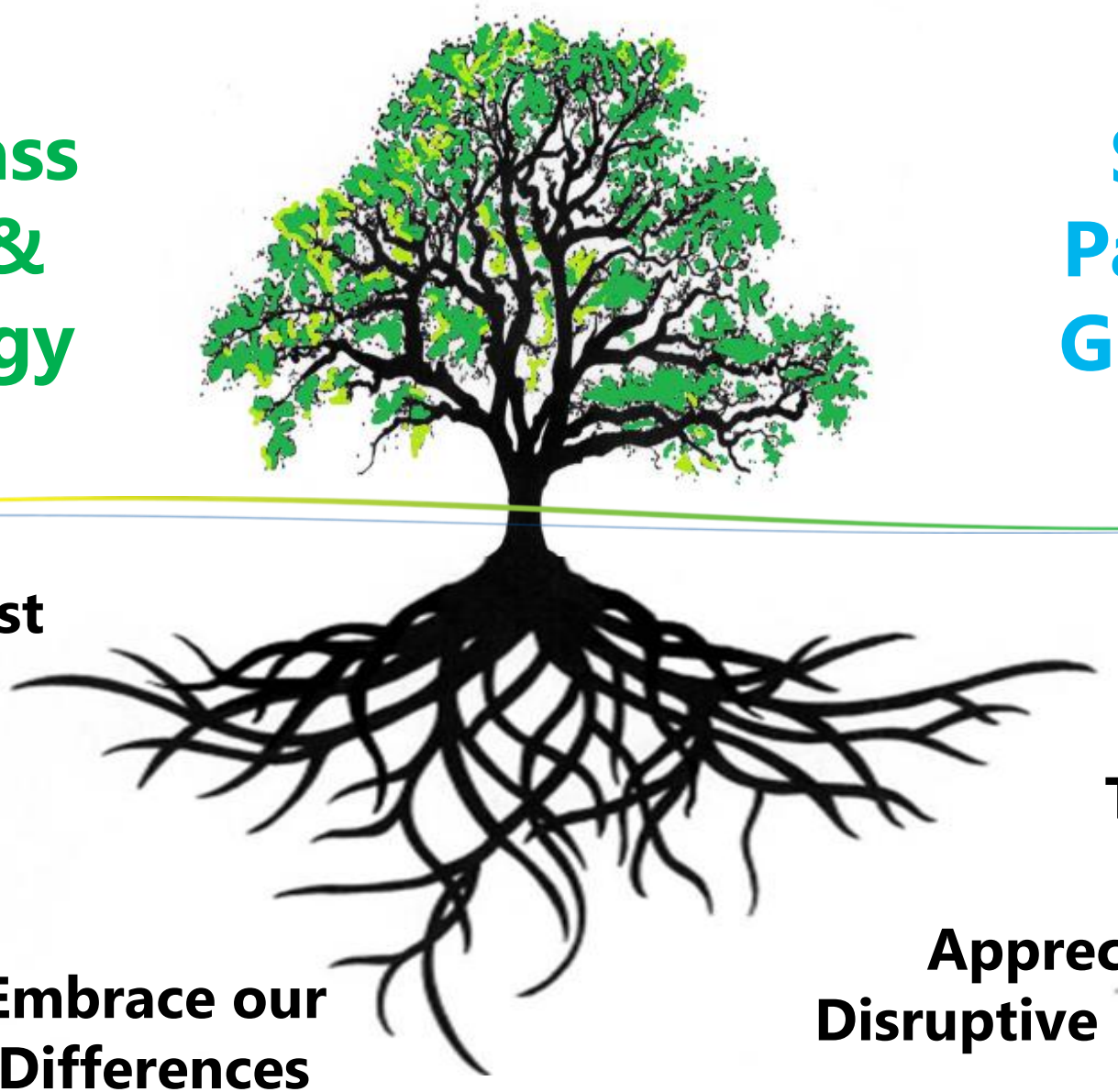


- **Comparable Kd activity with natural siRNA**
- **Low cost & easy manufacture**
- **RNase resistance**
- **Reduction of IFN induction**
- **Avoidance of off-target**

Mindsets & Behaviors which Nourish

World Class Science & Technology

Serve Patients Globally



Trust

Collaboration

Blend the Best of East and West

Transparency

Create Unity

Appreciate Disruptive Mindset

Embrace our Differences

Daiichi-Sankyo
cancerenterprise

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

R&D Day 2019
Progress Report

Antoine Yver, MD, MSc
Executive VP & Global Head R&D Oncology

Today's Agenda

1 Introduction

2 DS-8201: The Data

3 DS-8201: The Collaboration

4 ADC Portfolio: Data and CDP Updates

5 DXd ADC ILD

6 "3 and Alpha"

7 News Flow and Future Events

Today Marks A Critical Step on Our Journey

Daiichi-Sankyo cancerenterprise

2016

Cancer Enterprise Strategy

- Accelerated DS-8201 and scale of manufacturing (300M$ CAPEX)
- Predicted 2019 crunch point for CE, needing ~100% RD Unit Budget

2017

R&D Strategy and Cancer Enterprise 2025

- '7 in 8' CE 2025
- Enhanced CE allocation of R&D resources

2018

ADC Franchise Strategy

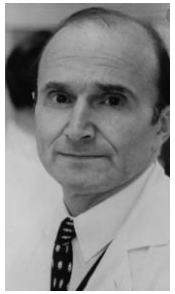
- Highlighted the scope of opportunity offered by the DXd platform
- Defined choices for operating model to maximize the ADC franchise value
- Validated ADC strategy with AZ agreement

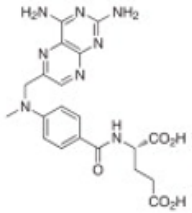
2019

"3 and Alpha" Strategy

History of Antibody Drug Conjugates (ADCs)

Paul Ehrlich





George Mathé

1913
Paul Ehrlich described the concept of a "magic bullet" and drug targeting (i.e. a 'haptophore' that can deliver a 'toxophore' selectively to a tumor)

1958
MTX* linked to an antibody directed toward leukemia cells

1967
ADCs proposed; immunoradioactive agent disclosed

1972
Noncovalent linked ADC tested in animal models

1975
Production of mABs using hybridoma-based technology

Covalent linked ADCs tested in animal models

1983
Clinical trials w/ ADC vindesine-αCEA

1988
Humanized mAbs reported

1991
Immunogenicity of mouse mAbs a serious limitation in development of ADCs

1993
ADC w/ highly potent cytotoxin calicheamicin

2000
First FDA approved ADC (Mylotarg®)

2010
Mylotarg® withdrawn from market

2011
Adcetris® approved

2013
Kadcyla® approved

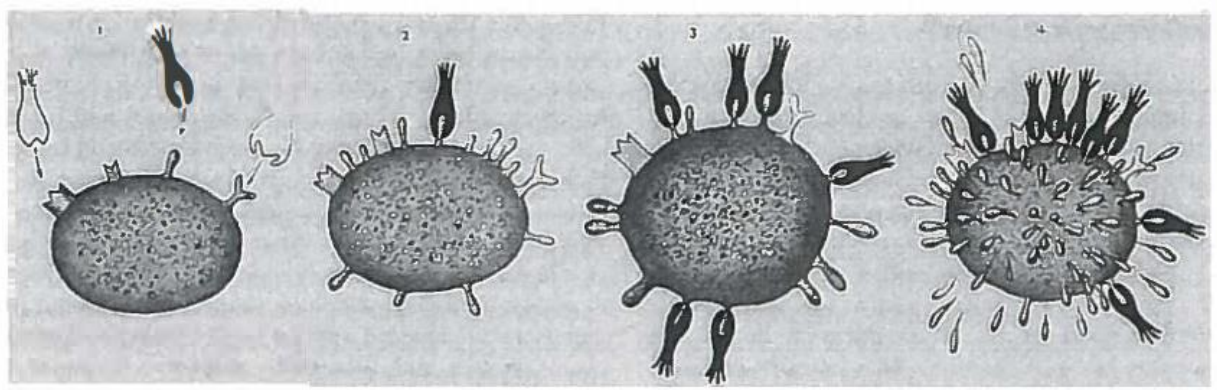
1910 | 1920 | 1930 | 1940 | 1950 | 1960 | 1970 | 1980 | 1990 | 2000 | 2010

*MTX = methotrexate

Adapted from *Drug Discovery Today*

History of ADCs

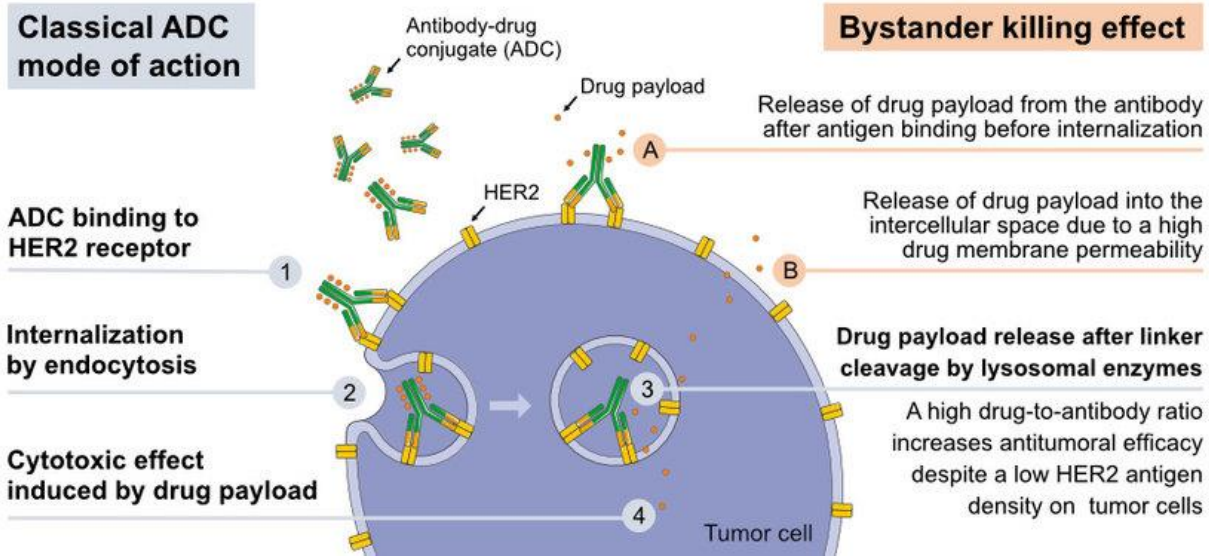
From a brilliant concept to DXd break-through technology



Ehrlich's early (1900) views "on cellular metabolism, and the mode of toxin action and antitoxin formation during the process of immunization" (Courtesy of the Royal Society)

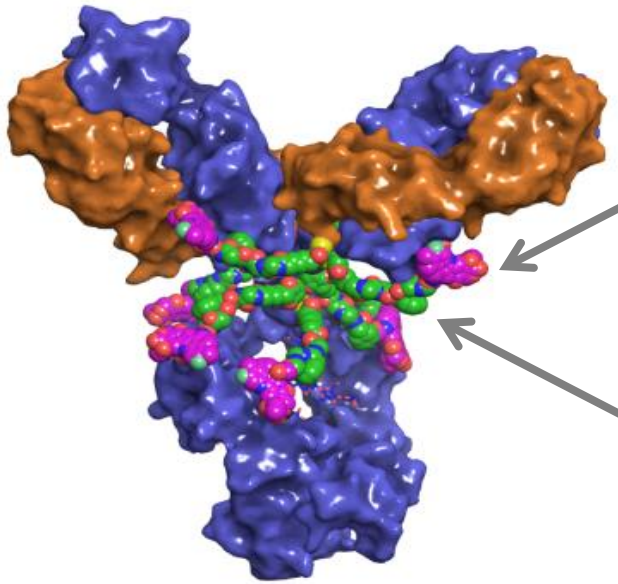
1913 Nobel Prize

DS-8201
2019



DXd ADC ‘Smart Chemo’ Technology Platform

Seven major innovations | Daiichi Sankyo has created seven major technologies on two critical components of the ADC: payload and linker



PAYLOAD

- A novel MOA of cytotoxic Topoisomerase 1 inhibitor
- 10 times more potent than SN38
- A high cell membrane cross-penetration that creates a “bystander effect” to kill neighboring tumor cells
- Short systemic half-life of released payload

LINKER

- High stability, sparing non-cancerous normal tissue from exposure to toxicity
- Selectively cleaved by lysosomal enzymes that tend to be upregulated in tumors
- High number of payload molecules per antibody (Drug-Antibody Ratio; DAR)

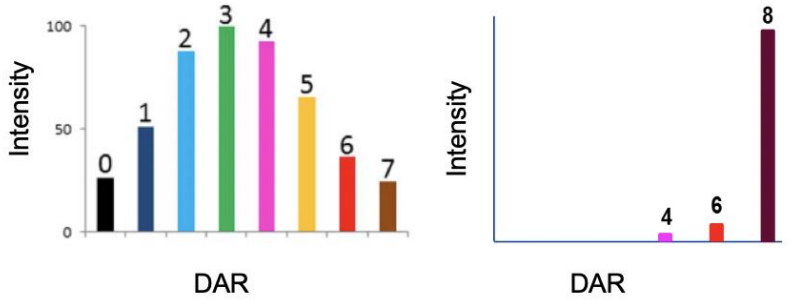
Additional Technology for DXd ADCs

Drug Antibody Ratio (DAR) 4 Conjugation

DAR8: DS-8201, U3-1402

High Drug Antibody Ratio
Compared to T-DM1

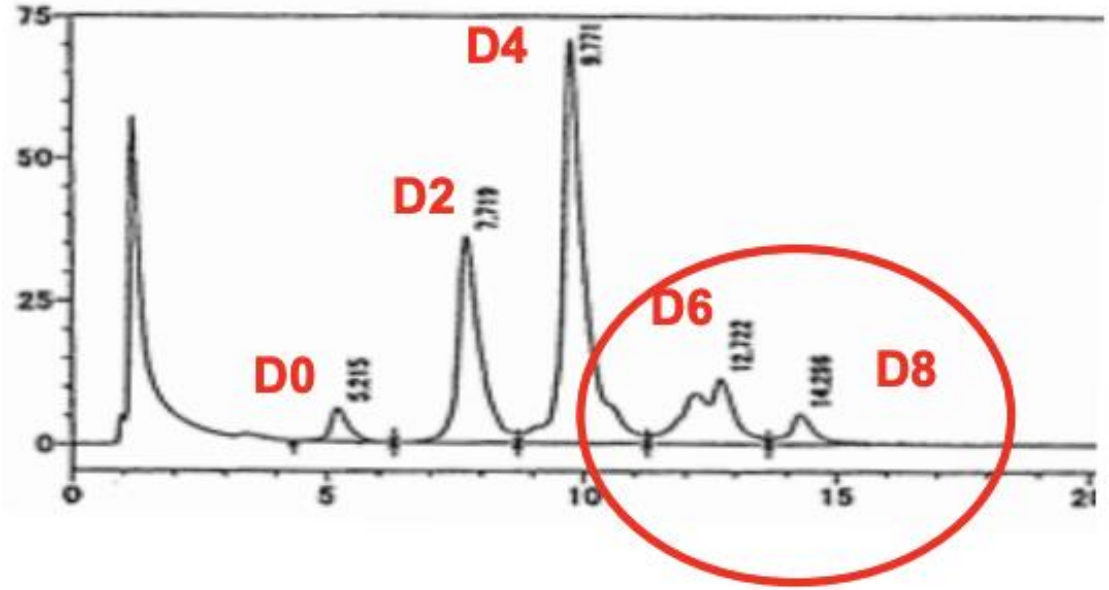
	T-DM1	DS-8201
Antibody	Trastuzumab	Anti-HER2 Ab
Payload	Tubulin inhibitor (DM1)	DNA Topoisomerase I inhibitor (DXd)
DAR	3.5	7-8



Source: Ogitani Y *et al.*, Clin. Cancer Res. 2016; 22:5097-5108, Marcoux J *et al.*, Protein Science 2015; 24:1210-1223

DAR4: DS-1062, DS-7300

D4-enriched DAR4



Today's Agenda

1 Introduction

2 DS-8201: The Data

3 DS-8201: The Collaboration

4 ADC Portfolio: Data and CDP Updates

5 DXd ADC ILD

6 "3 and Alpha"

7 News Flow and Future Events

Trastuzumab Deruxtecan (DS-8201) in HER2-Positive Metastatic Breast Cancer Previously Treated With T-DM1: DESTINY-Breast01 Study

Ian Krop, Cristina Saura, Toshinari Yamashita, Yeon Hee Park, Sung-Bae Kim, Kenji Tamura, Fabrice André, Hiroji Iwata, Yoshinori Ito, Junji Tsurutani, Joohyuk Sohn, Neelima Denduluri, Christophe Perrin, Kenjiro Aogi, Eriko Tokunaga, Seock-Ah Im, Keun Seok Lee, Sara Hurvitz, Javier Cortes, Caleb Lee, Shuquan Chen, Lin Zhang, Javad Shahidi, Antoine Yver, Shanu Modi

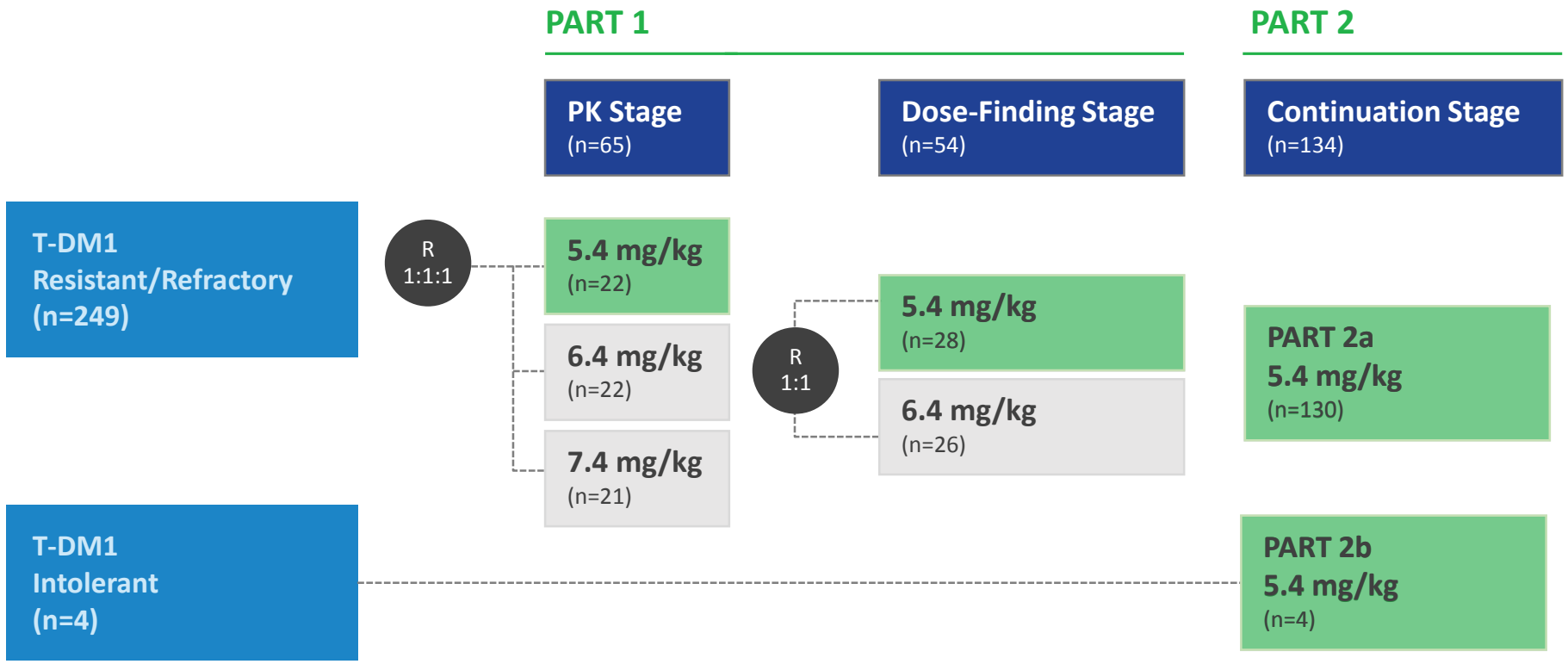
On behalf of the DESTINY-Breast01 investigators

These data are published simultaneously in NEJM on Dec 11, 2019 *Link to NEJM*

DESTINY-Breast01 Study Design:
An Open-Label, Multicenter, Phase 2 Study

Population

- ≥18 years of age
- Unresectable and/or metastatic BC
- HER2-positive (centrally confirmed on archival tissue)
- Prior T-DM1
- Stable, treated brain metastases were allowed



Endpoints

- **Primary:** confirmed ORR by independent central imaging facility review per RECIST v1.1
- **Secondary:** investigator-assessed ORR, DCR, DOR, CBR, PFS, OS, PK and safety

Data Cutoff: August 1, 2019

- **79 patients** (42.9%) are ongoing
- **105 patients** (57.1%) discontinued, primarily for progressive disease (28.8%)

Patient Baseline Characteristics

	Patients T-DXd 5.4 mg/kg (N=184)[a]
Age, median (range), years	55.0 (28-96)
Female, %	100
Region, % Asia / North America / Europe	34.2 / 28.8 / 37.0
ECOG performance status 0 / 1 / 2, %	55.4 / 44.0 / 0.5
Hormone receptor positive / negative / unknown, %	52.7 / 45.1 / 2.2
HER2 expression, %[b] IHC 3+ IHC 2+; ISH+ /IHC 1+; ISH+	 83.7 15.2 / 1.1
Presence of visceral disease, %	91.8
History of brain metastases, %	13.0

[a]All 184 patients received ≥1 dose of T-DXd. [b]HER2 status was centrally assessed on archival tissue according to guidelines of the American Society of Clinical Oncology–College of American Pathologists.

ECOG, Eastern Cooperative Oncology Group; IHC, immunohistochemistry; ISH, in situ hybridization.

Patient Baseline Characteristics *(cont'd)*

Median prior lines of cancer therapy: 6 (range 2-27)

Prior Treatment[a]	Patients, % T-DXd 5.4 mg/kg (N=184)
Trastuzumab	100
T-DM1	100
Pertuzumab	65.8
Other anti-HER2 therapies	54.3
Hormone therapy	48.9
Other systemic therapy	99.5

[a]Therapies for locally advanced or metastatic breast cancer, including hormone therapy.

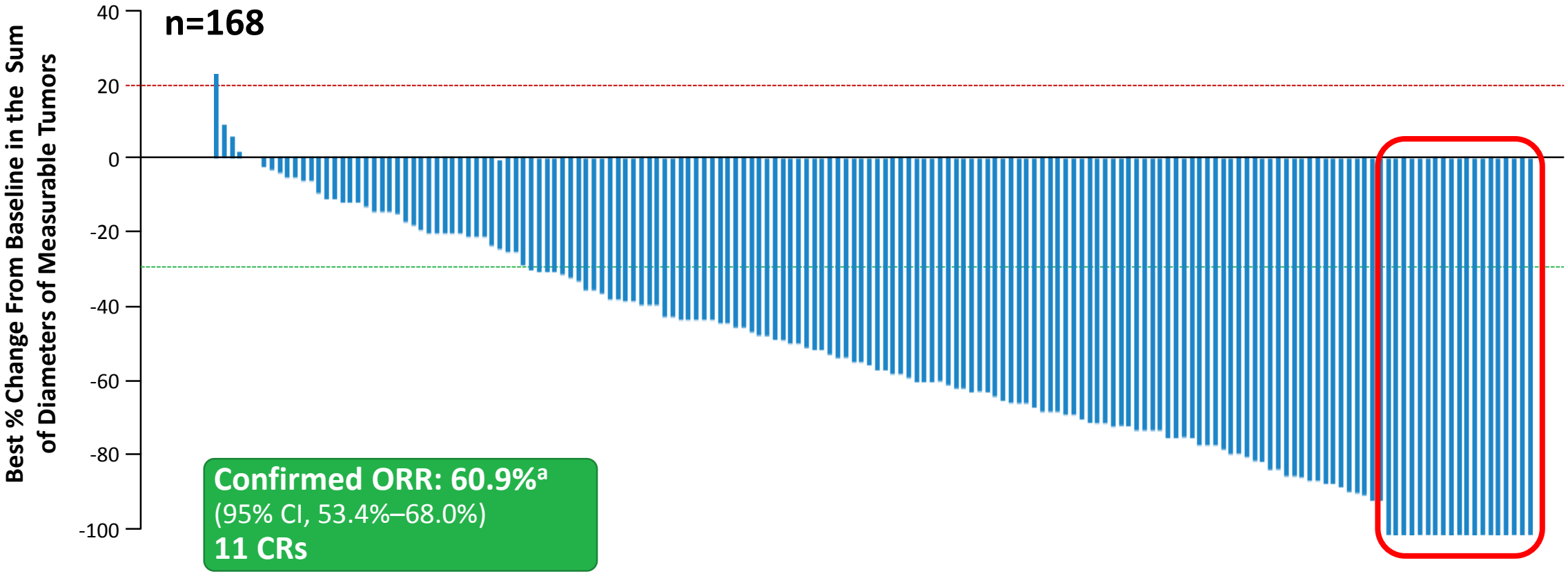
Primary Endpoint: Overall Response Rate

Intent-to-treat analysis	Patients T-DXd 5.4 mg/kg (N = 184)
Confirmed ORR by ICR	**60.9% (n = 112)** (95% CI, 53.4%-68.0%)
CR	6.0% (n = 11)
PR	54.9% (n = 101)
SD	36.4% (n = 67)
PD	1.6% (n = 3)
Not evaluable	1.1% (n = 2)
DCR	97.3% (95% CI, 93.8%-99.1%)
CBR × 6 months	76.1% (95% CI, 69.3%-82.1%)
Duration of response, median	14.8 months (95% CI, 13.8-16.9)

- Median time to response was 1.6 months (95% CI, 1.4-2.6 months)

CBR, clinical benefit rate (SD for ≥6 mo + CR + PR); CR, complete response; DCR, disease control rate (CR + PR + SD); ICR, independent central review; ORR, objective response rate (CR + PR); PD, progressive disease; PR, partial response; SD, stable disease.

Best Change in Tumor Size

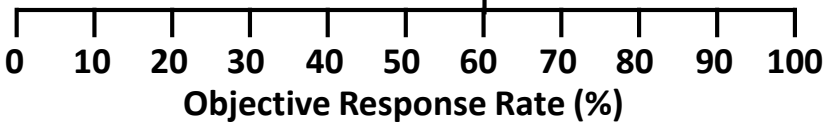


The line at 20% indicates progressive disease; the line at −30% indicates partial response.

[a] Includes all patients who received T-DXd 5.4 mg/kg (intent-to-treat analysis; N=184).

Overall Response Rate by Subgroup

		ORR, %	[95% CI]
All Patients[a]	N=184	**60.9**	[53.4-68.0]
Prior pertuzumab	Yes (n=121)	**64.5**	[55.2-73.0]
	No (n=63)	**54.0**	[40.9-66.6]
Hormone receptors	Positive (n=97)	**57.7**	[47.3-67.7]
	Negative (n=83)	**66.3**	[55.1-76.3]
Brain metastasis	Yes (n=24)	**58.3**	[36.6-77.9]
	No (n=160)	**61.3**	[53.2-68.8]
Presence of visceral disease	Yes (n=169)	**60.4**	[52.6-67.8]
	No (n=15)	**66.7**	[38.4-88.2]
Region	Asia (n=63)	**58.7**	[45.6-71.0]
	North America (n=53)	**62.3**	[47.9-75.2]
	Europe (n=68)	**61.8**	[49.2-73.3]
ECOG performance status	0 (n=102)	**65.7**	[55.6-74.8]
	1 (n=81)	**55.6**	[44.1-66.6]
HER2 positive	IHC 3+ (n=154)	**63.0**	[54.8-70.6]
	IHC 1+/2+ (n=28)	**46.4**	[27.5-66.1]

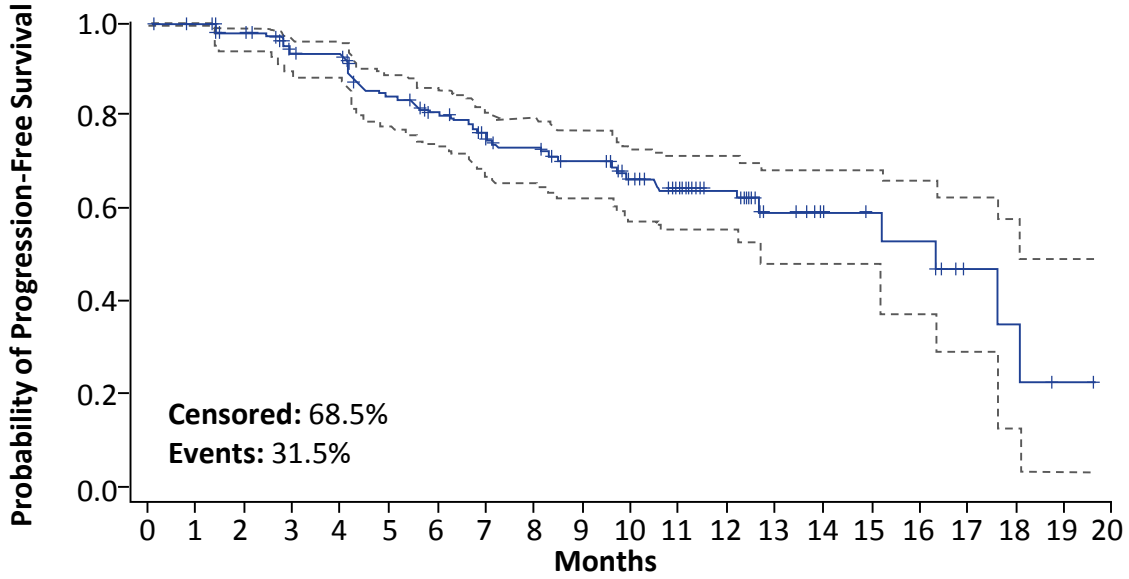


[a]Patients who received T-DXd 5.4 mg/kg.

Progression-Free and Overall Survival

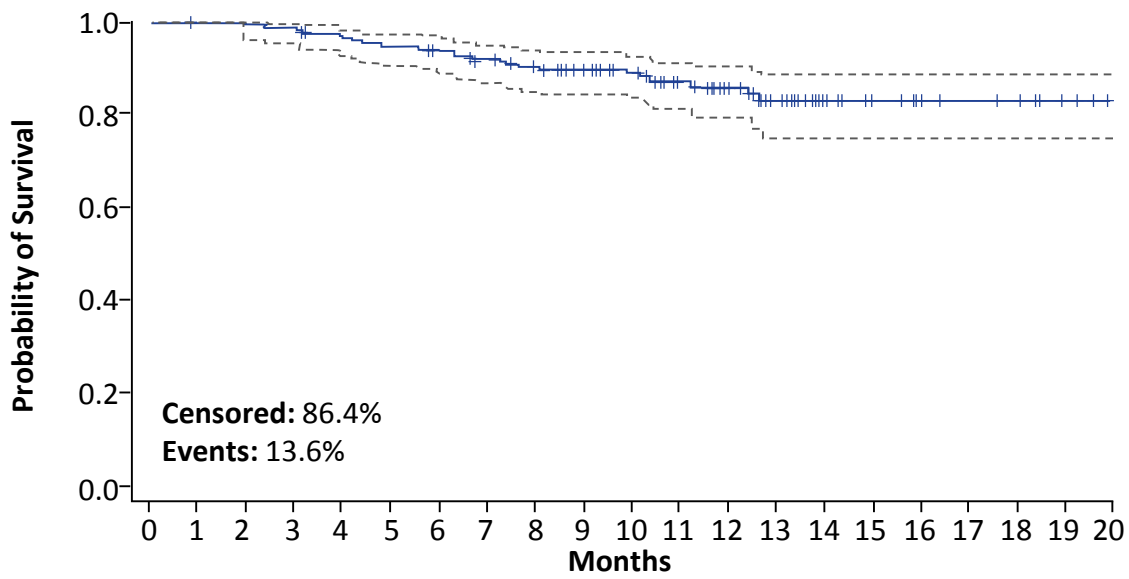
Progression-Free Survival

Median: 16.4 months (95% CI, 12.7-NE)



Overall Survival

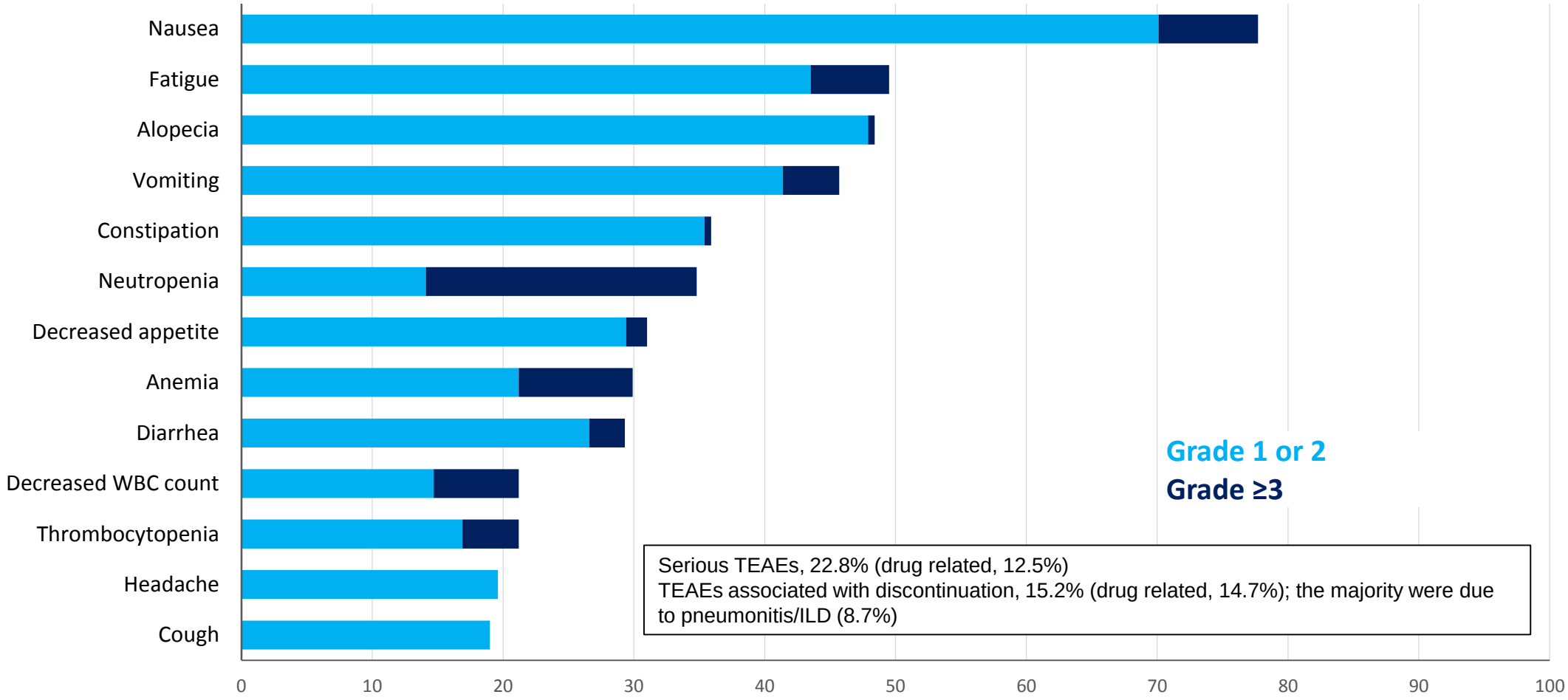
Median: Not reached (95% CI, NE-NE)



- Median follow-up, 11.1 months (range, 0.7-19.9 months)
- Median PFS in the 24 patients with brain metastases was 18.1 months (95% CI, 6.7-18.1 months)[a]

Patients who received T-DXd 5.4 mg/kg.
CI, confidence interval; NE, not estimable.

Treatment-emergent Adverse Events in >15% of Patients



Patients who received T-DXd 5.4 mg/kg.

Adverse Events of Special Interest: LVEF

	Patients who received T-DXd 5.4 mg/kg (N=184)					
Preferred Term, n (%)	**Grade 1**	**Grade2**	**Grade 3**	**Grade 4**	**Grade 5**	**Any Grade/ Total**
Cardiac failure	1 (0.5)	0	0	0	0	1 (0.5)
Cardiac failure congestive	0	1 (0.5)	0	0	0	1 (0.5)
Ejection fraction decreased[a]	0	2 (1.1)	1 (0.5)[b]	0	0	3 (1.6)

- No events of cardiac failure with LVEF decline were reported
- No patients had an LVEF of <40% or a decrease of ≥20% at any timepoint
- 4 out of the 5 subjects continued on treatment for 2–18 cycles

[a]All patients were asymptomatic and recovered/recovering after interruption of study treatment.
[b]LVEF was >55% during treatment.
LVEF, left ventricular ejection fraction.

Adverse Events of Special Interest: Interstitial Lung Disease (ILD)

	Patients who received T-DXd 5.4 mg/kg (N=184)					
Preferred Term, n (%)	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**	**Any Grade/ Total**
Interstitial lung disease	5 (2.7)	15 (8.2)	1 (0.5)	0	4 (2.2)	**25 (13.6)**

Drug related; ILD was determined by the Independent ILD Adjudication Committee based on 44 preferred terms.

Among the 25 total events:

- Median time to investigator-reported onset was 193 days (range, 42-535 days)
- 13 of 20 patients with grade ≥2 ILD received corticosteroids
- 7 patients recovered, 2 were recovering, 12 were either outcome unknown or not followed until resolution, and 4 died
- Of the 4 fatal cases, onset was from 63-148 days, 3 received steroids as part of treatment, and death occurred 9-60 days after ILD diagnosis

Recommendations: Monitor for symptoms. Hold T-DXd and start steroids as soon as ILD is suspected

ILD, interstitial lung disease.

DS-8201*

How does it compare vs historical HER2 agents in HER2 metastatic 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	**16.4m**
DoR	20.2m	20.7m	12.6m	9.7m	**14.8m**
OS	56.5m	53.7m	30.9m	22.7m	**NE**
ORR	80%	60%	43.6%	31%	**60.9%**
Median prior Rx for adv. disease	0	0	1	4	**6** 100% prior T-DM1 66% prior pertuzumab

[1]CLEOPATRA (NEJM 2012), [2]MARIANNE (J Clin Oncol 2017), [3]EMILIA (NEJM 2012), [4]TH3RESA (Lancet Oncol 2017),
[5]Lancet Oncology, April 29, 2019, m: Month, NR:Not Reached
*DS-8201 is an investigational agent; efficacy and safety have not been established.

So what have we seen so far…..?

- ADC concept was first described in 1913, and it took until now to really break through

- **DS-8201 is**, first and foremost, a massively advanced **technological break through**
  - It was designed to achieve best-in-class technology
  - It delivers unique practice-changing evidence

- **Breast cancer doctors don't 'think' ILD**
  - We do not shy away from discussing the importance of monitoring, and actively screening and treating any suspicion of ILD

DS-8201 | Remarkable Speed in Development & Manufacturing Scale up

DS-8201
First Patient Ever
Sep. 2015

[fam-] trastuzumab deruxtecan
BLA: Aug. 2019

~ 4 Years

Keytruda® is 2nd fastest US biologics ever:
FTIH to US market 4.5 years… so DS-8201 can possibly break this precedent

Japan NDA submitted & accepted 09 Sep. 2019; EU MAA tracking to plan

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DS-8201 | Strategic Collaboration with AstraZeneca

Unique Science

Daiichi-Sankyo | AstraZeneca

Extensive expertise in oncology

Opportunity for strategic collaboration with excellent partner with a rich heritage in breast cancer

Accelerate building in-house oncology business infrastructure, while optimizing resources

Maximize product value oncology products

- Earlier penetration in global market
- Expand to new indications

DS-8201 | Immediate Benefits of the Collaboration

Together, we have achieved much!

Daiichi-Sankyo | AstraZeneca

Optimized Resources with Accelerated Development

- Regulatory submissions on time with joint review and rapid alignment
- Joint clinical operations working group to accelerate study initiation
- Leverage AZ's ongoing platform studies (HUDSON/BEGONIA) with DS-8201 cohort
- Joint IT working group to support upcoming DS-8201 studies

Maximizing Product Value

- Joint Clinical Development Plan (CDP) updated with **26** new studies
- Multiple indications studied in parallel
- Joint Translational / CDx Working Group to optimize patient selection and execution across the program
- Collaboration with ex-US development teams to penetrate global markets
- Partnerships with patient advocacy groups in support of ongoing DESTINY trials

DS AZ Collaboration Fully Finances ADC's Development

- At a speed and scale DS alone could not have supported
- Whilst preserving DS' ability to progress the rest of our portfolio

- Next fiscal year 2020, we'll spend externally
  - ✓ DS-8201: ~175% of current DS-8201 FY2019 spend (Daiichi Sankyo part)
  - ✓ DS-1062 and U3-1402: ~175% of current FY2019 spend on these 2 assets

Our Obligation for DS-8201

Transform treatment for HER2 tumors, as they will newly be defined

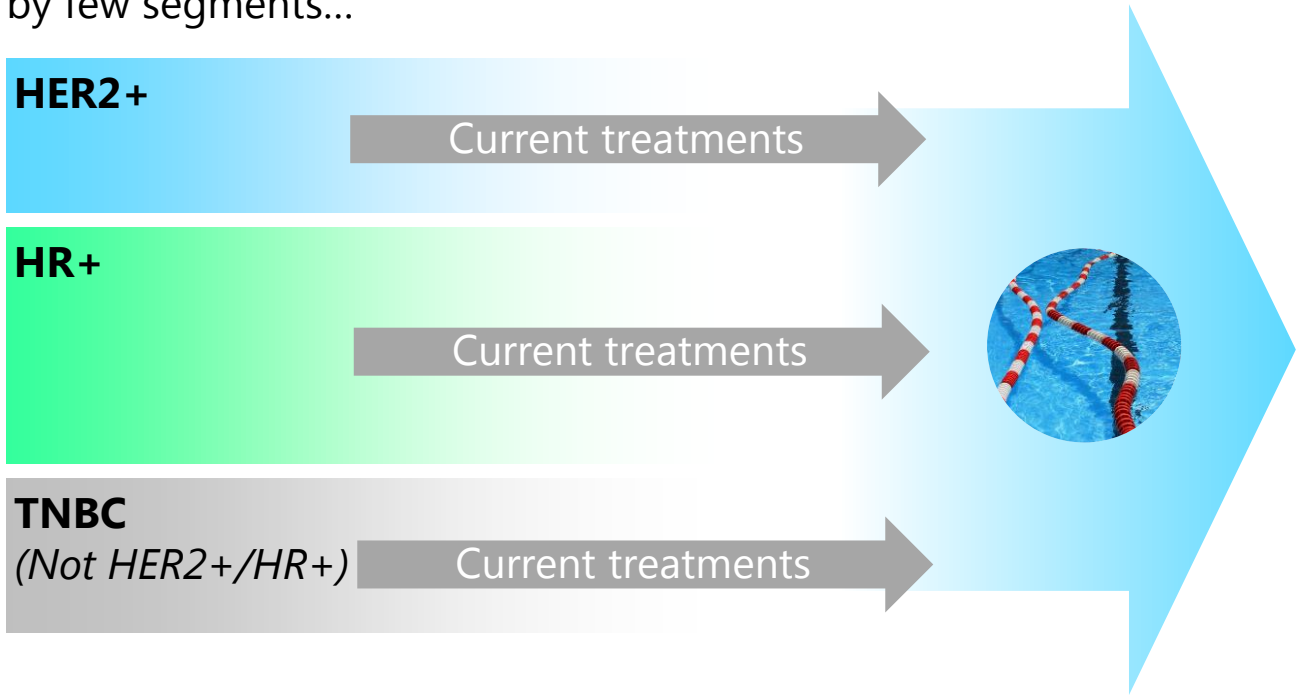
HER2+ met BC	**Establish DS-8201 as the new SoC in HER2+ BC**	**2020-2022:** • Establish DS-8201 as SOC in 3L • Move quickly into 2L based on head-to-head data
HER2+ early BC		• Optimize opportunity in earlier settings
HER2 Low met BC	**Redefine the BC treatment paradigm**	Disrupt the current BC treatment paradigm with new HER2 Low characterization Optimize testing and access as the first targeted agent for HER2 Low patients
Other tumors	**Expand leadership across other tumors**	Transform treatment across HER2 tumors (NSCLC, GC, CRC)

Changing the Breast Cancer Clinical Paradigm

Breaking swim lanes

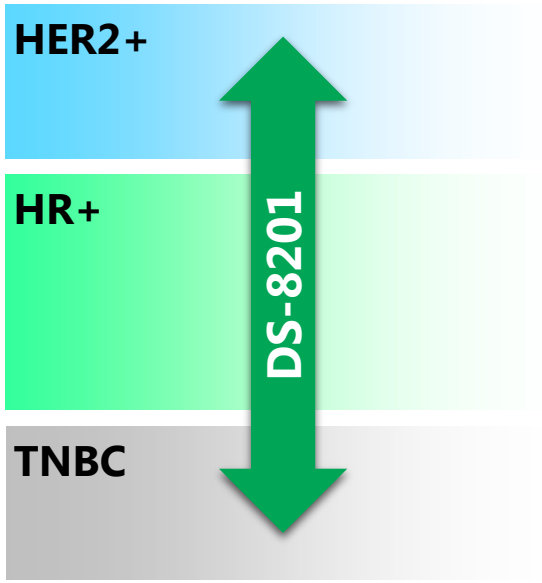
Traditional Paradigm

Patients and treatments defined by few segments…



Future Paradigm

Define new biology-driven characterization



DS-8201 Vision | Transform Treatment for HER2 Tumors

Starting 16 studies in next 18 months

Extend use of DS-8201 to GC, NSCLC and CRC

Develop **combination strategy** / Explore tumor-agnostic opportunities

Start 6 Registration & 4 Ph2 studies in next 18 mo

Expand leadership across HER2 expressing tumors

Create a **new treatment paradigm** in HER2low mBC

Shape a new CDx framework in mBC

Start 2 Registration studies & 1 Ph2 study in the next 18 mo

Redefine Breast Cancer treatment paradigm

Build on unprecedented data in HER2+

Start 2 Registration & 1 Ph2 studies in next 18 mo

Establish DS-8201 as the new SOC in HER2+ Breast Cancer

Summary of CDP of DS-8201: directional view

Green: Today's focus (Studies newly aligned with AZ)

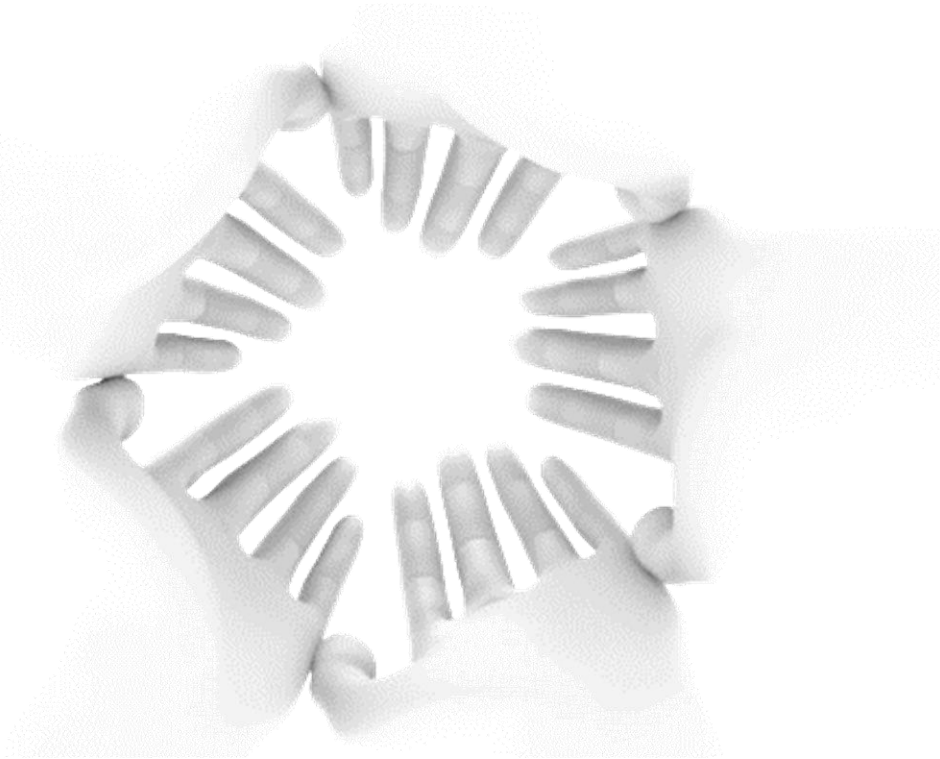
Total 43 studies

Tumors	# of studies	Deal defined Studies	Added Studies
Breast Cancer HER2+	**9**	4 studies (3 DS ongoing studies, 1 new registrational study)	5 studies (4 Registrational intent & 1 Platform)
Breast Cancer HER2 Low	**7**	2 studies (1 DS ongoing studies, 1 new registrational study)	5 Studies (3 Registrational intent & 2 Platform)
Lung	**7**	2 studies (1 DS ongoing studies, 1 new Ph2 study)	5 Studies (4 Registrational intent & 1 Ph1/2)
Gastric	**5**	2 studies (2 DS ongoing studies)	3 studies (2 Registrational intent & 1 Ph1/2)
Colorectal Cancer	**6**	1 Studies (1 DS ongoing studies)	5 Studies (4 Registrational intent & 1 Ph1/2)
Tumor Agnostic	**3**	N/A	3 studies (1 Registrational intent & 2 Ph1/2)
I/O Combination (other partners)	**2**	2 Studies (2 DS ongoing studies)	N/A
Multiple tumors (FIH)/Clin pharm/Safety	**4**	4 Studies (completed or ongoing)	N/A

The Alliance Vision

Transform treatment for ***HER2*** **Tumors**

Our obligation to patients is beyond what one company can achieve alone.



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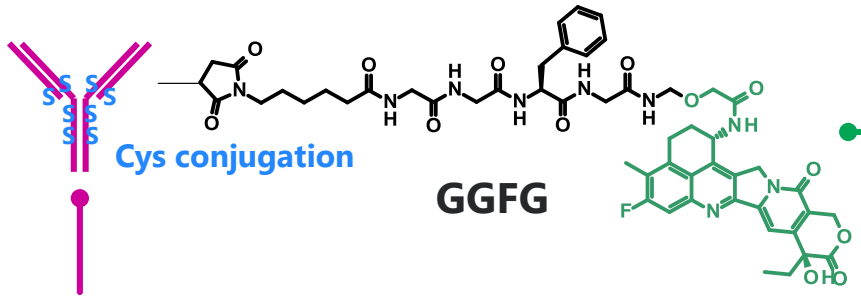
DS-1062 | TROP2 DXd ADC with D4-Enriched DAR4

TROP2 ADC is designed to be best in class



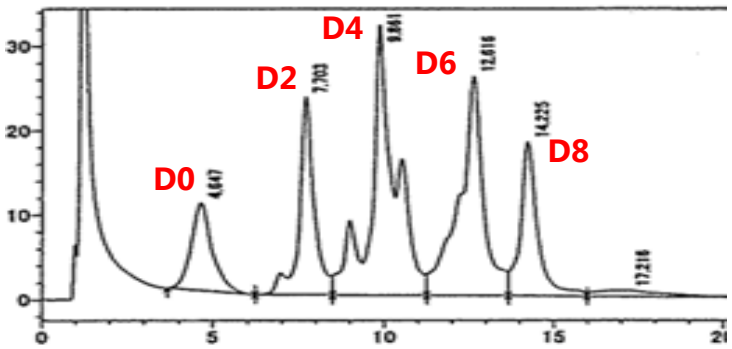
Antibody
Humanized anti-TROP2 monoclonal antibody (hIgG1)

Payload
Topoisomerase I inhibitor

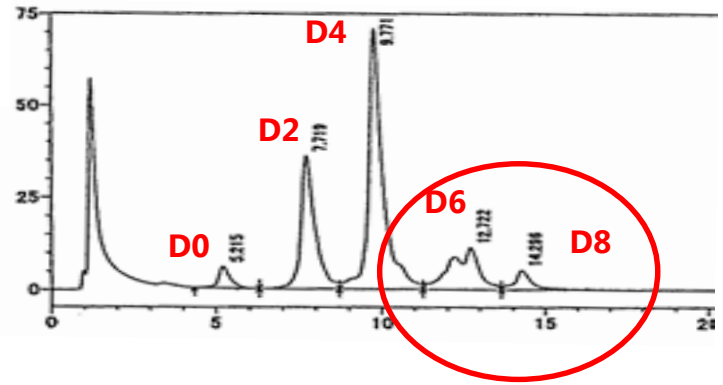
D4-enriched to protect safety margin

Non-selective DAR4		D4-enriched DAR4

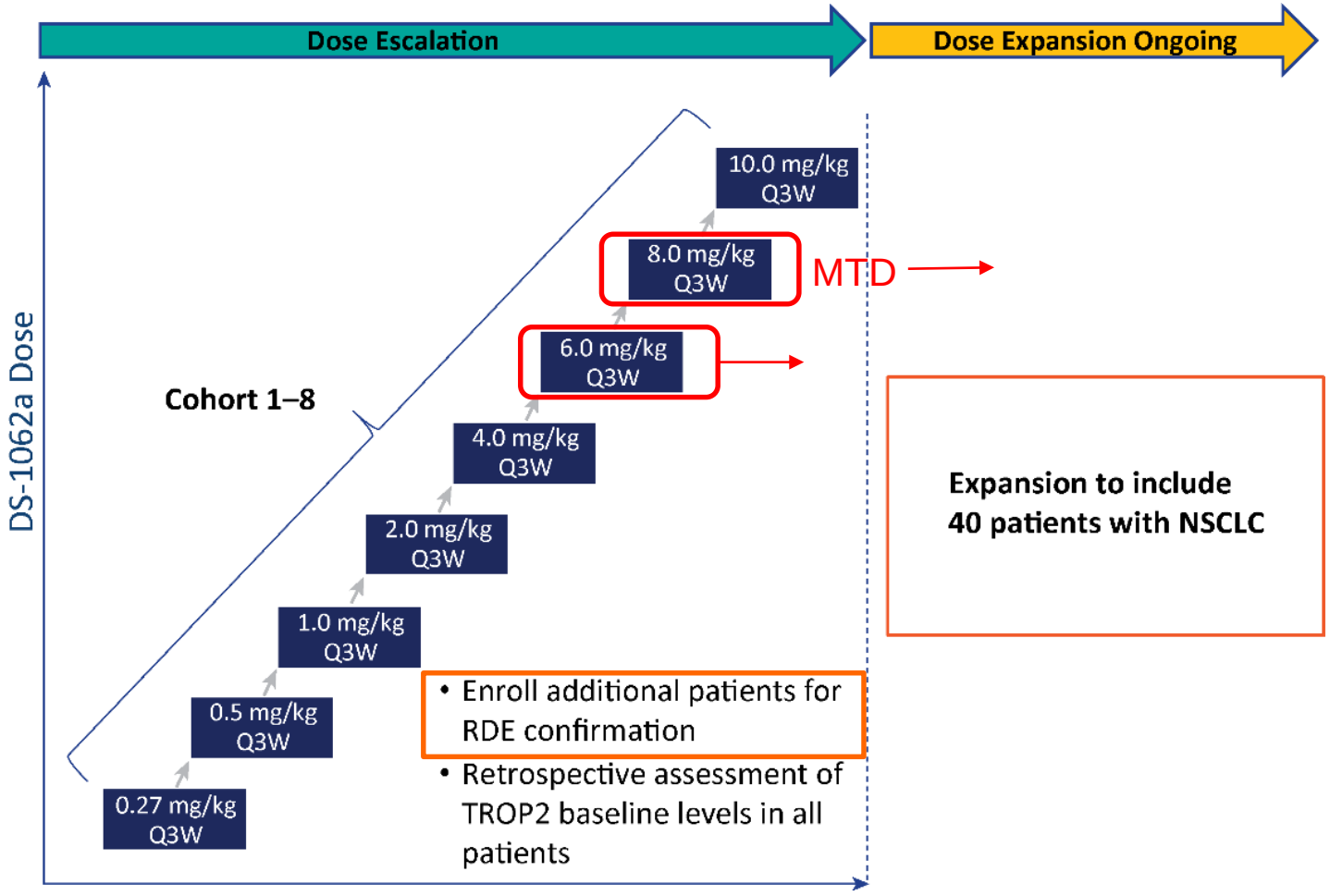
HIC



Optimized conjugation method



DS-1062 | Phase 1 Study Design (NCT03401385)



- Ongoing first-in-human, US and Japan dose escalation and expansion phase 1 study of DS-1062 in unselected pts with unresectable advanced NSCLC relapsed/refractory to SOC
  - Male (57.7%)
  - Stage IV disease (88.5%)
  - Adenocarcinoma histology (73.1%)
  - ECOG PS 1 (80.8%)
  - Failed prior immune checkpoint inhibitors (86.5%)

DLT, dose-limiting toxicity; ECOG PS, Eastern Cooperative Oncology Group performance status; NSCLC, non-small cell lung cancer; Pt, patient; Q3W, every 3 weeks; RDE, recommended dose for expansion; SOC, standard of care; TROP2, trophoblast cell-surface antigen 2.

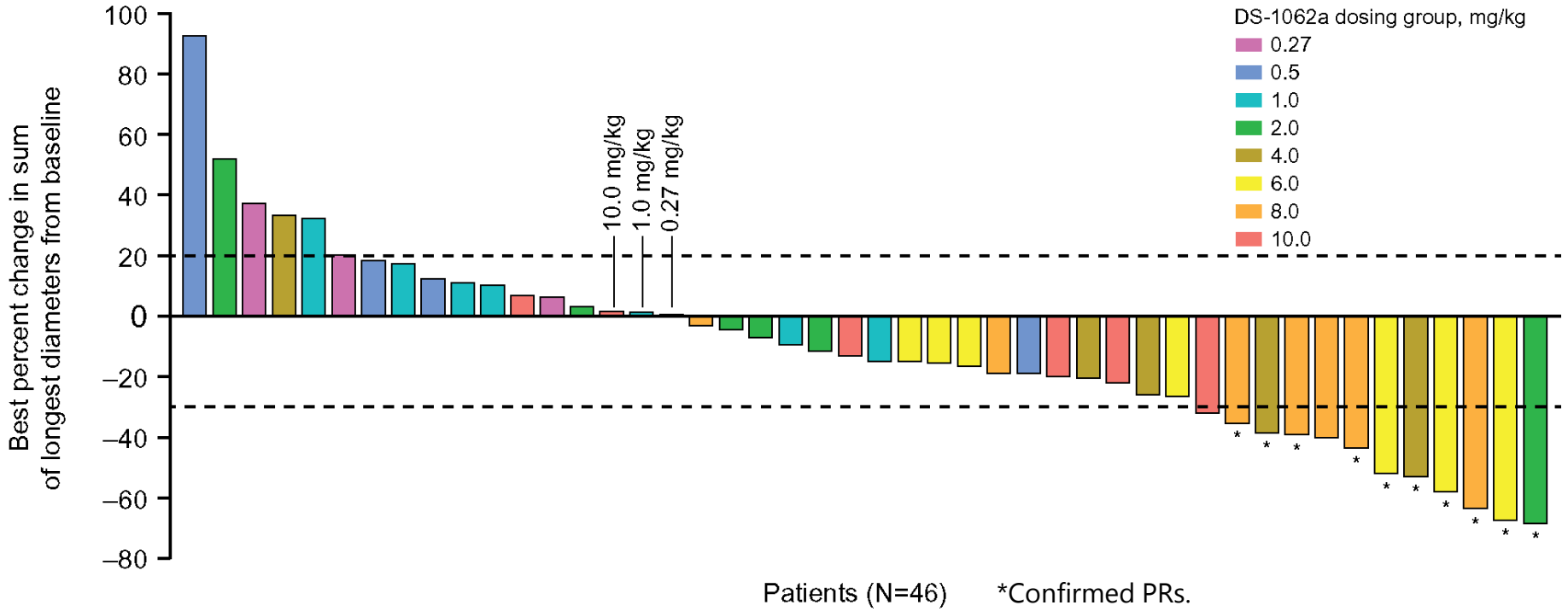
Data cut-off 03Jul2019

Source: Heist-R *et al.*, Abstract #MA25.10, WCLC 2019

DS-1062 | Tumor Response

12 PRs (10 confirmed; 2 too early to confirm) across all doses in dose escalation

- At the 8-mg/kg dose there were 5/7 PRs and 2/7 SDs, and 6/7 pts are ongoing

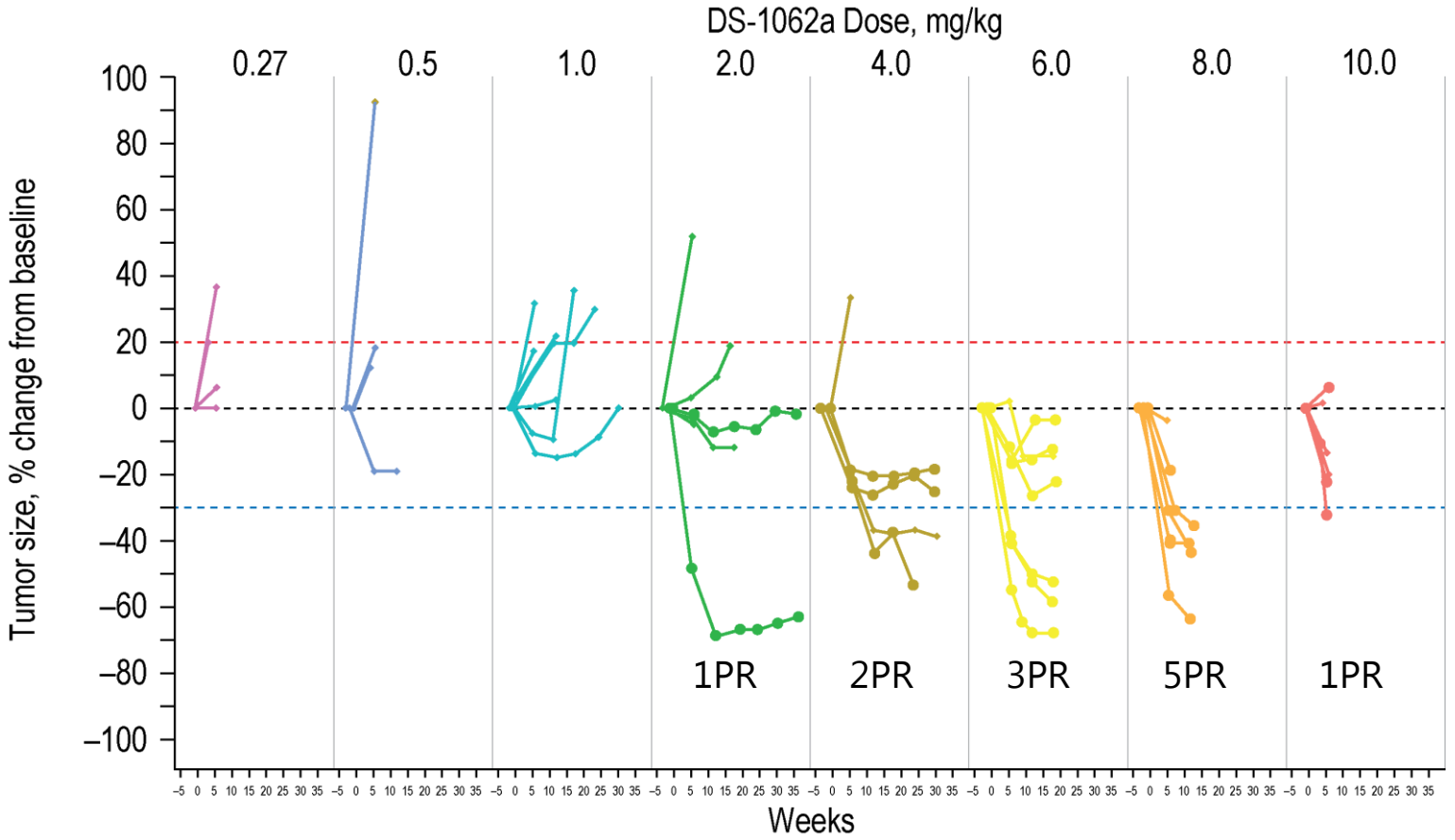


Data cut-off: July 3, 2019.
ALK, anaplastic lymphoma kinase; EGFR, epidermal growth factor receptor, HER2; human epidermal growth factor receptor 2; PD, progressive disease; PR, partial response; Pt, patient; SD, stable disease.

Source: Heist-R *et al.*, Abstract #MA25.10, WCLC 2019

DS-1062 | Tumor Response

Clear dose-effect on frequency of response



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ALK, anaplastic lymphoma kinase; EGFR, epidermal growth factor receptor, HER2; human epidermal growth factor receptor 2; PD, progressive disease; PR, partial response; Pt, patient; SD, stable disease.

Source: Heist-R *et al.*, Abstract #MA25.10, WCLC 2019

DS-1062 | Safety

TEAEs, regardless of causality, (in ≥10% of pts), n (%) (N=52)					
	All Grades	Grade ≥3		All grades	Grade ≥3
Any TEAE	48 (92.3)	22 (42.3)	Constipation	7 (13.5)	0
Fatigue	19 (36.5)	2 (3.8)	Cough	7 (13.5)	0
Nausea	19 (36.5)	0	Diarrhea	7 (13.5)	0
Alopecia	15 (28.8)	0	ALT increased	6 (11.5)	0
Decreased appetite	14 (26.9)	0	Weight decreased	6 (11.5)	0
Anemia	12 (23.1)	0	Dehydration	5 (9.6)	0
Stomatitis/mucosal inflammation	12 (23.1)	2 (3.8)	Dyspnea	5 (9.6)	1 (1.9)
Vomiting	12 (23.1)	0	Headache	5 (9.6)	0
Infusion related reaction	11 (21.2)	0	Pain	5 (9.6)	1 (1.9)
Rash	8 (15.4)	0			

Data cut-off: 03 Jul 2019

- DLT at 10 mg/kg;[a] MTD at 8 mg/kg median exposure duration was 10.6 (range 3.0–43.1) weeks
- Serious TEAEs in 14 (26.9%) pts and death in 3 (5.8%) pts; no deaths were related to study drug
- TEAEs associated with dose reduction,[b] interruption, or discontinuation[c] in 5 (9.6%), 5 (9.6%), and 2 (3.8%) pts, respectively
- One pt (1.9%) with disease progression treated with the 6.0 mg/kg dose developed a pulmonary adverse event of special interest of respiratory failure (grade 5), adjudicated as not an ILD
  - Including cases post-data cutoff, 4 not-yet adjudicated possible ILD reports were observed (1 grade 2 pneumonitis [6.0 mg/kg], 1 grade 2 organizing pneumonia [8 mg/kg], 1 grade 2 pneumonitis [8 mg/kg], and 1 grade 5 [respiratory failure in a pt with disease progression; 8.0 mg/kg])

[a]2 DLTs occurred at the 10-mg/kg dose; 1 pt with mucosal inflammation and another pt with stomatitis. One DLT occurred at the 6-mg/kg dose in a pt with rash maculopapular.
[b]The most frequent TEAE leading to dose reduction was mucosal inflammation (2 pts [3.8%], 10-mg/kg group).
[c]TEAEs leading to drug discontinuation (1 pt each) were pleural effusion (0.27 mg/kg) and pain (2.0 mg/kg).

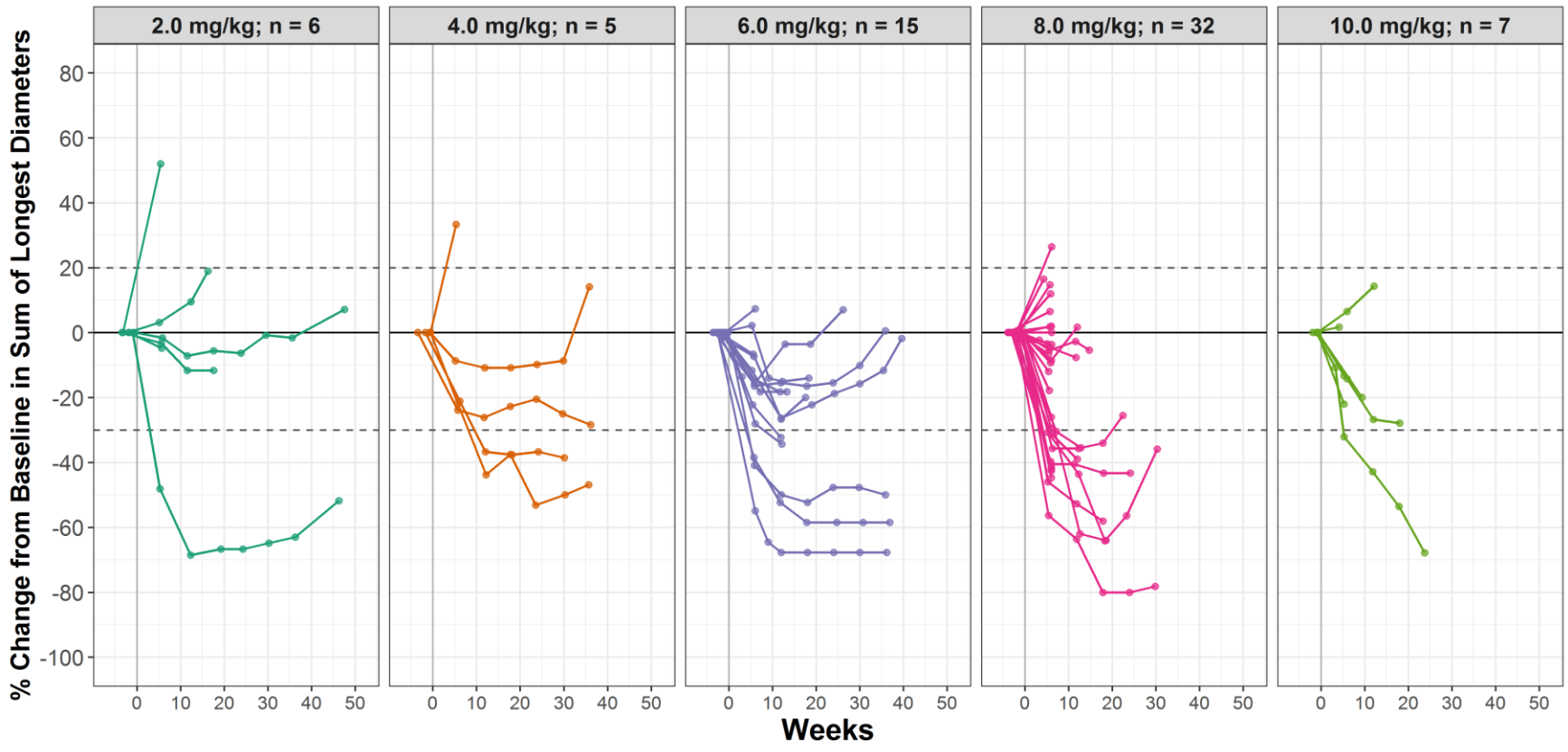
ALT, alanine aminotransferase; DLT, dose-limiting toxicity; ILD, interstitial lung disease; MTD, maximum tolerated dose; PD, progressive disease; Pt, patient; RDE, recommended dose for expansion; TEAE, treatment-emergent adverse event.

Source: Heist-R *et al.*, Abstract #MA25.10, WCLC 2019

DS-1062 | Phase 1 Recent Update | Efficacy* (as of Nov. 16 2019, preliminary data)

Dose dependent increase in tumor response in heavily pretreated, unselected NSCLC patients having progressed on standard of care, including immune checkpoint inhibitors, EGFR inhibitors, and ALK inhibitors

- 6/8 10mg/kg subjects discontinued quickly due to AEs
- 83% of patients received a prior immune check point inhibitor



*Source: Internal data on file at Daiichi Sankyo.

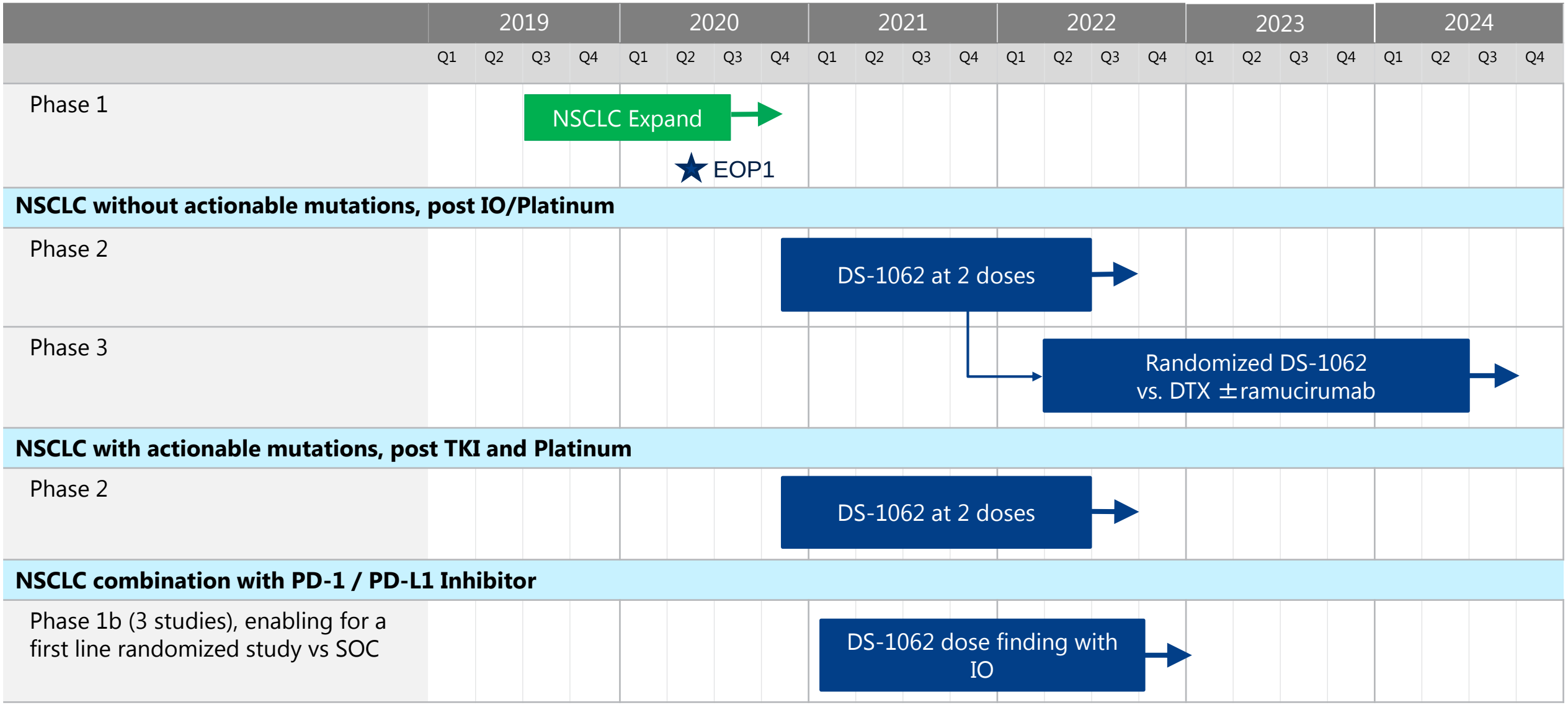
DS-1062 | What It Means for Daiichi Sankyo?

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

Early clinical results indicate that DS-1062 maintains clear activity, dose effect, durability and tolerability – ILD to watch

- **DXd portability** further established, added technology of **D4-enriched DAR4 conjugation** validated
- Driven by emergent NSCLC data, **differentiation vs IMMU-132** appears credible
- **Fast-to-market** US path emerging in NSCLC

DS-1062 | NSCLC Development Plan

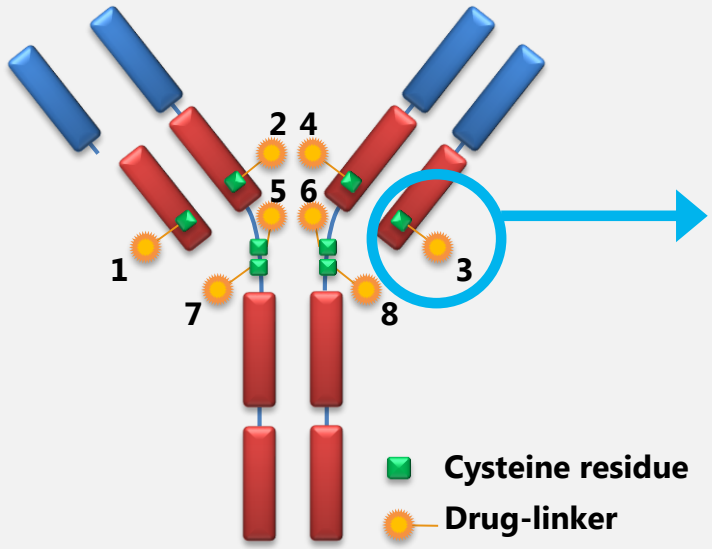


All dates are approximative

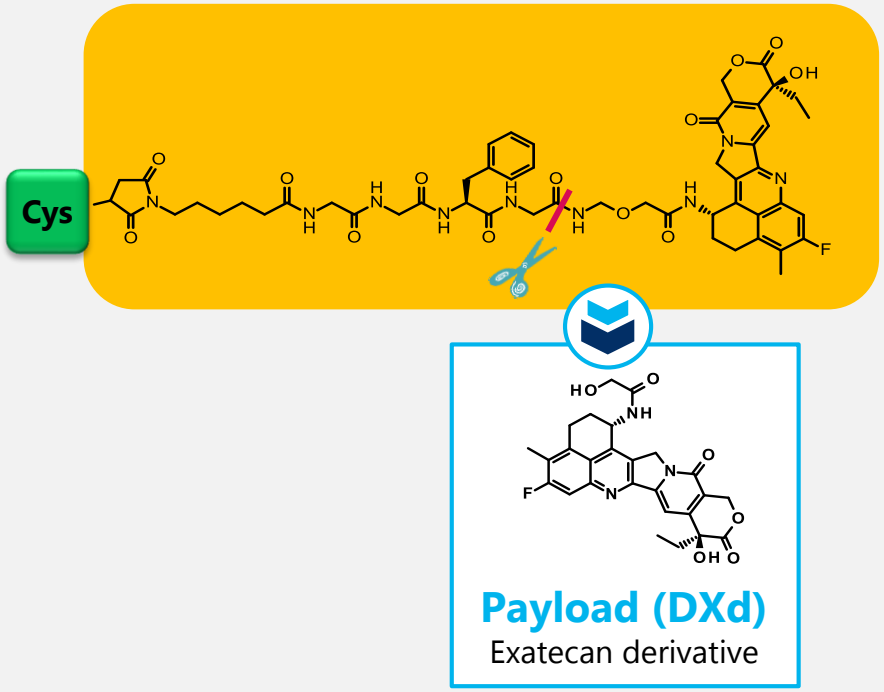
U3-1402 | HER3 Targeted ADC

U3-1402 Design Features
Payload MOA: Topo I inhibitor
High potency of payload
High drug-to-antibody ratio (~8:1)
Payload with short systemic half-life
Stable linker-payload
Tumor-selective cleavable linker
Bystander effect

Anti-HER3 Antibody



Proprietary Drug-linker and Payload



Payload (DXd)
Exatecan derivative

Topoisomerase I inhibitor

Conjugation Chemistry

The drug-linker is conjugated to the antibody via cysteine residues

Potential First-in-class Drug

U3-1402 | Phase 1 NSCLC EGFRm

Eligibility Criteria

- **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 TKIs) was required for retrospective analysis of HER3 expression**

U3-1402 Dose Escalation (N = 30)

Received ≥ 1 dose of U3-1402 IV Q3W

- **6.4 mg/kg (n = 5)**
- **5.6 mg/kg (n = 12)**
- **4.8 mg/kg (n = 9)**
- **3.2 mg/kg (n = 4)**

Patient Disposition[a]

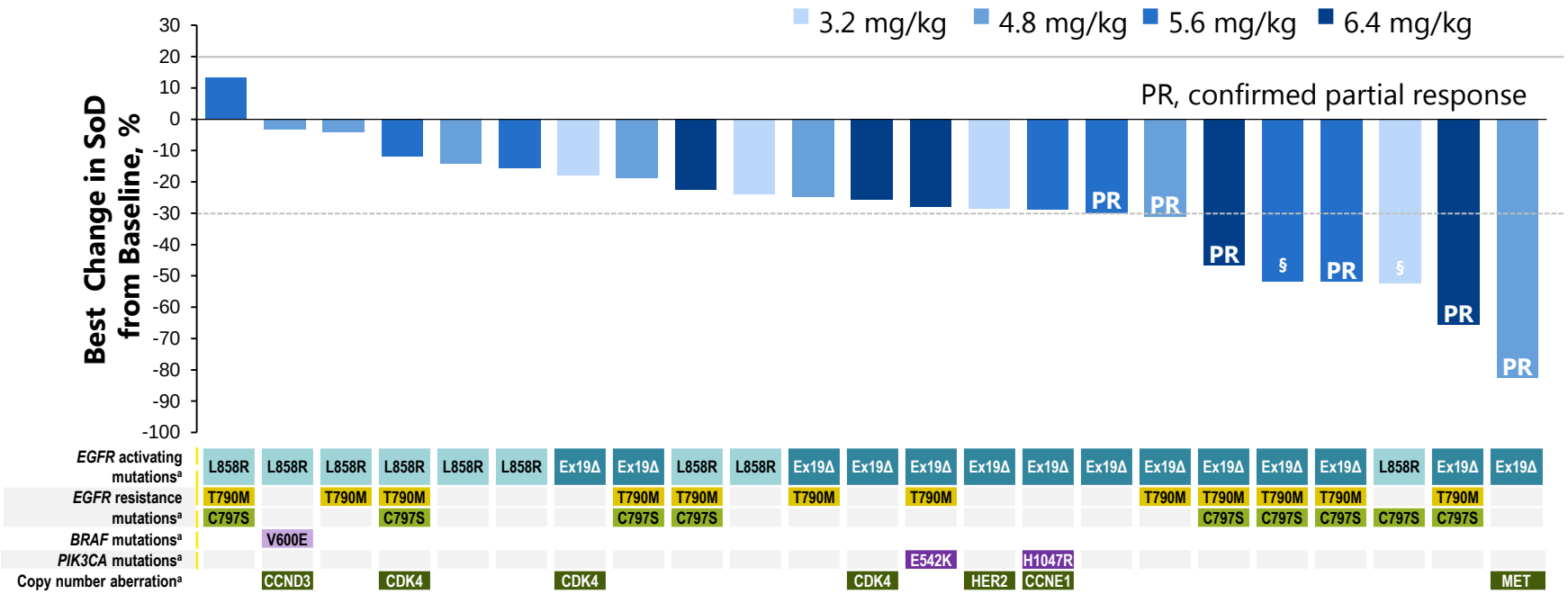
- **Ongoing**, n = 17
- **Discontinued**, n = 13
  - Progressive disease: 9
  - Consent withdrawal: 2
  - Clinical progression: 1
  - AE: 1

Objectives	**Primary:** Safety and tolerability of U3-1402 and RDE determination	**Secondary:** Antitumor activity of U3-1402	**Exploratory:** Biomarkers of U3-1402 antitumor activity

A phase 1 study of U3-1402 in NSCLC (NCT03260491). [a]Data cutoff of May 3, 2019.
AE, adverse event; EGFR, epidermal growth factor receptor; HER3, human epidermal growth factor receptor 3; IV, intravenously; NSCLC, non-small cell lung cancer; Q3W, every 3 weeks; RDE, recommended dose for expansion; TKI, tyrosine kinase receptor.

Source: Yu H et al., Abstract #MA21.06, WCLC 2019

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



n = 23
Median follow-up: 4.5 months

A phase 1 study of U3-1402 in NSCLC (NCT03260491). §2 patients had ≥ 30% reduction in SoD, which were not considered confirmed PRs; 1 experienced transient tumor size reduction and 1 had not yet been confirmed at data cutoff. [a]Performed centrally using Oncomine™ Comprehensive Assay v3 from formalin-fixed, paraffin-embedded tumor tissue. Results from local testing are included for patients where tissue was unavailable for central analysis. Additional mutations detected from cfDNA in blood collected prior to treatment with U3-1402 using GuardantOMNI assay are included. For cfDNA analysis, a minor allelic frequency of 1% was used as a threshold for detection of mutations. The copy number data from cfDNA are not shown.
cfDNA, cell-free DNA; EGFR, epidermal growth factor receptor; HER3, human epidermal growth factor receptor 3; PR, partial response; SoD, sum of diameters; TKI, tyrosine kinase receptor.

Source: Yu H et al., Abstract #MA21.06, WCLC 2019

U3-1402 | What It Means for Daiichi Sankyo?

Early clinical results indicate that U3-1402 appears active in NSCLC, adding to breast cancer activity previously reported

- Targeting HER3 with U3-1402 may be a **practical approach to treat EGFR-mutant** NSCLC with diverse mechanisms of resistance to EGFR TKIs

  HER3 expression post-TKI seems to be frequent and stable

- **Fast-to-market** US path emerging in NSCLC

U3-1402 | Beyond Lung Cancer | Metastatic Breast Cancer

Observed **frequent and durable antitumor activity** in the initial cohorts of the **metastatic breast cancer** program

- As the breast cancer study (J101) progressed, the consistency of this response pattern became variable
- Also observed frequent but transient and reversible thrombocytopenia in cycle 1, unlike with other DXd ADCs

FTIH to August 2018 cumulative breast cancer experience (n=42)

- ✓ ORR: 42.9% (18/42)
- ✓ Disease Control Rate: 90.5%

August 2018 to August 2019 additional breast cancer experience (n=82)

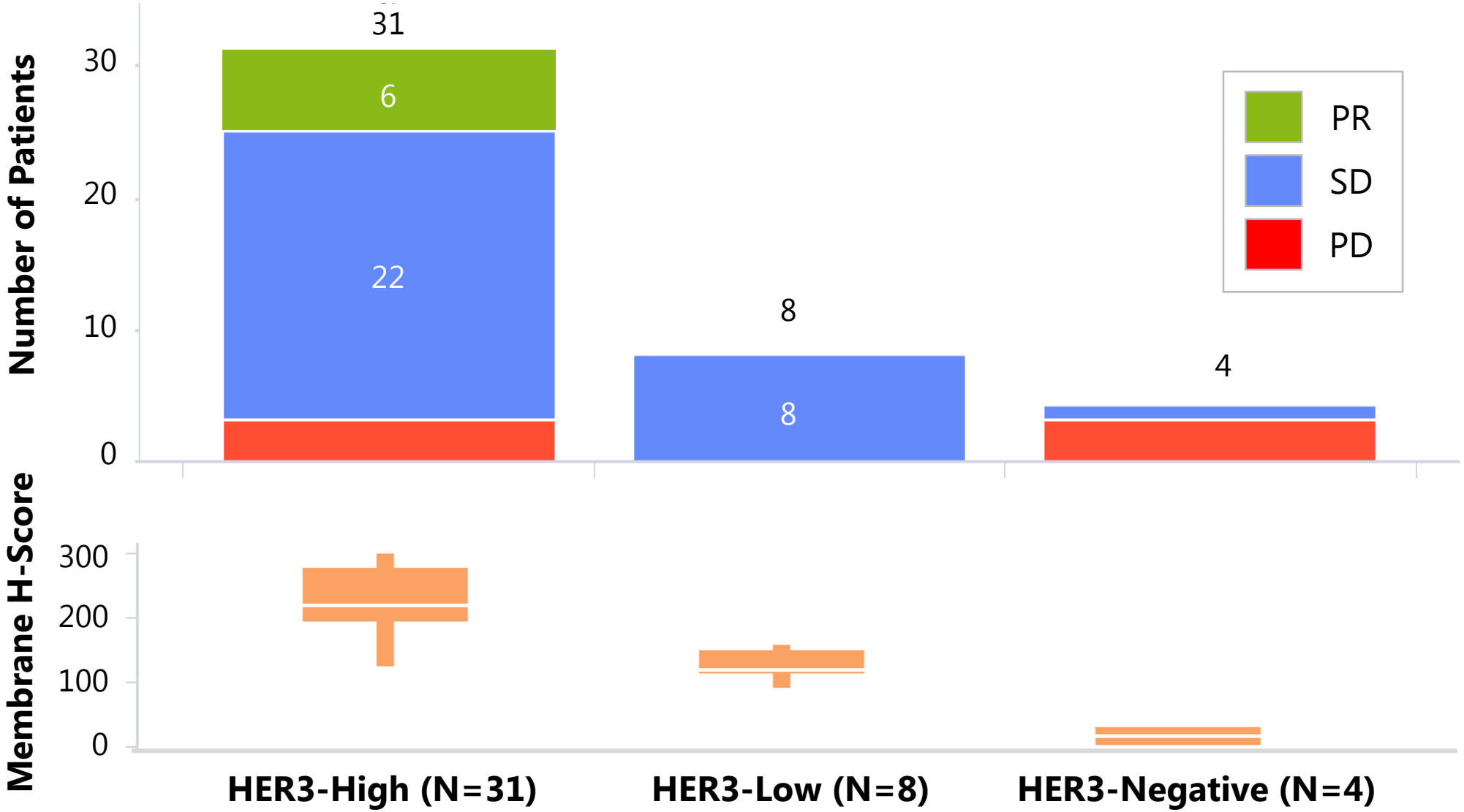
- ✓ ORR: 17.1% (14/82)
- ✓ Disease Control Rate: 89.0%

What have we learned

- **HER3 expression in breast cancer is more variable and heterogeneous** than anticipated
  - **IHC detection, even if specific might not be sensitive enough** to best select the breast cancer population most likely to benefit
- HER3 expression in breast cancer appears to be dynamic, unlike in lung cancer or HER2 in breast cancer

U3-1402 | Breast Cancer: Best Overall Response by IHC

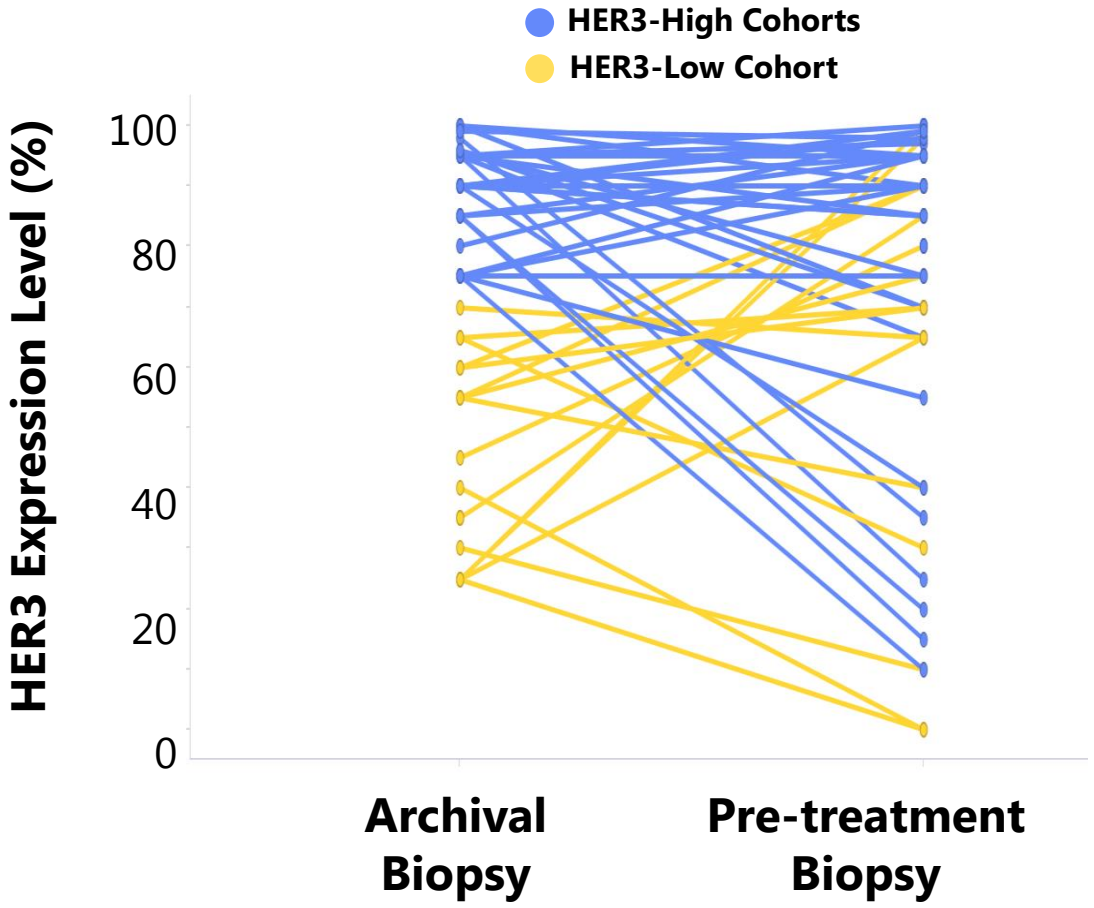
Assessed on Pre-treatment Fresh Biopsy (N=43)*



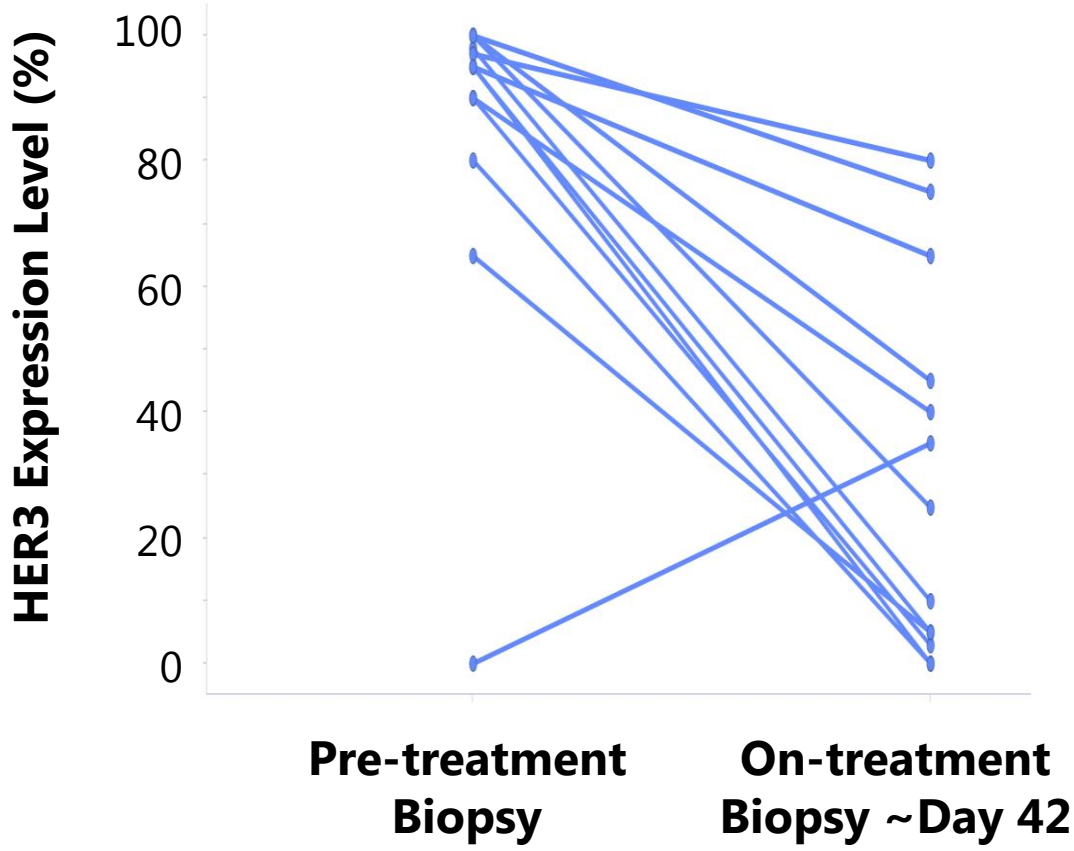
*Source: Internal data are preliminary and on file at Daiichi Sankyo.

U3-1402 | HER3 Expression in Breast Cancer

HER3 Expression Variability in Breast Cancer Over Time*



HER3 Expression Level Decreases During U3-1402 Treatment in Breast Cancer*



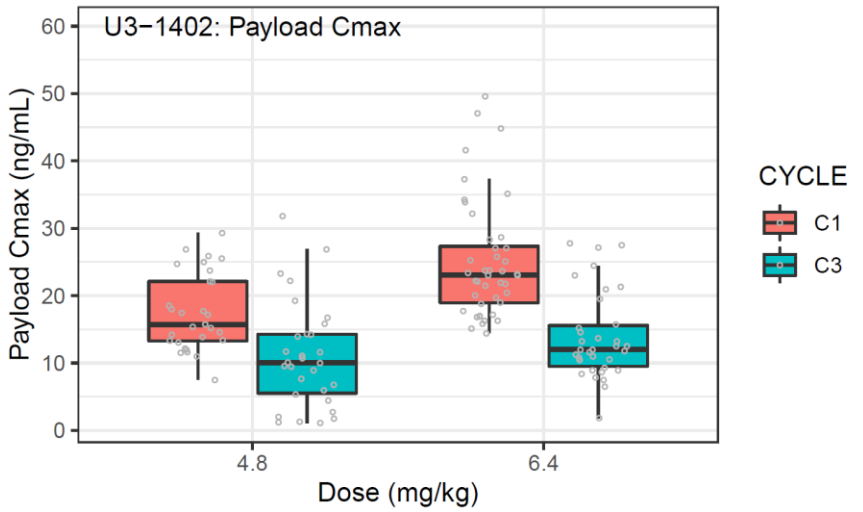
*Source: Internal data are preliminary and on file at Daiichi Sankyo.

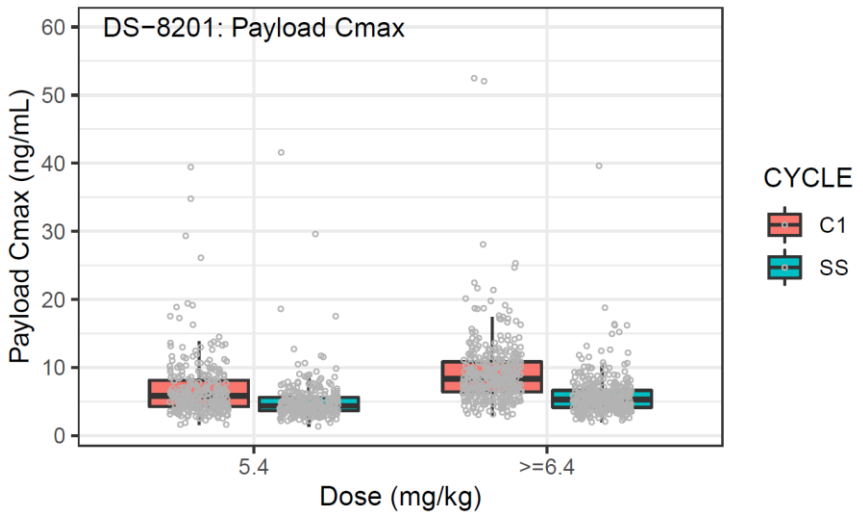
U3-1402 | Payload Release Profile and Thrombocytopenia Rate Distinct from DS-8201 at cycle 1*

U3-1402
Cycles 1 and 3

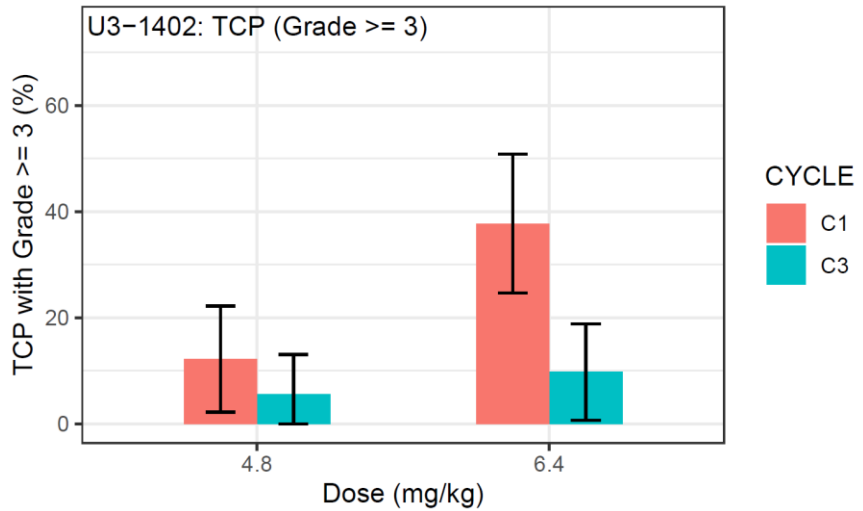
DS-8201
Cycles 1 and 3

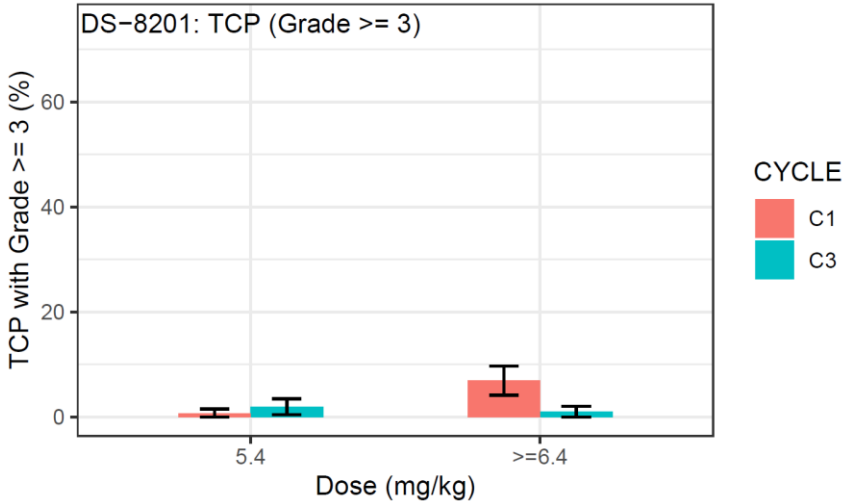
Payload





Thrombocytopenia



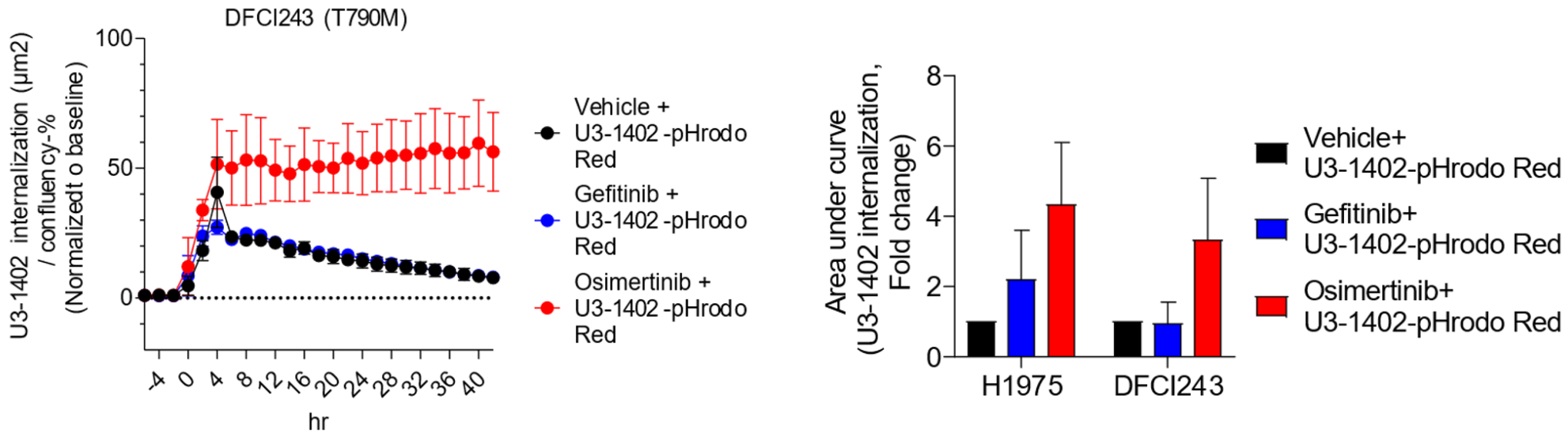


*Source: Internal data are preliminary and on file at Daiichi Sankyo.

Sustained Internalization Rate of U3-1402 in EGFRm Lung Cancer*

Monotherapy or in Combination with Osimertinib

Quantification of Internalization Over Time



*Data are preliminary

Courtesy of Dr. Pasi Janne, Dana Farber Cancer Institute

U3-1402 | What Does It Mean for Daiichi Sankyo?

Lung cancer: EGFRm presents a clear opportunity

- HER3 consistently expressed and internalized post TKI
- Combination with osimertinib will be pursued

Breast cancer: biology of receptor (dimerization / internalization / trafficking) is substantially altered by yet unknown factor(s)

- Intensive translational research ongoing (MSKCC, MDACC, SOLTI, and others)

Colorectal and **Prostate** cancers: Phase 2 studies planned

DS-7300 | Press Release (31 Oct 2019)

Daiichi-Sankyo

Passion for Innovation. Compassion for Patients.®

2019.10.31

Company name: DAIICHI SANKYO COMPANY, LIMITED
Representative: Sunao Manabe, Representative Director, President and CEO
(Code no.: 4568, First Section, Tokyo Stock Exchange)
Please address inquiries to Junichi Onuma,
Vice President, Corporate Communications Department
Telephone: +81-3-6225-1126
https://www.daiichisankyo.com

Daiichi Sankyo Initiates Clinical Trial with its 4th DXd Antibody Drug Conjugate, DS-7300, in Collaboration with Sarah Cannon Research Institute

- First-in-human phase 1/2 study evaluating DS-7300, a B7-H3 targeting ADC, in patients with advanced/unresectable or metastatic solid tumors
- B7-H3 is a protein overexpressed in various types of cancers
- DS-7300 is the fourth ADC to enter the clinic utilizing Daiichi Sankyo's proprietary DXd technology and the first being jointly developed in a strategic partnership with Sarah Cannon Research Institute

Nashville, Tenn., Tokyo, Munich and Basking Ridge, NJ - (October 31, 2019) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) and Sarah Cannon Research Institute (Sarah Cannon) announced today that the first patient has been dosed in a first-in-human phase 1/2 study evaluating DS-7300, an investigational B7-H3 targeting antibody drug conjugate (ADC), in patients with various advanced solid tumors that have progressed on standard treatments or for whom no standard treatment exists.

The study is the first in the strategic oncology partnership announced between Daiichi Sankyo and Sarah Cannon, designed to expedite and optimize global clinical development of Daiichi Sankyo's novel ADCs and other targeted cancer therapies by combining the operational and scientific expertise of both organizations.

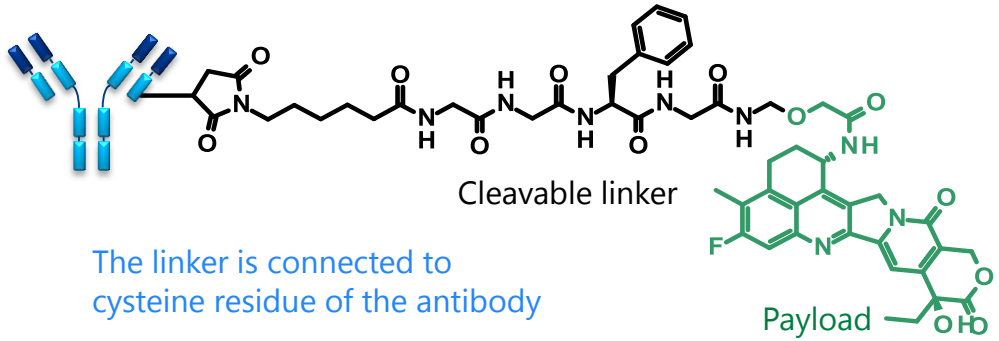
DS-7300 is the fourth ADC in clinical development utilizing Daiichi Sankyo's proprietary DXd technology and was designed to target and deliver chemotherapy inside cancer cells that express the B7-H3 protein. B7-H3 is frequently overexpressed in various types of cancers and has been associated with disease progression and poor prognosis in many tumor types.[1] No B7-H3 targeting therapies are currently approved for treatment of any cancer.

Daiichi Sankyo Initiates Clinical Trial with its 4th DXd Antibody Drug Conjugate, DS-7300, in Collaboration with Sarah Cannon Research Institute

- First-in-human phase 1/2 study evaluating DS-7300, a B7-H3 targeting ADC, in patients with advanced/unresectable or metastatic solid tumors
- B7-H3 is a protein overexpressed in various types of cancers
- DS-7300 is the fourth ADC to enter the clinic utilizing Daiichi Sankyo's proprietary DXd technology and the first being jointly developed in a strategic partnership with Sarah Cannon Research Institute

DS-7300 | DXd ADC Targeting B7-H3-Expressing Tumors

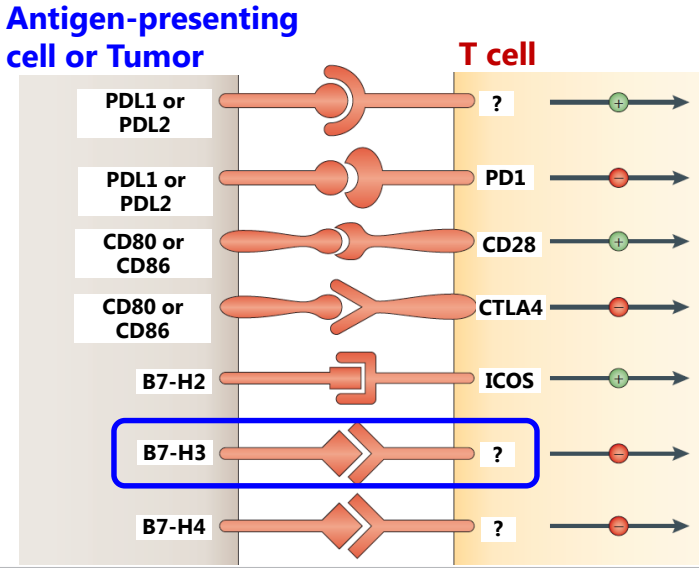
DS-7300 (anti-B7-H3 ADC)



mAb	anti-B7-H3 IgG1
Payload	DXd
DAR	4
Major MoA	Cancer cell killing by DXd
Competitor	MGC018 by MacroGenics (P1 study initiated in Nov2018; ongoing)

B7-H3 (CD276)

- B7-H3 is highly expressed in various solid cancers and expressed at low levels in normal tissues.
  - Anti-B7-H3 ADC antibody internalization rate 19-27%/3hr, comparable to trastuzumab
- B7-H3 is a type I transmembrane protein belonging to the B7 family which includes immune checkpoint molecules such as CTLA-4 ligands, and PD-L1.
- The function of B7-H3 yet to be elucidated.



Nature Reviews 2012, 12, 252–264

DS-7300 | Phase 1 Study Design

Dose Escalation

Key Objectives: Finding recommended dose for Expansion and determine evidence of preliminary efficacy

Dose Expansion

Key Objectives: Preliminary efficacy, ORR, and additional safety

Collection of archival and fresh tissue (pre-, on-treatment) biopsies-

Advanced or Metastatic Solid Tumors

Head and Neck, squamous-esophageal cancer, squamous NSCLC, Bladder, Sarcoma, Endometrial

- Regardless of B7-H3 expression (no preselection)
- mCRM, N = ~36
- Determine RDE based on safety (primary), PK, preliminary efficacy, and Biomarker

Cohort 1: SCCHN

Cohort 2: Sq-Esophageal Ca

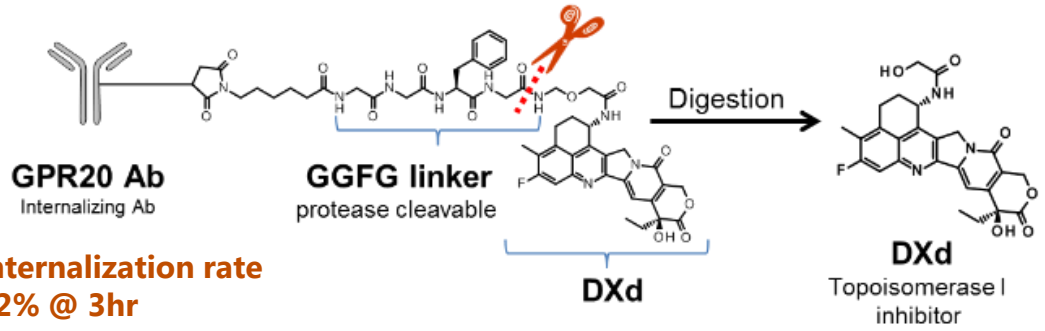
Cohort 3: Sq-NSCLC

- N~ 40 for each cohort (1-3)
- Regardless of B7-H3 expression (no preselection)
- Additional or alternative indications may be added to expansion cohorts based on preliminary signals of activity

DS-6157 | GPR20 ADC

DS-6157

Drug / Antibody Ratio = 8



Internalization rate
72% @ 3hr

GPR20

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

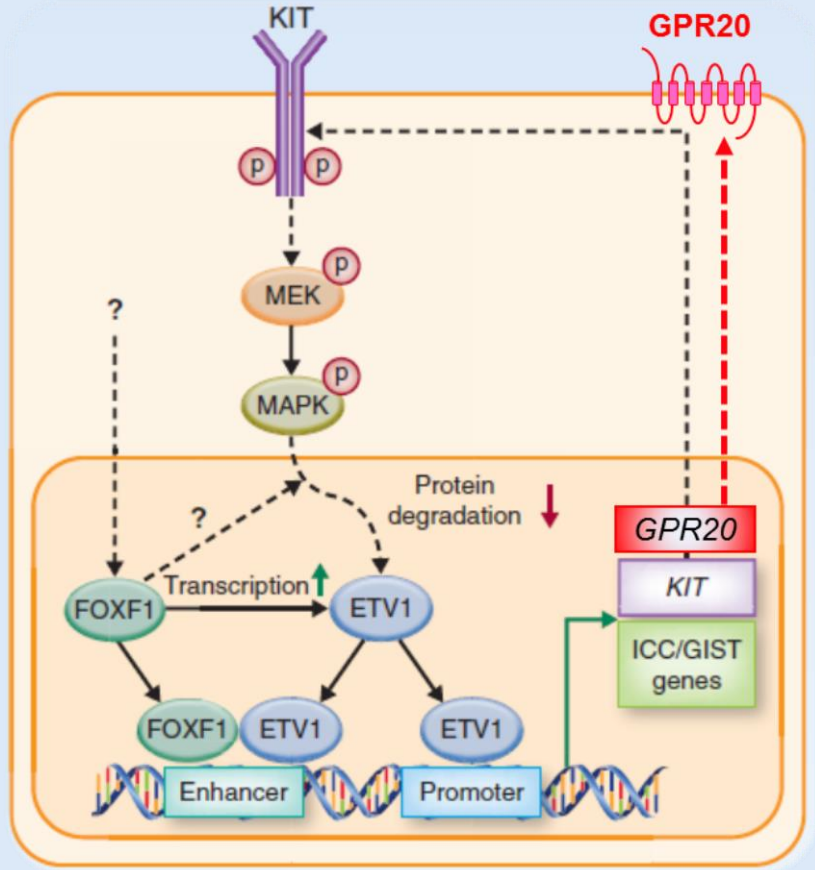
GIST

- **Mesenchymal tumor of GI tract, rare disease**
- **Stomach: 60%, Small intestine 35%**
- **Oncogenic mutation in KIT (78%) or PDGFRA (7.5%) gene**
- **Three TKIs were approved**

DS-6157

- **First in class GPR20 ADC, having different MOA than TKIs approved in GIST therapy**
- **Initial target indication is IM-resistant GIST**
- **Q3w, IV dosing regimen**

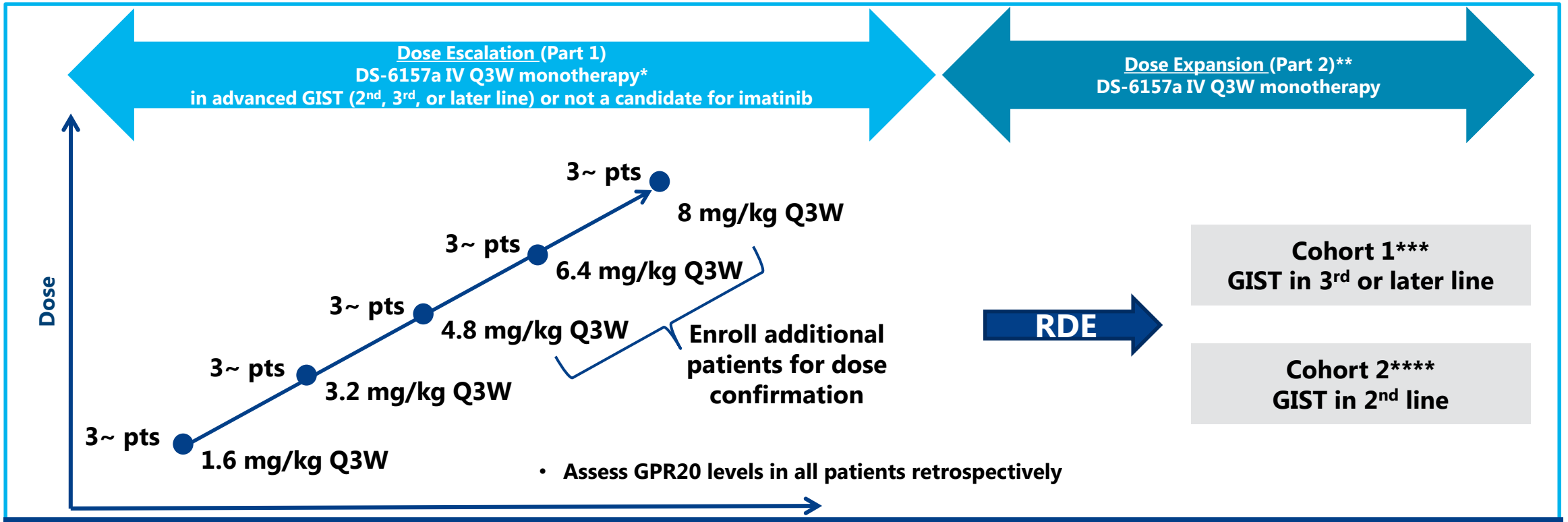
GPR20 is one of the ICC/GIST lineage-specific factors whose gene expression is regulated by FOXF1 and ETV1



GGFG: glycine-glycine-phenylalanine-glycine
DXd: DX-8951 derivative
FOXF1: Forkhead box F1
ETV1: ETS variant 1, a member of the ETS (E twenty-six) family of transcription factors

Chi P. et al, *Cancer Discov.* 2018;8(2):146-149, 234-251. (modified)

DS-6157 | Phase 1 Study Design



	Escalation	Expansion
Study Region	**US, +(Japan)**	**US, Japan, (+ Other countries: TBD**
Potential Study Sites	**DFCI, other sites, (NCCE in Japan)**	**DFCI, other sites, (NCCE in Japan)**

GIST: gastrointestinal stromal tumors; RDE: recommended dose for expansion; BLRM: Bayesian logistic regression model; DFCI: Dana Farber Cancer Institute; NCCE: National Cancer Center Hospital

*These are planned doses. Actual dose levels will be determined by clinical toxicity findings in each dose cohort & the BLRM. Higher or intermediate doses may also be considered.

**DS-6157a dose will be determined in Dose Escalation (Part 1).

***Cohort 1 includes subjects who have been previously treated with imatinib & at least one post-imatinib treatment.

****Cohort 2 will be initiated after efficacy is demonstrated (≥20% confirmed objective response rate in a minimum of 10 subjects treated with DS-6157a at RDE) in Dose Escalation & Dose Expansion Cohort 1. Cohort 2 will be initiated in the United States only.

Today's Agenda

1 Introduction

2 DS-8201: The Data

3 DS-8201: The Collaboration

4 ADC Portfolio: Data and CDP Updates

5 DXd ADC ILD

6 "3 and Alpha"

7 News Flow and Future Events

Investigator Safe Use Campaign for ILD Detection & Management

1st Phase Campaign: Awareness (Early calendar 2019 for DS-8201)

Goal: Drive ILD awareness, detection, and management

Daiichi-Sankyo | AstraZeneca

- Comprehensive education of MSLs
- Develop tools for MSLs to use in proactive direct communication with treating physicians

Develop internal understanding & external communication plans

HCPs

- Prioritize investigators with patients on treatment
- Ensure continuous education and 'top of mind' status, through numerous outlets (in-person, online)

Give HCPs tools to reduce ILD severity and improve management

Resources for Patients

- Educate patients around risk of ILD and need to self-monitor for symptoms

Drive awareness and give patients tools to support detection & management

DS-8201: did you screen for, and mitigate against ILD today?

DS-8201 | FDA 90-Day Safety Update Summary and To-Date

- In HER2-positive 5.4 mg/kg, compared to safety data in submission, no significant changes in most AE and no new safety signal. Frequency of most AEs increased slightly.
- The most notable findings are:
  - Discontinuation associated with TEAE increased from 8.2% to 15.2%, mainly driven by new events of low grade ILD
  - Adjudicated drug-related any grade ILD increased from 8.2% to 13.5%
    - New adjudicated related ILD events included 2 grade 1, 7 grade 2 and 1 grade 3
- **It is important to note that after the phase 1 Safe use campaign was initiated, majority of the new cases were low grade (1 and 2) and only 1 subject was diagnosed with grade 3 ILD – no new grade 4 or 5 reported program-wide at treatment doses of 5.4 mg/kg**

U3-1402 | ILD (Adjudicated Outcomes) Summary

		Number (%) of Subjects with Each CTCAE Grade Reported by Adjudication Committee					
		1	2	3	4	5	Total
N = 205 Doses (1.6-8.0 mg/kg) Median exposure 4.4 months (0.7-30.2) Mean exposure(SD) = 5.76mo (4.973)	Adjudicated[a]	1 (0.5)	7 (3.4)	3 (1.5)	0	1 (0.5)	12 (5.9)
	Adjudicated as ILD	1 (0.5)	6 (2.9)	3 (1.5)	0	1 (0.5)	11 (5.4)
	Adjudicated as Drug-related	1 (0.5)	4 (2.0)	3 (1.5)	0	1 (0.5)	9 (4.4)[b]

[a] Consisted of events based on 44 PTs selected for ILD adjudication – terms adjudicated as ILD – pneumonitis, interstitial pneumonia, radiation pneumonitis

b- the 2 cases considered not related to the study drug, were considered related to prior radiation therapy

DS-1062 | ILD (Adjudicated Outcomes) Summary

All potential ILD cases as of 18 Oct 2019 have been adjudicated

		Number (%) of Subjects with Each CTCAE Grade Reported by Adjudication Committee					
		1	2	3	4	5	Total
N=88 subj Median exposure 7.1 wks (3.0-54.0 wks) Mean (SD) – 13.4 (11.9)	Adjudicated[a]	0	3 (3.4)	0	0	3 (3.4)[b]	6 (6.8)
	Adjudicated as ILD	0	3 (3.4)	0	0	1 (1.1)	4 (4.5)
	Adjudicated as Drug-related	0	3 (3.4)	0	0	1 (1.1)	4 (4.5)

[a] Consisted of events based on 44 PTs selected for ILD adjudication – events adjudicated as ILD : pneumonitis, respiratory failure and organizing pneumonia

[b] The other 2 events not adjudicated as ILD were adjudicated as Disease progression per the ILD AC

What's Next?

- DS and AZ have convened an advisory board consisting of oncologists and radiologists in order to discuss the ILD management algorithm and the current inclusion/exclusion criteria
- As a result, the management algorithm of ILD has been updated and a new phase of the Safe Use Campaign has been started across the ADC Franchise
  - the algorithm is more prescriptive and will assist the treating physicians in managing their patients
- The inclusion/exclusion criteria have been refined to exclude patients that could be at higher risk of developing ILD

HCPs

Today's Agenda

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Evolving the Strategic Platform from "7 in 8" to "3 and Alpha"

2017 Strategic Intent

By 2025, Cancer Enterprise will be a leading world-class organization focused on 3 pillars, and will have delivered 7 valuable NMEs (approved, launched and accessed)

Lead in Smart-Treatment with BIC & FIC ADC	Establish a competitive Hematology Franchise	Lead with break-thru science
▪ Maximize existing Smart-Chemo portfolio ▪ Develop next generation of Smart-Chemo ▪ Deliver disruptive Smart-treatments	▪ Lead in the FLT3 segment ▪ Expand beyond FLT3 segment ▪ Expand beyond AML	▪ Deliver Best in Class NME or First in Class disruptive MOA NME ▪ Embed new technologies to magnify the value of science
3	3	1

7 NMEs in 8 years
A Science Machine and a X-functional Value Creation Team

2019 Realities

- ADCs meeting / exceeding expectations in the clinic, leading to expanded resource needs
- Quizartinib at risk of not achieving broad approval (RR or 1st line)

2019 Strategic Intent

- Fully optimize the three ADCs (DS-8201, DS-1062, U3-1402)
- Keep critical attention on the potential of the alpha assets to contribute to a robust science and technology driven portfolio

Maximizing Development of 3 ADC's with Breadth & Depth Expansions

Daiichi-Sankyo cancerenterprise

Maximize

DS-8201

- Co-development partnership with AZ
- Accelerated and broadened geographical coverage
- Expansion into multiple indications

Swift and independent development of the next ADCs

DS-1062

- Fast to market as late line NSCLC patient population
- Potential expansion into first line NSCLC (IO Combo) and indications with high TROP-2 level
- Massive scale up of our manufacturing capacity which creates relief on supply access

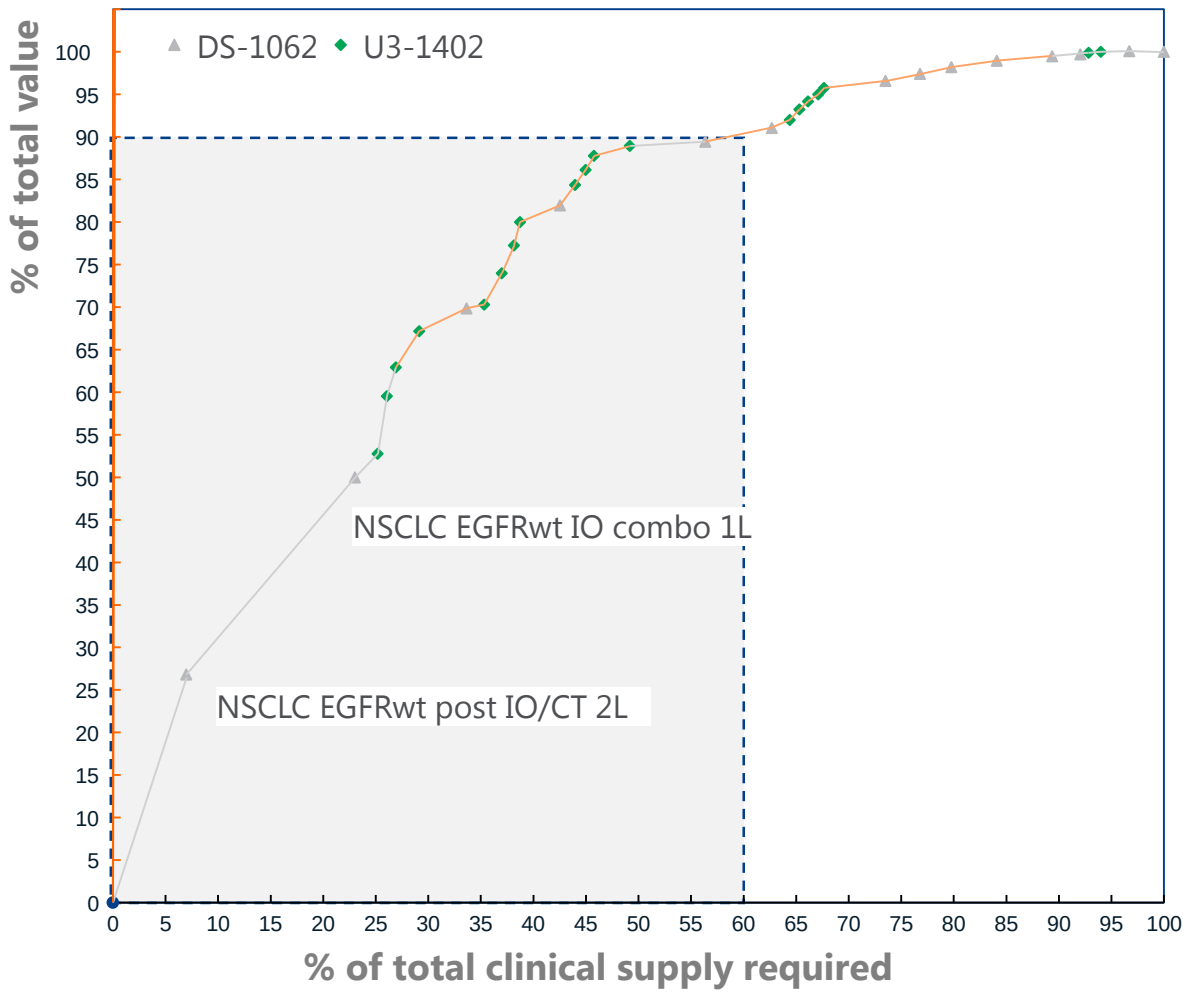
U3-1402

- Fast to market potential
- Positive early results with monotherapy and expansion into combination with osimertinib

Science-informed precision medicine
Full development of 3 ADC's based on the unique biology of both the DXd technology and the vector/receptor

Maximizing Value of Development

Cumulative risk adjusted value (revenue – dev cost) and cumulative clinical supply demand



Top 17 indications for DS-1062 and U3-1402 give ~90% of the value and require ~60% of clinical supplies (& ~55% of RD costs)

Indication prioritization ensures focused and optimized use of resources

- We are **actively prioritizing our indications** based on potential value and clinical development requirements
- Potential risk **cannibalization** across assets on the same indication is **considered** if and only if the biology is truly overlapping

What is the “3 and Alpha” Strategy?

3 lead ADCs

DS-8201: maximize value with co-development partnership with AZ

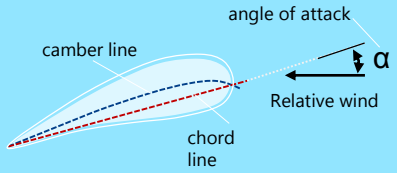
DS-1062: Substantial opportunities across multiple indications

U3-1402: fast to market

Science-informed precision medicine:
three ADCs based on the unique biology of DXd technology and the vector/receptor

Alpha

Alpha = angle of attack and speed of elevation



Alpha = Performance far exceeding benchmark index

Alpha= **the cutting edge and power of true innovation delivering drugs changing SOC**

Daiichi-Sankyo

Major R&D Pipeline

As of December 2019

		Generic Name/Project Code/ MOA	Target Indication	Region	Stage
3 ADCs		[fam-] trastuzumab deruxtecan/ DS-8201/anti-HER2 ADC	Breast cancer (HER2 positive post T-DM1)	JP/US/EU/ Asia	BLA/N DA P3
			Breast cancer (HER2 positive vs T-DM1)	JP/US/EU/ Asia	P3
			Breast cancer (HER2 low expression)	JP/US/EU/ Asia	P3
			Gastric cancer (HER2 positive, 3L)	JP/Asia	P2
			Colorectal cancer (HER2 expressing)	JP/US/EU	P2
			NSCLC (HER2 expressing/mutant)	JP/US/EU	P2
			Breast and bladder cancer (with nivolumab)	US/EU	P1
		U3-1402/anti-HER3 ADC	Breast cancer (HER3 expressing)	JP/US	P1
			EGFRm NSCLC	JP/US	P1
		DS-1062/anti-TROP2 ADC	NSCLC	JP/US	P1
Alpha	Oncology	Quizartinib/FLT3 inhibitor	AML (relapsed/refractory)	Asia	P3
			AML (1st line)	JP/US/EU/ Asia	P3 LCM
		Pexidartinib/ CSF-1/KIT/FLT3 inhibitor	Tenosynovial giant cell tumor	EU	P3
		Axicabtagene ciloleucel/ Axi-Cel®/anti-CD19 CAR-T	B-cell lymphoma	JP	P2
		DS-1647(G47Δ)/oncolytic HSV-1	Malignant glioma	JP	P2
		Valemetostat/DS-3201/ EZH1/2 inhibitor	Adult T-cell leukemia/lymphoma	JP	P2
			Non-Hodgkin's Lymphoma (PTCL)	JP/US	P1
			AML, ALL	US	P1
			Small cell lung cancer	US	P1

		Generic Name/Project Code/ MOA	Target Indication	Region	Stage
Alpha	Oncology	Milademetan/DS-3032/ MDM2 inhibitor	Solid tumor (liposarcoma)	JP/US	P1
			AML	JP/US	P1
		PLX2853/BET inhibitor	AML	US	P1
		DS-1001/ Mutant IDH1 inhibitor	Glioma	JP	P1
		DS-1205/AXL inhibitor	NSCLC (with gefitinib)	JP	P1
			NSCLC (with osimertinib)	Asia	P1
		DS-7300/anti-B7-H3 ADC	Solid tumor	JP/US	P1
	Specialty Medicines	Edoxaban/FXa inhibitor	Atrial fibrillation in the very elderly	JP	P3 LCM
		Prasugrel/anti-platelet agent	Ischemic stroke	JP	P3 LCM
		Esaxerenone/MR-Antagonist	Diabetic nephropathy	JP	P3 LCM
		Mirogabalin/$\alpha_2\delta$ ligand	Central neuropathic pain	JP/Asia	P3 LCM
		DS-1040/TAFIa inhibitor	Acute ischemic stroke, acute pulmonary thromboembolism	JP/US/EU	P1
		DS-5141/ENA-oligonucleotide	Duchenne type muscular dystrophy	JP	P1
		DS-1211/TNAP inhibitor	Inhibition of ectopic calcification	US	P1
	Vaccine	VN-0107/MEDI3250/live attenuated influenza vaccine nasal spray	Prophylaxis of seasonal influenza	JP	NDA
		VN-0105/DPT-IPV/Hib	Prevention of pertussis, diphtheria, tetanus, poliomyelitis and Hib infection	JP	P3
		VN-0102/JVC-001/ Measles-mumps-rubella vaccine	For measles, mumps, and rubella prophylaxis	JP	P2

ALL: acute lymphocytic leukemia, AML: acute myeloid leukemia, NSCLC: non-small-cell lung cancer, PTCL: peripheral T-cell lymphoma

ADC Development Coalition with a Selected CRO

Integrated Delivery Model meeting both Companies' needs

Daiichi Sankyo Needs

- **Innovative** – Changing the CRO/sponsor dynamic with concentrated effort on innovation & early integration, joint tactical decisions
- **DS core competency retention** – enables Daiichi Sankyo to retain & develop core competencies
- **Financial alignment** – that aligns CRO/sponsor objectives and supports CRO accountability
- **Efficient & predictable operational delivery** – commitment to driving/reducing clinical development timelines
- **Site & Patient Centric Approach** – early engagement from protocol development through market access
- **Flexibility and scalability** – ability to adapt and adjust strategy and resource in a dynamic research environment
- **Assurance of quality** – robust quality management plan & access to transparent portfolio data enabling DS "Right" touch

CRO Needs

- **Science –** involved in world-class science which in turns motivate CRO employees
- **Respect and Trust –** CRO's voice to be considered and heard by sponsor will result in CRO employee retention and performance
    - i.e. not be considered "a service provider" to a sponsor
- **Financial alignment and incentives –** that align CRO/sponsor and supports CRO accountability for performance based on regulatory approval(s)

Today's Agenda

1 Introduction

2 DS-8201: The Data

3 DS-8201: The Collaboration

4 ADC Portfolio: Data and CDP Updates

5 DXd ADC ILD

6 "3 and Alpha"

7 News Flow and Future Events

Upcoming News

DS-8201

HER2 Positive mBC Pivotal Phase 2 Study – DESTINY-Breast01

- JP: NDA submitted and accepted on September 9, 2019
- US: PDUFA date: April 29, 2020
- EU: MAA submission planned for 1H FY2020

HER2 Positive mGC Pivotal Phase 2 Study – DESTINY-Gastric01

- JP/S. Korea TLR anticipated for 4Q FY2019

ASCO 2020 Planned Presentations

- DESTINY-Breast01 Update
- DESTINY-Gastric01 Results
- Colorectal Phase 2
- NSCLC Phase 2
- Breast/Bladder – Nivolumab Combo – Phase 1
- Translational Research

DS-1062

ASCO 2020 Planned Presentation

- NSCLC Phase 1 Expansion Update

Upcoming News

U3-1402

WCLC 2020 Planned Presentation

- NSCLC Phase 1 Expansion Update

Pexidartinib

Tenosynovial Giant Cell Tumor

- EU: under review for 1H FY2020 decision

DS-1647 (G47Δ)

Malignant Glioma

- JP: NDA submission in 2H FY2019

Cancer Enterprise | Deliver, Scale Up, Lead

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

FY2019 R&D Major Milestones (As of December 2019)

	Project	Target Indications and Studies	FY2019				FY2020
			Q1	Q2	Q3	Q4	Q1~
3 ADCs	DS-8201	P2 pivotal: breast cancer (HER2 positive post T-DM1)		**JP/US submitted**			EU submission
		P2 pivotal: gastric cancer (HER2 positive, 3L) (JP/Asia)					JP submission
		P2: gastric cancer (HER2 positive post trastuzumab) (US/EU)		**Study started**			
		P1: breast cancer and NSCLC with pembrolizumab			Study start planned		
	U3-1402	P1: NSCLC		**Started dose expansion**			
	DS-1062	P1: NSCLC		**Started dose expansion**			
Alpha	Quizartinib	P3: AML (relapsed/refractory)	**JP approved US CRL**		**JP launched EU received EMA CHMP negative opinion**		
	Pexidartinib	P3: tenosynovial giant cell tumor (US/EU)		**US approved/ launched**			EU decision
	DS-1647	IIS: malignant glioma (JP)			Submission		
	DS-3201	P1: small cell lung cancer (US)	**Study started**				
		P2: Adult T-cell leukemia/lymphoma			**Study started**		
	DS-1205	P1: NSCLC with osimertinib (Asia)	**Study started**				
	DS-7300	P1/2: solid tumors			**Study started**		
	DS-6157	P1: gastrointestinal stromal tumors (GIST)				Study start planned	
	Laninamivir	P3: influenza (nebulizer formulation) (JP)	**Approved**		**Launched**		

AML: acute myeloid leukemia, CRL: complete response letter, NSCLC: non-small-cell lung cancer

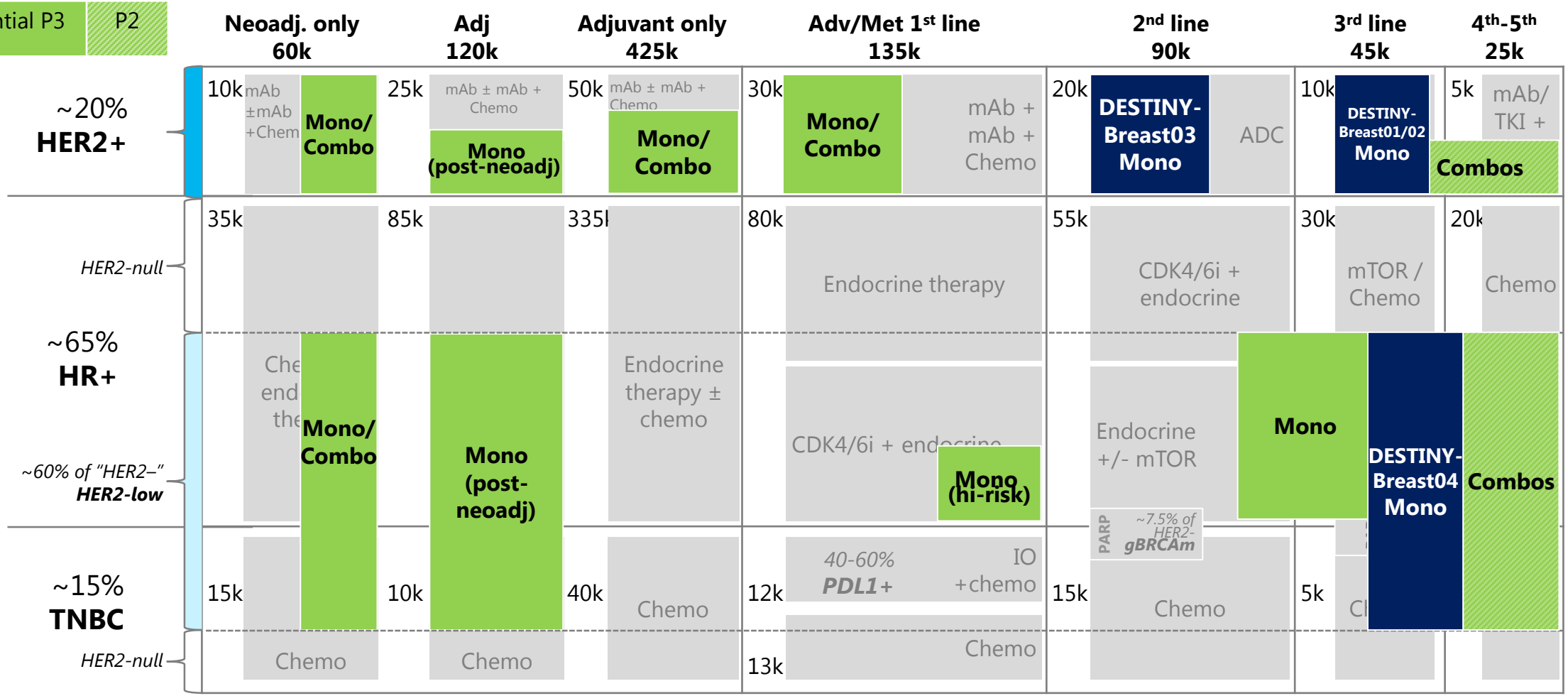
Underlined in red: new or updated from FY2019 Q2, blue: achieved

DS-8201 | Breast Cancer CDP | Comprehensive Plan

Daiichi-Sankyo cancerenterprise

Ongoing P3 | P2 | Potential P3 | P2

As of Nov 15, 2019

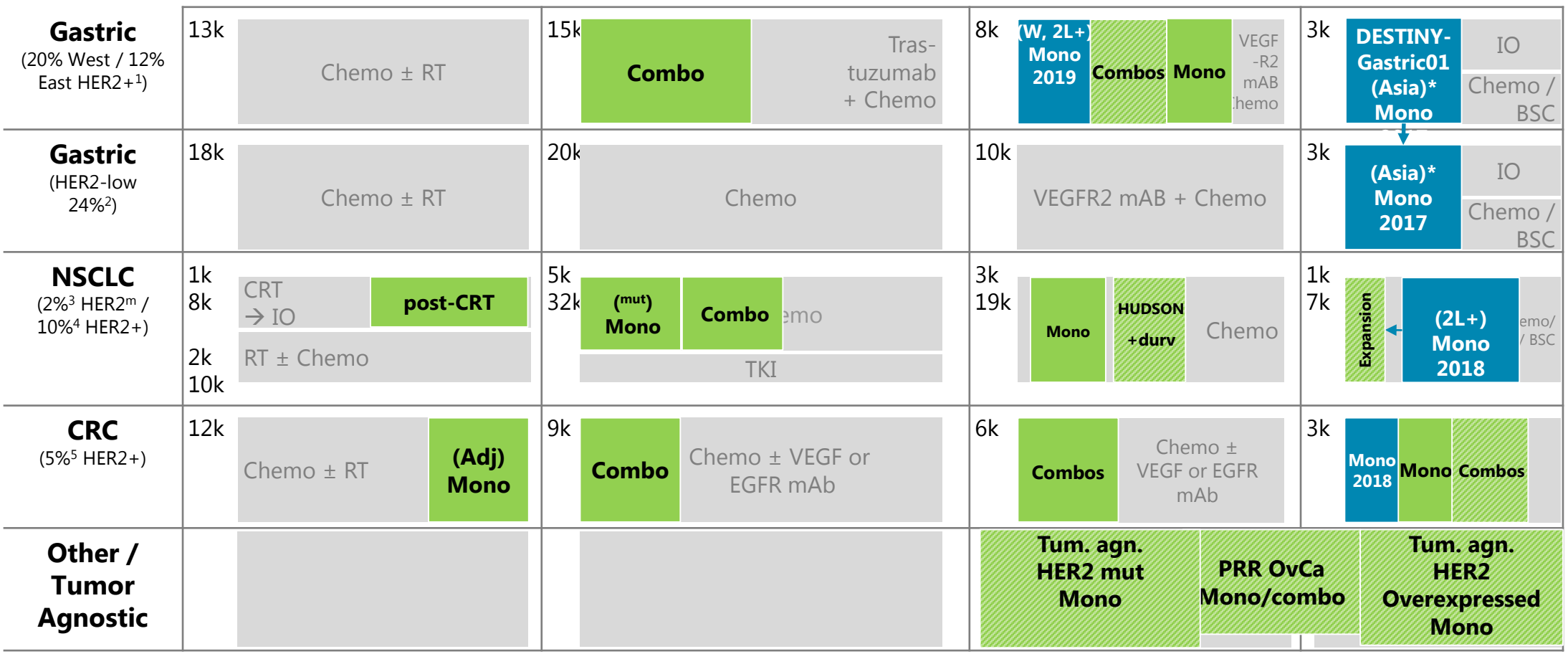


- Simplified view of SOC in G7 shown above – not meant to be patient flow or full representation of regimen shares; biomarker overlap not well characterized
- Drug-treated patients G7 markets in 2025 (source: Kantar, rounded to nearest 5k). 80% of Stg IIIbc patients included in metastatic as not resectable with curative intent (to be validated in MR)
- †Multi-indication basket

DS-8201 | Non-Breast Cancer CDP

Ongoing P3 | P2 | Potential P3 | P2

As of Nov 15, 2019



- Drug-treated patients G7 markets in 2025 (source: Kantar for total patients, rounded to nearest 1k; Prevalence per below; Gastric includes GEJ adeno, rates sourced from DRG)
- Wide range of HER2+ prevalence reported in literature. Same prevalence assumed across lines of therapy given limited data; may differ between early & metastatic
- [1,2]ToGA, GOLD [3]Range: 1-4% for HER2m (Peters 2014) [4]Range: 2-19% for IHC 3+ or 3+/2+ (Hisch 2002, Zinner 2004, Heinmoller 2003) [5]Range:1-7% for IHC3+ (Sienna 2018)
- *Registrational Ph2 in Japan/Korea, with exploratory cohort in IC2+/1+ ; †Multi-indication basket

Abbreviations

Abbreviations	
AE	Adverse event
BTD	Breakthrough therapy designation
CR	Complete response
CRL	Complete response letter
DCR	Disease control rate
DLT	Dose limiting toxicity
DOR	Duration of response
EGFR	Epidermal growth factor receptor
MTD	Maximum tolerated dose
ORR	Overall response rate Objective response rate
OS	Overall survival
PD	Progress disease
PFS	Progression-free survival
PR	Partial response
SD	Stable disease
TEAE	Treatment emergent adverse event

Contact address regarding this material

Daiichi Sankyo Co., Ltd.

Corporate Communications Department

TEL: +81-3-6225-1126

Email: DaiichiSankyoIR@daiichisankyo.co.jp