Aiming to become a "top pharmaceutical company"

Development Portfolio of Chugai Pharmaceutical

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Executive Vice President
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Yutaka Tanaka

December 16, 2014

Forward-Looking Statements

This presentation may include forward-looking statements pertaining to the business and prospects of Chugai Pharmaceutical Co., Ltd. (the "Company"). These statements reflect the Company's current analysis of existing information and trends. Actual results may differ from expectations based on risks and uncertainties that may affect the Company's businesses.

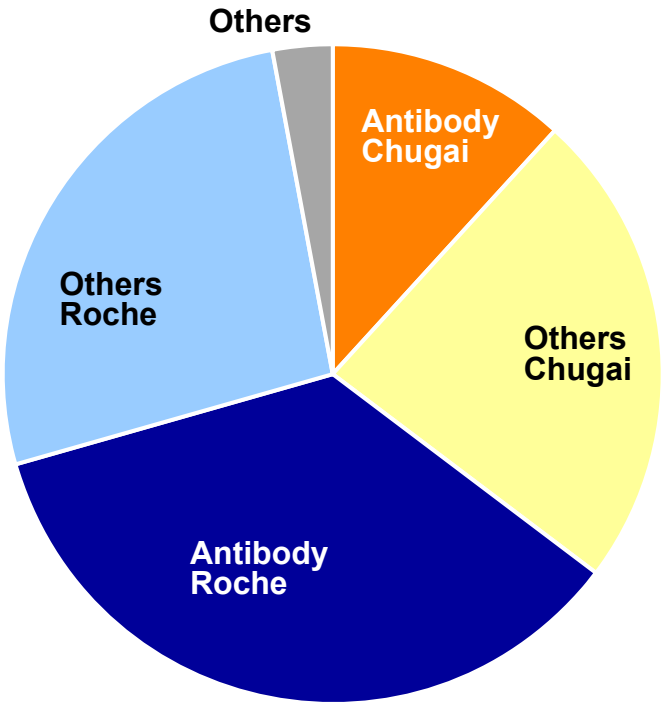
Although this presentation includes information regarding pharmaceuticals (including products under development), the information is not intended as any advertisement and/or medical advice.

Product/Project Portfolio

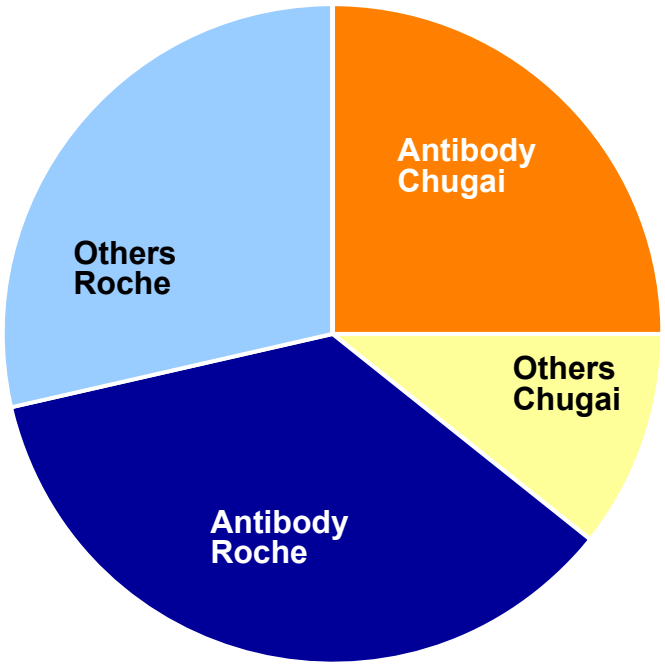
	P1,P2	P3, Filed	Launched
Cancer	XEL (PI3K), GC33 (PI3K), CKI27 (CD79b), BRAF (KAD), ALC (GA101), PER (PD-L1)		AVA, RIT, TAR, HER, PER, KAD, XEL, NEU, ALC
Bone/joint		BON	ACT, EDR, SVE, ALF, BON
Kidney			MIR, EPO, OXA
Transplantation/ immunity/ infection			CEL, PEG, COPE, TAM
Autoimmunity	ACT	ACT, SA237	
Central nervous system	mGluR5, MAO-B, GABA	Aβ	
Other fields	ACE910, CIM331, URC102	aIL-13	SIG

Yellow : in-house project

Antibody Projects in Development



2009



2014

* Number-of-projects basis (each line-extension was counted)

Oncology Portfolio

		Cytotoxicity	Molecular Targeting Therapy		
			Tumor cell targeting	Anti-angiogenesis	Immuno-therapy
Colorectal		Xeloda		Avastin	
Breast	HER2+	Xeloda	**Herceptin, Perjeta, Kadcyla**		
	HER2-			Avastin	
Lung	EGFR+		Tarceva	Avastin	**RG7446* (PDL1)**
	ALK+		Alecensa		
	Others				
Stomach	HER2+	Xeloda	**Herceptin, Perjeta*, Kadcyla***		
	HER2-				
Blood			Rituxan, GA101*, Polatuzumab vedotin*		
Others			Tarceva,GC33*, CKI27*, vemurafenib*, pictilisib*, taselisib*	Avastin	

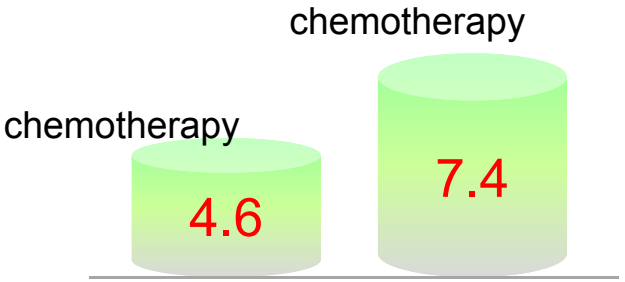
* Under development

Contribution of Targeting Therapies

Tumor cell targeting

HER2(+) Breast cancer

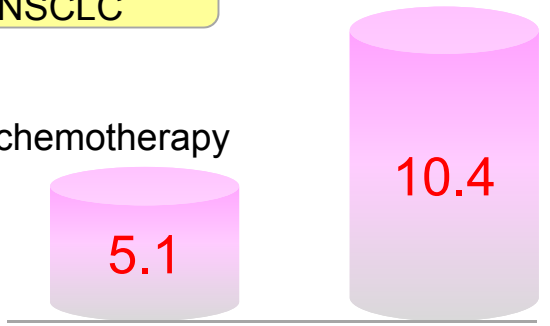
+ **Herceptin**



Slamon DJ, et al. NEJM 2001; 344:783-792

EGFR mut(+) NSCLC

Tarceva

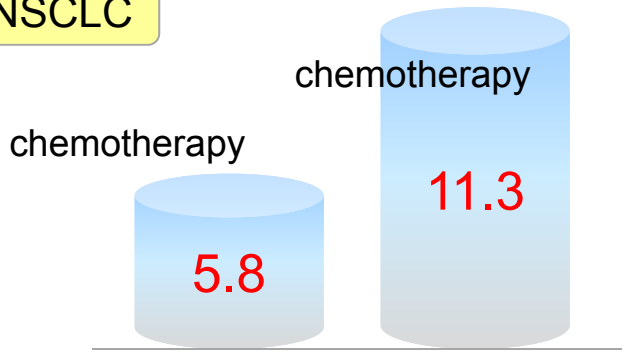


Clin Cancer Res 2014, 20, 2001–10

Anti-angiogenesis

NSCLC

+ Avastin



Gray R et al. JCO 2009; 27(30):4966-72

Red letters:
Progression-free survival (month)

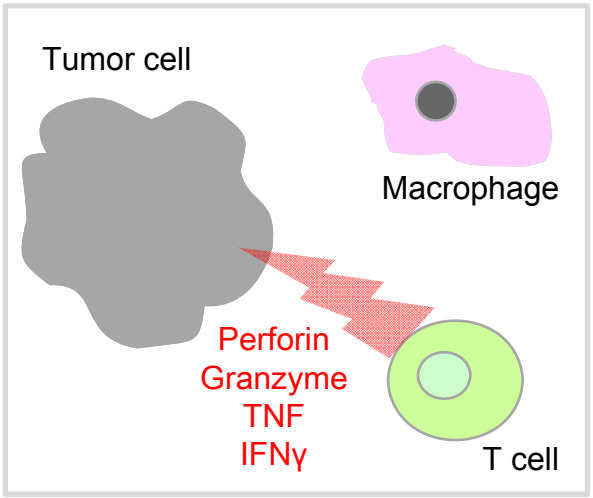
Expectations for Cancer Immunotherapy

Progress of Cancer Immunotherapy

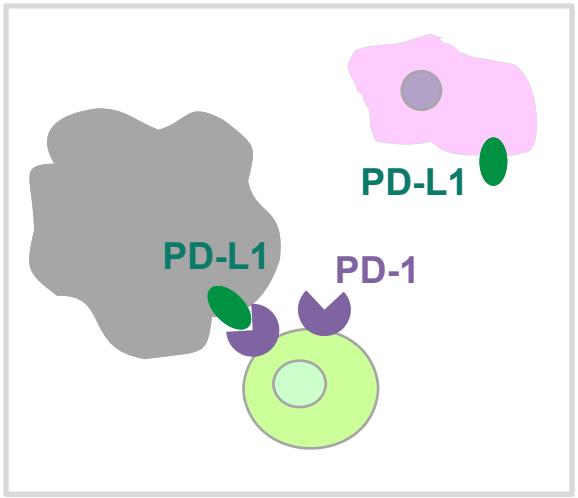
Immuno-modulator → Cancer vaccine → Immuno-checkpoint inhibitor T cell therapy

Immuno-checkpoint inhibitors:
Break immune tolerance of tumor cells

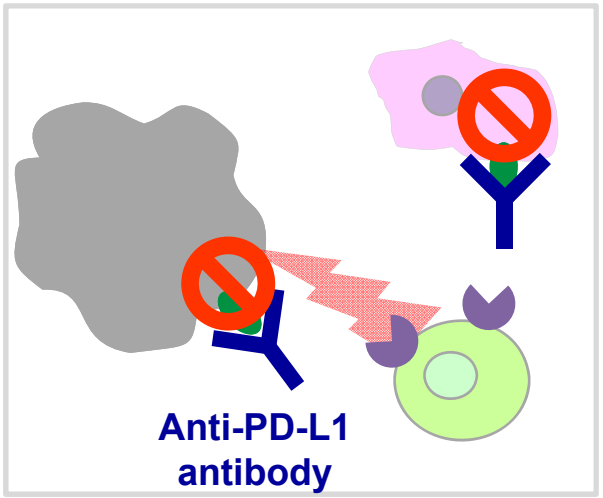
[conceptual illustration]



Activated T cells attack tumor cells as non-self antigens by using perforin, granzyme and other factors (immune response)

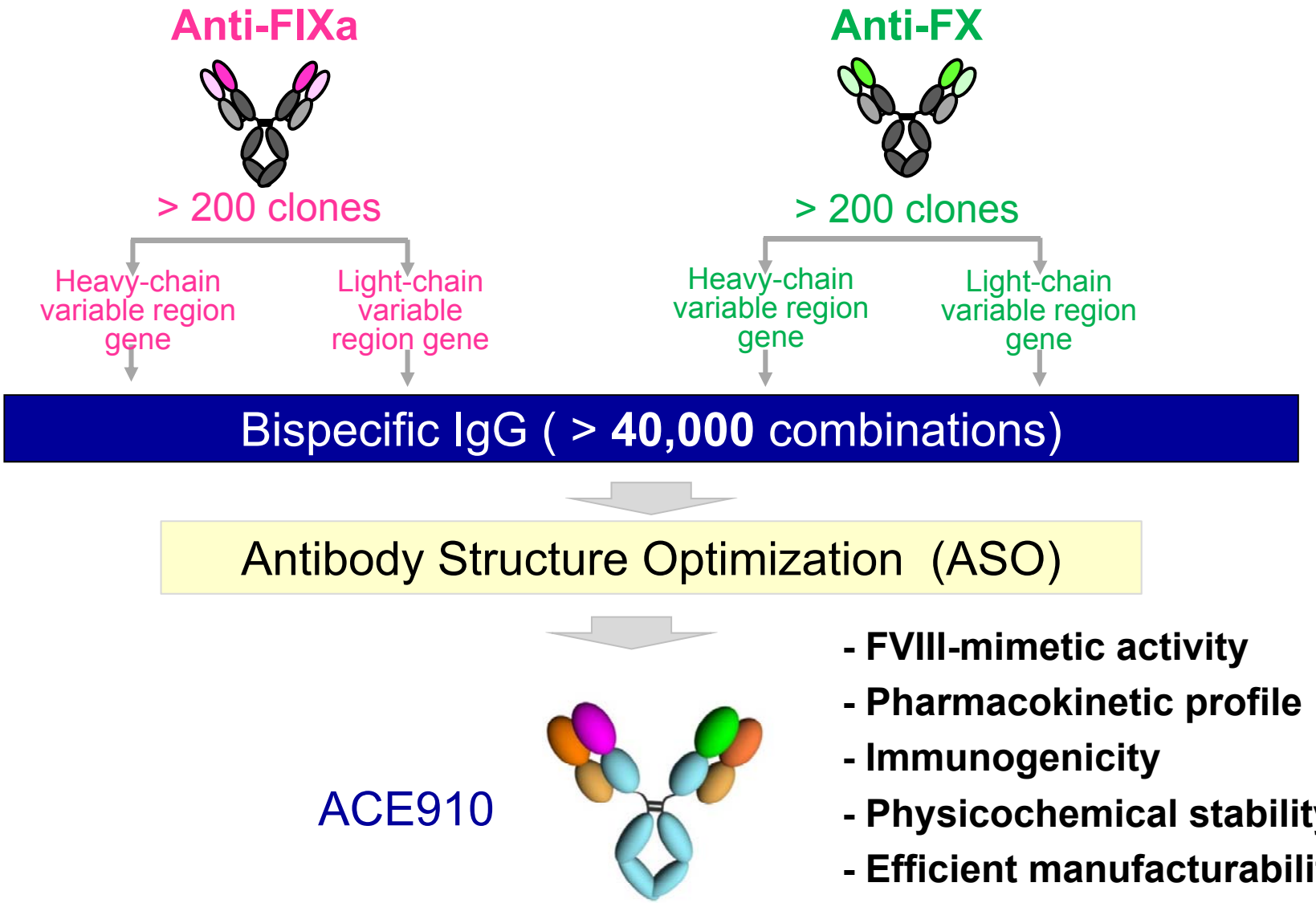


Tumor cells and macrophages express PD-L1 and suppress activation of T cell (immune tolerance)



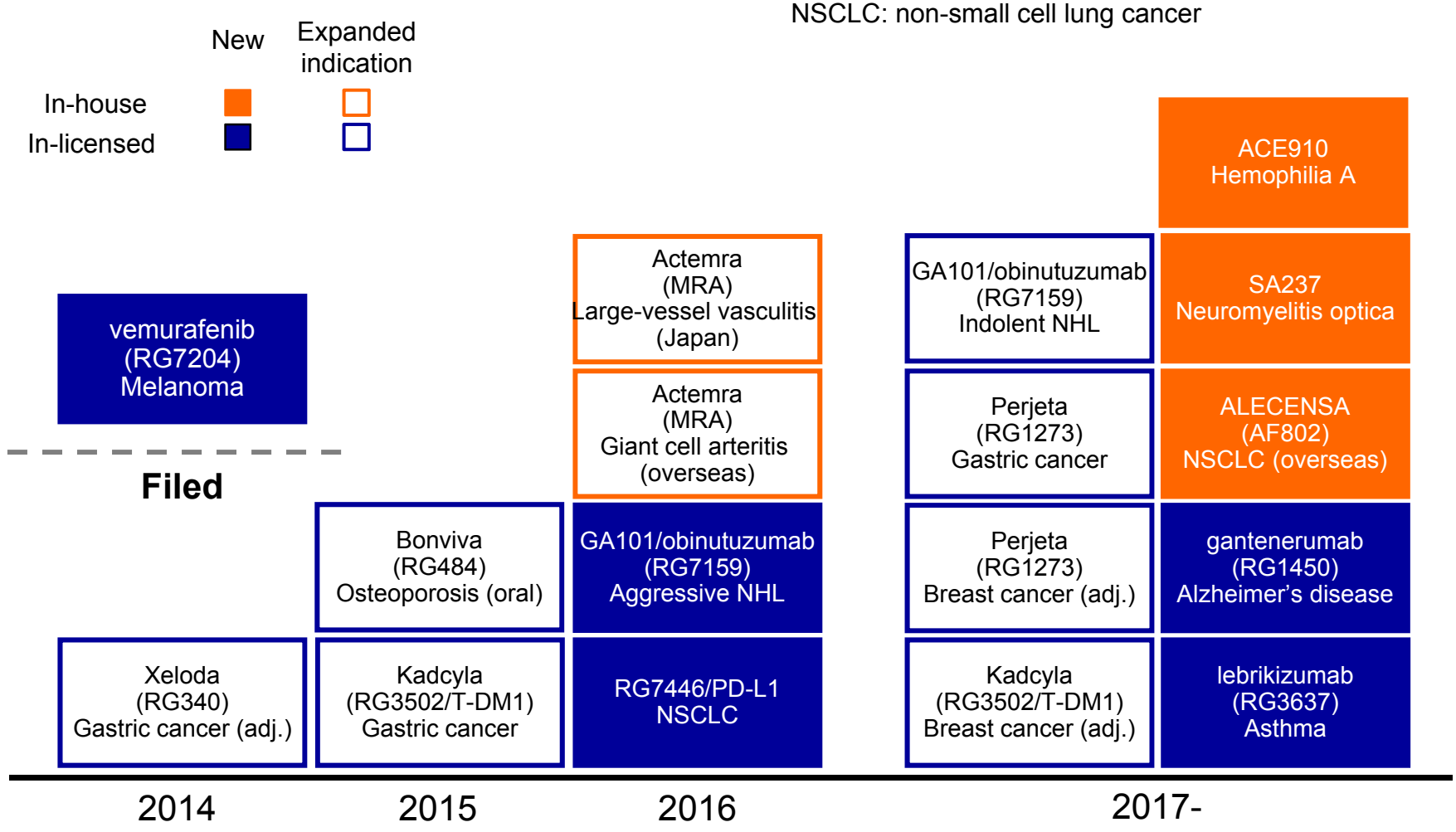
Anti-PD-L1 antibodies block PD-1/PD-L1 pathway (immune-checkpoint) and the immune response to tumor resumes

Bispecific Antibody ACE910



Projected Submissions

Adj: adjuvant therapy, NHL: non-Hodgkin's lymphoma,
NSCLC: non-small cell lung cancer



Overview of HER2 Franchise

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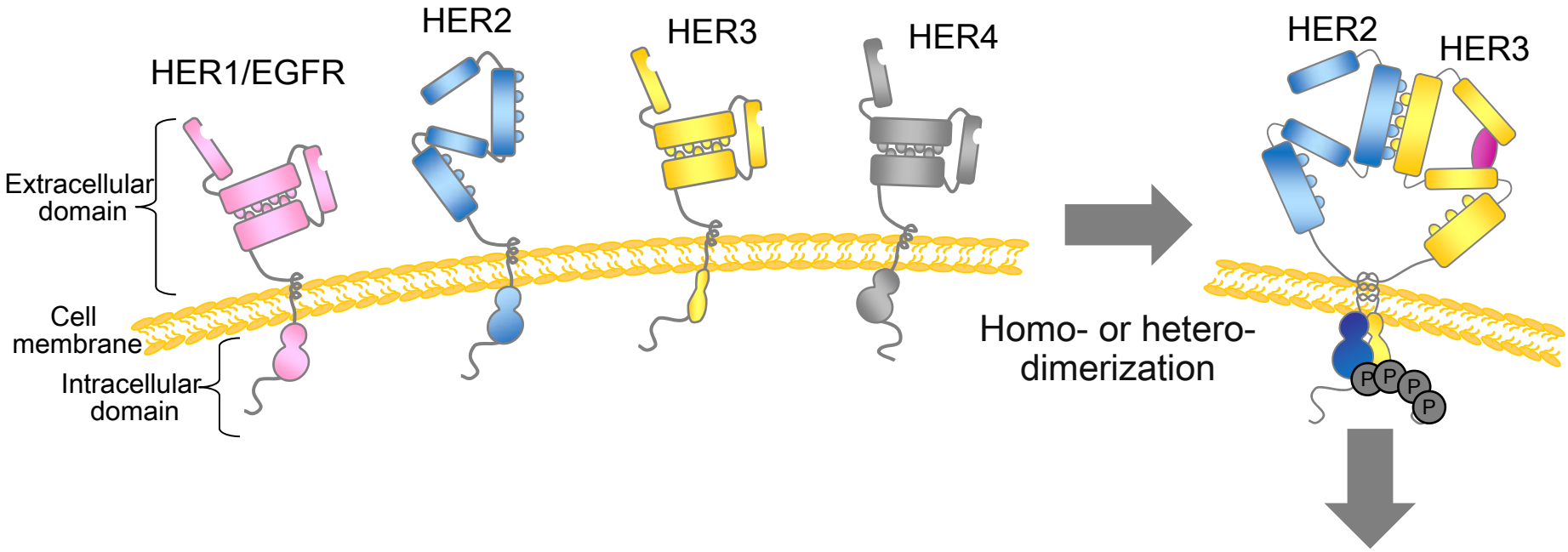
December 16, 2014

Function of the HER Family and Tumor Growth

- HER = Human Epidermal Growth Factor Receptor

[Conceptual Illustration]

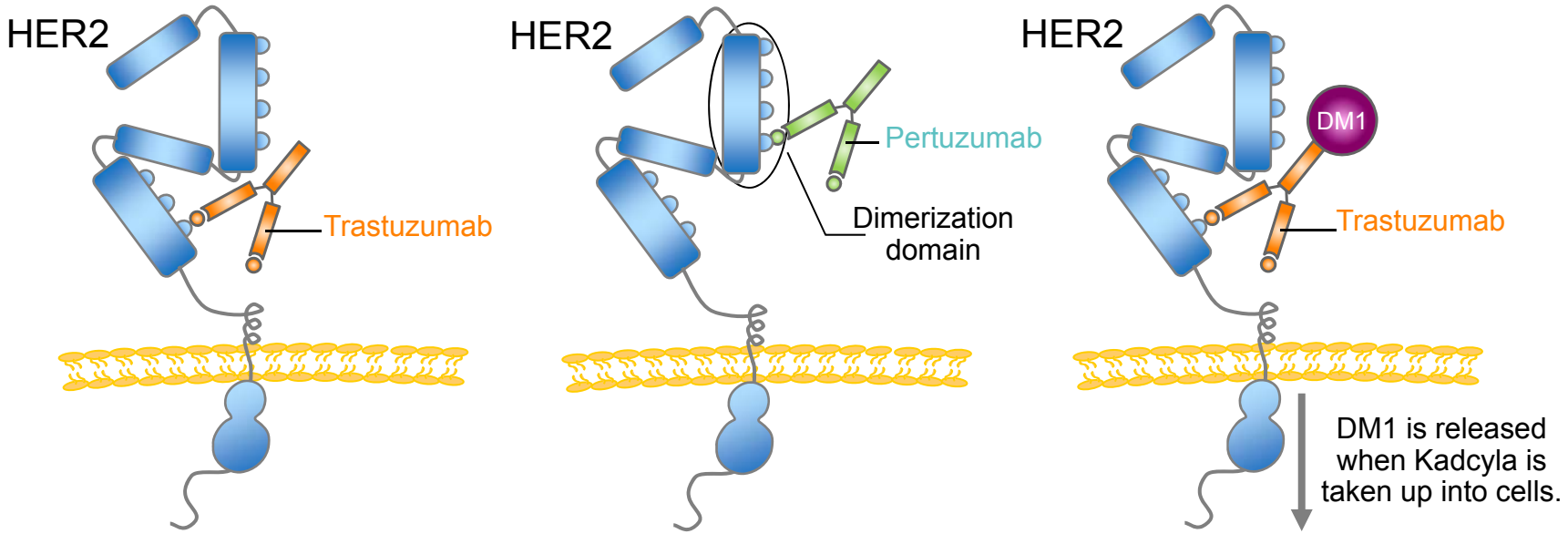


Dimers transmit signals, such as to accelerate cell proliferation and inhibit apoptosis

Yarden Y, et al. Nat Rev Mol Cell Biol 2001;2:127-137

Mode of Action of Anti-HER2 Antibodies

[Conceptual Illustration]

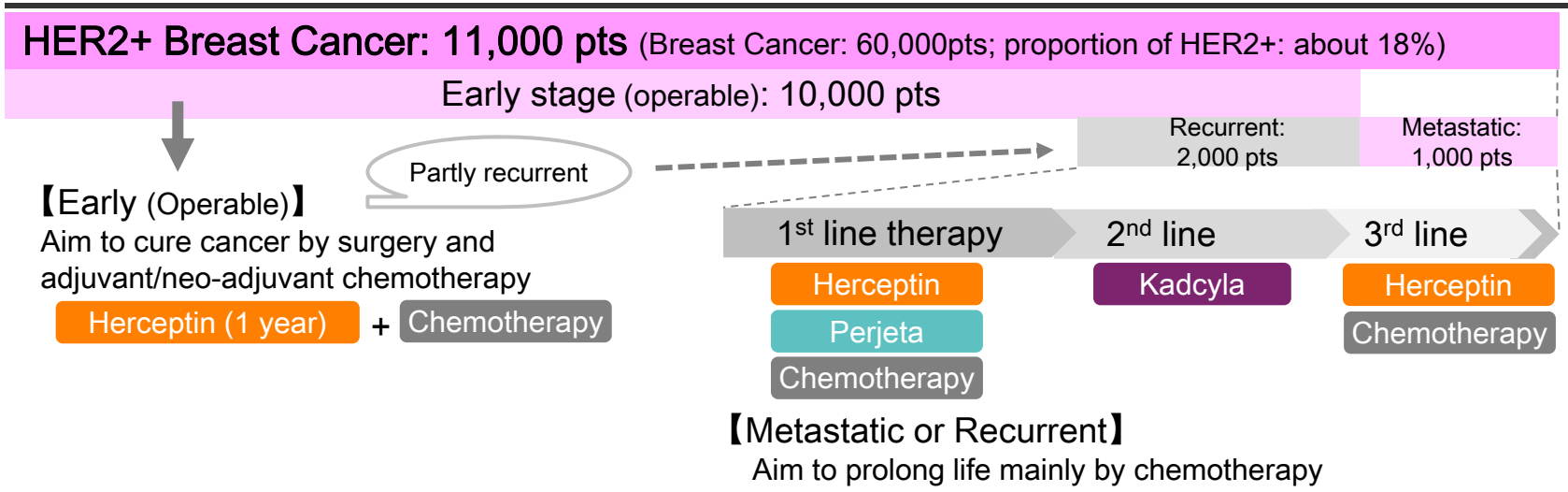


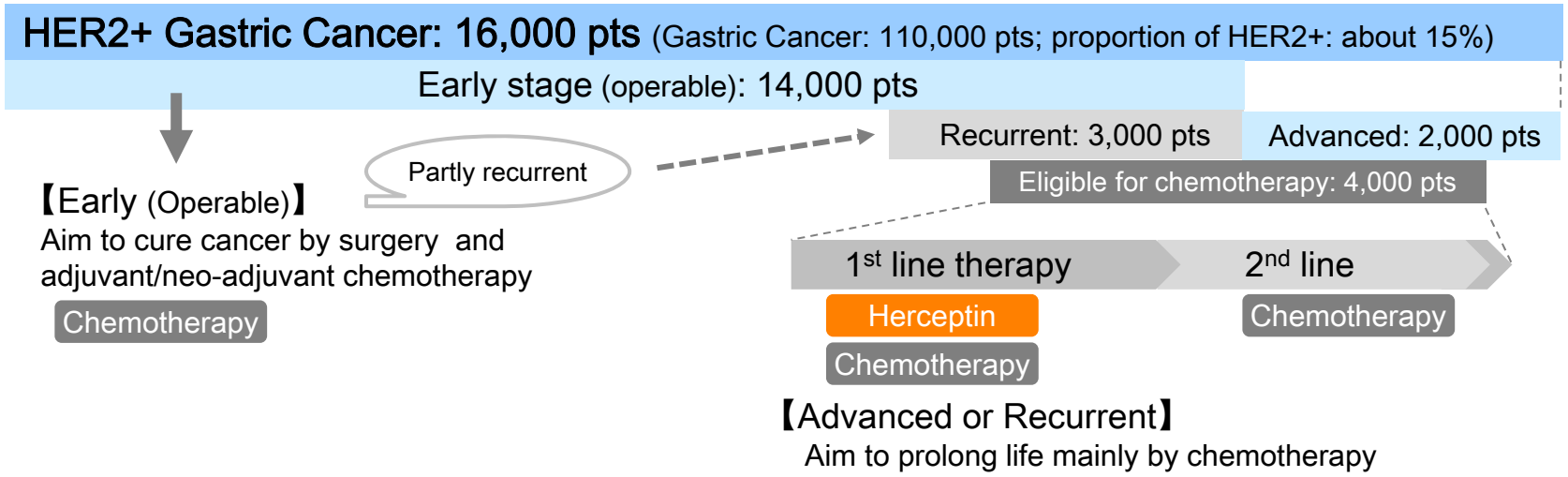
	Herceptin (HER)	Perjeta (PER)	Kadcyla (KAD)
Generic name	Trastuzumab	Pertuzumab	Trastuzumab emtansine
Major mode of action	- Inhibits HER2 signal transduction - Induces ADCC activity[1]	- Inhibits HER2 dimer formation - Induces ADCC activity[1]	- Inhibits HER2 signal transduction - Induces ADCC activity[1] - DM1 induces apoptosis
Launch in Japan	June 2001	September 2013	April 2014

1. ADCC: Antibody-dependent cellular cytotoxicity

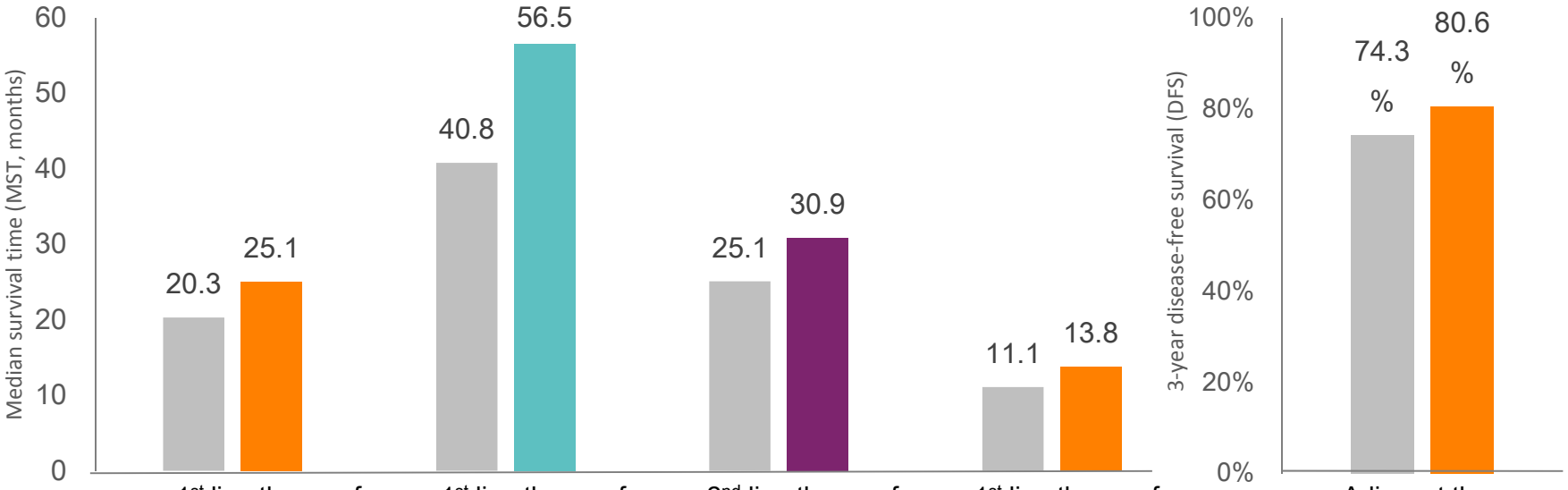
Baselga J. et al. Nat Rev Cancer. (2009) 9, 463

Number of Yearly Breast or Gastric Cancer Patients in Japan (In-house Estimation) and the Positioning of the HER2 Franchise





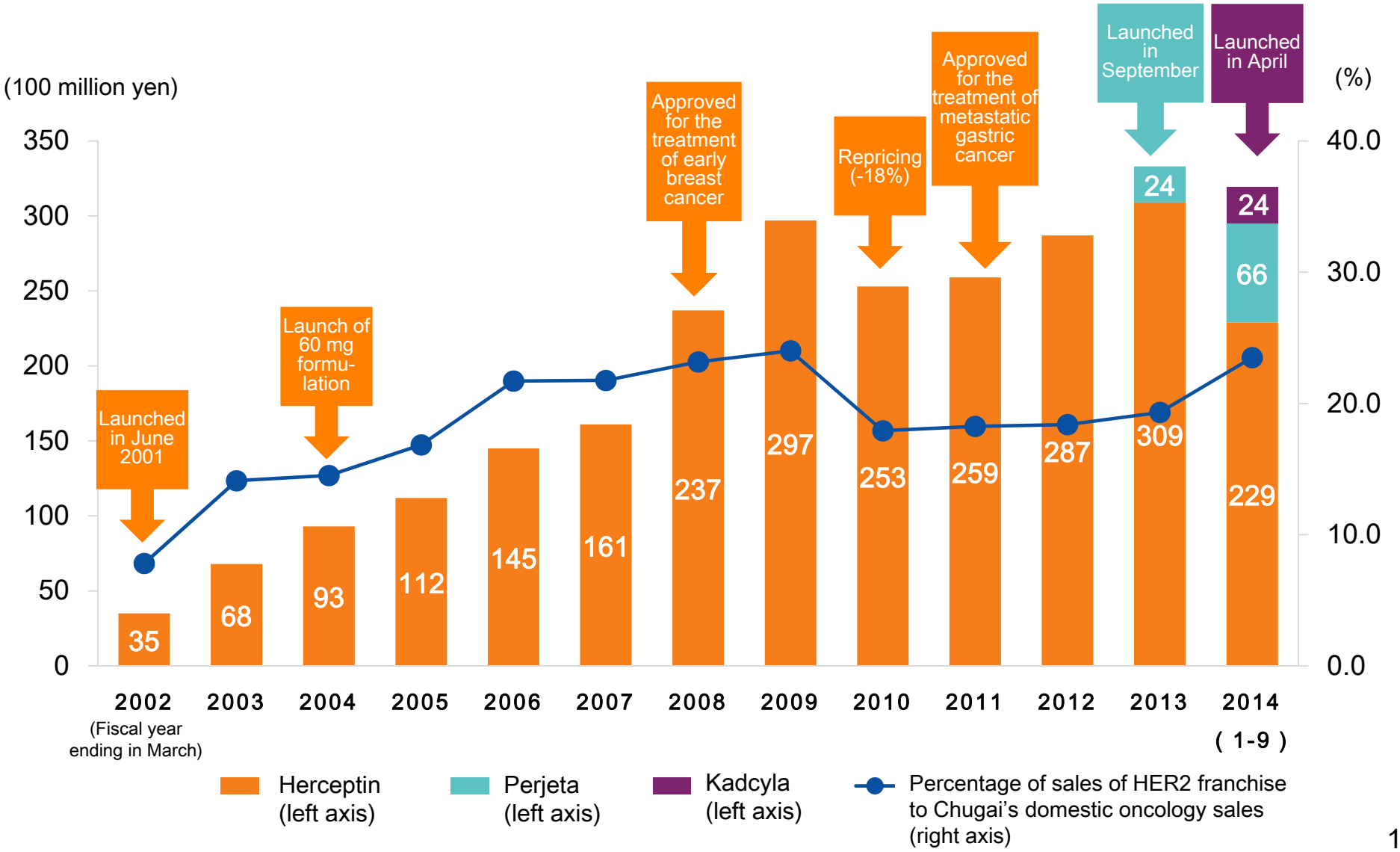
HER2 Franchise Contribution to Survival



	1st line therapy for metastatic or recurrent breast cancer[1]	1st line therapy for metastatic or recurrent breast cancer[2]	2nd line therapy for metastatic or recurrent breast cancer[3]	1st line therapy for advanced or recurrent gastric cancer[4]	Adjuvant therapy for early breast cancer[5]
Study	H0648g	CLEOPATRA	EMILIA	ToGA	HERA
Control group	Docetaxel	Docetaxel + Herceptin	Xeloda + lapatinib	Xeloda or 5-FU + cisplatin	Observation
Test group	Docetaxel + Herceptin	Docetaxel + Herceptin + Perjeta	Kadcyla	Xeloda or 5-FU + cisplatin + Herceptin	1-year treatment with Herceptin
Hazard ratio	HR =0.80	HR = 0.68	HR = 0.65	HR = 0.74	HR = 0.64
P value	P = 0.046	P = 0.0002	P < 0.001	P = 0.0046	P < 0.0001
PFS (months)	4.6 vs 7.4	12.4 vs 18.5	6.4 vs 9.6	5.5 vs 6.7	-

1. Slamon DJ, et al. NEJM 2001; 344:783-792, 2. Roche, 3. Verma S, et al. NEJM 2012; 367:1783-1791,
4. Bang YJ, et al. Lancet 2010; 376:687-697, 5. Smith I, et al. Lancet 2007; 369:29-36

Sales Trend in Japan



Future Development Plan

HER2+ Breast Cancer: 11,000 pts (Breast Cancer: 60,000pts; proportion of HER2+: about 18%)

Early stage (operable): 10,000 pts

Recurrent: 2,000 pts | Metastatic: 1,000 pts

Partly recurrent

【Early (Operable)】
Aim to cure cancer by surgery and adjuvant/neo-adjuvant chemotherapy

Herceptin (1 year) + Chemotherapy

APHINITY Trial: HER +PER +Chemo

KAITLIN Trial: KAD +PER

1st line therapy → 2nd line → 3rd line

1st line therapy: Herceptin, Perjeta, Chemotherapy

2nd line: Kadcyla

3rd line: Herceptin, Chemotherapy

MARIANNE Trial: KAD +PER

【Recurrent or Metastatic】
Aim to prolong life mainly by chemotherapy

HER2+ Gastric Cancer: 16,000 pts (Gastric Cancer: 110,000 pts; proportion of HER2+: about 15%)

Early stage (operable): 14,000 pts

Recurrent: 3,000 pts | Advanced: 2,000 pts

Eligible for chemotherapy: 4,000 pts

Partly recurrent

【Early (Operable)】
Aim to cure cancer by surgery and adjuvant/neo-adjuvant chemotherapy

Chemotherapy

1st line therapy → 2nd line

1st line therapy: Herceptin, Chemotherapy

2nd line: Chemotherapy

GATSBY Trial: KAD

JACOB Trial: HER +PER +Chemo

【Advanced or Recurrent】
Aim to prolong life mainly by chemotherapy

Regimens Expected to be Clinically Available in the Near Future

	1st line therapy for metastatic or recurrent breast cancer	Adjuvant therapy for early breast cancer
Study	MARIANNE trial	APHINITY trial
Phase	Phase III global study	Phase III global study
Number of patients	1,092	4,803
Control group	Herceptin + taxane	Chemotherapy + Herceptin + placebo
Test group	Kadcyla + Perjeta	Chemotherapy + Herceptin + Perjeta
Primary endpoint	Progression-free survival (PFS)	Disease-free survival (DFS)
Data to be published in	2015	2016

Aiming to become "Top Pharmaceutical Company"

Overview of anti PD-L1 Antibody RG7446 (MPDL3280A)

CHUGAI PHARMACEUTICAL CO., LTD.
Oncology Lifecycle Management Dept.
Mikio Sakai

December 16, 2014

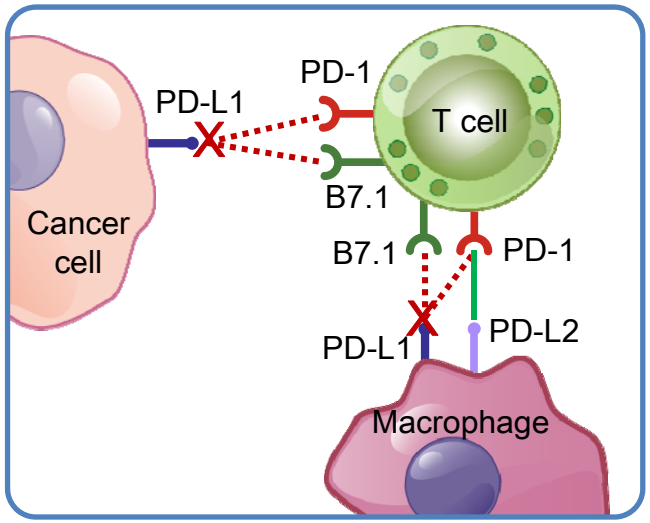
Mode of Action of Anti PD-L1 Antibody and Anti PD-1 Antibody

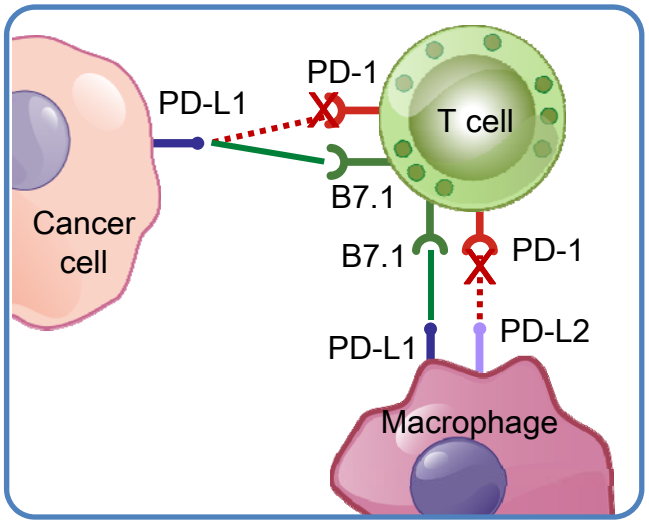
Anti PD-L1 antibody

- Inhibits the binding between PD-L1 expressed on tumors and PD-1 and B7.1 expressed on T cells
- Inhibits the transmission of inhibitory signals from two pathways to T cells[1, 2, 3)]
- Because the anti-PD-L1 antibody does not inhibit the binding between PD-L2 and PD-1, little influence is expected on the homeostasis of the immune system, thus it is not likely to induce autoimmune responses[1)]

Anti PD-1 antibody

- Inhibits the binding between PD-L1 expressed on tumors and PD-1 expressed on T cells
- Inhibits the transmission of inhibitory signals to T cells, but does not inhibit the transmission of other inhibitory signals initiated by the binding between PD-L1 and B7.1[1, 2, 3)]
- Because anti-PD-1 antibody inhibits the binding between PD-L2 and PD-1, some influences are expected on the homeostasis of the immune system, thus it is likely to induce autoimmune responses[1, 4)]





1. Chen DS, et al. Clin Cancer Res 2012; 18: 6580-6587; 2. Paterson AM, et al. J Immunol 2011; 187: 1097-1105
3. Yang J, et al. J Immunol 2011; 187: 1113-1119; 4. Brahmer JR, et al. N Engl J Med 2012; 366: 2455-2465

PD-L1 Expression in Patients with Different Types of Cancer

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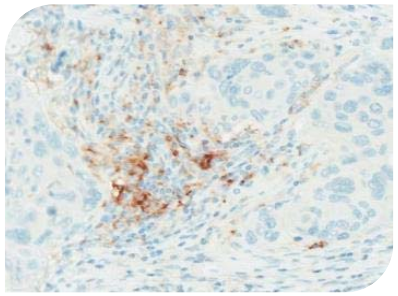
PD-L1 is widely expressed on tumor cells or tumor-infiltrating immune cells

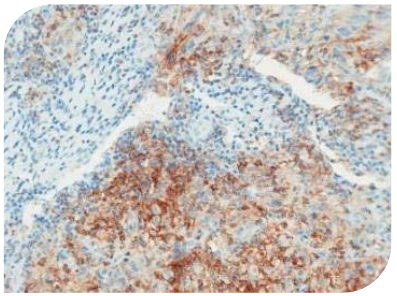
PD-L1 prevalence[1,2,3)]

Tumor type	Incidence	Non-trial study[1, 2, *, ‡)]	Phase I study[3)]	
	Japan 2010[5)]	Immune cells[§)] (≈%)	Immune cells[*)]	Tumor cell[‡)]
NSCLC (Non-small cell lung cancer)	107,241	45%	26%	24%
Renal cell carcinoma	21,130	20%	25%	10%
Melanoma	NA	40%	36%	5%
Bladder cancer[4)]	19,219	N/A	27%	11%
Head and neck squamous cell carcinoma	15,560[5)]	33%	28%	19%
Gastric cancer	125,730	N/A	18%	5%
Colorectal cancer	118,979	45%	35%	1%
Pancreatic cancer	32,330	N/A	12%	4%

PD-L1+ immune cells NSCLC[1)]



PD-L1+ tumor cells Melanoma[1)]



* PD-L1 positive defined as patients with ≥5% tumour infiltrating immune cells positive for PD-L1;
‡ Surgical tumour specimens; § PD-L1 positive defined as patients with ≥5% tumour cells positive for PD-1;
1. Kohrt H, et al. SITC 2013; 2. Roche/Genentech data; 3. Herbst R, et al. Nature 2014; 515: 563-567; 4. Powles T, et al. Nature 2014; 515: 558-562; 5. Cancer statistics in Japan 2013 (Center for Cancer Control and Information Services, National Cancer Center)

Anti PD-L1 Antibody / Anti PD-1 Antibody Under Development in Japan

		Indication	P1	P2	P3	Filed	Approved
Anti PD-L1 antibody	RG7446	NSCLC			■		
	MEDI4736	NSCLC			■		
	MSB0010718C	Merkel cell cancer		■			
		Gastric cancer		■			
		NSCLC		■			
Anti PD-1 antibody	Nivolumab	Melanoma					■
		Renal cell carcinoma			■		
		NSCLC			■		
		Head and neck cancer			■		
		Gastric cancer			■		
		Esophageal cancer		■			
	Pembrolizumab	NSCLC		■			
		Melanoma		■			

The development stage shows the most advanced study within each indication.

PD-L1 and Companion Diagnostics

Different companion diagnostics are under development with different cut-off values

	Nivolumab (aPD-1)	Pembrolizumab (aPD-1)	RG7446 (aPD-L1)	MEDI4736 (aPD-L1)
CoDX (antibody)	Dako/IHC (28-8)	Dako/IHC (22C3)	Ventana/IHC (SP142)	Ventana/IHC (SP263)
Using cells	Tumor	Tumor	Tumor infiltrated Immune cell (or Tumor)	-
Cut-off PD-L1 expression	5% PD-L1 (cut-off)	1% PD-L1 (cut-off)	≥10% (IHC: 3) ≥ 5% (IHC: 2/3) ≥ 1% (IHC: 1/2/3)	-

(Chugai data)

Global Development of RG7446

Indication	P1	P2	P3
NSCLC (monotherapy / combination therapy)	✓	✓	✓
Bladder cancer	✓	✓	✓
Renal cell carcinoma (monotherapy / combination therapy)	✓	✓	
Malignant melanoma	✓		
Solid tumor (monotherapy / combination therapy)	✓		
Colorectal cancer	✓		
Blood cancer (combination therapy)	✓		

✓ Study ongoing ✓ Study planned (Roche data)

Response Rate by PD-L1 Expression in Patients with NSCLC

High response rate has been observed in the subgroup with high PD-L1 expression on tumor-infiltrating cells[1, 2)]

PD-L1 Expression (Immune cell)	Overall Response Rate (%)	Progression of disease (%)
IHC 3	83 (5/6)	17 (1/6)
IHC 2/3	46 (6/13)	23 (3/13)
IHC 1–3	31 (8/26)	38 (10/26)
All patients[§)]	23 (12/53)	40 (21/53)

§ Including 7 patients with unknown PD-L1 status

1. Soria JC, et al. ESMO 2013 (Abstract 3408)
2. Herbst R, et al. Nature 2014; 515: 563-567

Clinical Trials of RG7446 in Patients with Locally Advanced or Metastatic NSCLC

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Roche Roche Group

FIR (PII): PD-L1+ Locally Advanced or Metastatic NSCLC (primary endpoint: overall response rate)

PD-L1+ NSCLC (n=130) → RG7446 1,200mg, iv, every 3 weeks

BIRCH (PII): PD-L1+ Locally Advanced or Metastatic NSCLC (primary endpoint: overall response rate)

PD-L1+ NSCLC (n=635) → RG7446 1,200mg, iv, every 3 weeks

POPLAR (PII): Locally Advanced or Metastatic NSCLC (2nd/3rd line) (primary endpoint: overall survival)

NSCLC (2nd/3rd line) (n=287) → Docetaxel 75mg/m^2, iv, every 3 weeks
NSCLC (2nd/3rd line) (n=287) → RG7446 1,200mg, iv, every 3 weeks

OAK (PIII): Locally Advanced or Metastatic NSCLC (2nd line) (primary endpoint: overall survival)

NSCLC (2nd line) (n=850) → Docetaxel 75mg/m^2, iv, every 3 weeks
NSCLC (2nd line) (n=850) → RG7446 1,200mg, iv, every 3 weeks

Phase III trials for 1st line and adjuvant therapy are under preparation (ClinicalTrials.gov)

Response Rate by PD-L1 Expression in Patients with Bladder Cancer (Judged by Physicians)

PD-L1 Expression (Immune cell)	Overall Response Rate (%, 95% CI)	PD-L1+ vs PD-L1− Overall Response Rate (%, 95% CI)
IHC 3 (n=10)	60 (27, 85)	52 (34, 69)
IHC 2 (n=23)	48 (27, 68)	
IHC 1 (n=24)	17 (6, 37)	14 (6, 28)
IHC 0 (n=12)	8 (0, 35)	

One patient with unknown IHC status not included in table

- The overall response rate was 52% in patients with IHC 2/3, most of them pre-treated with platinum-based therapies.
- The overall response rate was 14% in patients with IHC 0/1.
- Rapid tumor shrinkage was observed.
- Of the 22 responders, 19 maintained tumor shrinkage at the time of data cut-off.
- The median progression free survival was 24 weeks in patients with IHC 2/3, and eight weeks in patients with IHC 0/1.

Bellmunt J, et al. ESMO 2014 (Abstract 6984)

Clinical Trials of RG7446 in Patients with Locally Advanced or Metastatic Bladder Cancer

Breakthrough Therapy Designation granted by the FDA for bladder cancer

Phase I

- High response rate was observed in PD-L1 positive patients
- Phase I results provide support for pivotal studies

Phase II (Primary endpoint: Overall Response Rate)

Locally Advanced or Metastatic Bladder Cancer (n=330) → RG7446 1,200mg, iv, every 3 weeks

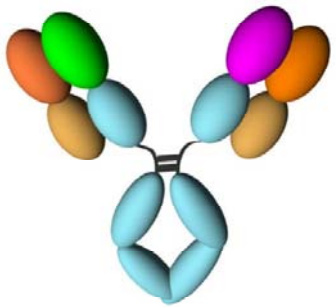
Phase III

- To be initiated in 2014
- Participation from Japan has been decided

Aiming to become a "top pharmaceutical company"

Overview of ACE910

Antibody mimicking Coagulation factor Eight, by connecting factor 9 & 10



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Primary Lifecycle Management Dept.
Hiroshi Motegi

December 16, 2014

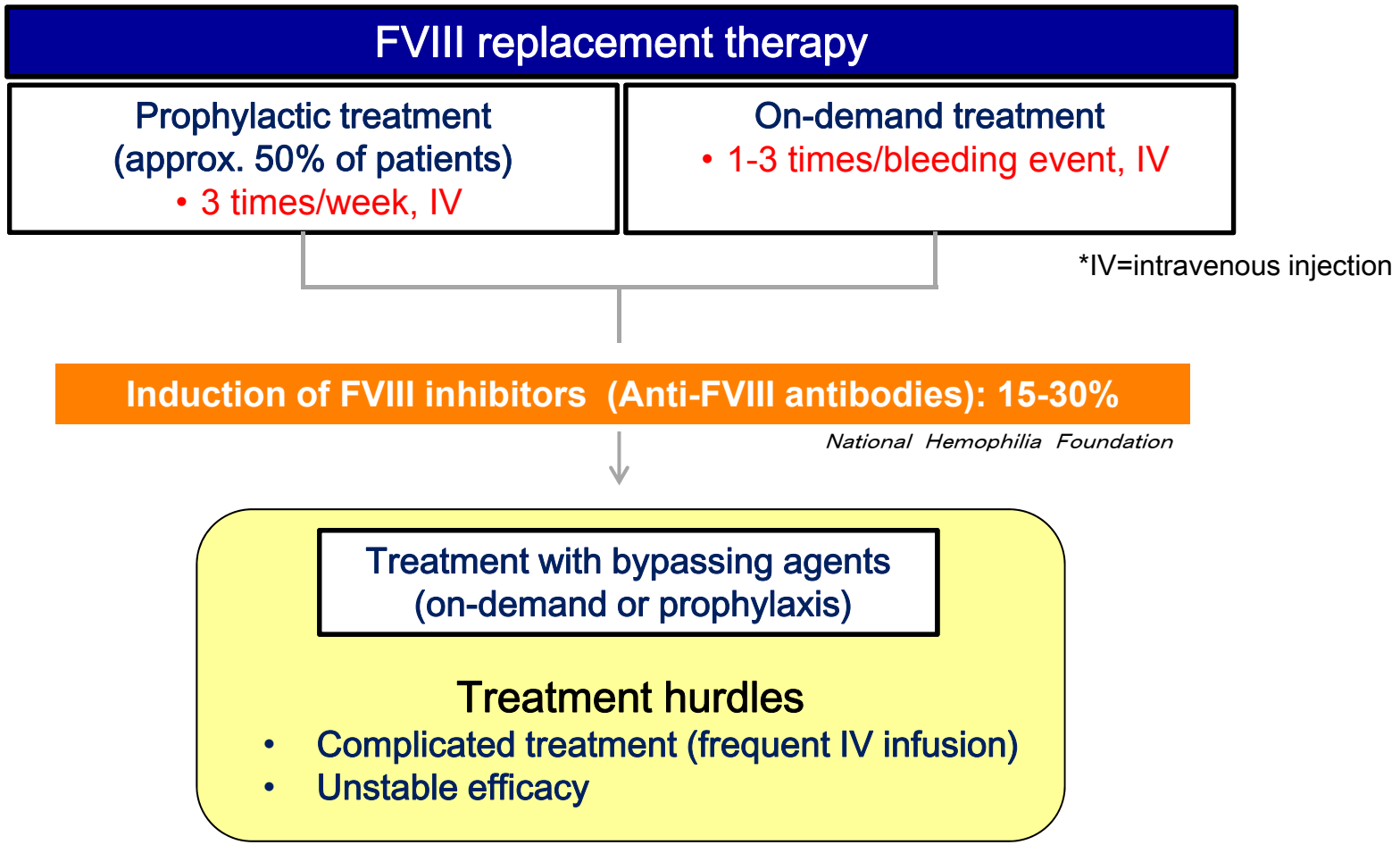
About Hemophilia A

- Definition
  - Hemophilia A is an inherited deficiency in clotting factor VIII (FVIII), which causes impairment of hemostatic function (bleeding disorder)
- Causes
  - X-linked recessive trait (prevalence: approx. one in 10,000 male births)
- Symptoms
  - Difficulty of hemostasis of hemorrhages caused by bruise or overload on joint results in large hematoma as well as difficulty of hemostasis in case of wound, surgery and tooth extraction
  - Complication such as arthritis damages QOL of hemophilia patients

	Severe	Moderate	Mild
% of normal FVIII	<1%	1 ~ 5%	5 ~ 40%
Rate of patients	60%	15%	25%
Bleeding frequency	Approx. 30 times/year	One/a few months	One or twice/year

National Hemophilia Foundation
Hemophilia A GeneReviews

Unmet Medical Needs in Hemophilia A



Concept of ACE910

FVIIIa-mimetic Bispecific Antibody

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Roche Roche Group

Mode of action

Support the interaction between FIXa and FX

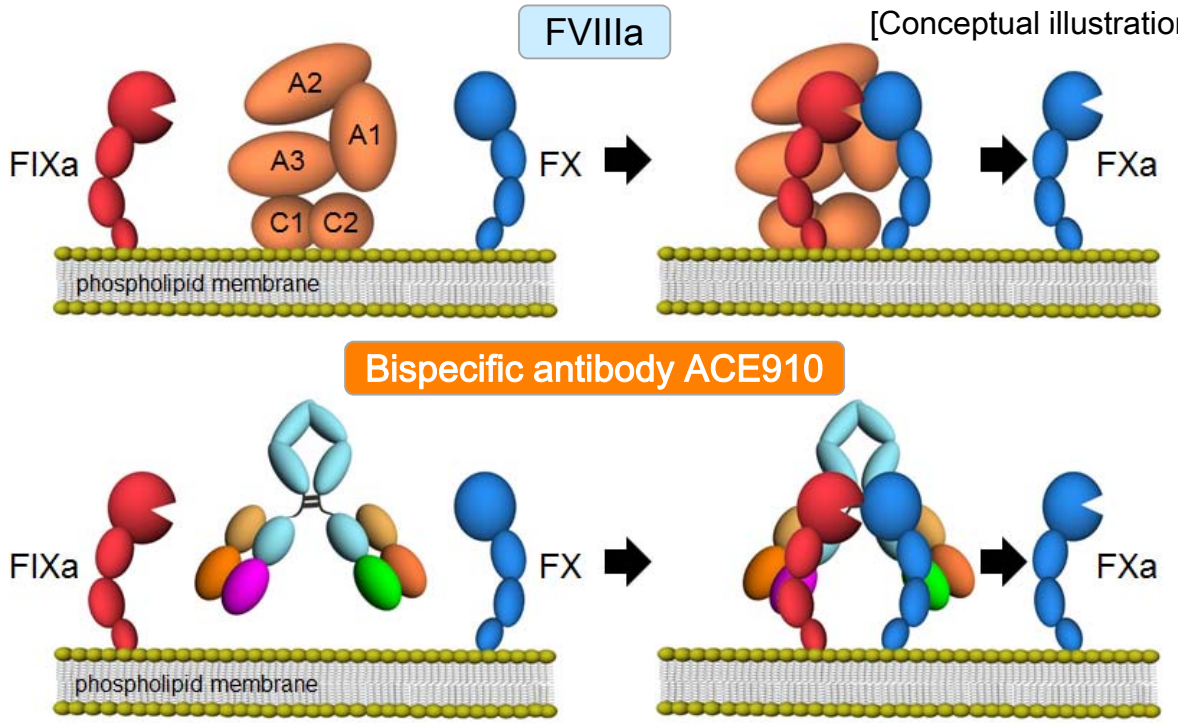
↓

Promote FX activation

↓

Accelerate coagulation

[Conceptual illustration]



Expected features of ACE910

- Subcutaneous injection (SC) available, longer half-life, low dosing frequency
- Effective in patients irrespective of the presence of FVIII inhibitors
- Unlikely to induce FVIII inhibitors

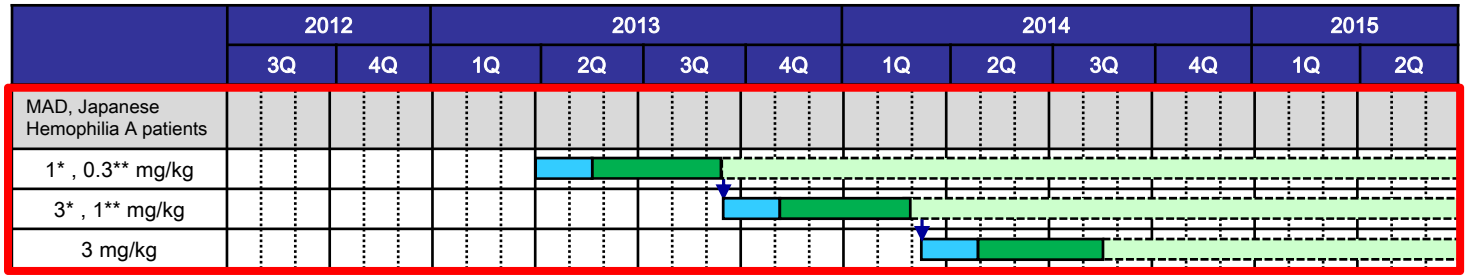
Kitazawa, et al. Nature Medicine 2012;18(10):1570

Sampei, et al. PLoS One 2013;8(2):e57479

Muto, et al. J Thromb Haemost 2014;12:206

Phase I study

	Subject	Dosage
Part A	Healthy volunteers: Japanese n=40 (placebo n=10)	0.001～1 mg/kg (5 dose), inter-individual, single-ascending dose
Part B	Healthy volunteers: Caucasian n=24 (placebo n=6)	0.1～1 mg/kg (3 dose), inter-individual, single-ascending dose
Part C	Hemophilia A patients: Japanese n=18	0.3～3 mg/kg (3 dose), inter-individual, multiple-ascending dose

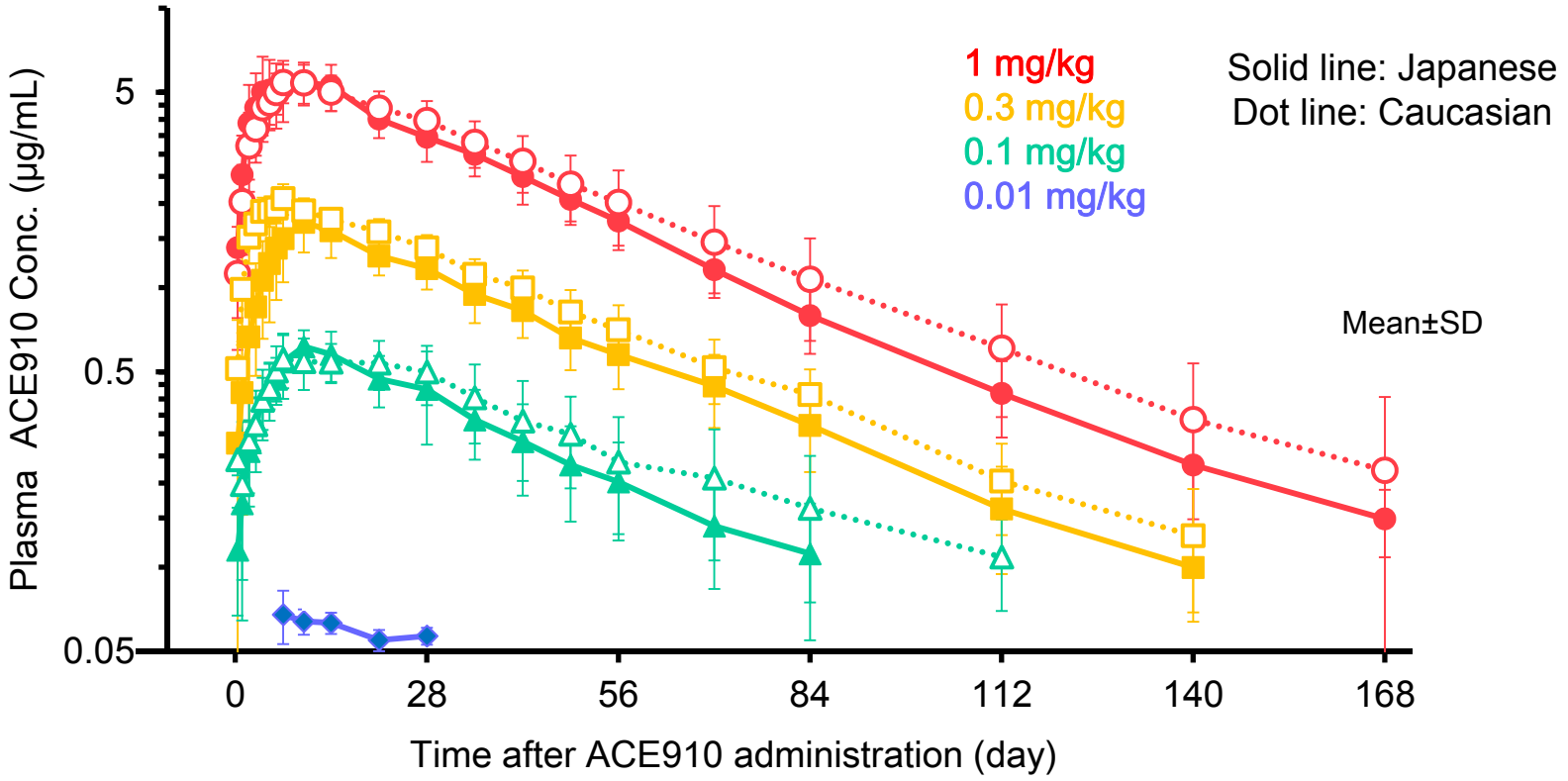


* : Initial loading dose
** : Second and subsequent doses

Enrollment period
Assessment period：final patient dosing
Extension phase (Ph1/2 extension part)

Cited from clinical trial documents of "Phase 1 study of ACE910 in healthy volunteers and hemophilia A patients" and "Extension study of the Phase 1 study of ACE910 in hemophilia A patients"

Healthy Volunteer Data: Time Course of Plasma ACE910 Concentration



- Dose-proportional increase in Cmax and AUC was observed.
- The mean half-life was 28.3 to 34.4 days.
- The Japanese and Caucasian subjects showed similar PK profiles.

Patient Data

Safety and Prophylactic Efficacy Profiles of ACE910, a Humanized Bispecific Antibody Mimicking the FVIII Cofactor Function, in Japanese Hemophilia A Patients Both without and with FVIII inhibitors: First-in-Patient Phase 1 Study

Midori Shima[1], Hideji Hanabusa[2], Masashi Taki[3], Tadashi Matsushita[4], Tetsuji Sato[5], Katsuyuki Fukutake[6], Naoki Fukazawa[7], Shingo Maisawa[7], Koichiro Yoneyama[7], Keiji Nogami[1]

[1] Nara Medical University, [2] Ogikubo Hospital,
[3] St. Marianna University School of Medicine Hospital,
[4]Nagoya University Hospital,
[5] University of Occupational and Environmental Health Hospital,
[6] Tokyo Medical University Hospital, [7] Chugai Pharmaceutical Co., Ltd.

Demographics and Baseline Characteristics

- The Annualized Bleeding Rate (ABR) of 6 months prior to this study in the C-1 cohort was higher than that of other 2 cohorts.
- Other demographic characteristics were well-balanced between the cohorts.

		C-1 cohort n=6	C-2 cohort n=6	C-3 cohort n=6
Median age, years (min - max)		32 (17 - 51)	30 (12 - 58)	33 (12 - 58)
Pts age <18 years, n (%)		1 (16.7)	1 (16.7)	1 (16.7)
Median weight, kg (min - max)		60.4 (40.8 - 81.2)	56.1 (48.1 - 81.7)	66.0 (48.8 - 78.2)
Non-inhibitor pts, n (%) Inhibitor pts, n (%)		2 (33.3) 4 (66.7)	2 (33.3) 4 (66.7)	3 (50.0) 3 (50.0)
ABR 6M prior to study entry,	Mean (SD) Median (min - max)	37.9 (25.2) 32.5 (8.1 - 77.1)	19.6 (9.8) 18.3 (10.1 - 38.6)	15.9 (11.9) 15.2 (0 - 32.5)
Target Joint*, n (%)		6 (100)	6 (100)	3 (50.0)

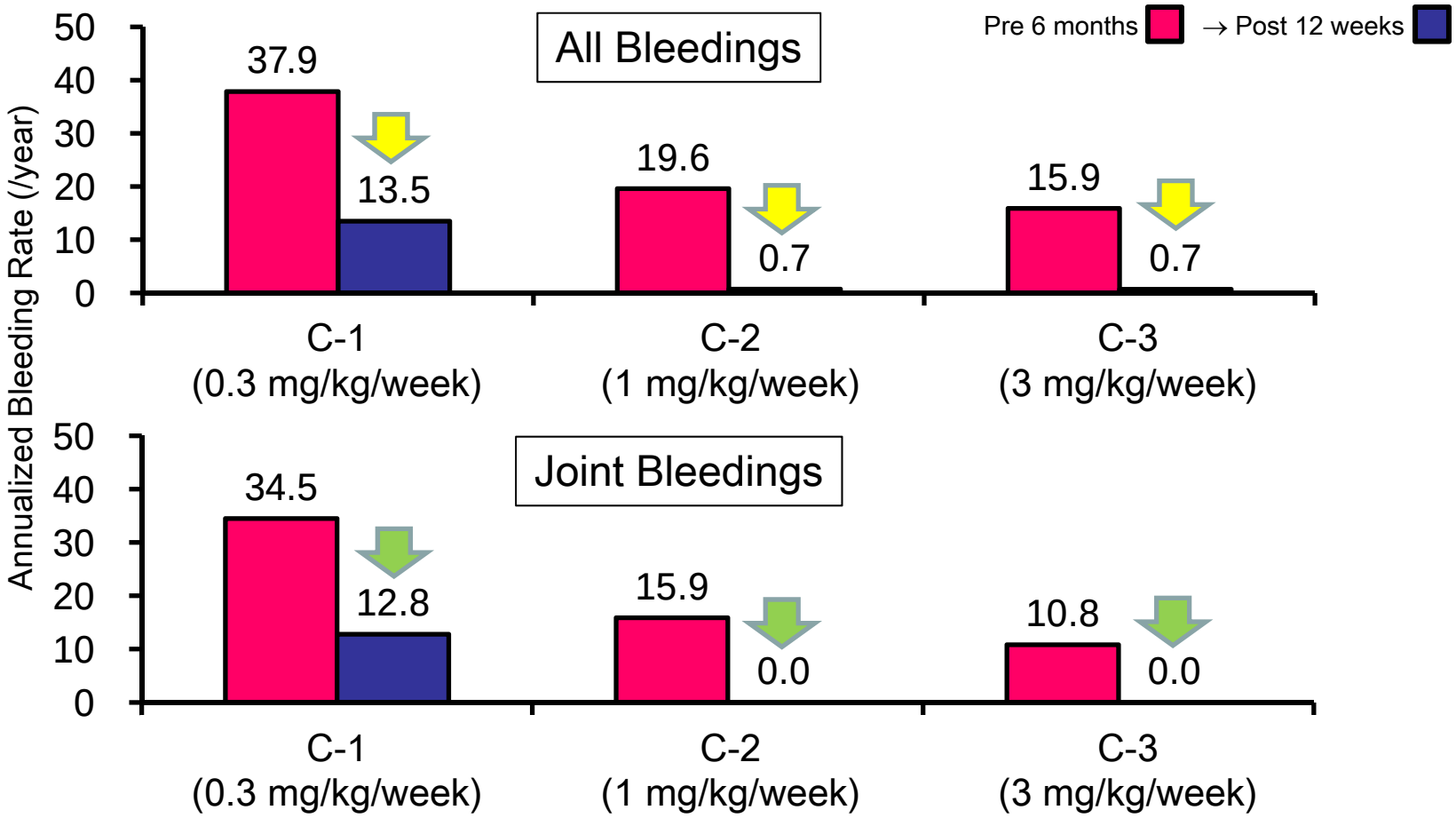
* Joint in which 3 or more spontaneous bleeds have occurred within a 6-month period.

Safety Results

- All AEs were of mild intensity, except for 2 moderate AEs not related to ACE910 administration
  - Upper respiratory tract infection (C-2 cohort), headache (C-3 cohort)
- One patient in the C-2 cohort discontinued ACE910 administration due to injection site erythema of mild intensity.
- No evidence of clinically relevant abnormalities of coagulation as indicated by clinical findings or laboratory tests (D-dimer, FDP, TAT and PT-INR).
- No thromboembolic AEs were observed, even when ACE910 was given concomitantly with FVIII products or bypassing agents as on-demand therapy for bleeding events.
- No anti-ACE910 antibodies were developed during the 12 weeks course of ACE910 administrations.

Well-tolerated safety profile at
12 weeks course of administration

The Mean ABR by Week 12



- The mean ABR in all cohorts were remarkably reduced.
- Joint bleeding was completely controlled in the C-2 and C-3 cohort.

Summary & Conclusion

Safety	• Once-weekly SC ACE910 administration up to 3 mg/kg was well tolerated. • No anti-ACE910 antibodies were developed in the 12 weeks of the study.
PK&PD	• Plasma ACE910 trough level increased in a dose-dependent manner. • Shortening of APTT and promotion of thrombin generation were observed after the start of ACE910 dosing.
Efficacy	• Once-weekly SC ACE910 prophylaxis demonstrated a promising efficacy profile in severe hemophilia A patients irrespective of the presence of FVIII inhibitors. • No joint bleeds were observed in 1 mg/kg and 3 mg/kg groups in the 12 weeks of the study.

ACE910 is expected to offer an effective and convenient prophylactic treatment option for hemophilia A, including patients with FVIII inhibitors and/or with venous access difficulty.

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