Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2017
R&D Day

DAIICHI SANKYO CO., LTD

George Nakayama
Chairman and CEO

December 13, 2017

Forward-Looking Statements

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Management Policy Transformation

Global Pharma Innovator with Competitive Advantage in Oncology

Until 2015

- CVM area
- PCP focus

2016-2020
5-Year Business Plan

Transformation toward 2025 Vision

2025 Vision

- **Primary Focused Area**
  - **Oncology**
- **New Horizon Area**
  - **Pain, CNS Disease, Heart･Kidney disease, Rare diseases**

Management Policy Transformation

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Global Pharma Innovator with Competitive Advantage in Oncology

Until 2015

- CVM area
- PCP focus

2016-2020
5-Year Business Plan

Transformation toward 2025 Vision

2025 Vision

Invest selectively in oncology and create organizational structure to achieve 2025 Vision

- Bring in more expertise and create new organizational structure to accelerate oncology development and launches
- Enhance manufacturing capabilities for DS-8201 launch
- Shift and enhance R&D resources toward oncology to maximize project value

Bring in More Expertise and Create New Organizational Structure to Accelerate Oncology Development and Launches

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- **Create R&D organizational structure to accelerate oncology development and launches**
- **Hire top oncology experts:**
  - **Our new leaders each have built decades-long careers in oncology**
  - **All have been integral in developing and/or launching successful cancer therapies for multiple top 10 oncology companies (e.g., Astra-Zeneca, Pfizer, BMS, Novartis Oncology, Pharmacia, Schering-Plough)**

Oncology R&D Sub Unit	Newly established Global Oncology Marketing	Newly established Global Medical Affairs
• **Tom Held**: ADC Franchise Lead • **Arnaud Lesegretain**: AML Franchise Lead • **Masato Murakami**: Oncology biomarker function lead	**Thierry Gruson** Head of Global Oncology Marketing	**Dalila Oulid-Aissa** Head of Global Oncology Medical Affairs

- **Shifting resources toward oncology**
- **Further enhancing translational research and biomarker development**

Cancer Enterprise is
- the concept that all Units/Organizations who are willing to contribute to oncology business are organically collaborating with each other
- not an official Unit/Organization but a company-wide cross functional team

Enhance Manufacturing Capabilities for DS-8201 Launch

- **Enhance DS's manufacturing capabilities for DS-8201 launch**
- **Utilize CMO for back-up manufacturing sites**
- **Enhance manufacturing capabilities to supply timely for other ADC clinical trial**

15.0 Bn JPY investment to enhance ADC manufacturing capabilities

Increase production of clinical trial supply by utilizing and enhancing current capabilities

Establish new facility at Tatebayashi for antibody

Enhance DS's manufacturing capabilities and established back-up sites utilizing CMO

For acceleration of development

For commercialization

Extensive use of three domestic plants (Tatebayashi, Onahama, Hiratsuka) and one EU plant (Pfaffenhofen)

Shift and Enhance R&D Resources toward Oncology to Maximize Project Value

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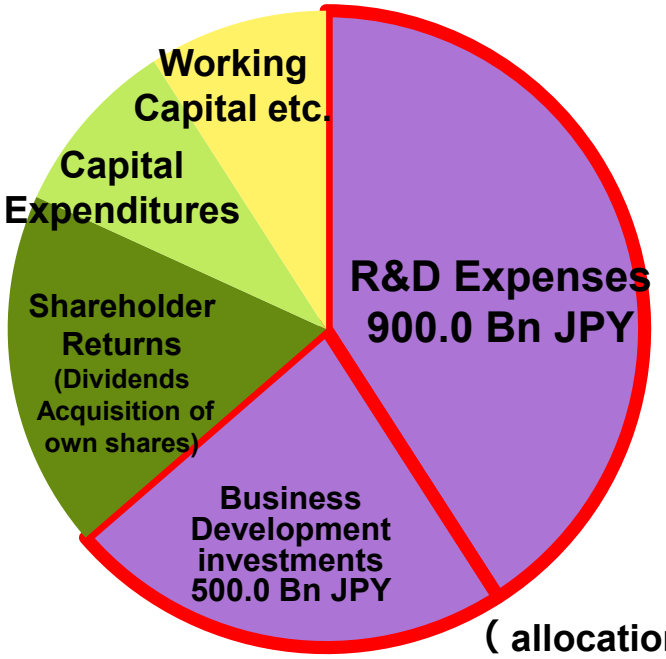
5-Year Business Plan



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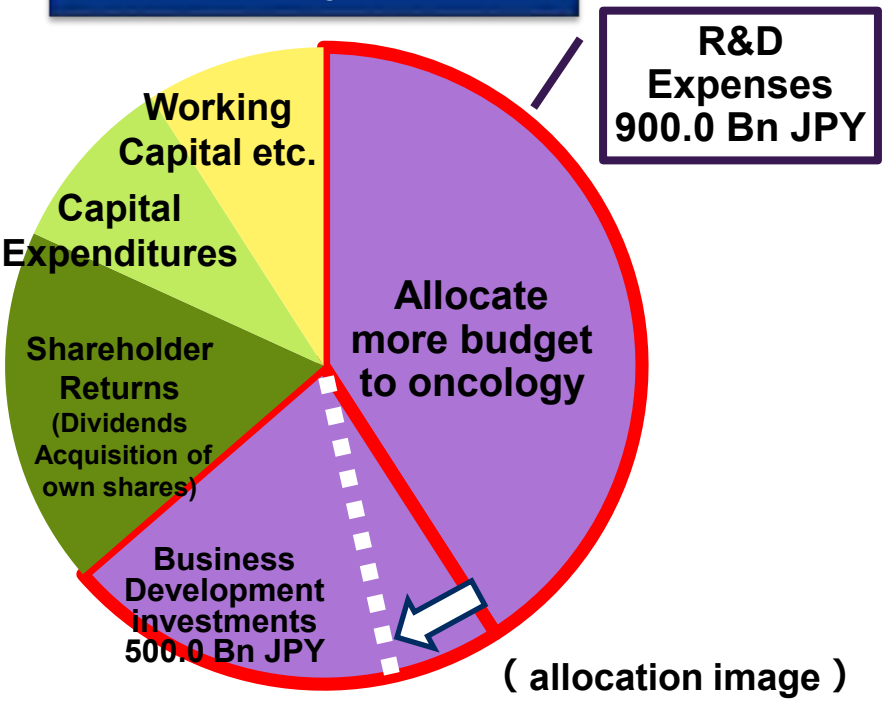
After readjustment



(allocation image)

- Allocate more budget to oncology within 900.0 Bn JPY (decrease budget of other area)
- 500.0 Bn JPY for business development investments may be used for internal investments

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cancerenterprise

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

Daiichi Sankyo Cancer Enterprise
A Force Today, A Leader Tomorrow

December 13, 2017

Antoine Yver MD MSc
Exec VP & Global Head R&D Oncology, Chair Cancer Enterprise

Daiichi Sankyo Cancer Enterprise | **An 18-Month Journey**

May 2016
Introduction

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December 2016
Portfolio assessment & prioritization
- AML and ADC Franchises
- DS-8201 flagship asset

December 2017
Delivering on goals
- Cancer Enterprise 2025 Vision
- Update on progress & short term prospects

2016 2017

CE 2025 | **A *Force* Today, A *Leader* Tomorrow**

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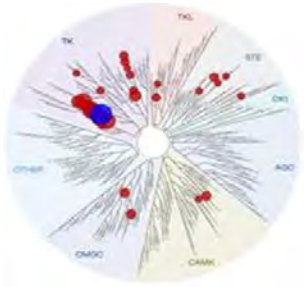
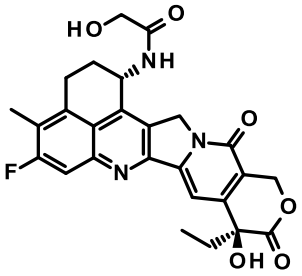
Today's Roadmap

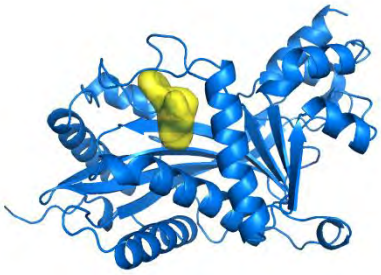
1. **Cancer Enterprise 2025**
   - DS: A Science Company
   - "7 in 8": 7 Distinct NMEs in Next 8 Years
2. Cancer Enterprise: Delivering Now
   - DS-8201: Flagship ADC
   - ADCs: Next Generation
   - Quizartinib: Establishing AML Presence
3. Other Updates and Q&A

Daiichi Sankyo is **Very Unique**

Outstanding medicinal chemistry, antibody engineering & discovery biology







Exceptional scientific attitude

Solve almost any problem when the right questions are asked

CE Sources of **Value and Competitive Advantage**

1 World-Class Research	• Strong foundation in science with exceptional scientific attitude • Focused on smart chemo*/AML Hem Franchise/disruptive** FIC
2 Exceptional Focus	• Relentless focus on aligning biology to unmet needs • Drugs that address biology differentially • Fit-for-purpose development • Development success defined by market access and launch
3 Agile Execution	• Nimble and agile global delivery (US/JP/China footprint) with heavy reliance on external networks
4 Challenging Goals	• Aim for high goal • Innovative partnership/funding
5 Launch Excellence	• Cross-functional value creation team developing pipeline and delivering drugs to patients • Seamless integration with Pharma Tech, Medical Affairs, Market Access and Commercial

*Smart-Chemo: delivering chemotherapy agent precisely to the target and killing tumor cells specifically

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

Cancer Enterprise | **2025 Vision "7 in 8"**

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

Lead in Smart-Treatment with BIC & FIC* ADC	Establish a Competitive Hematology Franchise	Lead with Breakthrough Science
• **Maximize existing Smart-Chemo portfolio** • **Develop next generation of Smart-Chemo** • **Deliver disruptive Smart-Treatments**	• **Lead 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 Cross-Functional Value Creation Team
Changing Standard of Care (SOC) with Each NME

*BIC: Best in Class
FIC: First in Class

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

CE 2025 | **Lead in "Smart-Treatment" with BIC and FIC**

3 Best-in-class, Smart-Chemo NMEs Changing SOC

7 new* clinical-stage assets, including at least 1 disruptive smart treatment

1 Maximize Existing Smart-Chemo DS-8201, U3-1402	• Speed to selected patient subgroups and expand to broader populations / earlier lines • Position Smart-Chemo as modality of choice for combinations • Address China opportunity and challenges
2 Develop Next Generation Smart-Chemo	• Generate BIC or FIC Smart-Chemo NMEs • Innovate to enhance Smart-Chemo (masking, chemo-combo, target mechanisms of resistance) • Pivot development to be *target*-centric, agnostic of organ
3 Deliver Disruptive Smart-Treatments	• Apply DS technology to create disruptive smart treatments to sustain CE leadership beyond 2025

*assumes an average of 1 new clinical stage asset/year

CE 2025 | **Establish a Competitive Hematology Franchise**

3 NMEs in AML Changing SOC

4-5 new* clinical stage assets, of which at least 2 in hematologic malignancies other than AML

1 Lead in FLT3 Mutant Segment Quizartinib mono/combo	• Potential submission in 2018 for Relapsed/Refractory • Best-in-class potential in 1st line setting • Establish quizartinib as backbone for combination • Lead in understanding mechanisms of resistance
2 Expand Beyond FLT3 Mutated AML	• Accelerate development of combinations • Enrich portfolio with innovative complementary MOAs • Business development & licensing for best-in-class clinical stage asset
3 Expand Beyond AML	• Follow the science of current assets beyond AML • ADC approach based on next generation technology

*aim at competitive position in fiercely competitive arena with limited numbers of targets

CE 2025 | **Lead with Breakthrough Science**

1 NME with a disruptive MOA or BIC profile, changing SOC

7 new clinical stage assets and **dynamic translational biomarker(s)**

1 Deliver BIC or FIC Assets with Disruptive MOA

- Leverage DS-1205 (AXL) and DS-1055 (undisclosed) to position CE as leader in delivering disruptive BIC/FIC
- Lead the science by identifying and selecting new target MOA through internal discovery and partnership

2 Embed New Technologies to Magnify the Value of Science

- Incorporate “real time” biomarker with liquid biopsies
- JP CAR-T program technology as foundation for next generation cell therapy

Cancer Enterprise | **Major Clinical Pipeline** (Dec. 2017)

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Franchise	Project Code	Potential Tumors	Preclinical	Phase 1	Pivotal	Designation
ADC	DS-8201 (Her2)	Breast, Gastric IO combo, other Her2+				Breakthrough
	U3-1402 (Her3)	Breast, NSCLC				
	DS-1062 (TROP2)	NSCLC				
AML	Quizartinib (FLT3)	AML 1st/2nd				Fast track
	DS-3032 (MDM2)	AML, Solid Tumors				
	DS-3201 (EZH1/2)	AML, ATL, BCL				
	PLX51107 (BRD4)	AML				
	DS-1001 (IDH1m)	AML, Glioma				
Breakthrough	Pexidartinib (CSF-1R)	TGCT (Tenosynovial Giant Cell Tumor)				Breakthrough
	DS-1205 (AXL)	NSCLC				
	KTE-C19 (CD19 CAR-T)	BCL (B-cell lymphoma) (Japan)				Breakthrough
	DS-1647 (Oncolytic virus)	GBM (glioblastoma multiforme) (Japan)				SAKIGAKE

Daiichi Sankyo Cancer Enterprise 2025

Science Company

Clear Source of Competitive Advantage

7 in 8

Aggressive but Realistic Ambition

CE 2025 | **A *Force* Today, A *Leader* Tomorrow**

Today's Roadmap

1. Cancer Enterprise 2025
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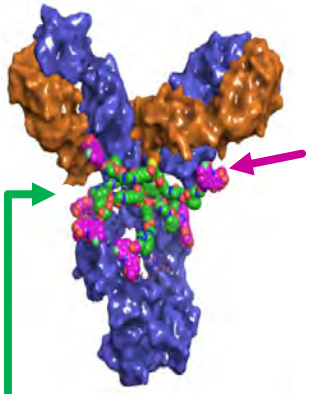
ADC | **Franchise Focus and Flagship Asset**

ADC Franchise

Clinical Stage

Antibody target	Lead indications	Discovery	Pre-clinical	Phase 1	Pivotal
DS-8201 Her2	Breast, Gastric				
U3-1402 Her3	Breast, NSCLC				
DS-1062 TROP2	NSCLC				
DS-7300 B7-H3	Solid Tumors				
DS-6157	GIST				
DS-6000	Renal, Ovarian				

DS-8201 Flagship Asset



Payload

- Novel cytotoxic MOA
- 10X more potent vs SN38
- High cell membrane cross-penetration for bystander effect, killing neighboring tumor cells
- Short systemic half-life

Linker

- High stability, sparing non-cancerous tissue from toxicity
- Selectively cleaved by lysosomal enzymes that are upregulated in tumor cells
- High number of payloads per antibody (DAR, drug antibody ratio)

ADC | **DS-8201** (trastuzumab deruxtecan)

DS-8201 Flagship Asset

Breakthrough Therapy Designation (BTD)

In patients with Her2 advanced breast cancer who have received trastuzumab, pertuzumab, and progressed after T-DM1

First agent with BTD for Her2 disease

Pivotal Development

DESTINY-Breast01
DESTINY-Gastric01

Strategic Partnerships

Bristol-Myers Squibb (nivolumab)
Puma (neratinib)

Data Presentations

ASCO, ESMO, JSMO, SABCS, ASCO GI

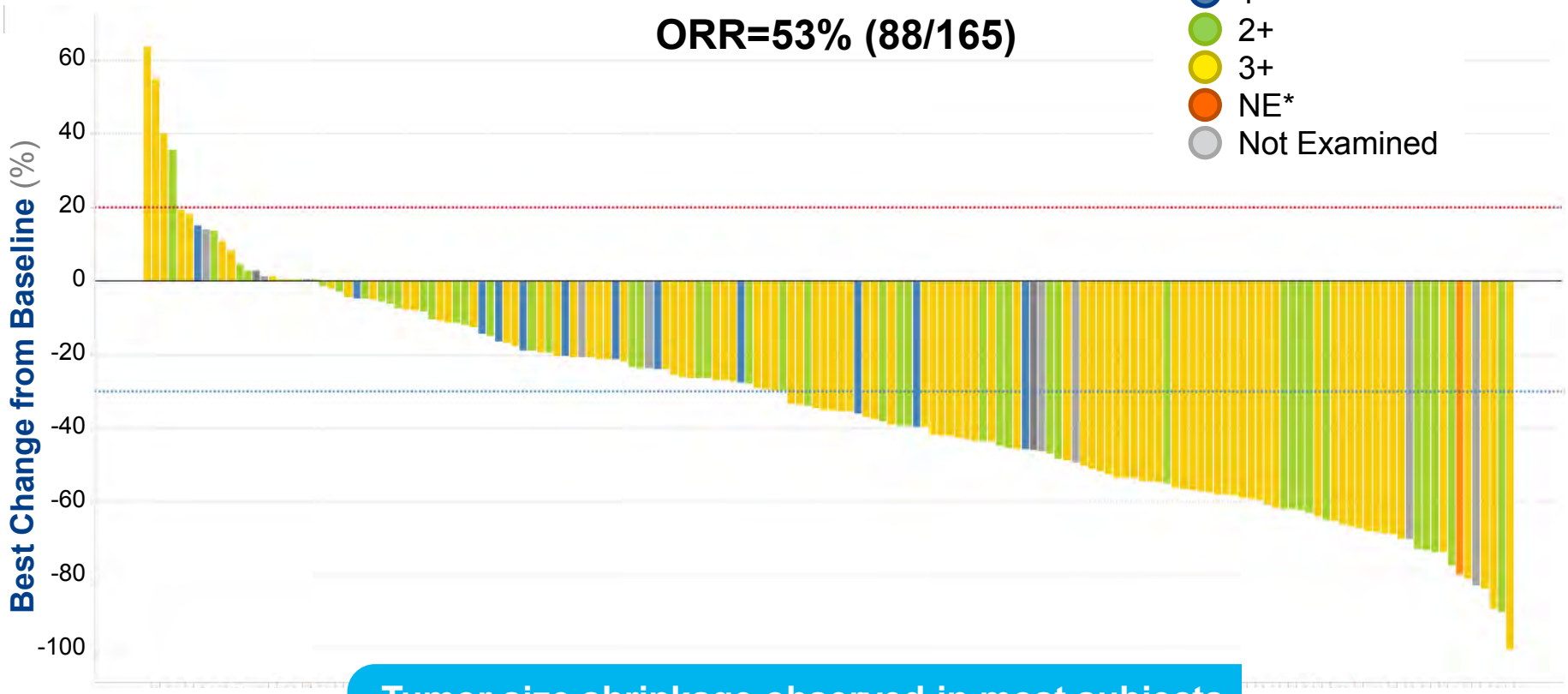
News

- Tracking to plan
- FDA comprehensive BTD meeting mid-December, 2017
- **Further acceleration pending**
  - Contemplating BLA in FY2019
  - Expanding *beyond* Her2 breast/gastric

ADC | **DS-8201** Preliminary Activity

Phase 1 | Any Her2-expressing tumor (n=165)

5.4 + 6.4 mg/kg

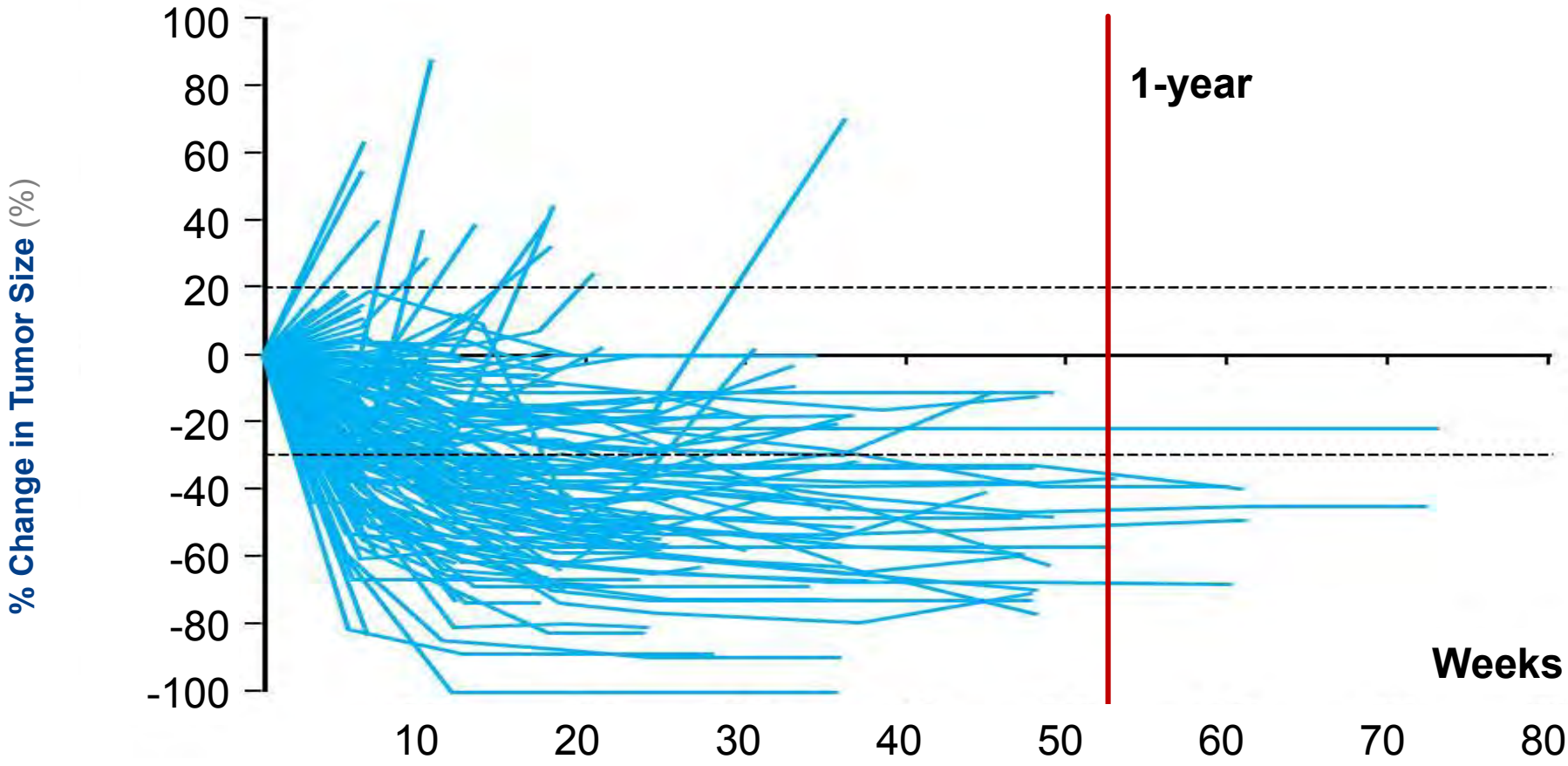


Tumor size shrinkage observed in most subjects

*NE: Not Evaluated (same as Not Examined)

ADC | **DS-8201** Preliminary Activity

Phase 1 | Any Her2-expressing tumor
5.4 + 6.4 mg/kg

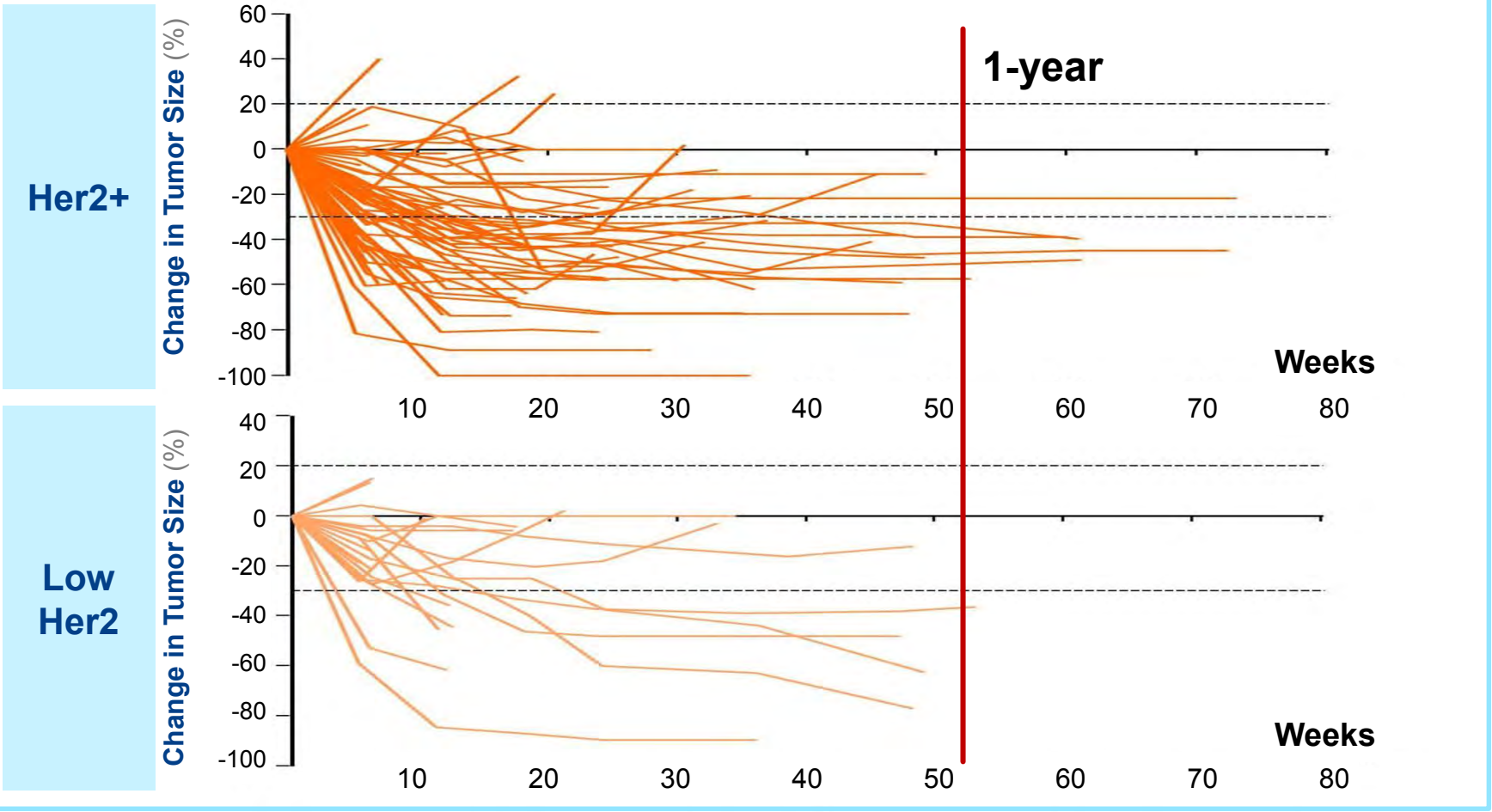


Tumor size control durable in majority of subjects

ADC | **DS-8201** Preliminary Activity

Phase 1 | Her2-expressing breast cancer (n=105)

5.4 + 6.4 mg/kg



ADC | **DS-8201** Preliminary Activity in Her2 Breast/Gastric Cancer

Clinical efficacy

Breast

SABCS 2017

	ORR	Disease Control Rate	PFS Median (months) - range
Her2 Positive (trastuzumab & T-DM1 failure)			
All	**61%** (35/57)	**95%** (54/57)	**10.4** (1.2+, 16.8+)
HR Positive	**56%** (22/39)	**92%** (36/39)	**NR** (1.2+, 16.8+)
HR Negative	**75%** (12/16)	**100%** (16/16)	**10.4** (1.2+, 14.1+)
Prior pertuzumab	**62%** (31/50)	**94%** (47/50)	**10.3** (1.2+, 16.8+)
Her2 Low			
All	**32%** (6/19)	**84%** (16/19)	**NR** (0.5, 12.2+)
HR Positive	**31%** (5/16)	**88%** (14/16)	**NR** (1.2+, 12.2+)
HR Negative	**0%** (0/2)	**50%** (1/2)	**7.6** (0.5, 7.6)

Gastric

ASCO 2017, to be updated at ASCO GI Jan. 2018

	ORR	Disease Control Rate
Her2 Positive		
All	**44%** (16/36)	**89%** (32/36)
Prior CPT 11	**44%** (8/18)	**94%** (17/18)

Sources: Doi T, *et al*. ASCO, 2017. Modi S, *et al.* SABCS, 2017.

N/A – Not Available

ADC | **DS-8201** Treatment-Emergent Events

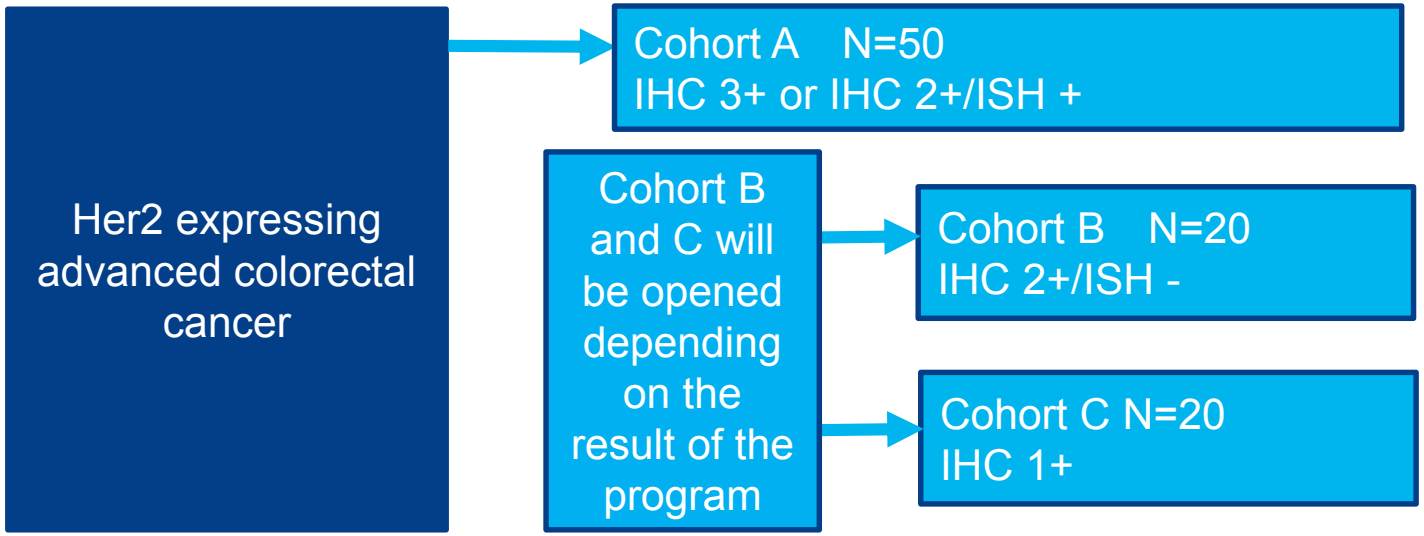
Treatment-emergent events, any grade (>20%)
All subjects with 5.4 or 6.4 mg/kg (N = 185, as of 15 Oct 2017)

	n (%)				
Preferred Term (MedDRA v18.0.)	Grade 1	Grade 2	Grade 3	Grade 4	Any
Hematologic					
Anaemia	14 (7.6)	22 (11.9)	25 (13.5)	2 (1.1)	63 (34.1)
Platelet count decreased	27 (14.6)	14 (7.6)	13 (7.0)	6 (3.2)	60 (32.4)
Neutrophil count decreased	1 (0.5)	17 (9.2)	23 (12.4)	8 (4.3)	49 (26.5)
White blood cell count decreased	5 (2.7)	17 (9.2)	21 (11.4)	3 (1.6)	46 (24.9)
Gastrointestinal disorders					
Nausea	99 (53.5)	25 (13.5)	7 (3.8)	0 (0.0)	131 (70.8)
Decreased appetite	64 (34.6)	34 (18.4)	9 (4.9)	0 (0.0)	107 (57.8)
Vomiting	51 (27.6)	9 (4.9)	3 (1.6)	0 (0.0)	63 (34.1)
Diarrhea	43 (23.2)	11 (5.9)	3 (1.6)	0 (0.0)	57 (30.8)
Constipation	45 (24.3)	6 (3.2)	1 (0.5)	0 (0.0)	52 (28.1)
Others					
Alopecia	51 (27.6)	10 (5.4)	0 (0.0)	0 (0.0)	61 (33.0)
Malaise	31 (16.8)	12 (6.5)	2 (1.1)	0 (0.0)	45 (24.3)
Fatigue	26 (14.1)	11 (5.9)	1 (0.5)	0 (0.0)	38 (20.5)

Two cases of potential Grade 5 pneumonitis have been reported and will be assessed by an interstitial lung disease (ILD) adjudication committee

ADC | **DS-8201** CRC Phase 2 Study

DS-8201: CRC 3rd or subsequent line, planned to start from Q4 FY2017



Primary Endpoint	ORR
Secondary Endpoint	PFS, OS, DOR, DCR

ADC | **DS-8201** Comprehensive Translational Research

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Gaining Insights From Many Studies

Mechanism of Action (MOA)

Why does DS-8201 appear active in wide range of Her2-expressing tumors?

Mechanism of Resistance (MOR)

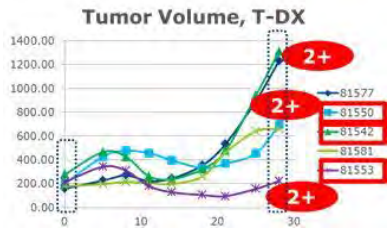
How do tumors become resistant to DS-8201?

Rationale for Combinations

What are complementary mechanisms beyond IO combination?

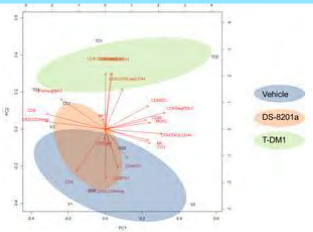
How might we develop for earlier lines of treatment?

RNA Seq | Exome Seq

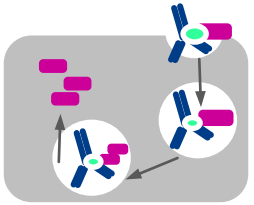


Trafficking Study

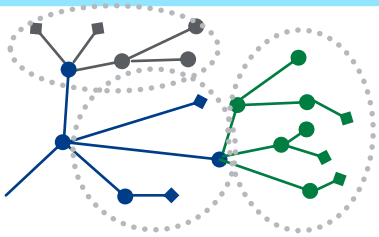
I/O Combination



Internalization

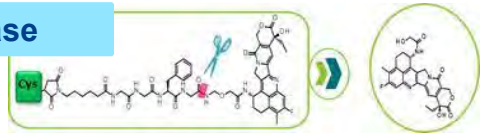


Modeling & Simulation



T-DM1 Resistance

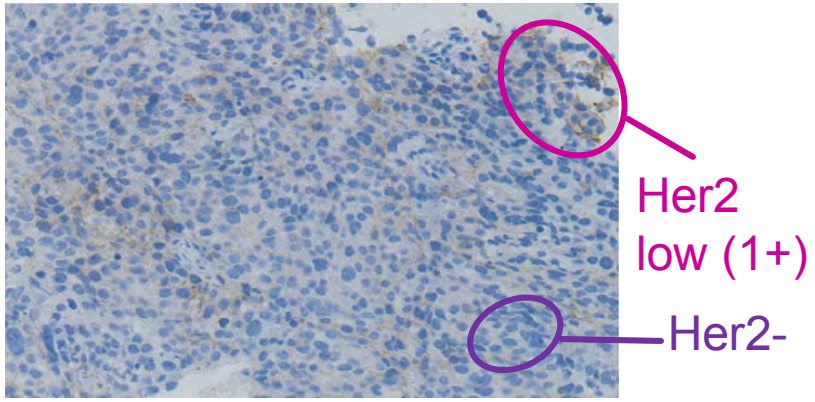
Payload Release



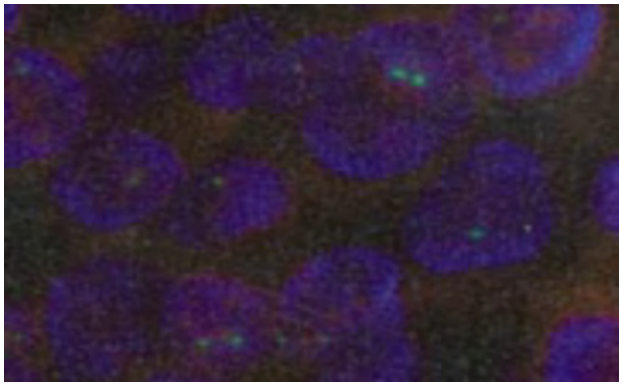
ADC | **DS-8201** Bystander Effect in **Low Her2**

Breast Her2 Low

Patient-derived xenograft ST565
(IHC 1+, FISH -)

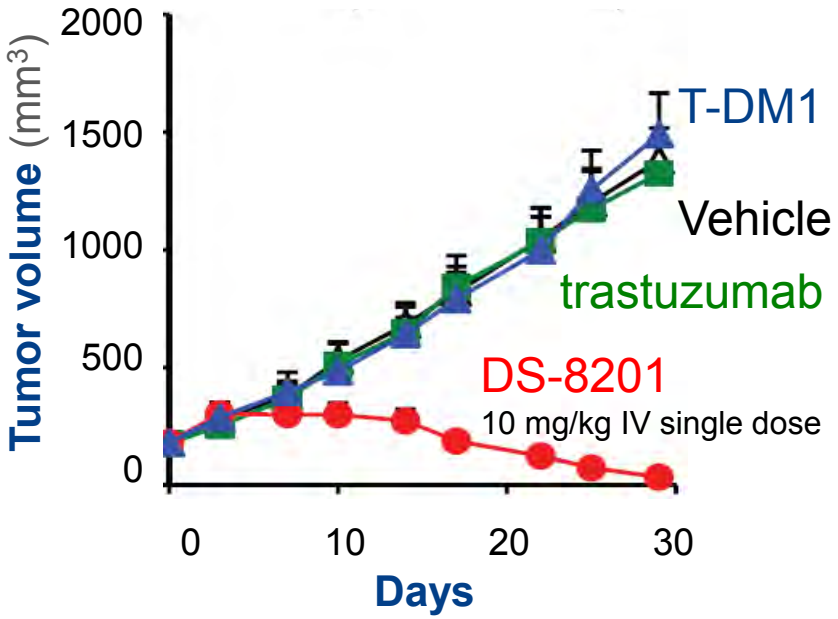


FISH negative (signal ratio 1.3)



Change in tumor volume (mm^3)

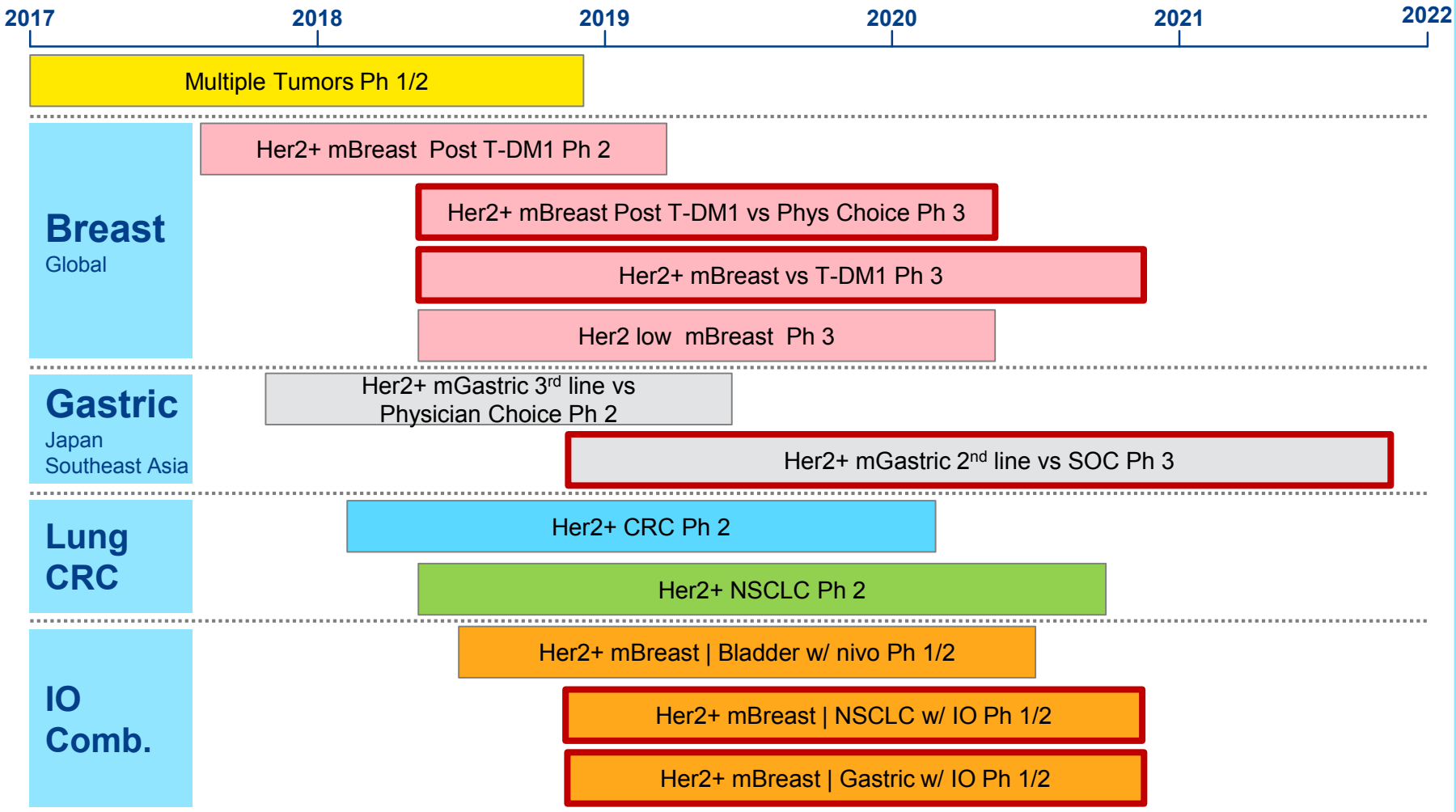
Patient-derived xenograft ST565



Source: Ogitani-Y et al., *Clin. Cancer Res.* 2016; 22:5097-5108

ADC | **DS-8201: Broad and Bold Program**

Estimated development timelines



Newly Disclosed Studies

ADC | **DS-8201** Program Meeting Goals

Current Studies

Pivotal Studies Actively Recruiting

230
Subjects enrolled program wide

DESTINY

DESTINY-Breast01
DESTINY-Gastric01

US, Japan Trial Sites
fully operational
Rest of world in early 2018

Planning & Other Activities

7
Additional studies in 2018, including:
Head-to-head vs T-DM1

2 IO Combo

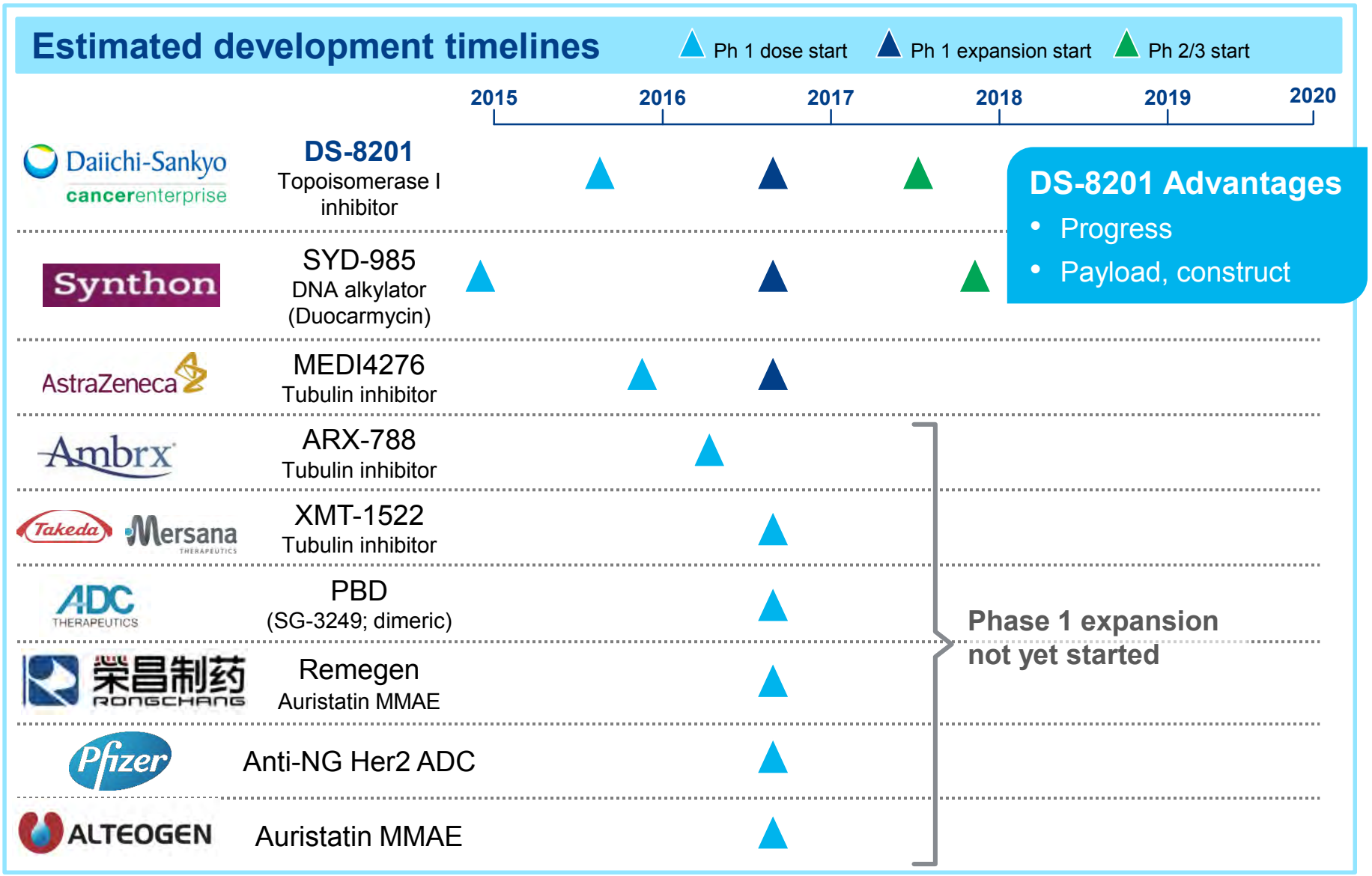
Drug Supply
On track

Agency Interactions
Japan PMDA
US FDA
EMA & EU HTAs
South Korea MFDS
China C-FDA

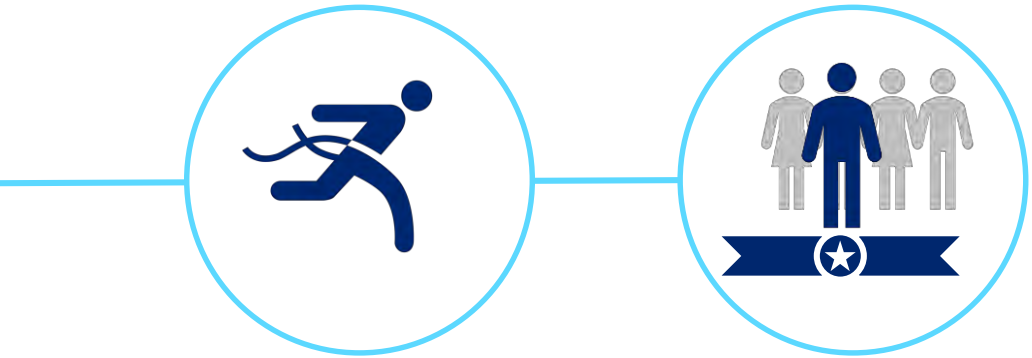
Leadership Roles Filled

News at ASCO GI and ASCO 2018

ADC | **DS-8201** is a Leader in Next Generation Her2 ADCs



ADC | **DS-8201** Delivering in Her2 Tumors



Leading Next Generation Her2 ADC

Contemplating FY2019 submission

Potential Best-in-Class

Pan-Her2

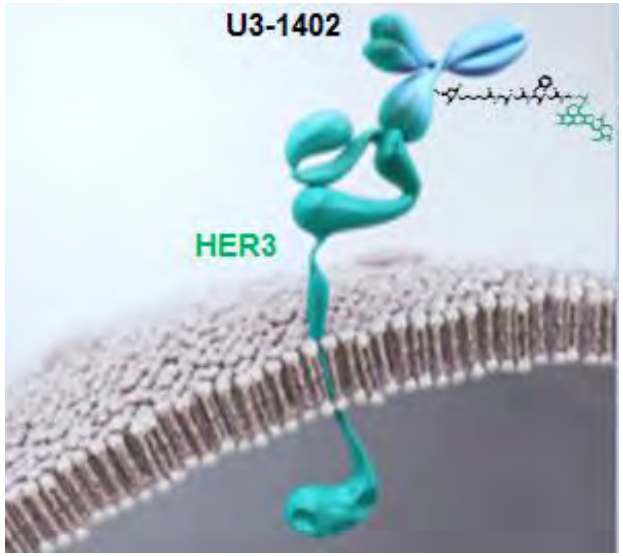
ADC+

Expansion Through Combination

IO, TKI

ADC | **U3-1402** A First-in-Class Opportunity

Her3 is an important target for ADC Smart-Chemo

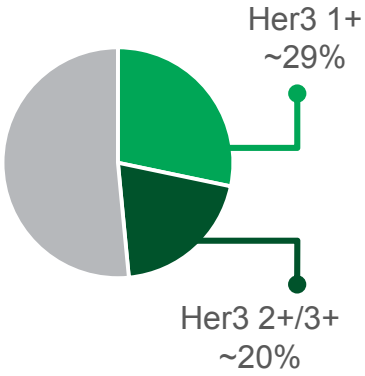


Same ADC Technology
DAR8

+

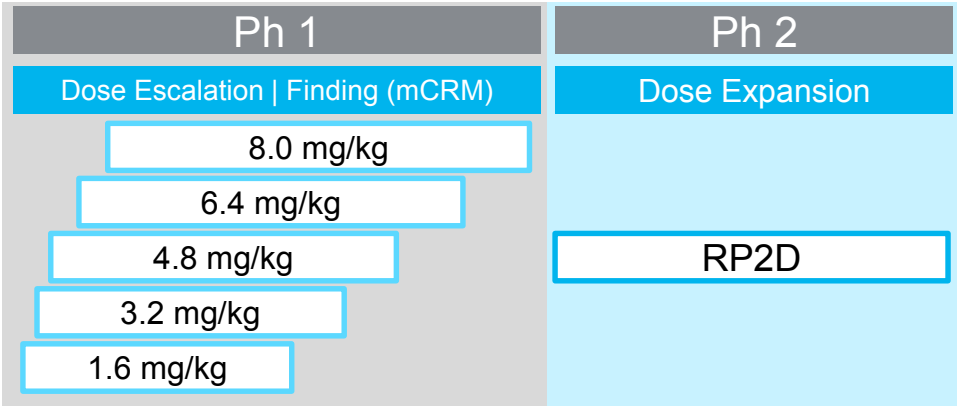
patritumab
Clinically validated mAb
Acceptable safety & tolerability in >300 subjects

Her3 Expression
In 188 screened breast cancer study patients



U101 Breast Study: Status

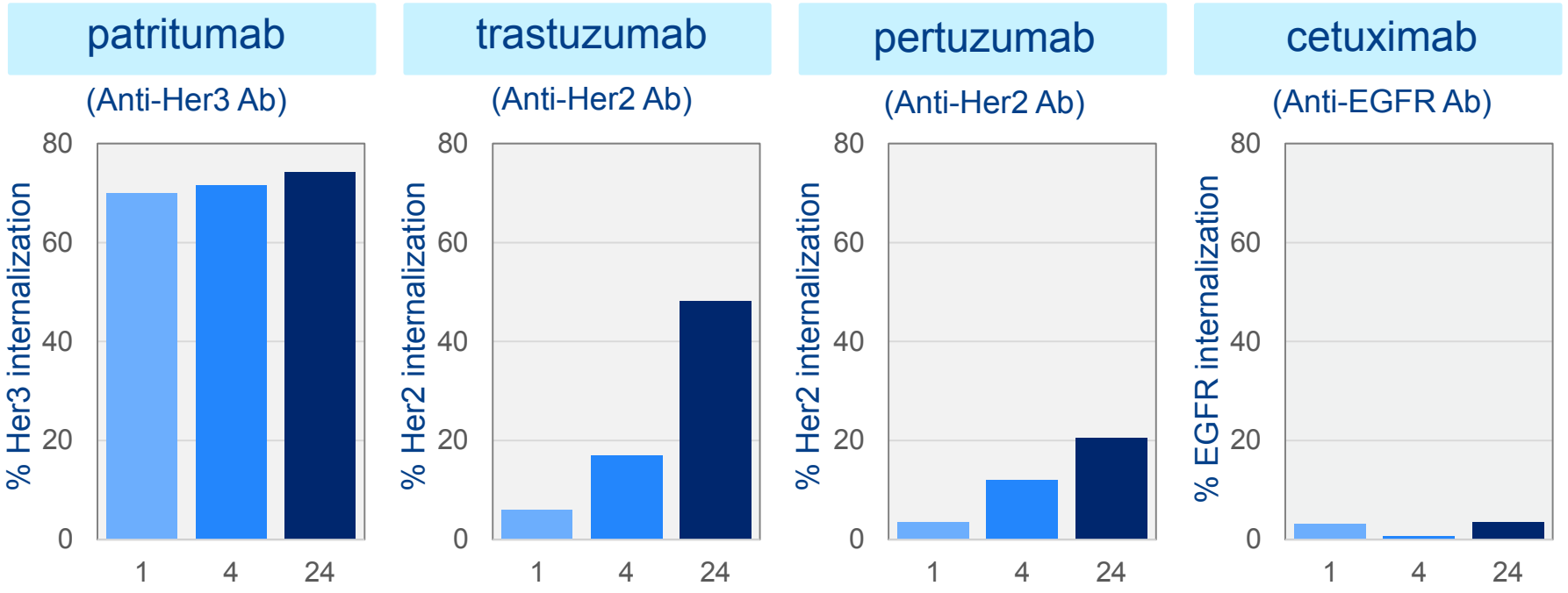
- Japan and now Global
- Dose escalation at 5th level (8.0 mg/kg, q3w)
- Manageable safety at 6.4 mg/kg
- **MTD not reached**
- **Partial responses and durable stable disease confirmed by investigator assessment (preliminary results)**
- **Data at ASCO 2018**



Source: *Clin Cancer Res* 2013 Jun 1;19(11):3078-87; *Cancer Chemother Pharmacol* 2014 Mar;73(3):511-6.

ADC | **High Her3 Internalization in Breast Cancer**

Her3 internalization rate, compared to Her2 or EGFR



T47D luminal breast cancer cells, expressing all 4 Her family members, determined by FACS

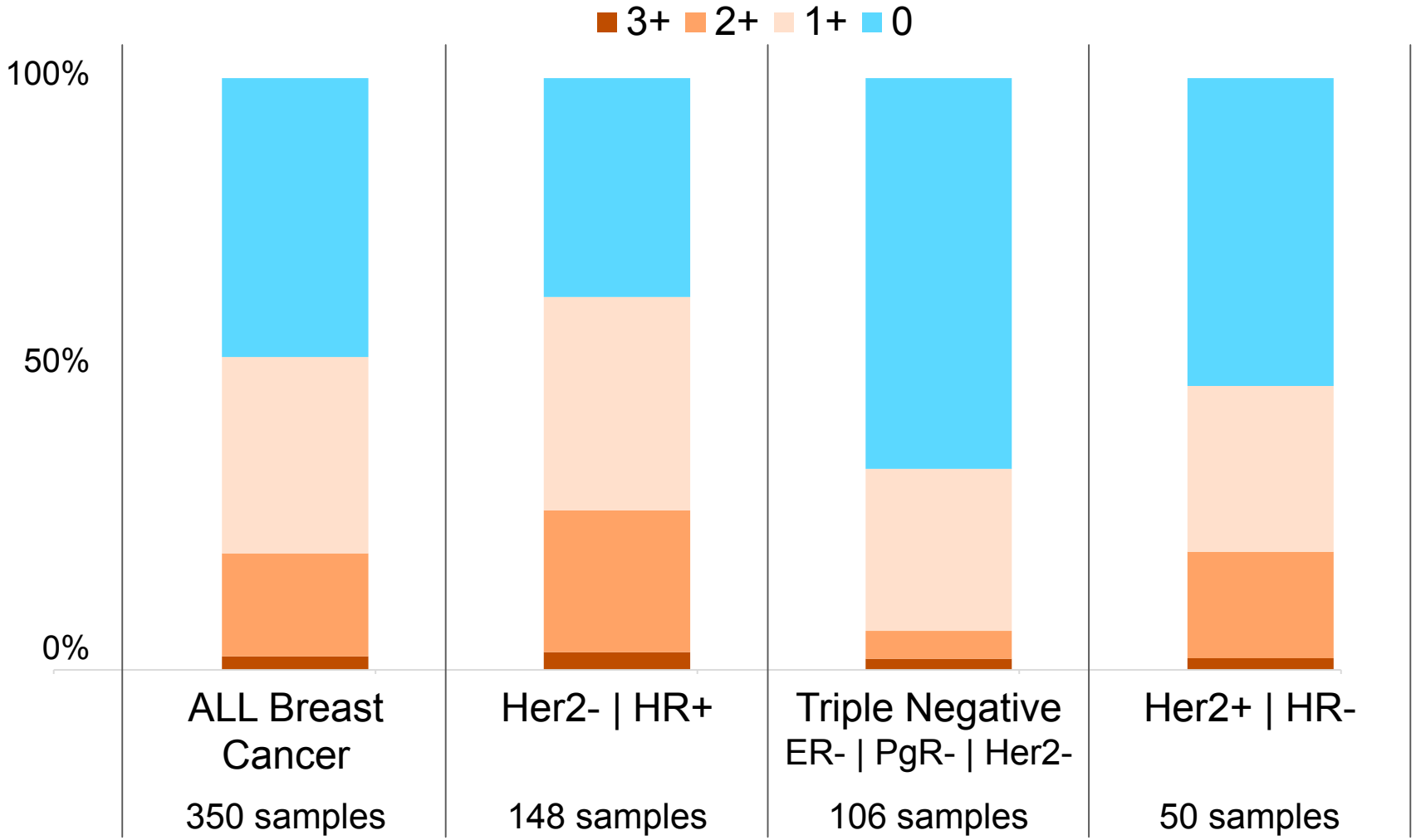
■:1 hour, ■: 4 hours, ■: 24 hours after treatment of Ab

Source: Hettmann T et al, 2010 AACR

ADC | **Her3 Expression in Breast Cancer**

Daiichi-Sankyo cancerenterprise

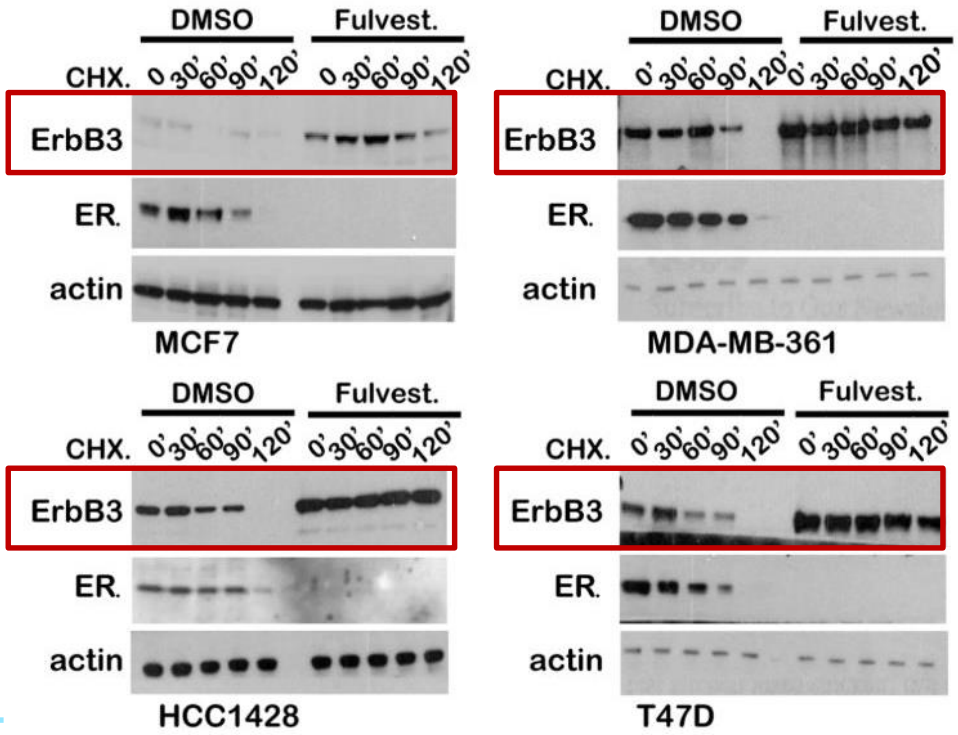
Her3 IHC on breast cancer subtypes; DS in-house data, tissue microarray

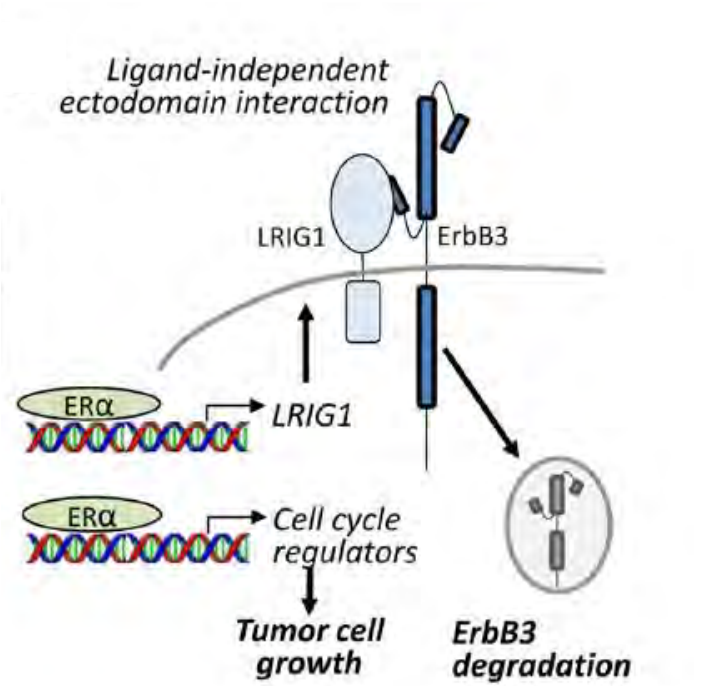


ADC | **Her3 Upregulation in Breast Cancer**

Her3 upregulation by hormone therapy

ERα-induced expression of LRIG1 maintains ErbB3 (Her3) at low levels in luminal breast cancer cells. Endocrine inhibitors, such as fulvestrant, tamoxifen, or aromatase inhibitors cause reduced LRIG1 expression levels, allowing ErbB3 accumulation at the cell surface.





Source: *Oncogene;* 2016 Mar 3;35(9):1143-52

ADC | **U3-1402** Also an Opportunity in NSCLC

U3-1402: U102 Phase 1/2 Study in NSCLC EGFRm

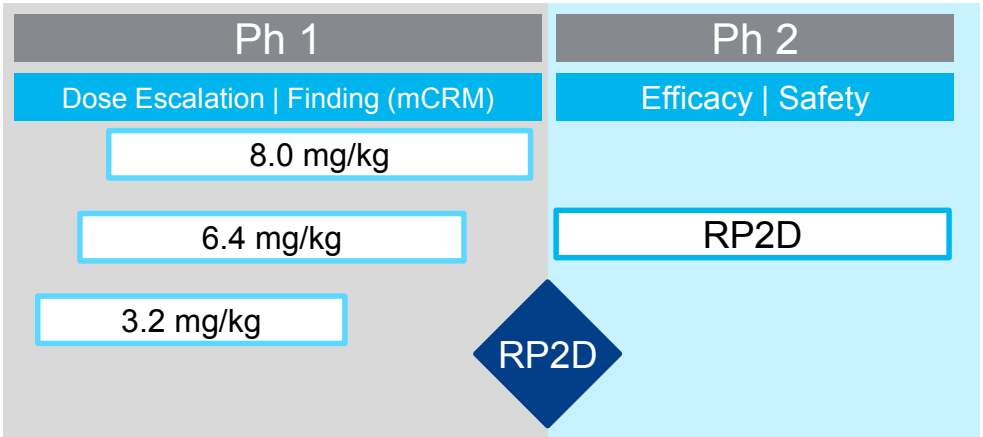
Target indication
NSCLC EGFRm, T790M+ osimertinib failure or T790M- EGFR TKI refractory

Her3
Not prospectively screened

Her3 Prevalence

~75%
Her3 1+/2+/3+
In-house
n=44 IHC Ventana

Current Status
- First subject dose 3.2 mg/kg
- **Fast to market track**

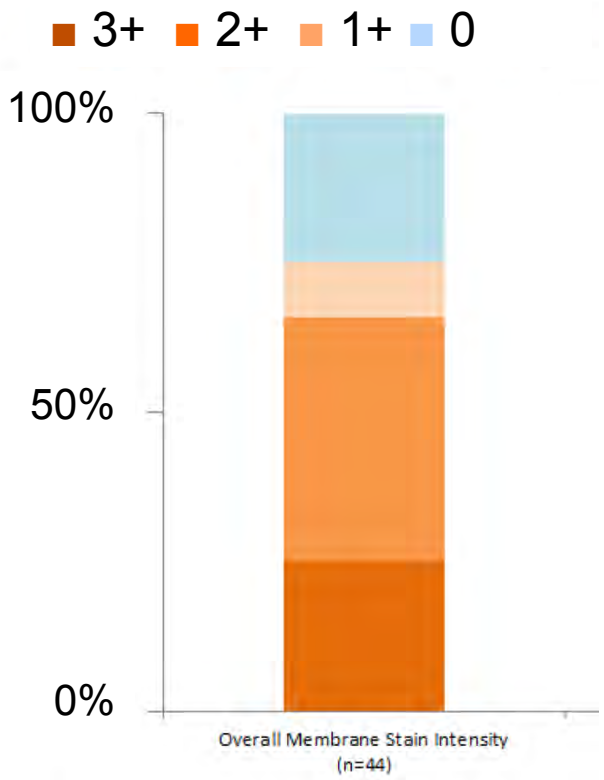


ADC | **Her3 Expression in NSCLC & Other Tumors**

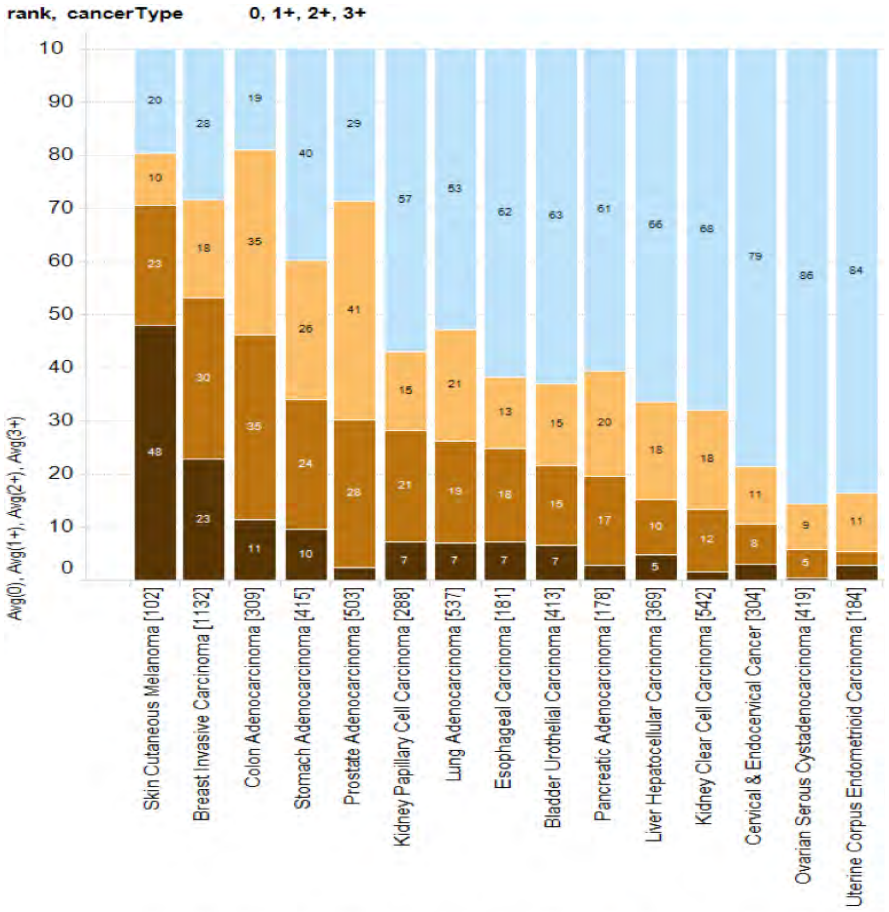
Her3 expression IHC | mRNA

NSCLC EGFRm

Ventana formulation lock assay
N=44 clinical samples (data on file)



TCGA* mRNA Her3

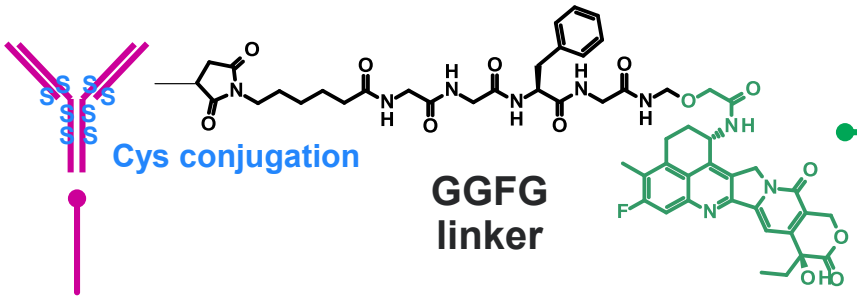


Her 3 expression in various cancer types

*The Cancer Genome Atlas

ADC | **DS-1062** is Our Third ADC Reaching the Clinic

TROP2 ADC is designed to be best in class



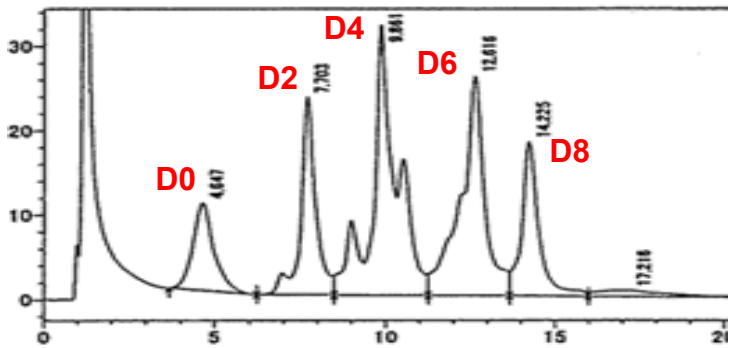
Payload
Topoisomerase I inhibitor

Antibody
Humanized anti-TROP2 monoclonal antibody (hIgG1)

Selective-DAR4 to protect safety margin

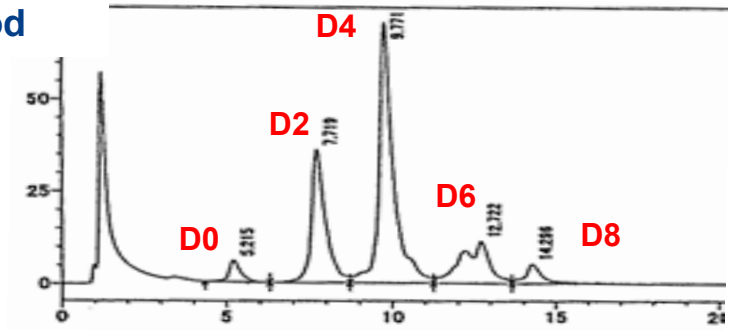
Non-selective DAR*4

HIC



Optimized conjugation method

Selective DAR4

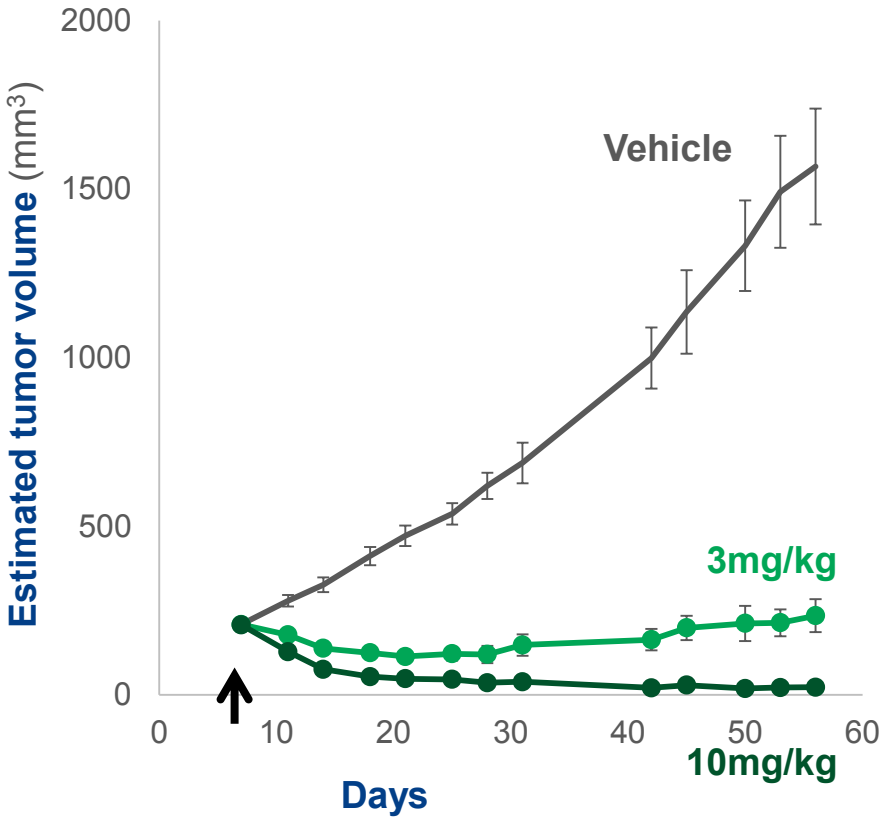


*drug-antibody ratio

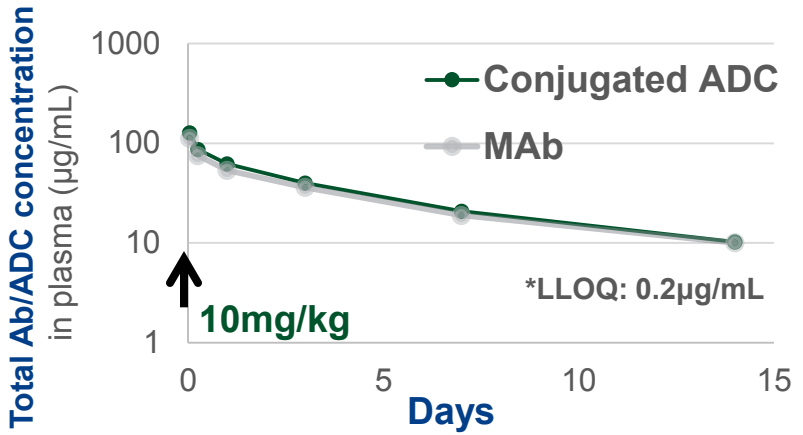
ADC | **DS-1062** Exhibits Strong Anti-Tumor Activity

Xenograft mice models

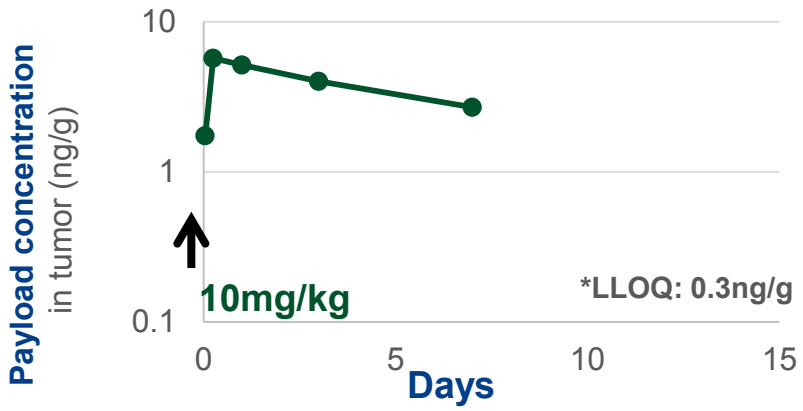
NCI-N87 (Gastric) [TROP2 IHC: 3+]



Total Ab/ADC in plasma



Payload in tumor

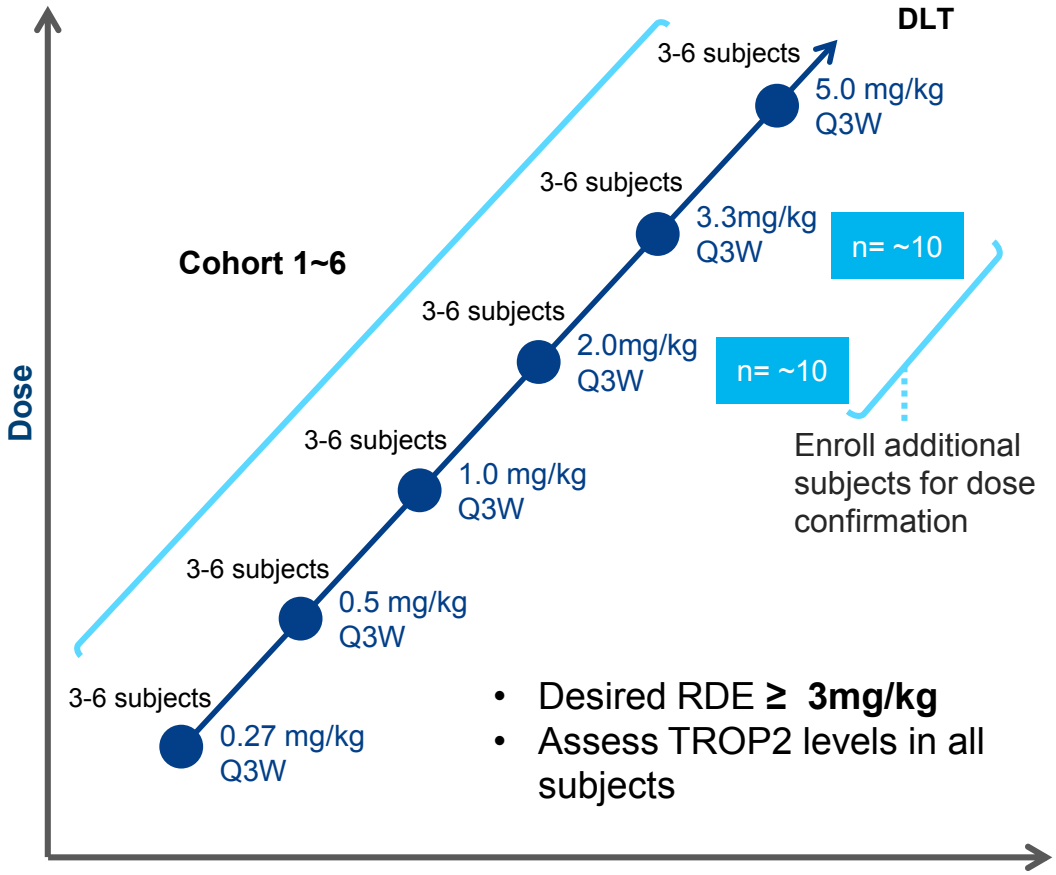


Able to deliver payload due to high stability in plasma

ADC | **DS-1062** Risk Mitigated to Substantiate Best-in-Class Potential

DS-1062 FIH Study: NSCLC ≥ 3rd line, planned to start from Q4 FY2017

Dose Escalation



Enroll additional subjects for dose confirmation

- Desired RDE ≥ **3mg/kg**
- Assess TROP2 levels in all subjects

Dose Expansion

n=40 in RDE* — PoC

Assess efficacy and safety for GO/NO-GO decision

Following NSCLC POC

- Open other expansion for other TROP2 tumors

PoC — **Expansion Indication 1**

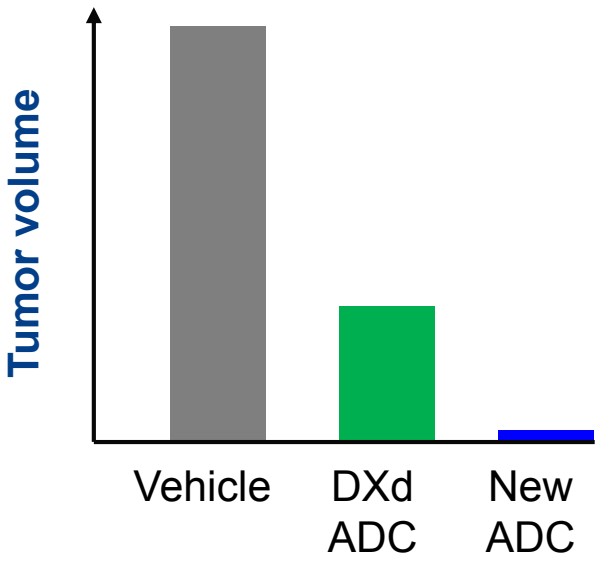
Expansion Indication 2

*RDE: Recommended dose for expansion

ADC | **Next-Gen ADC** is More Potent than Current ADC

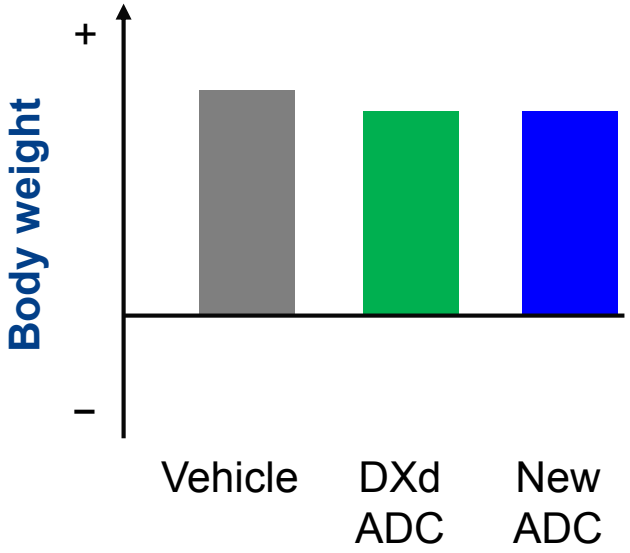
Daiichi-Sankyo cancerenterprise

Change in tumor size
after single injection at optimal dose



Tumor reduction

Change in body weight



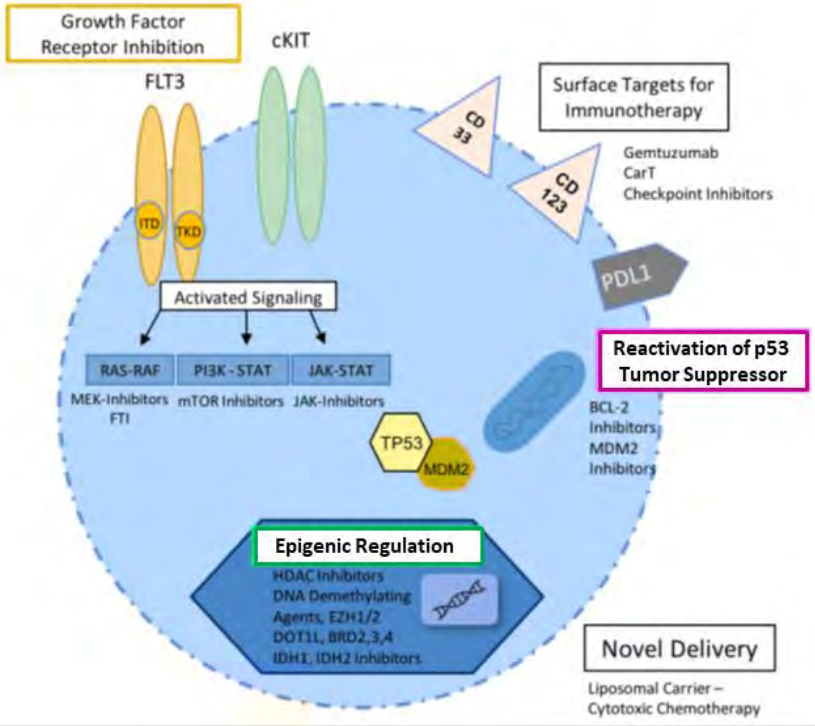
No relevant change

ADC | **In Summary**

- **Swiftly progressing ADCs**
- Proven **ability to modulate / adapt the technology** to the circumstances of the Smart-Chemo delivery carrier MAbs
- A compelling hint about what is coming next, with our **next generation ADC technology**

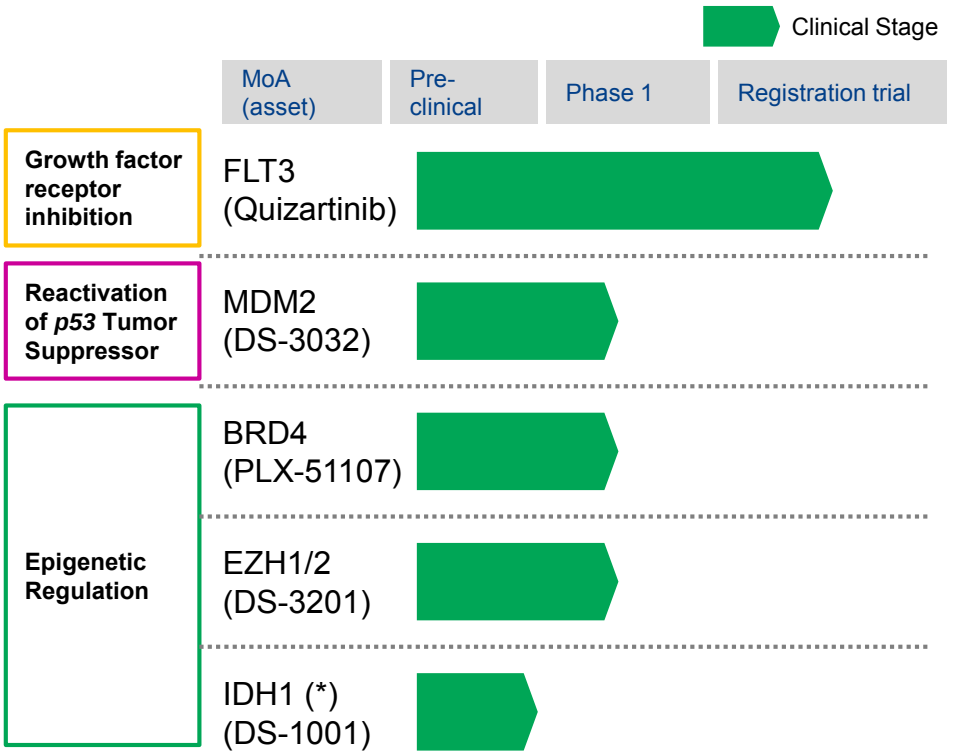
AML | **Our Pipeline**

Emerging classes of targets



Developing 3 of 6 emerging classes of targets

AML Franchise



- **Quicker development of combinations**
- **Address emergence of resistance**
- **Access and pricing flexibility**

(*): Ph1 in glioma. Preclinical development in AML.

Source: Adapted from Dohner-H *et al.*, NEJM 2015; 373:1136-1152, Thol-F *et al.*, Blood 2015; 126:319-327, Khan *et al.*, Clin Can Res, 2012; Ramos-N, *et al.*, J. Clin. Med. 2015; 4:665-695, Isidori-A *et al.*, Can Res Frontiers 2016; 2:226-251

AML | **Quizartinib**

Quizartinib AML Flagship Asset

Enrollment Completed

QuANTUM-R STUDY

Enrollment on Track
despite availability of midostaurin

QuANTUM-FIRST STUDY

Strategic Partnership
MD Anderson Cancer Center

Combination
Planning 1st novel-novel combination:
Quizartinib + DS-3032 (MDM2i)

ESMO17 and ASH17
11 abstracts

News

Tracking to plan

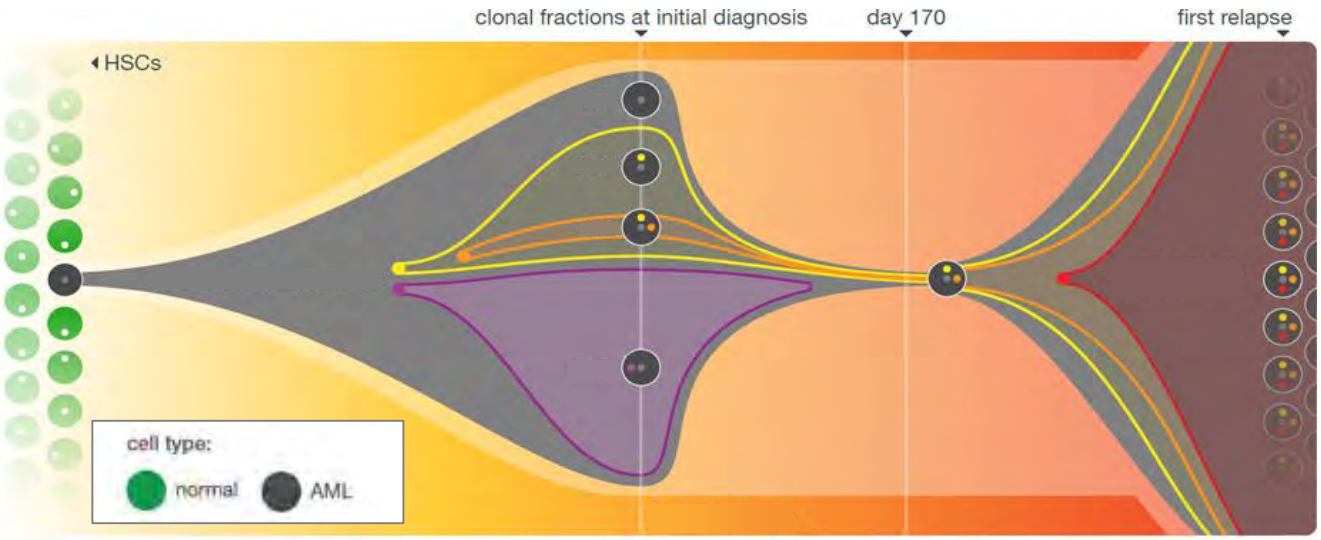
FIVE Axes

1. Global **simultaneous submissions**
2. **Accelerate** first-line AML study
3. **Deploy AML Franchise assets** through single agent and combination
4. Enhance through internal research and **collaborations**
5. **Enrich** with targeted business development / licensing

AML | **Complex Biology**

2 pivotal trials aimed at changing standard of care
by exploring role of a specific and potent FLT3 inhibitor

Clonal evolution Emergence of FLT3 addiction



Treatment algorithm for patients with FLT3 mutated AML

FLT3 mutated AML

Induction
Chemo +/- FLT3i

Consolidation Chemo
+/- transplant
+/- maintenance
+/- FLT3i

Salvage Chemo +/- transplant

QuANTUM-FIRST STUDY

Chemo + Quiz vs Chemo + Pbo

Chemo + Quiz vs Chemo + Pbo followed by Maintenance Quiz vs Pbo

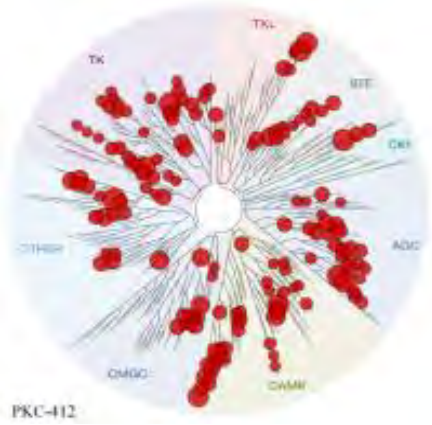
QuANTUM-R STUDY

Quizartinib vs salvage chemo

AML | **Quizartinib** is a Selective and Potent FLT3 Inhibitor

1st generation, multi-kinase

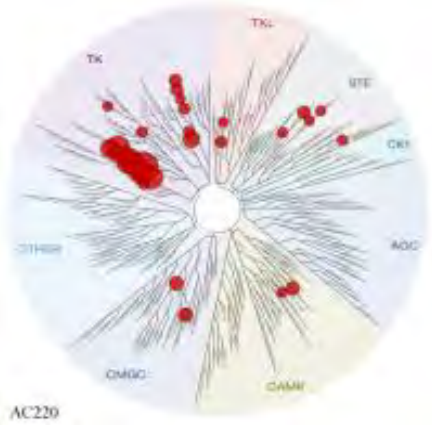
Midostaurin



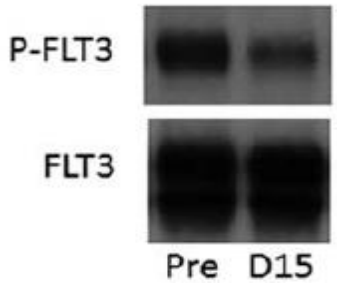
IC_{50} in plasma: 1700 nM

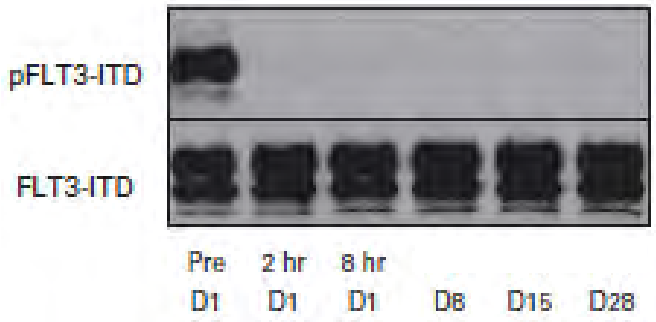
2nd generation, selective, potent

Quizartinib



IC_{50} in plasma: 18 nM





Sources: Davis MI et al. Nat Biotechnol. 2011; 29: 1046-51; Pratz *et al*. Blood 2010;115:1425; Strati *et al*. Am J Hematol. 2015; 90:276; Cortes *et al*. J Clin Oncol. 2013; 31:3681

AML | **Quizartinib** Strong Activity in Relapsed/Refractory AML

Monotherapy Phase 2

Midostaurin		Quizartinib	
0%	CR/CRp/CRi	**46-57%**	CR/CRp/CRi
3%	CR/CRp/CRi/PR	**71-78%**	CR/CRp/CRi/PR
38%	Reduced marrow blasts		
50 days	Median duration of response	**79 days**	Median duration of response

Sources: Fischer et al 2010; J Clin Oncol 28:4339-4345; Cortes JE, Perl AE, Dombret H, et al. J. Clin. Oncol. 2013;31(15 suppl):7012. Dohner H, Perf A, Rousselot P, et al. Haematologica. 2013;98(supplement 1):233.

AML | **Quizartinib** Establishing Backbone in FLT3 Segment

Daiichi-Sankyo cancerenterprise

QuANTUM-R STUDY

First & best-in-class potential

- Ph 3, registrational study, n=363
  - **Relapse/refractory FLT3-ITD AML**
  - Single agent study
  - Primary endpoint: Overall survival
- Japan Ph 2 study underway

Preparing for global submissions

- Enrollment complete Aug 2017
- Top Line: 1H FY2018
- Preparing for global “simultaneous” submissions in US EU JP ~2H FY2018

QuANTUM-FIRST STUDY

Best-in-class potential & key value driver

- Ph 3, registrational study, n=536
  - **Newly diagnosed FLT3-ITD AML**
  - Combination study with chemotherapy
  - Primary endpoint: Event-free survival
  - First subject randomized: September 2016
  - Global trial in 28 countries

Study ahead of initial projections

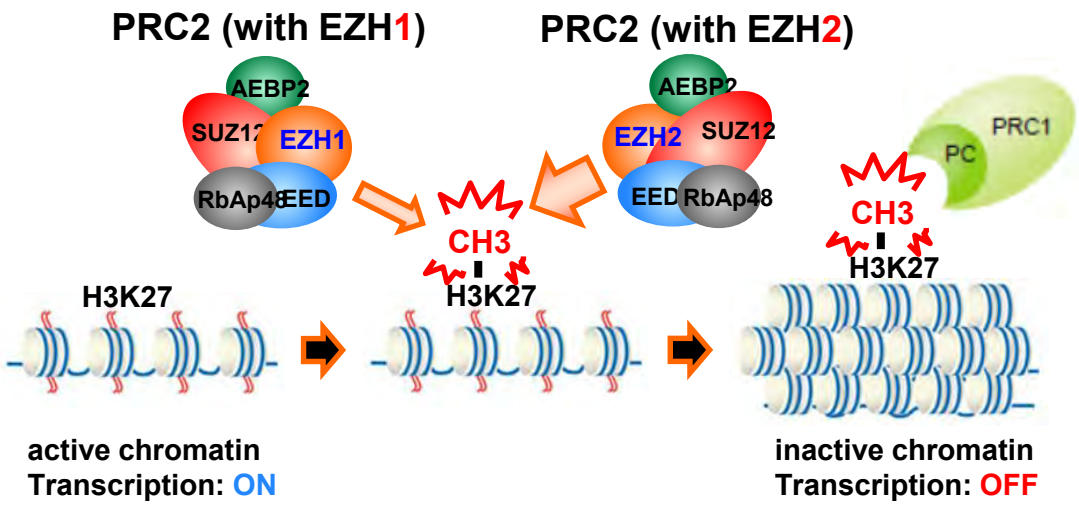
- >25% enrollment complete
- Focus on global deployment

AML | **DS-3201 (dual EZH 1/2 inhibitor)**

DS-3201

Potent and selective dual inhibitor of the histone methyltransferases (histone-modifying enzymes) EZH1 and EZH2 at histone H3 (H3K27)

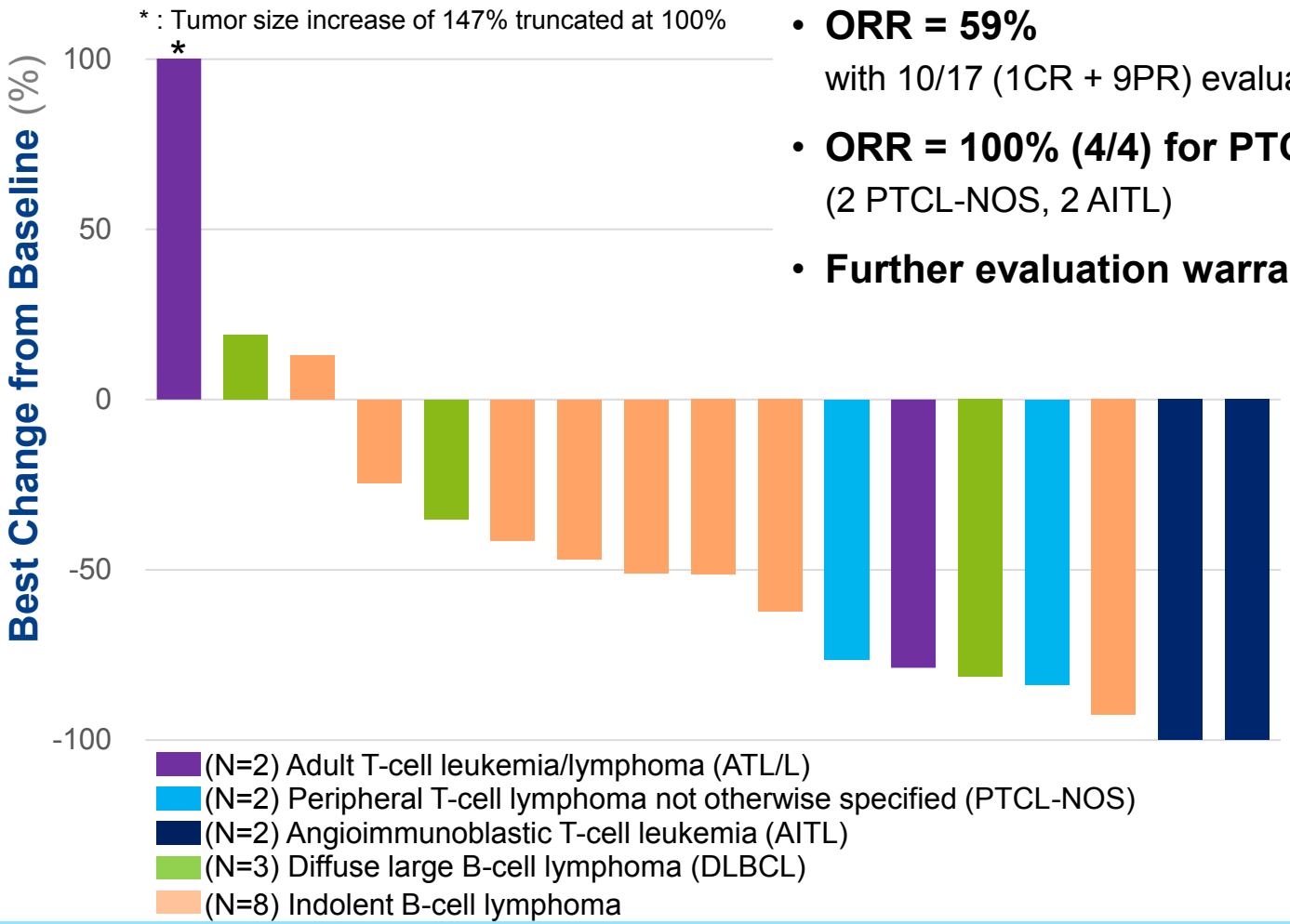
A promising new epigenetic approach



- Tri-methylation of H3K27 (H3K27me3) is negative regulator of tumor suppressor genes or cell differentiation genes
- **Dual inhibition of EZH1 and EZH2** is hypothesized to allow more potent blockade of hyper methylation of H3K27 and overcome compensatory mechanism between EZH1 and EZH2

Phase 1

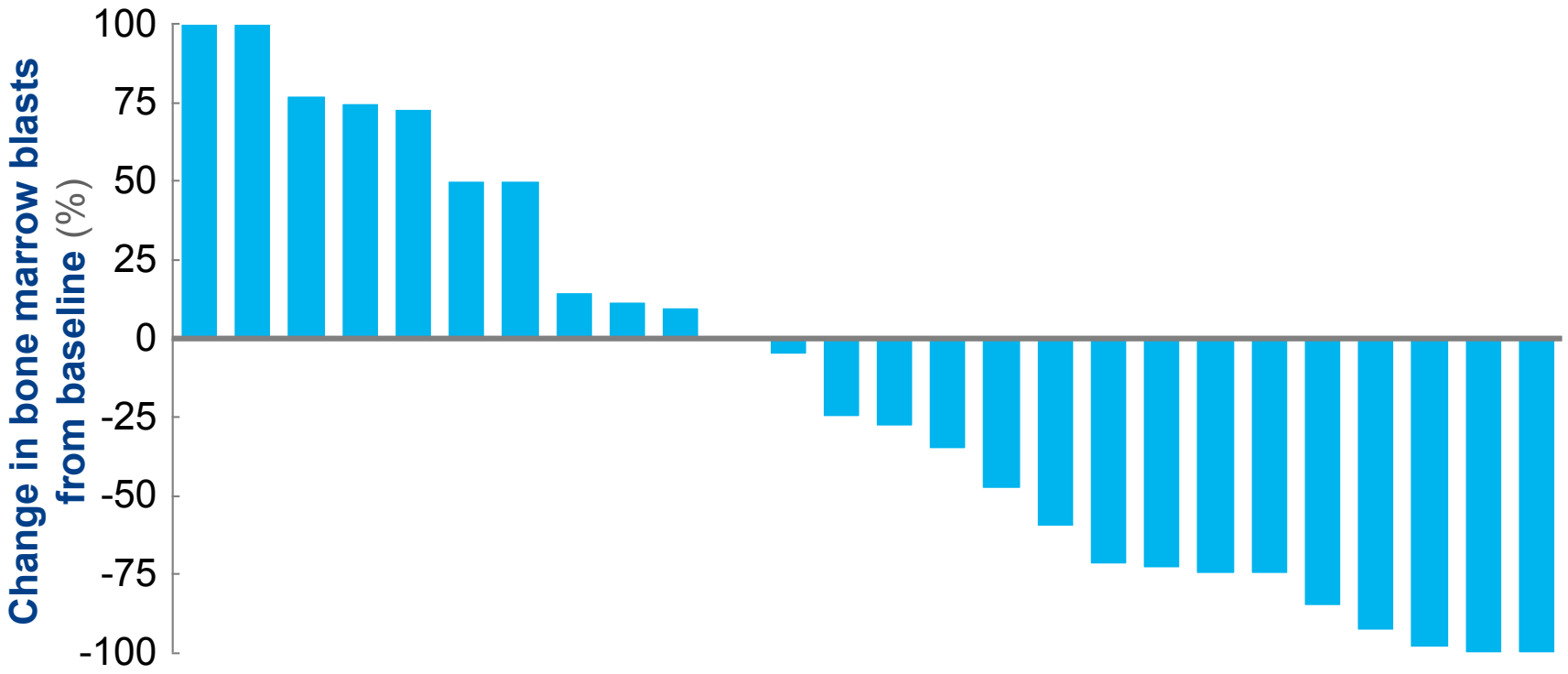
Preliminary results in relapsed or refractory Non-Hodgkin lymphomas



- **ORR = 59%**
  with 10/17 (1CR + 9PR) evaluable patients
- **ORR = 100% (4/4) for PTCL**
  (2 PTCL-NOS, 2 AITL)
- **Further evaluation warranted in ATL/L**

AML | **MDM2 Inhibitor (DS-3032)** ASH 2016 data

Preliminary activity of monotherapy DS-3032 in R/R AML and MDS patients, N=26 (Phase 1)



Bone marrow blast reduction in ~60% of evaluable subjects

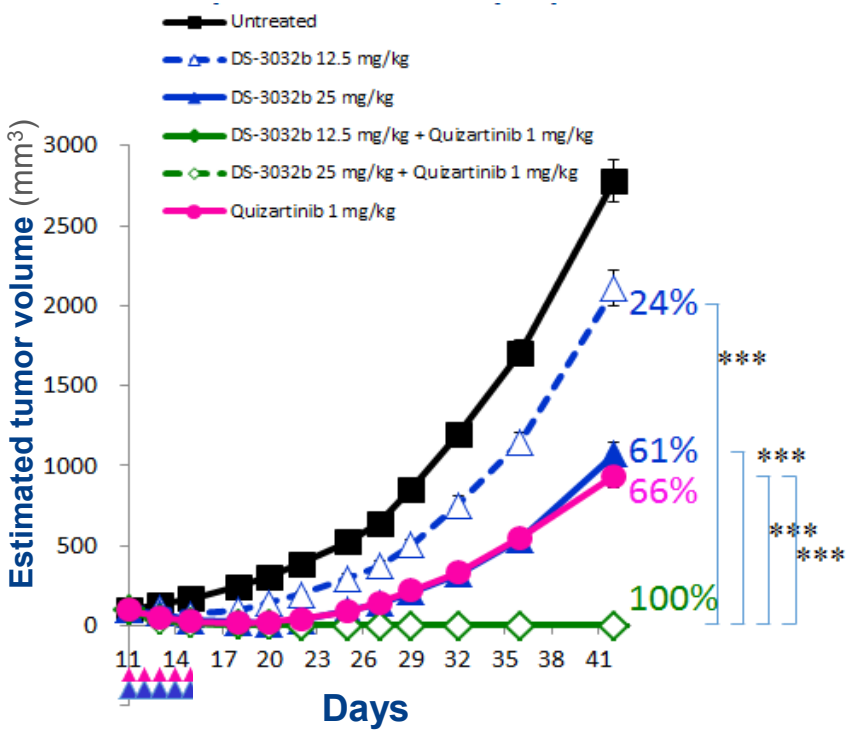
Source: DiNardo-N *et al.*, ASH 2016, abstract 593

AML | **Quizartinib** Accelerating Combinations

Novel-Novel Combo
Quizartinib + DS-3032 (MDM2i)

MV4

1 mpk Quizartinib + 12.5 or 25 mpk DS-3032b



Hypothesis: combining molecularly targeted agents with broad-acting mechanisms

- Address AML heterogeneity/complexity, including multiple mechanisms of resistance
- Extend benefits (depth and duration of response, transplant rate, survival) beyond single-agent FLT3i

Both drugs demonstrate single-agent activity in AML and initial safety profiles are established

Complementary profiles

- Non-overlapping, pro-apoptotic targets
- DS-3032 expected activity in TP53 wt AML
- FLT3-ITD mutated AML >95% TP53 wt

Preclinical

- Potential synergistic activity

AML | **In Summary**

QuANTUM-R STUDY

Delivering data and submission TLR 1H FY18

QuANTUM-FIRST STUDY

Accelerating global recruitment to exceed target enrollment in FY18

Expanding collaborations, business development and licensing to advance portfolio

Follow the science and expand beyond AML

Focusing on combinations within our own portfolio and external assets

CE 2025 | **A *Force* Today, A *Leader* Tomorrow**

Daiichi-Sankyo cancerenterprise

Today's Roadmap

1. Cancer Enterprise 2025
   - DS: A Science Company
   - "7 in 8": 7 Distinct NMEs in Next 8 Years
2. Cancer Enterprise: Delivering Now
   - DS-8201: Flagship ADC
   - ADCs: Next Generation
   - Quizartinib: Establishing AML Presence
3. **Other Updates and Q&A**

Kite Collaboration for Japan | Update

KTE-C19 (axicabtagene ciloleucel)

- Japan study design similar to ZUMA-1 study, aligned with PMDA
- Expect first patient enrollment in FY2018
- Technology transfer from Kite

- In Japan, Daiichi Sankyo is responsible for the development, commercialization and ultimately supply of axicabtagene ciloleucel (KTE-C19) after completing technical transfer of manufacturing

- The agreement includes optional licensing rights for Kite's product candidates that will progress to U.S. IND application filing three years after deal signing

Pexidartinib | Update

ENLIVEN Phase 3 study in TGCT/PVNS met its efficacy endpoints

1. Our intention is to proceed with formal pre-submission with US FDA on a narrow indication

2. Low single digit percent serious liver toxicity, with 2 cases program-wide resulting in or associated with either death or liver transplant in the context of bile duct loss syndrome

- The pembrolizumab combination is terminated for lack of compelling evidence of synergistic activity

Cancer Enterprise | **New Strategic Collaborations in 2017**

Daiichi-Sankyo cancerenterprise

Daiichi-Sankyo cancerenterprise

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

Key collaborations completed to date in 2017

KTE-C19 CAR T-cell
JPN Development
Jan 2017

Progress re Bi-specific Antibody Collaboration
July 2017

Target discovery
July 2017

G47Δ (DS-1647) Oncolytic Virus Orphan Drug Designation in JP
July 2017

DS-5010 (RETi) out- licensed to focus on our pipeline
Aug 2017

Combination Study DS-8201 + nivolumab
Aug 2017

Broad AML Collaboration, multiple pipeline assets
Sep 2017

ADC Collaboration
Oct 2017

Research Collaboration
Dec 2017

Combination DS-8201 + neratinib
Dec 2017

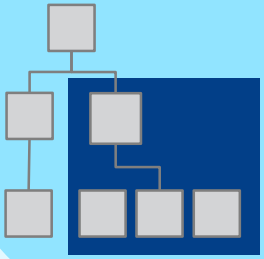
Research Collaboration
Dec 2017

Daiichi Sankyo Cancer Enterprise

Cutting-edge Science

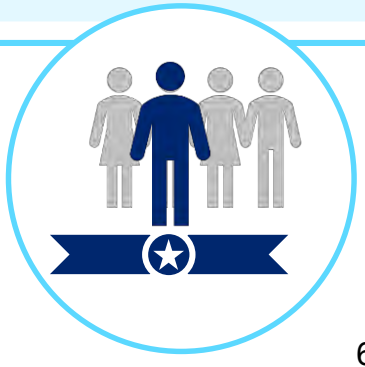
Valuable Portfolio

Delivery-focused, Capable & Agile Organization



Credible Progress & Clear Momentum

A FORCE here to stay, transforming Daiichi Sankyo into a recognized LEADER



Cancer Enterprise | **FY2018 Major R&D Milestones**

Project	Indication | Study	~Q4 FY2017	Q1	Q2	Q3	Q4
Quizartinib	QuANTUM-R AML 2nd line treatment Ph 3 (US | EU | Asia)		TLR			
	AML with DS-3032			Study initiation		
DS-8201	Her2+ Breast Post T-DM1 vs Phys Choice Ph3			Study initiation		
	Her2+ Breast vs T-DM1 Ph 3			Study initiation		
	Her2 low Breast Ph 3			Study initiation		
	Her2+ CRC Ph 2	Study initiation				
	Her2+ NSCLC Ph 2			Study initiation		
	Her2+ Breast | Bladder with nivolumab Ph 1/2	Study initiation				
	Her2+ Breast | NSCLC with IO Ph 1/2			Study initiation		
	Her2+ Breast | Gastric with IO Ph 1/2			Study initiation		
U3-1402	Her3+ Breast cancer Ph 1/2 (JP)		Ph 2 Part Start			
	EGFRm NSCLC Ph 1 (US)	Study initiation				
DS-1062	TROP2+ NSCLC First-in-human (US)	Study initiation				

A *Force* Today, A *Leader* Tomorrow

Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

Daiichi Sankyo R&D 2025 Vision

Glenn Gormley MD PhD
Senior Executive Officer
Global Head R&D

December 13, 2017

R&D 2025 Vision to Achieve Our 2025 Vision

Global Pharma Innovator with a Competitive Advantage in Oncology

Until 2015

- CVM area
- PCP focus
- Global products
- In-house
- Sales volume

2016-2020 5-Year Business Plan

Transformation toward 2025 Vision

2025 Vision

- Oncology business
- Specialty area
- Regional value
- Expansion of alliance
- Sustainable profit growth

Strategic Targets to achieve 5-Year Business Plan

Grow Edoxaban	Establish Oncology Business	Grow as No.1 Company in Japan	Expand US Businesses	Continuously Generate Innovative Medicine Changing SOC	Enhance Profit generation Capabilities

Established R&D Foundation for the 2025 Vision in 2015-17

- **Clearly defined 2 therapeutic Areas to focus on :**
  - **Oncology**
  - **Specialty Medicine (Specialty areas other than oncology* + LCM**)**

    * Pain, CNS disease, Heart-Kidney disease, Rare diseases
    ** Life Cycle Management

- **Transformed Research Organization to a Bio-venture Model**
  - **Units consisting of biology, pharmacology and medicinal chemistry**

- **Established the Biologics Unit**
  - **Consolidating the relevant parts of R&D and Pharmaceutical Technology to support the development of Biologics**

- **Simplified Decision Making**
  - **Greater team empowerment and fewer GEMRAD* decision Points**

    * Global Executive Meeting of Research And Development

Key Elements of the R&D 2025 Vision

- **Prioritize Oncology**
  With limited investment in Specialty Medicine
- **Shift Resources to align with priorities**
- **Invest in critical Capabilities to deliver**
- **Continue to establish diverse platforms and modalities**

Daiichi-Sankyo

Become a leading world-class science organization focused on 3 pillars

Lead in Smart-Treatment with BIC & FIC ADC	Establish a Competitive Hematology Franchise	Lead with Breakthrough Science
3	3	1

Deliver 7 NMEs in 8 years

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

*BIC: Best in Class
FIC: First in Class

Specialty Medicine | 2025 Vision

Protect near-term revenue and transition to specialty areas with high unmet medical need

Maximize near-term revenue

- Complete Development of late stage assets
- Support LCM of marketed products

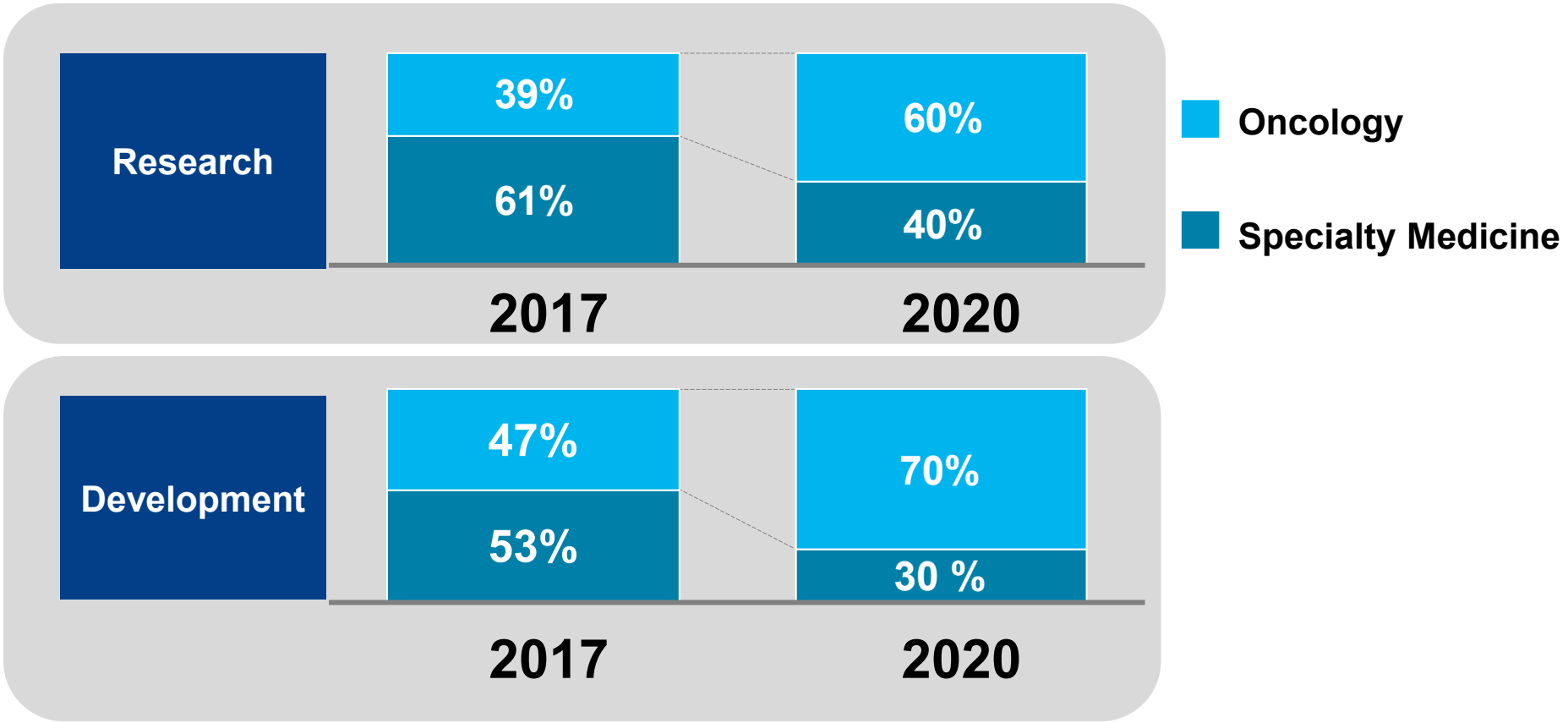
2 NMEs in 2018-20

Grow future franchises

- Focus on innovative products changing SOC in the areas of : Pain, CNS disease, Heart-Kidney disease, Rare disease

3 NMEs 2021-2025

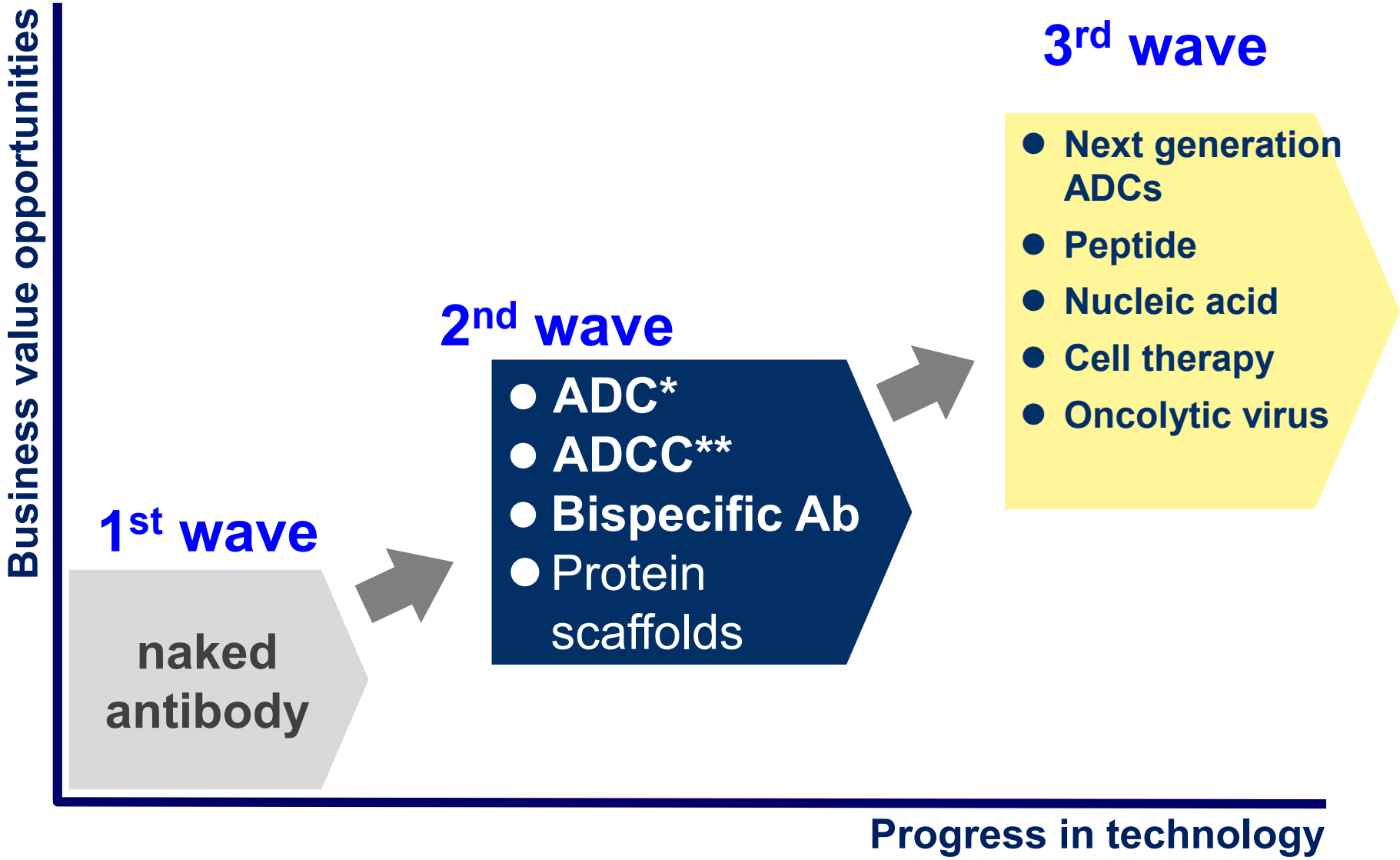
Shift Resources (Funding and People) from Specialty Medicine to Oncology



Invest in Critical Capabilities to Deliver Innovative Products

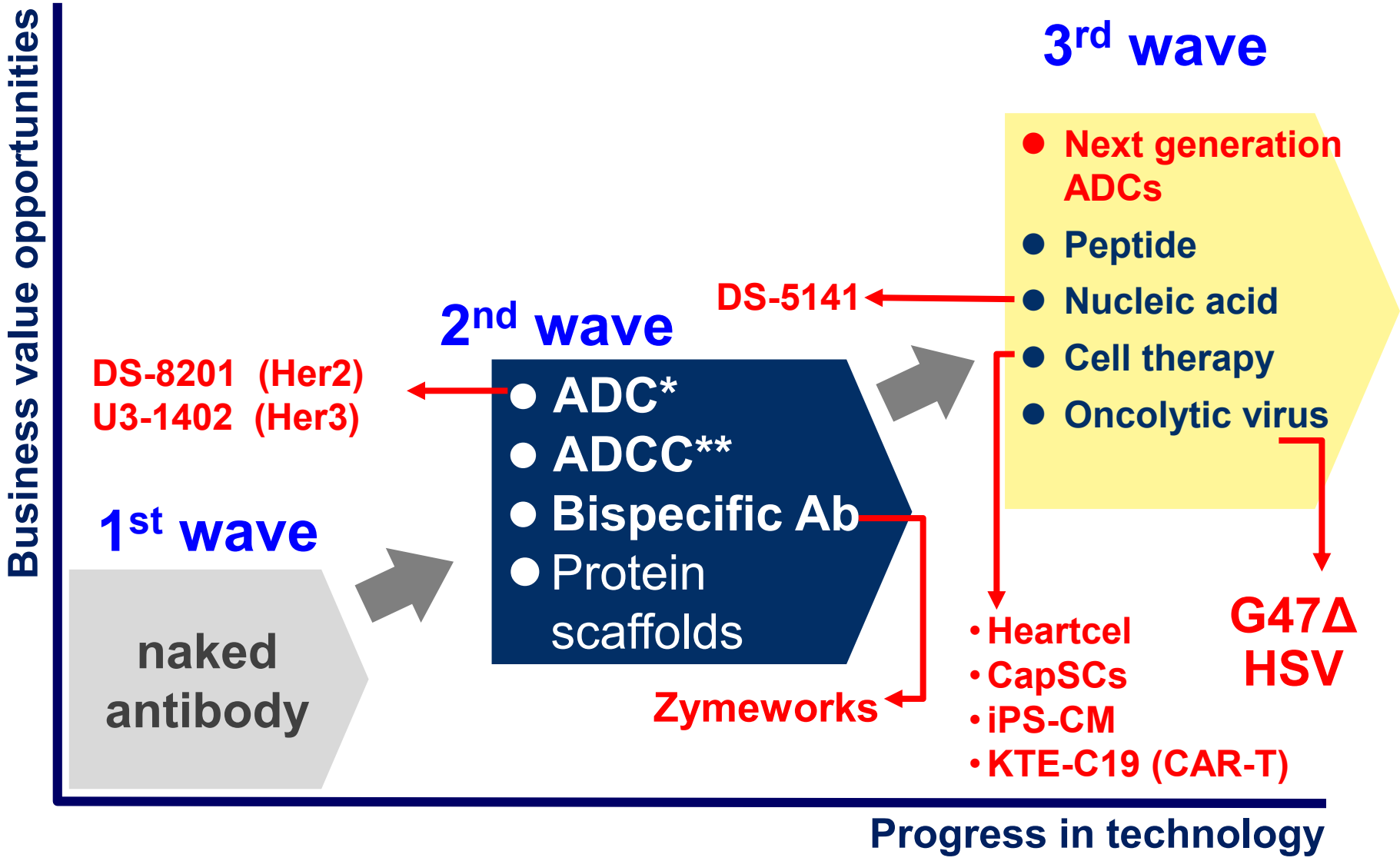
Capability	Objectives of investment
Enhance R&D IT infrastructure	• Support Global regulatory submissions
	• Reduce trial costs
	• Accelerate time lines
Expand translational research capabilities	• Closer alignment of discovery and clinical activities
	• Faster Proof of Concept
	• Identify new targets and indications

Continue to Establish Diverse Platforms and Modalities



* ADC: Antibody Drug Conjugate
**ADCC: Antibody Dependent Cellular Cytotoxicity

Continue to Establish Diverse Platforms and Modalities



* ADC: Antibody Drug Conjugate
**ADCC: Antibody Dependent Cellular Cytotoxicity

Overall Summary

- **We have an opportunity to meet or exceed our 2025 vision**

- **To do this R&D will continue to evolve :**
  - **Shifting the majority of our R&D investment (funding and People) to oncology to maximize the value of our ADC and AML portfolios**
  - **With a limited investment in specialty medicine, focus on priority disease areas that have the highest potential and diversify our risk**
  - **Investing in IT and Translational Medicine to enable continuous innovation**
  - **Continue to develop innovative platform technologies and modalities as source of new therapies**

A *Force* Today, A *Leader* Tomorrow

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

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