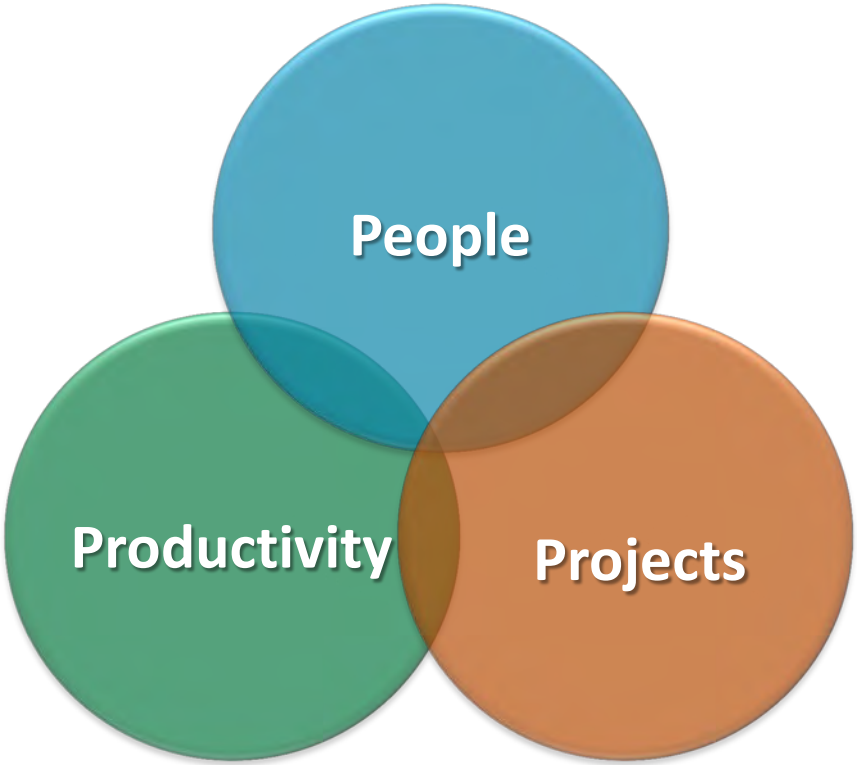
Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

Research and Development at Daiichi Sankyo



GLENN GORMLEY MD PhD
Global Head, Research & Development
Senior Executive Officer

Agenda of R&D Day

1. Research and Development Overview (Glenn Gormley)
2. Research Overview (Masahiko Ohtsuki)
3. Biologics Overview (Junichi Koga)
4. Development Overview (Mahmoud Ghazzi)
5. Closing (Glenn Gormley)

R&D Challenge: More Competitive External environment

- Declining number of approved NMEs
- Escalating R&D costs
- Growing share of biologics among approved NMEs

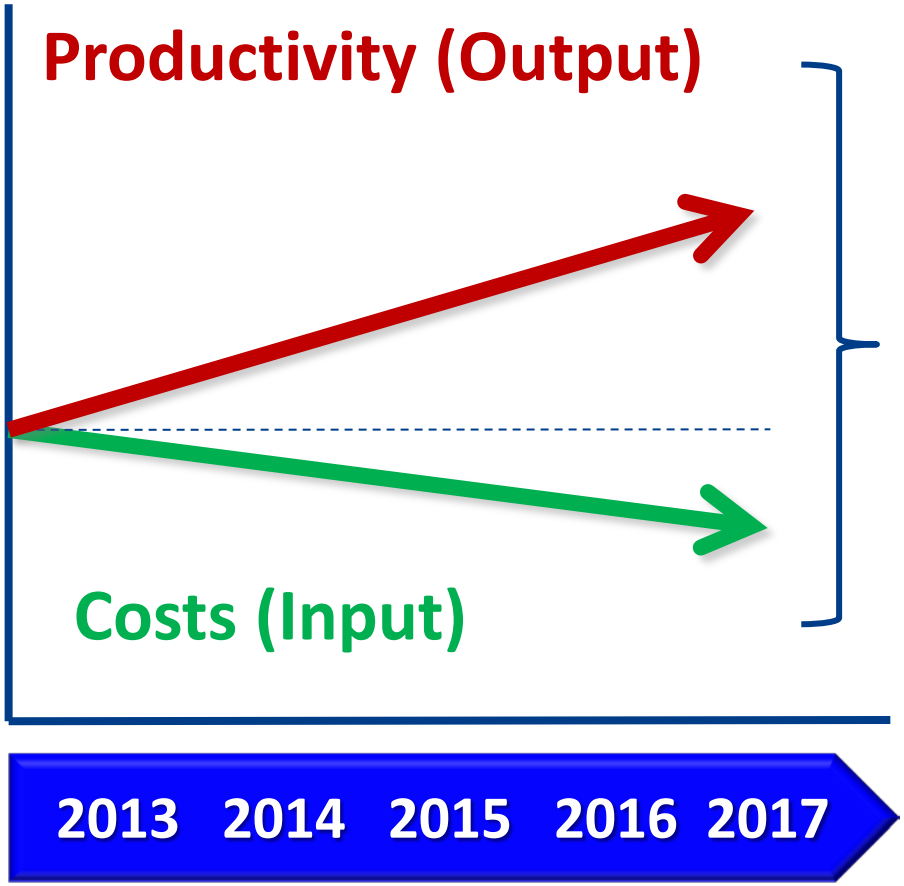
R&D Challenge: More Competitive External environment

- Declining number of approved NMEs
- Escalating R&D costs
- Growing share of biologics among approved NMEs

R&D response to Challenges: Increase Productivity

- **increase output at lower cost**
- **Accelerate development timelines**
- **Maximize the value of each R&D unit**

Global R&D 5 Year Business Plan



Drivers of success

- Leadership
- Innovation
- Efficiency
- Empowerment
- Smart Risk taking

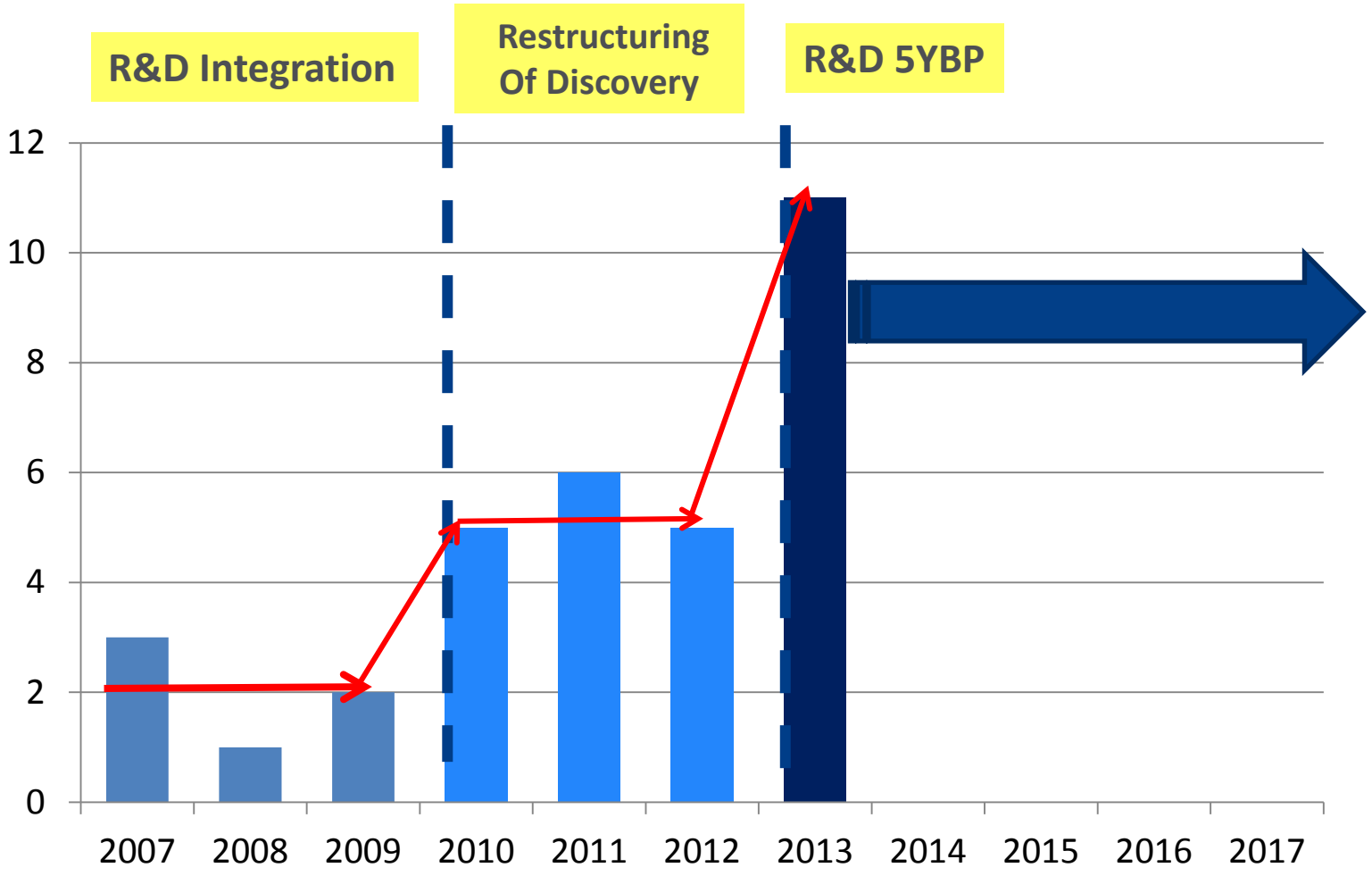
Global R&D 5 Year Business Plan
Key success factors

Daiichi-Sankyo

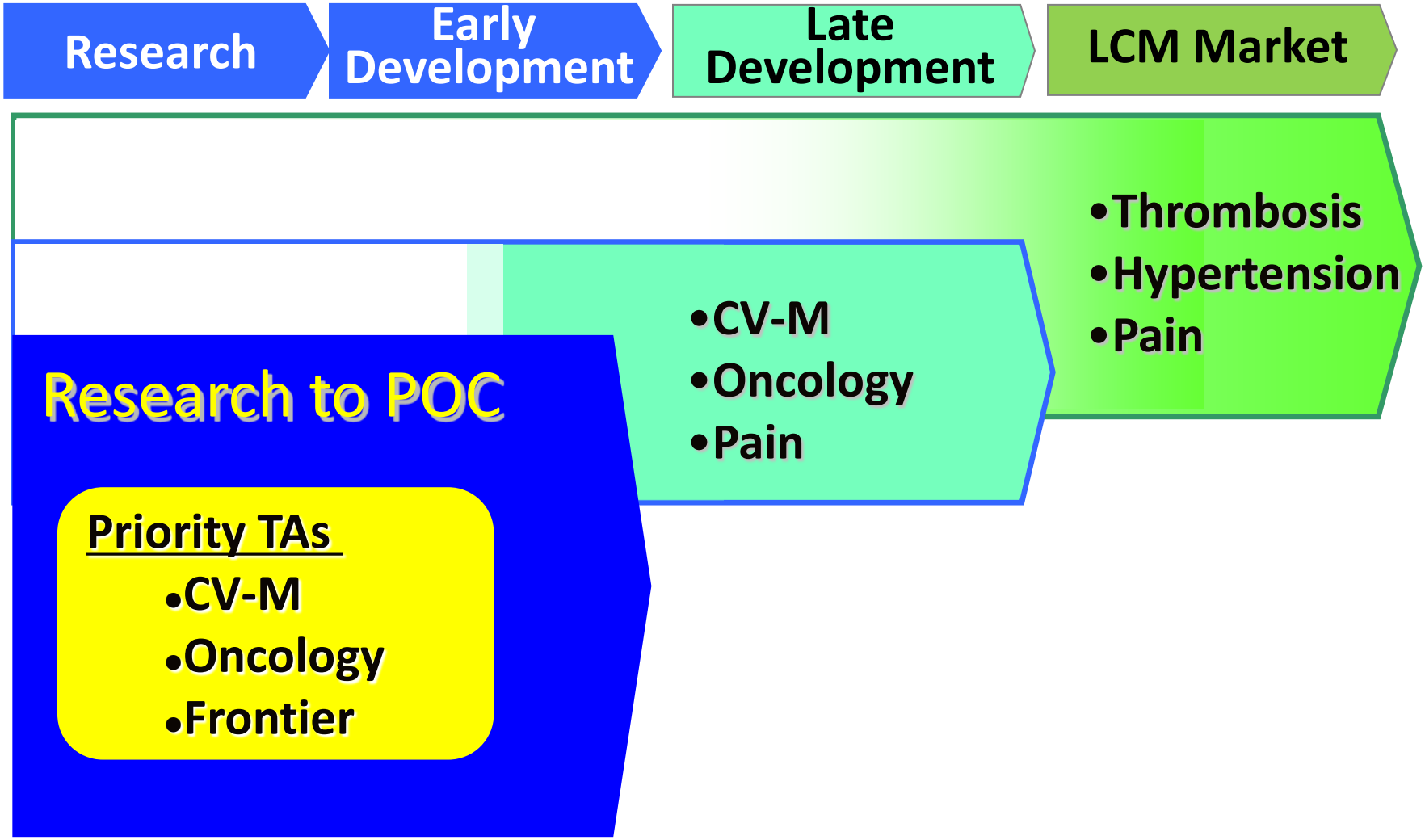
- Shorten R&D Timelines
- Focus on Personalized Medicine
- Enhance Leadership and Decision-Making
- Enhance Portfolio Management & Resource Planning
- Develop and Acquire global Talent
- Develop Global R&D IT Strategy

Productivity gains at Daiichi Sankyo

Number of Projects Entering Phase 1 development



Priority Areas at R&D Stages



Major R&D Pipeline

As of December 2014

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Therapeutic area	Phase 1	Phase 2	Phase 3	Application
Cardiovascular-Metabolics	**DS-1040** (Acute ischemic stroke / TAFIa inhibitor)	**CS-3150 (JP)** (Hypertensive / DM nephropathy / MR antagonist) **DS-8500 (JP)** (Diabetes / GPR119 agonist)	**Prasugrel (JP)** (CS-747 / ischemic stroke / anti-platelet agent) **Prasugrel (US)** (CS-747 / sickle Cell Disease / anti-platelet agent)	**Edoxaban (US/EU/Others)** (DU-176b / AF / oral factor Xa inhibitor) **Edoxaban (US/EU/Others)** (DU-176b / VTE / oral factor Xa inhibitor)
Oncology	**U3-1565 (US/JP)** (Anti-HB-EGF antibody) **DS-7423 (US/JP)** (PI3K / mTOR inhibitor) **DS-3078 (US/EU)** (mTOR inhibitor) **DS-3032 (US)** (MDM2 inhibitor) **PLX7486 (US)** (Fms / Trk inhibitor) **DS-8895 (JP)** (Anti-EPHA2 antibody) **DS-8273 (US)** (Anti-DR5 antibody) **PLX8394 (US)** (BRAF inhibitor) **DS-6051 (US)** (NTRK / ROS1 inhibitor)	**Patritumab (US/EU)** (U3-1287 / anti-HER3 antibody) **Vemurafenib (US/EU)** (PLX4032 / BRAF inhibitor) **PLX3397 (US)** (Fms / Kit/Flt3-ITD inhibitor)	**Tivantinib (US/EU)** (ARQ 197 / HCC / Met inhibitor) **Denosumab (JP)** (AMG 162 / breast cancer adjuvant / anti-RANKL antibody) **Nimotuzumab (JP)** (DE-766 / gastric cancer / anti-EGFR antibody) **Vemurafenib (US)** (PLX4032 / melanoma adjuvant / BRAF inhibitor) **Quizartinib (US/EU)** (AC220 / AML / FLT3 inhibitor)	
Others	**PLX5622** (Rheumatoid arthritis / FMS kinase inhibitor) **DS-1093** (Anemia of chronic kidney disease / HIF-PH inhibitor) **DS-3801** (Chronic obstipation / GPR 38 agonist) **DS-1971** (Chronic pain)	**Mirogabalin (JP)** (DS-5565 / chronic pain / α2δ ligand) **SUN13837 (US/EU)** (Spinal cord injury / modulator of bFGF signaling system) **Laninamivir (US/EU)** (CS-8958 / anti-influenza / out-licensing with Biota) **Ioforminol (JP)** (GE-145 / X-ray contrast media / angiography)	**Mirogabalin (US/EU)** (DS-5565 / Fibromyalgia / α2δ ligand) **Levofloxacin (JP)** (DR-3355 / anti-infection / New quinolone) **Denosumab (JP)** (AMG 162 / rheumatoid arthritis / anti-RANKL anti-body) **Hydromorphone (JP)** (DS-7113 / narcotic analgesic / opioid μ-receptor regulator) **CHS-0214 (JP)** (Etanercept BS / rheumatoid arthritis / TNFα inhibitor) **CL-108 (US)** (Acute pain / opioid μ-receptor regulator)	

Underline: Change from FY2014 2Q Financial Announcement

Targets for Approval and Launch

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	FY2014	FY2015	FY2016	FY2017	≥ FY2018
Japan	Edoxaban AF Edoxaban VTE Prasugrel CAD Denosumab GCTB	Levofloxacin Injection		Denosumab BC adj. Denosumab RA Etanercept BS RA Prasugrel CVA	**Oncology** Tivantinib DE-766 Patritumab Quizartinib PLX3397 Vemurafenib (LCM)
US	Edoxaban AF Edoxaban VTE		CL108 Acute Pain		**CV-M (CVM)** CS-3150 DS-8500 Prasugrel (LCM) Edoxaban (LCM)
Western Europe		Edoxaban AF Edoxaban VTE			**Others** Mirogabalin SUN13837 DS-7113 GE-145 Denosumab (LCM)
Others		Edoxaban AF&VTE (China･LTAM etc.)			

Decision Making Body for Global R&D Projects

Daiichi-Sankyo

Global Head of R&D
(Chair)

GH of Development

Corporate Strategy

GH of BD&L

GH of Research

Function
Committee
Chairs

GH of Biologics

GEMRAD

GH of RD Planning

GH of IP

GH of Global PM

Global Executive Meeting of Research
And Development

GH of Clinical
Safety and PV

Chief Medical Advisor

Regional Development Heads

PJ Team Leaders

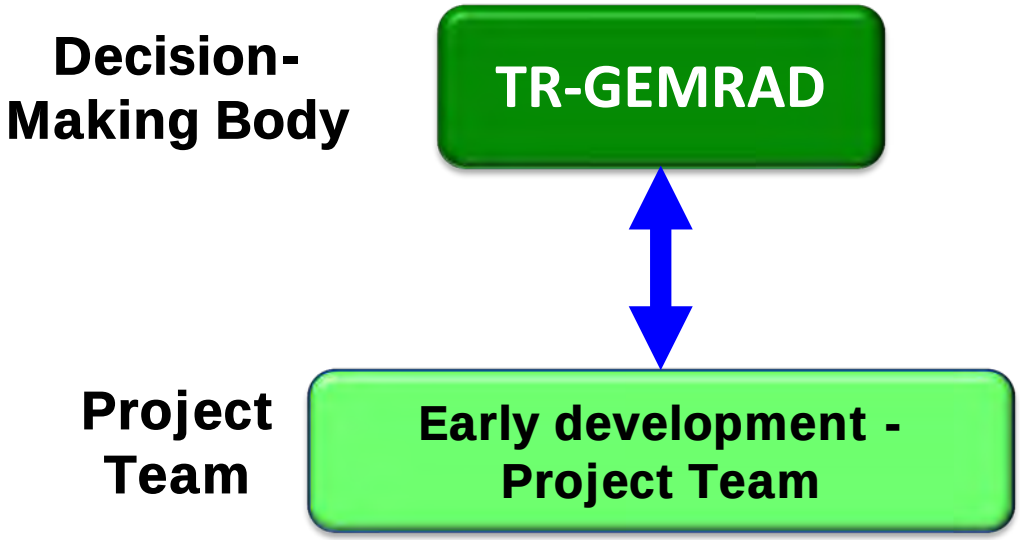
GH of Pharmaceutical
Technology

Daiichi Sankyo's Decision Making System:

Simple: One decision making body for all teams in early phase development

Fast: Monthly meetings

Aligned: All stakeholders represented at TR-GEMRAD and empowered

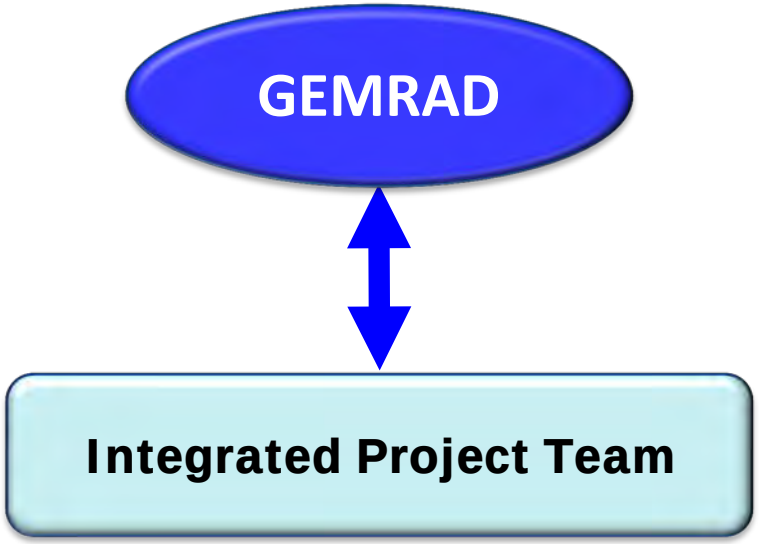


Daiichi Sankyo's Decision Making System:

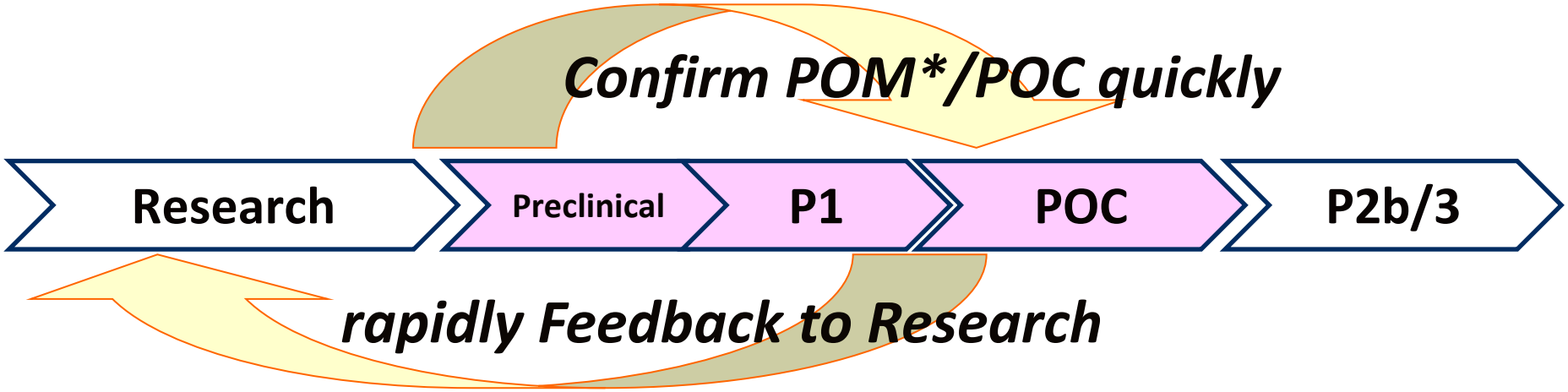
Simple: One decision making body for all teams in late phase development
Fast: Monthly meetings
Aligned: All stakeholders represented at GEMRAD and empowered

Decision-Making Body

Project Team



Translational Research Concept:



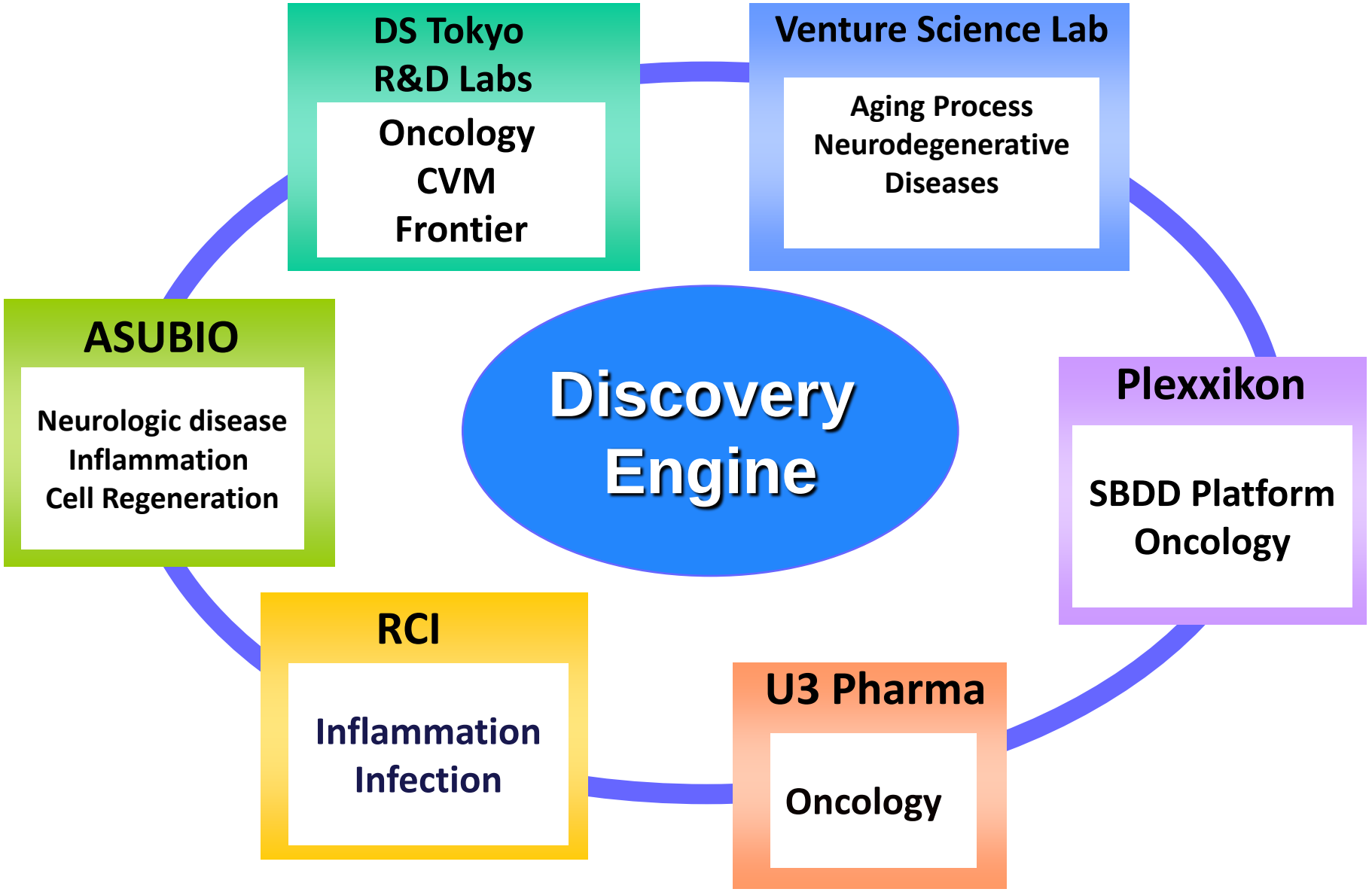
Research phase	Translational Research phase	Late Dev phase

In Translational research phase:

- Test key elements of Target Product Profile quickly
- Take smart risks to establish Proof of Concept
- Ensure continuous feedback loop to maximize learning

*POM: Proof of Mechanism

Global Sites for competitive theme creation



Venture Science Laboratories (VSL)
in-house Venture model

- Deliver innovative FIC products in a biotech-like lab
- Develop therapeutics and diagnostics for neurodegenerative diseases such as Alzheimer's disease through research collaboration with UCSF-IND (Institute for Neurodegenerative Diseases)

UCSF-IND

- World class academia laboratories focusing on neurodegenerative diseases led by Dr. Stanley B. Prusiner, recipient of Nobel Prize for research on prions in 1997

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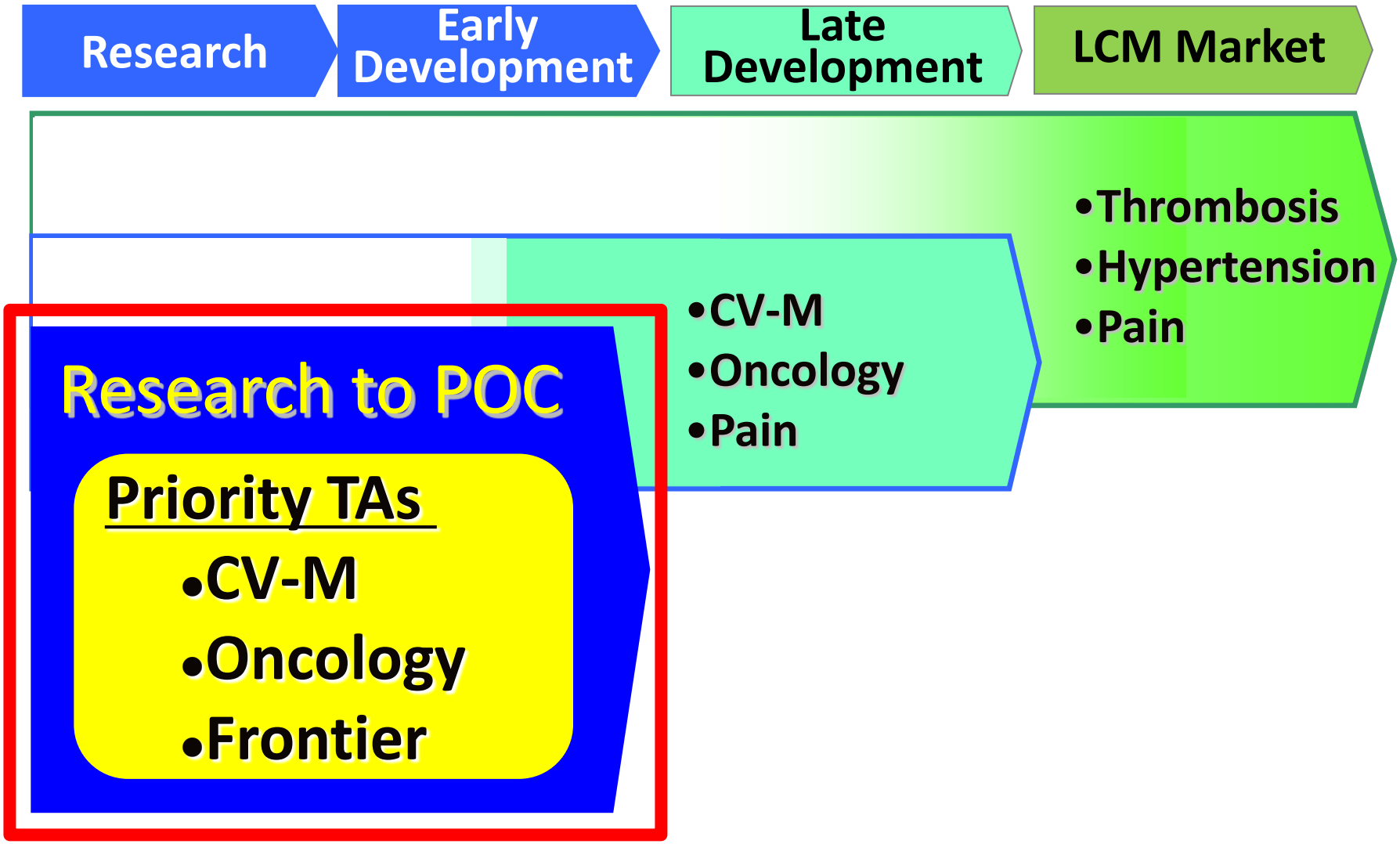
Research Overview

Masahiko Ohtsuki
Global Head of Research

Priority Areas at Research to POC



Mission for Global Research of Daiichi Sankyo

- Challenge high unmet medical needs by novel science and technologies
- Create a Competitive Pipeline and Deliver Innovative Products Quickly and Consistently to Patients

Approach in Priority Area

- **CV-M**：Utilizing past experience and strength and challenge to new approaches
- **Oncology**：Actively utilize open innovation and create strong franchise
- **Frontier**：Targeting First-In-Class drug discovery through new approach, Discovery Focus

Total care of thrombotic diseases

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Anti-platelet

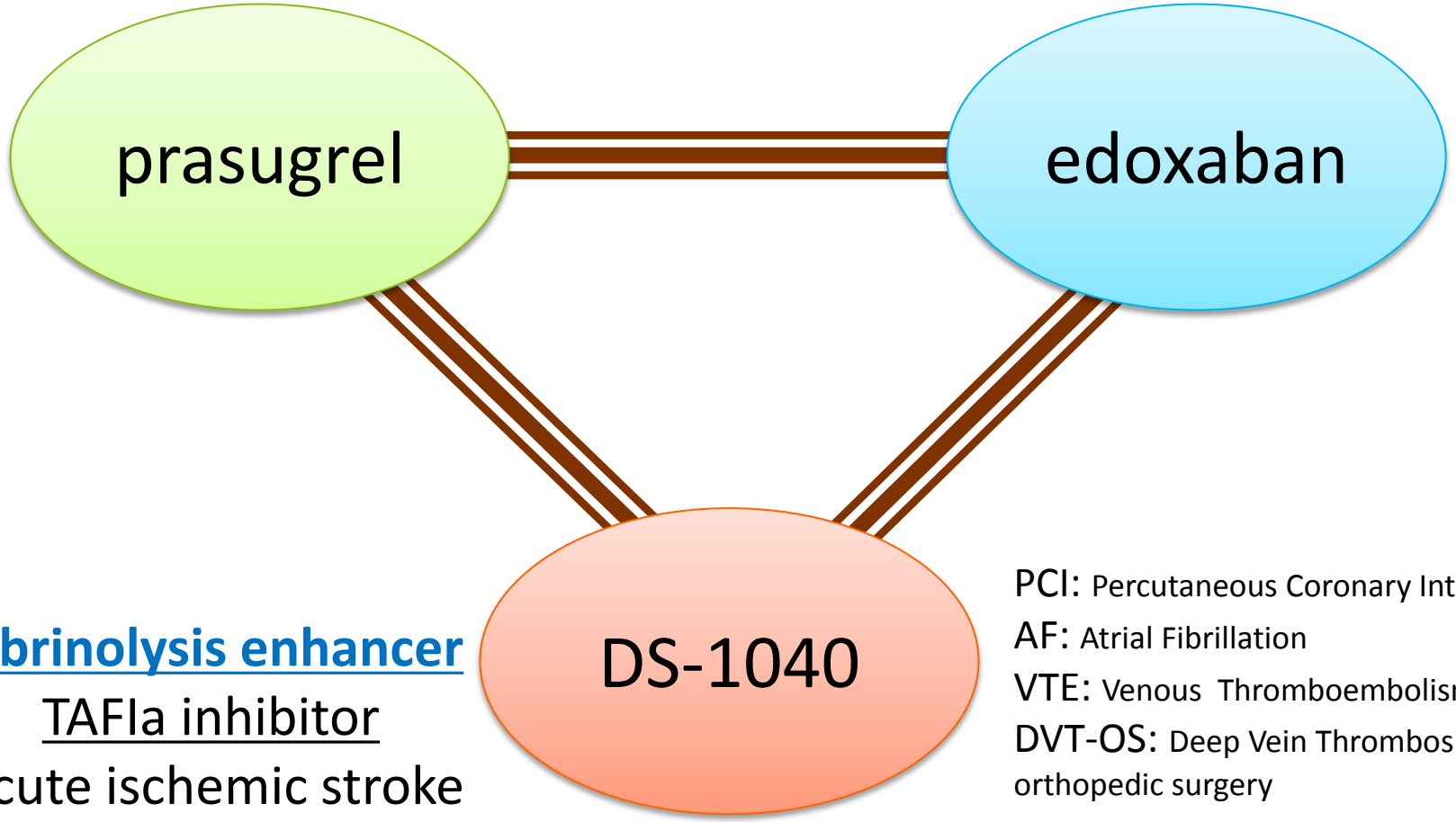
Oral $P2Y_{12}$ antagonist

PCI, stroke

Anti-coagulant

Oral Factor Xa inhibitor

AF, VTE, DVT-OS



Fibrinolysis enhancer

TAFIa inhibitor

Acute ischemic stroke

PCI: Percutaneous Coronary Intervention

AF: Atrial Fibrillation

VTE: Venous Thromboembolism

DVT-OS: Deep Vein Thrombosis after orthopedic surgery

DS-1040
TAFIa inhibitor brings safer thrombolysis

Daiichi-Sankyo

◆UMN in Acute Ischemic Stroke

- SOC for blood reflow: rt-PA (alteplase)
  - Very limited eligible patient
  - Strict applied condition including narrow therapeutic time window due to increasing intracranial hemorrhage (ICH) risk

◆TAFIa inhibitor brings safer thrombolysis

- TAFIa inhibitor would recruit plasminogen and tPA to fibrin surface followed by promoting thrombolytic effect of tPA/plasmin
  - Expected low ICH risk by localizing thrombolysis around the fibrin

Open Innovation is the key for success

Daiichi Sankyo

- Strong Medicinal Chemistry
- Unique Compound Library
- Experienced Pharmaceutical Science

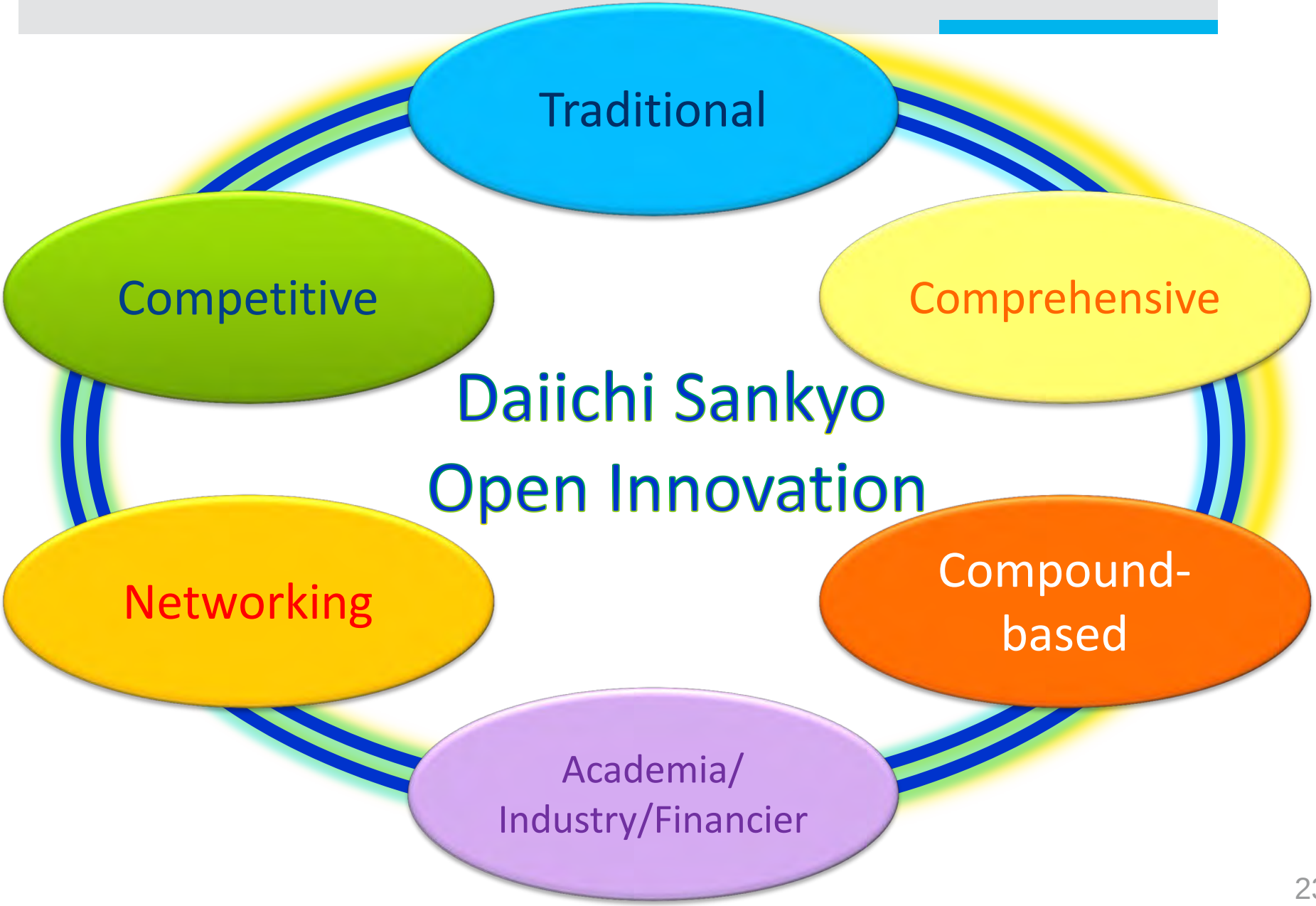
Academia

- Innovative Target
- Academic Network
- Scientific Excellence
- Clinical Insight

+ New Business Model

Discovery of Innovative Drug

Open innovation at Daiichi Sankyo



DS-3032: Mdm2 inhibitor for cancer

Traditional

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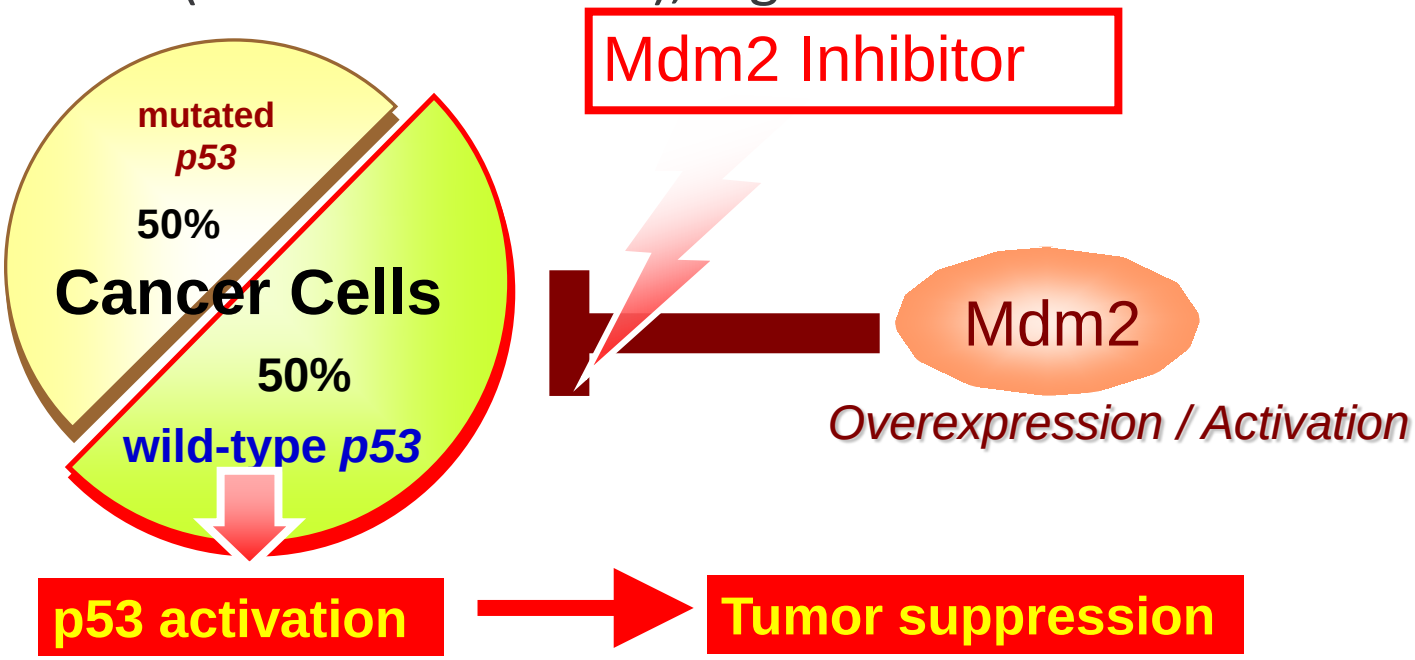
Mechanism of Action: Inhibition of MDM2-p53 interaction

Indication: Leukemia, solid tumor

Collaborator: UCSF (Frank McCormick), Rigel



Traditionally known WT genotype → p53 gene sequencing

DS identified WT phenotype → Gene signature

Select patients

IDH1 mutant inhibitor:
cancer drug with much lower adverse effect

Comprehen
-sive

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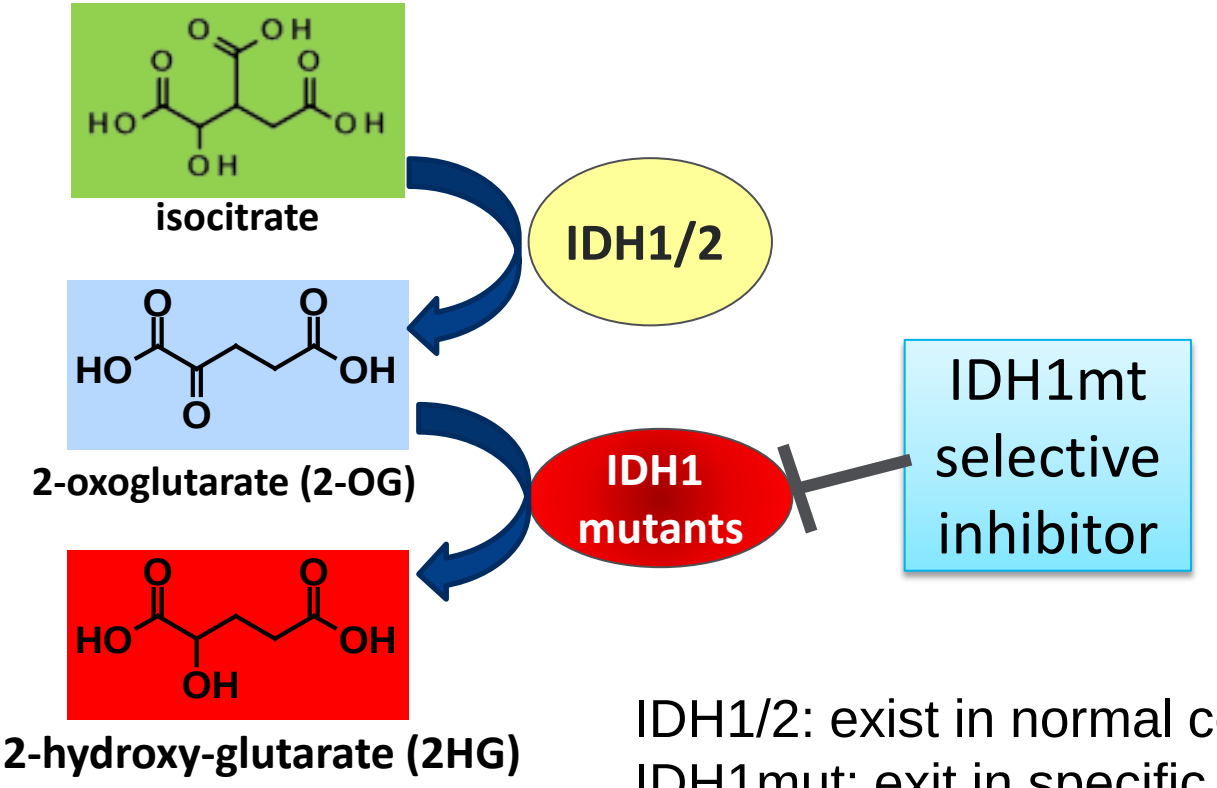
Mechanism of Action: Selective inhibition of IDH1 mutant

Indication: Leukemia, solid tumor (glioma etc)

Collaborator: National Cancer Center



IDH1/2: exist in normal cells

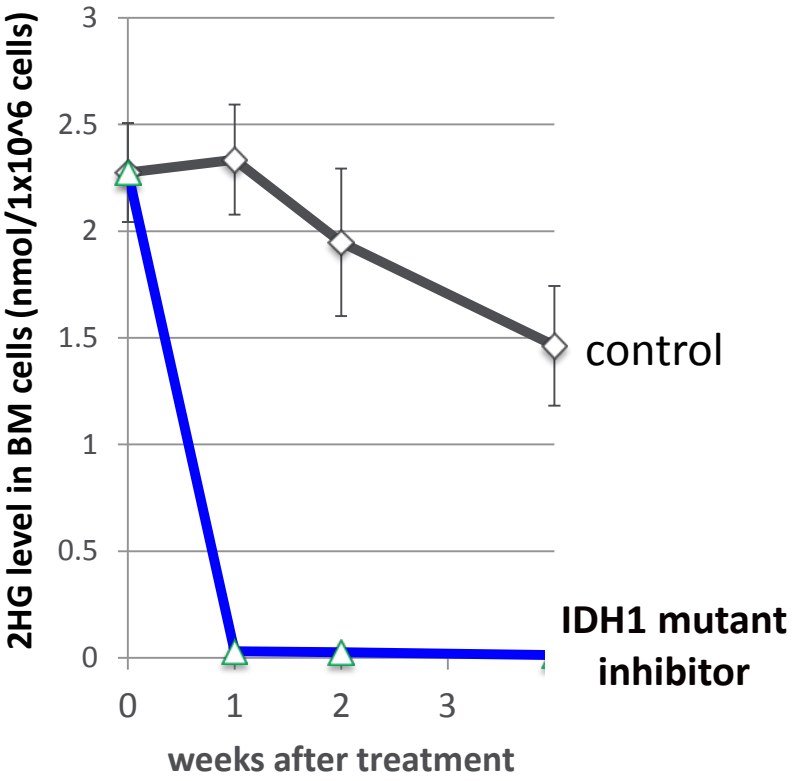
IDH1mut: exit in specific tumor cells

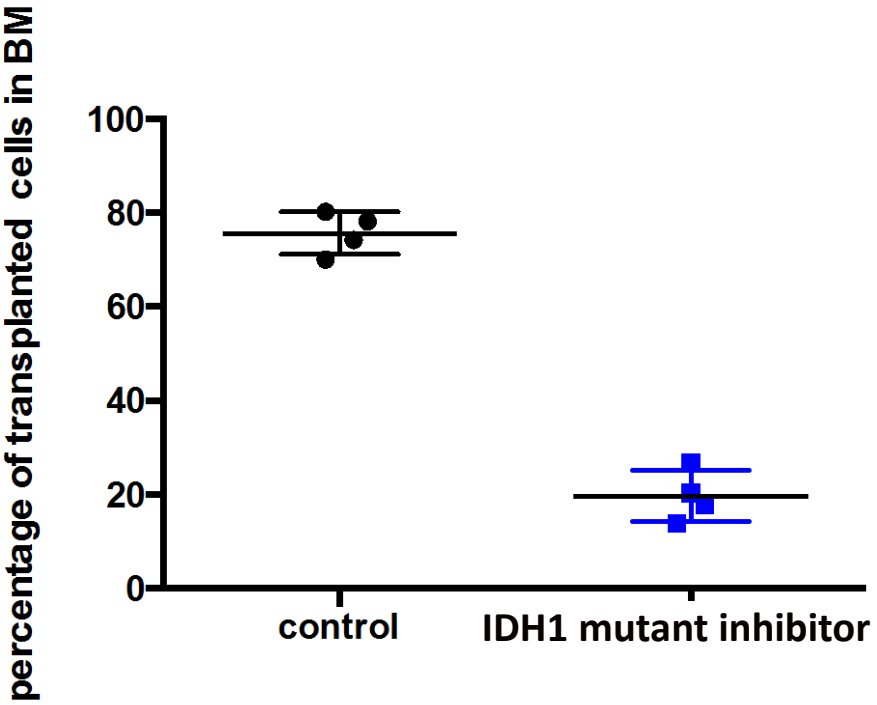
IDH1 mutant inhibitor is effective in leukemia model

Comprehen -sive

Daiichi-Sankyo

- Administration of IDH1 mutant inhibitor decreases 2HG level and AML cells





(National Cancer Center, Daiichi Sankyo 2014)

TaNeDS

“Take a New challenge for Drug discovery”

Competitive

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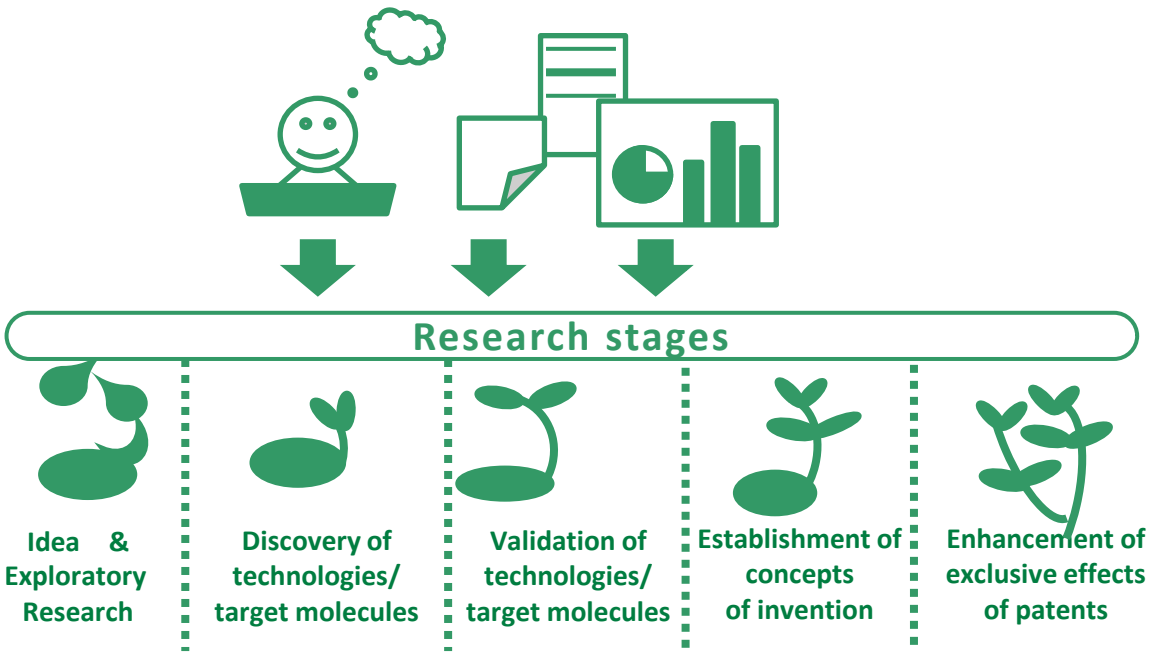
Multi-Entrance



Multi-Exit

collaborative research on drug creation

further investigations into discovered results

fostering intellectual property or technologies from a business viewpoint

utilization of OiDE projects

- Multi ENTRANCE

From preliminary ideas to strengthening IP

- Multi EXIT

From contract-based research to supported collaboration to establish a venture

FY	Entries	Selected
2014	234	24
2013	222	23
2012	250	20
2011	337	21

Access to a variety of academia:
Alliance with Virtici/Celdara Medical(VCM)

Networking

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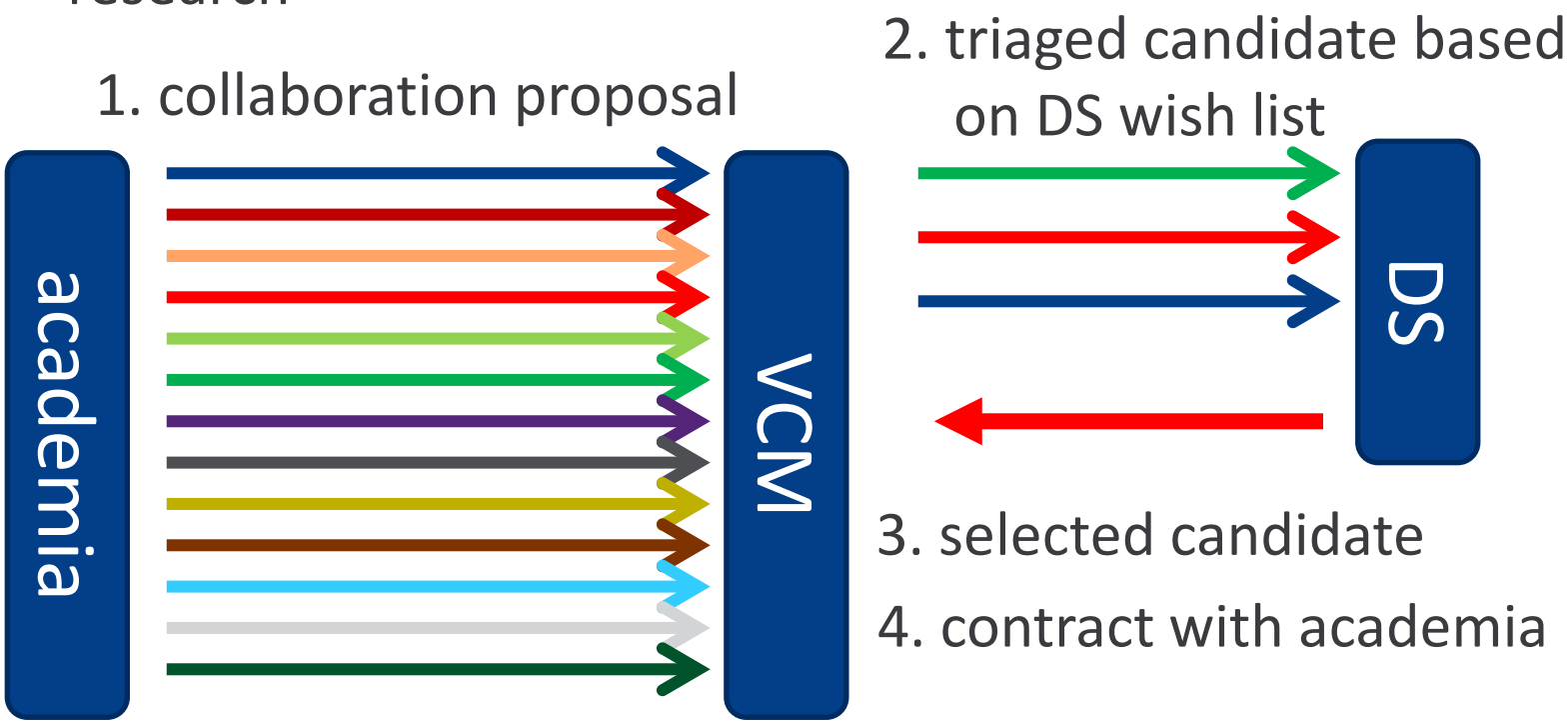
- Partnership for novel drug target identification research
- VCM gathers many collaboration proposals from their wide range academia network in US
- DS selects research projects and conduct drug discovery research



Library compounds exchange with Astellas: For better drug candidates

Compound -based

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Daiichi Sankyo

0.4 million Compounds for HTS

Astellas

0.4 million Compounds for HTS

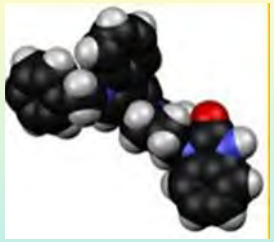
Share compounds

precompetitive

Possibility of obtaining hit compounds ↑

Diversity of hit compounds ↑

competitive

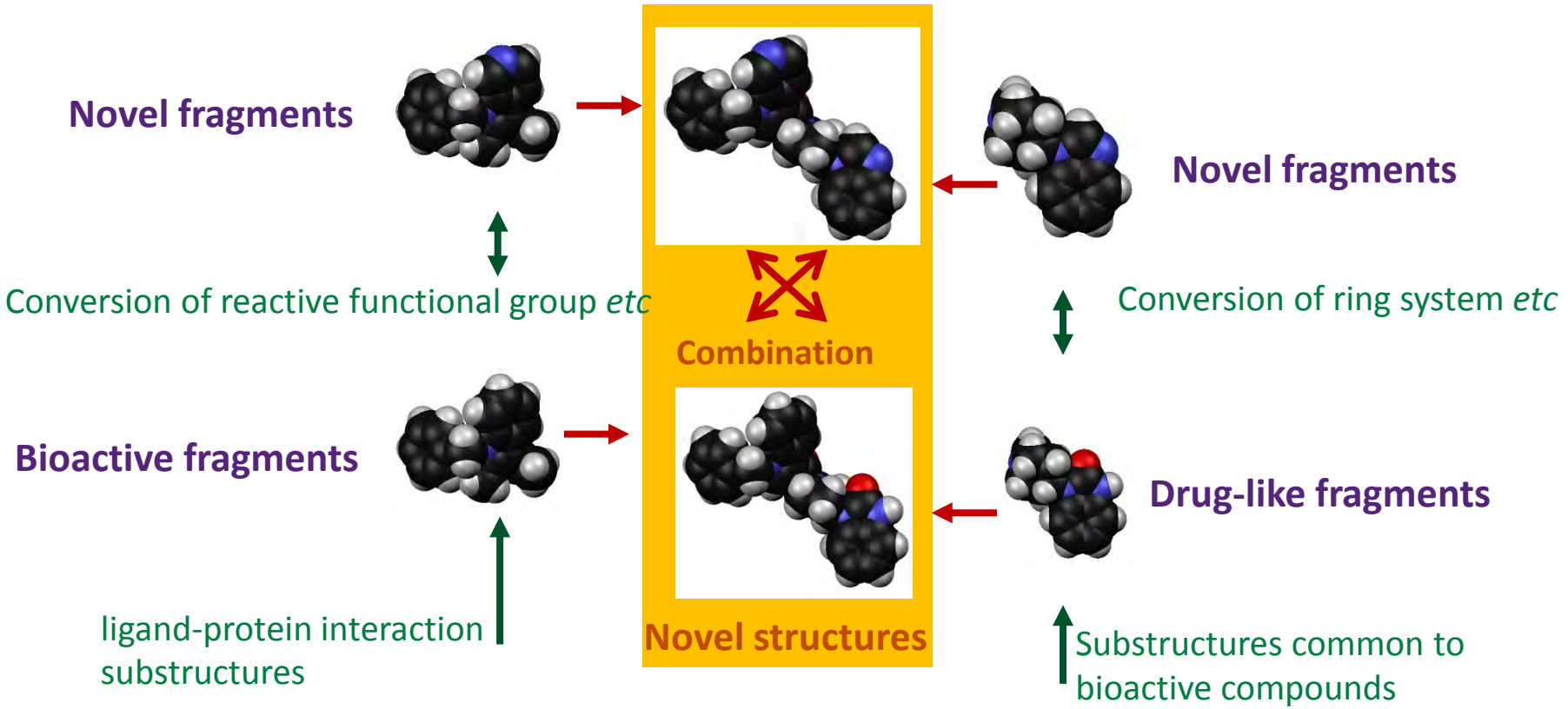


Better drug candidates

Designed compound library for high quality hit: Pharma Space Library

Compound -based

Daiichi-Sankyo



Synergistic combination between academia and Daiichi Sankyo

Compound-based

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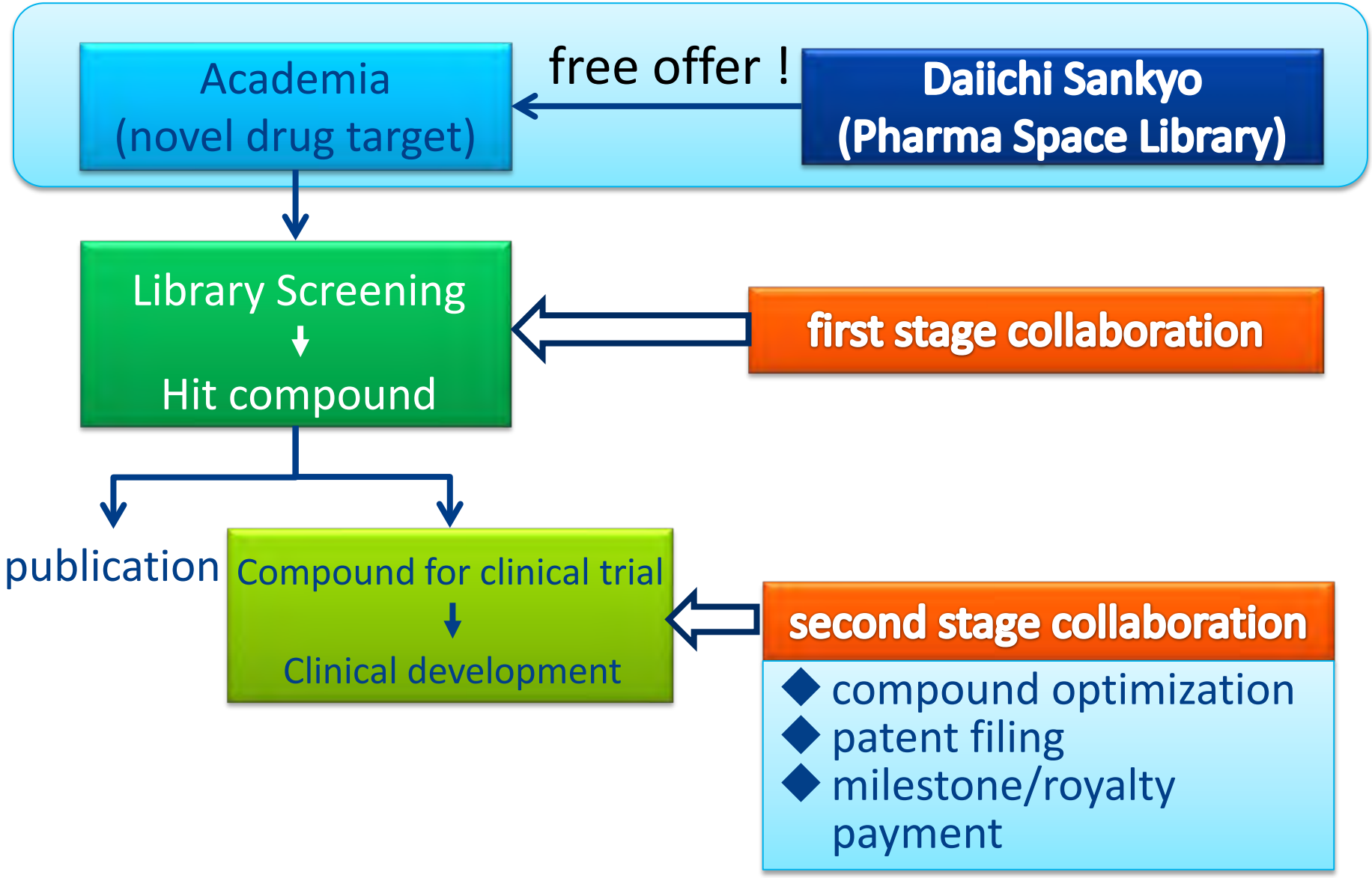

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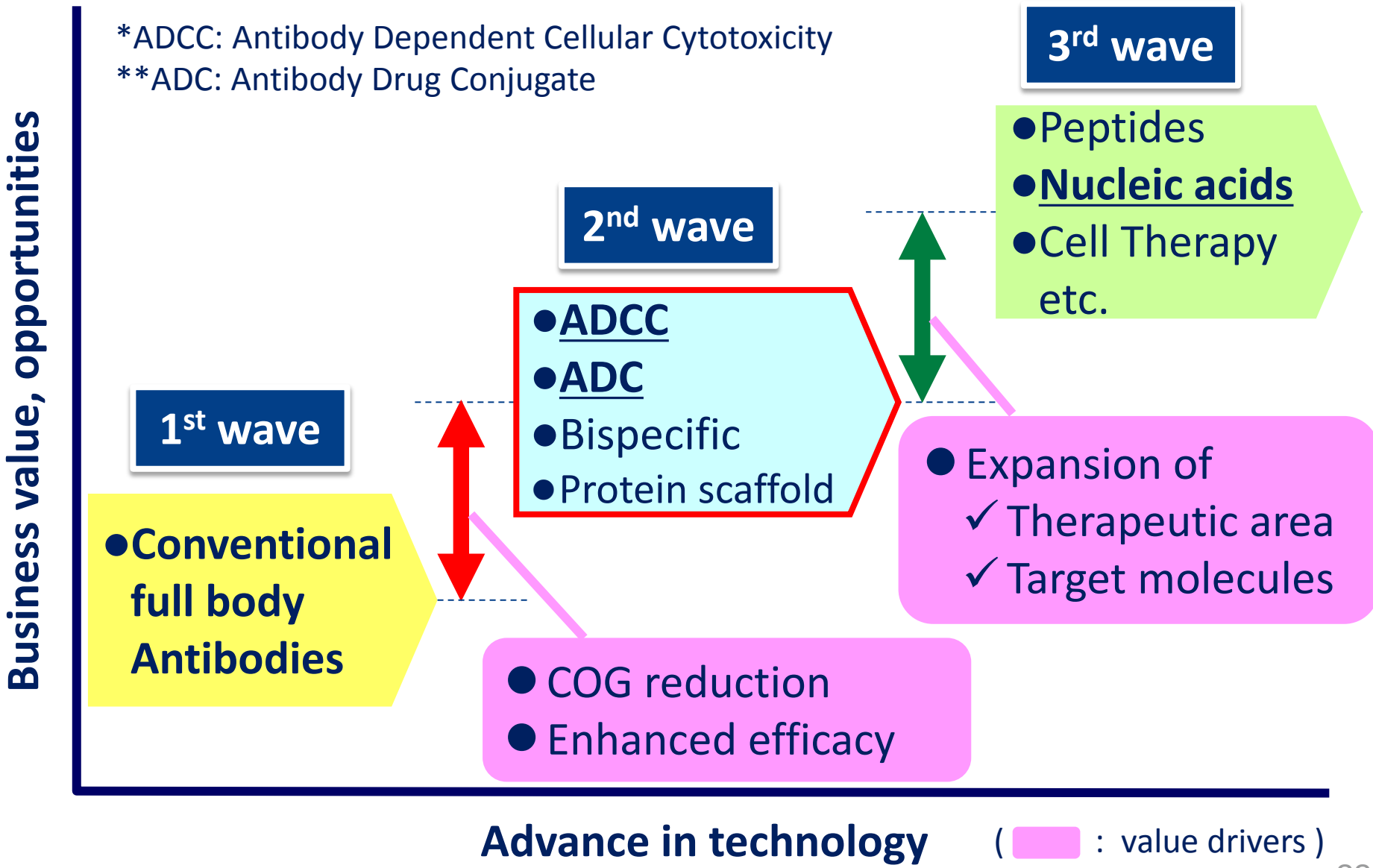
Biologics Overview

Junichi Koga

Global Head of Biologics

Strategy


*ADCC: Antibody Dependent Cellular Cytotoxicity
**ADC: Antibody Drug Conjugate
Business value, opportunities
1st wave
●Conventional full body Antibodies
2nd wave
●ADCC
●ADC
●Bispecific
●Protein scaffold
3rd wave
●Peptides
●Nucleic acids
●Cell Therapy
etc.
● COG reduction
● Enhanced efficacy
● Expansion of
✓Therapeutic area
✓Target molecules
Advance in technology
(: value drivers)

Stepwise approach for biologics business

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Preparatory → **"Jump-in" JPN/Asia** → **Launch in-house mfg* BS** → **Portfolio expansion**

Master Cell Bank development → **Establish in-house mfg* facility** → **Expand in-house mfg* facility**

* manufacturing

Biosimilar

JPN/Asia early entry to BS arena via alliance

Launch of in-house BS globally

Innovative

Innovative products/pipeline expansion

Profit maximization through full implementation of biologics business

Biologics Pipeline Growth & Progress

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Bio-Research engine creates RD candidates effectively.

	Discovery	Pre-clinical	Phase 1
2007	2	0	2
2012	10	4	1

As of Mar 2014	46	11	4 (New entry)

2nd wave (ADCC)

DS-8895a: anti-EPHA2 Ab

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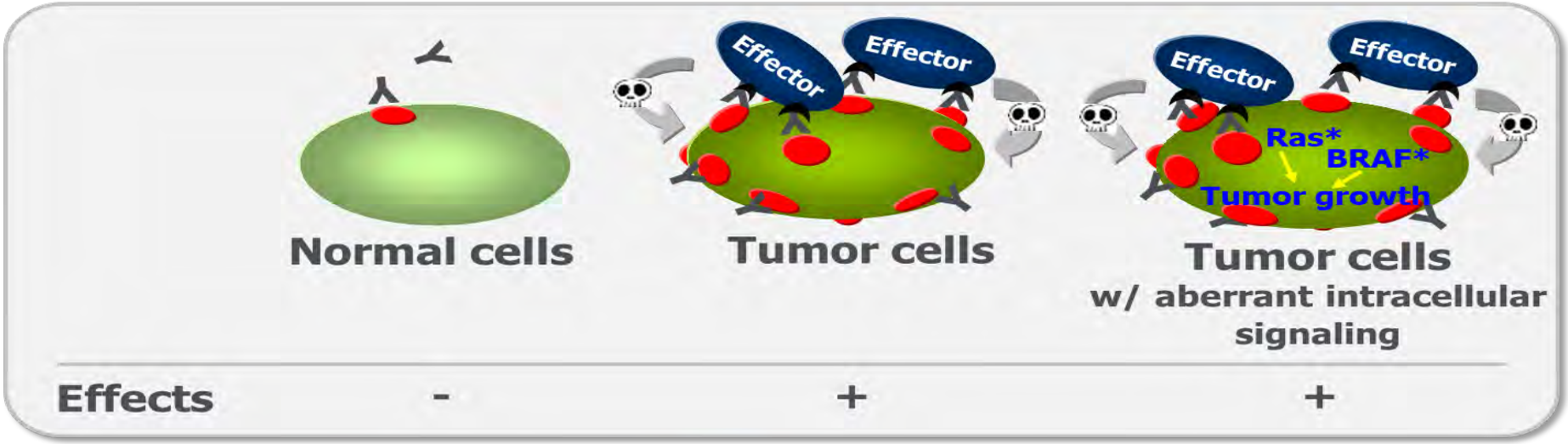
- EPHA2 is known to be highly expressed in multiple tumors (gastric, breast, lung, ovarian , colorectal cancer etc.)
- Potent ADCC activity
- It is effective even in the tumors with KRAS active mutation in preclinical models

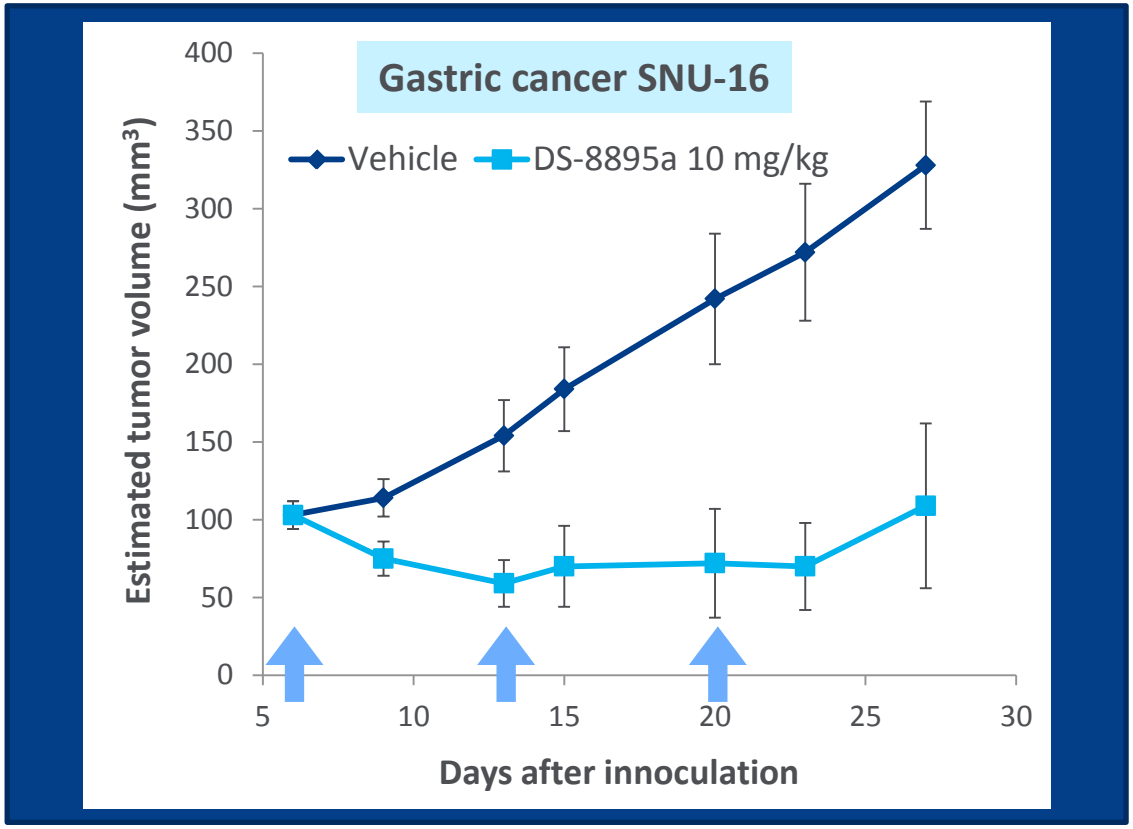


Y Antibody (DS-8895a)

EPHA2 Receptor

Effector Immune effector cells (mainly NK cells)

DS-8895a: anti-EPHA2 Ab



- One of the 2nd wave technologies, ADCC enhancement technology, was applied.
- DS-8895a is effective in EPHA2 positive preclinical tumor models including gastric, breast, lung, and ovarian cancer.
- Phase 1 study is ongoing.

2nd wave (ADC)

Antibody Drug Conjugate

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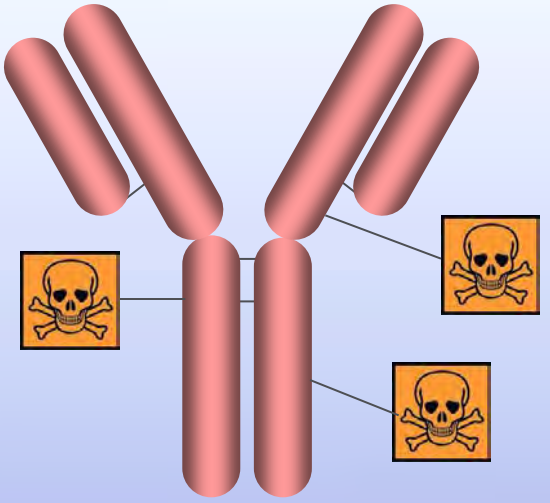


- **Strong Warhead (Drug)**
- **Functional Linker**
- **Appropriate target molecules and Ab**

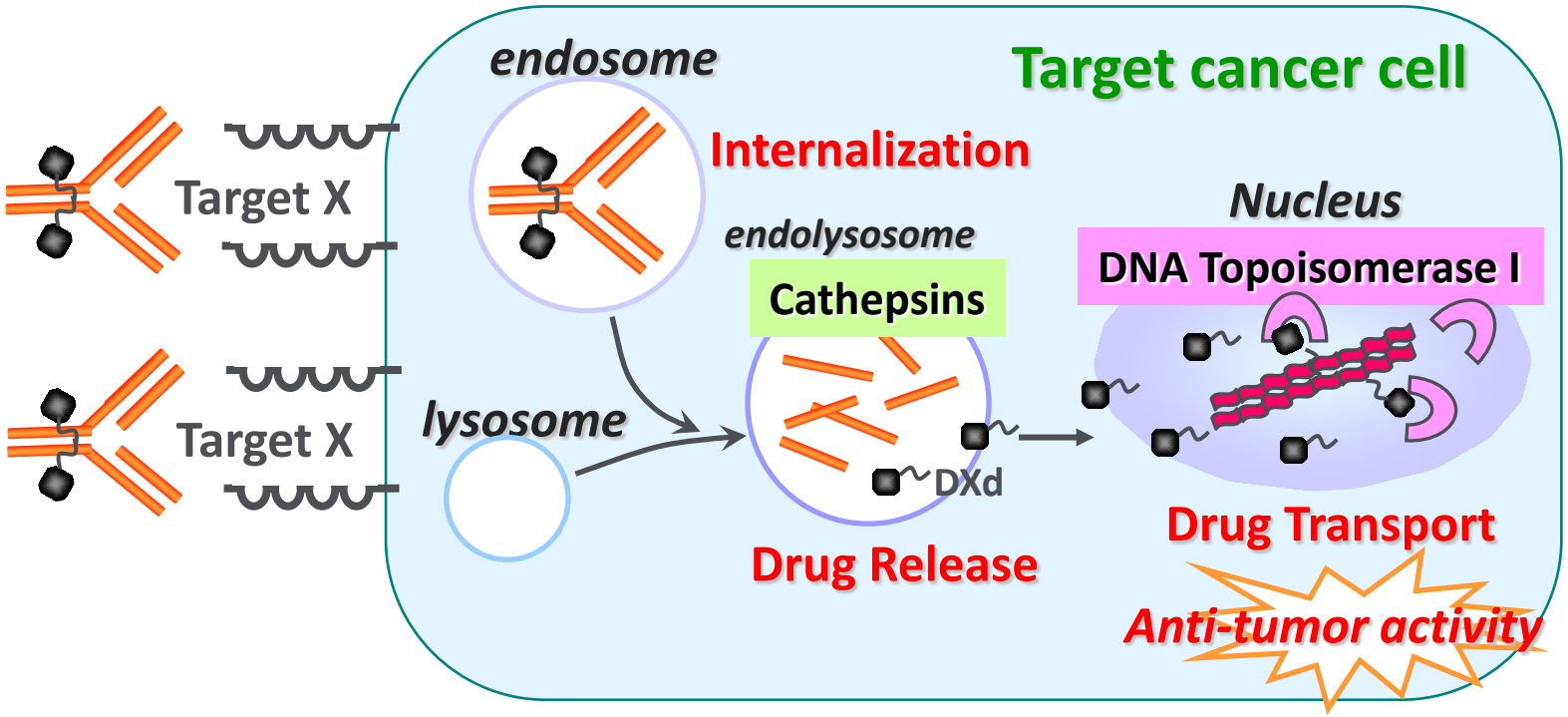
- **Enhance anti-tumor activity of Antibody**
- **Deliver enough amount of drug to the target tumor**

Provide ADCs which combine the features of Strong Anti-tumor Effect and Excellent Safety

DS original technology of ADC

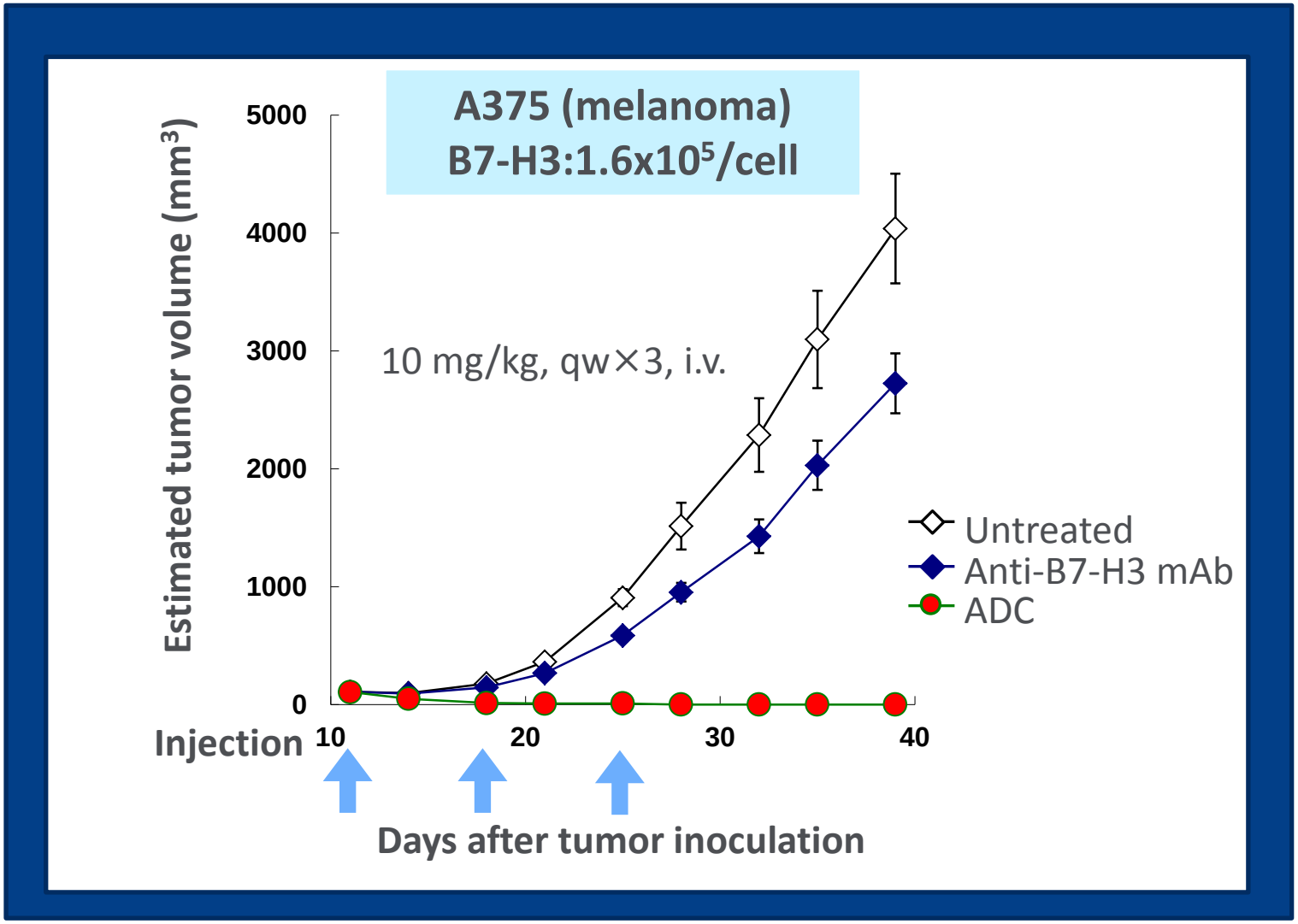
- Targeting to tumor specific Ags* prone to efficiently internalize
- Stable in blood, specific drug release by endolysosomal enzymes
- Unique and strong payload: Topoisomerase I inhibitor

* Antigens



Potential to be a global standard Payload/Linker system

B7-H3 ADC showed potent efficacy



Most advanced Abs mfg plant based on Single Use Bioreactor (SUB)

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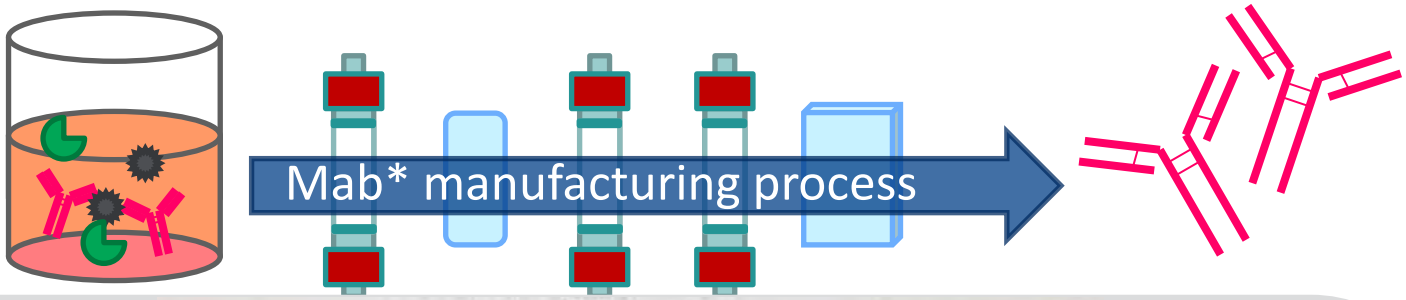
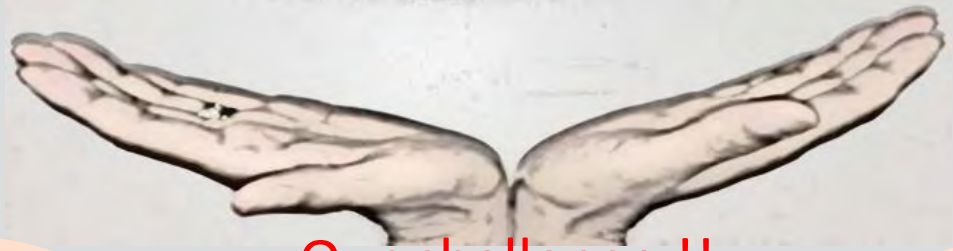
- Concept
  - Compliant with JP, US, EP GMP
  - Single Use - Facility Integration
  - Multiproduct facility
- Facility / Equipment
  - 2,000L SUB* x 2 x 2 lines
  - Two purification lines
  - Start of operation : Feb, 2012

*Single Use Bioreactor

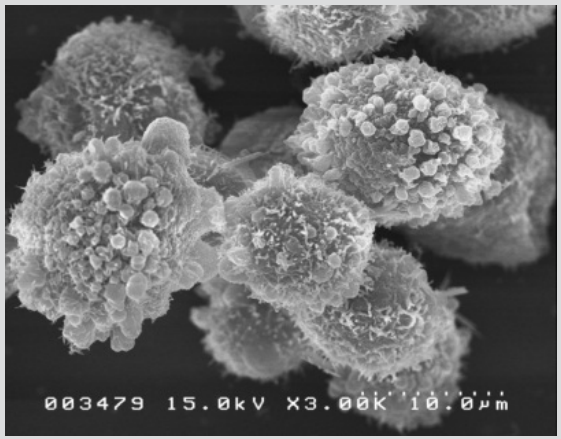
What is process development?





Our challenge !!

Host



Vector

Screening procedure

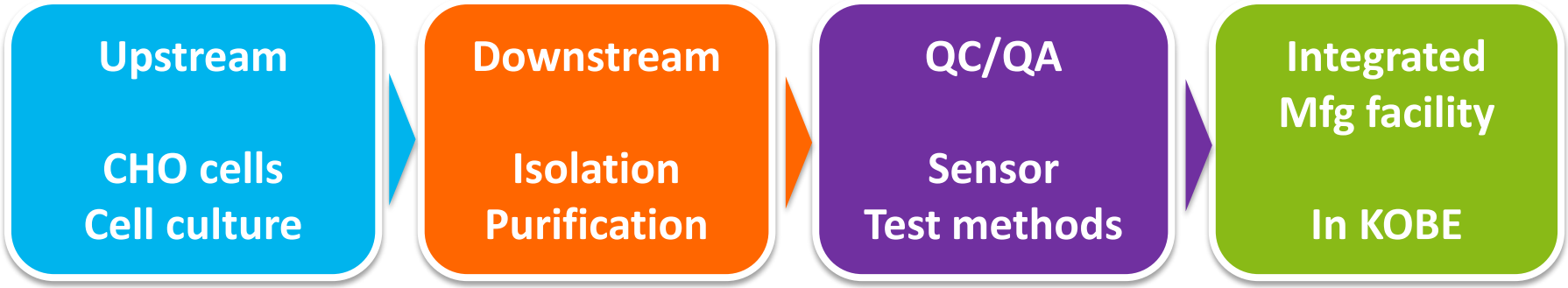
media

* Monoclonal antibody

Contribution to consortium* led by METI※

* Manufacturing Technology Research Association of Biologics (MAB)

- 4 Univ., 1 Research Inst., 2 NPO※ and 25 companies
- DS is the only pharmaceutical company in MAB
  - To establish upstream techs
  - To identify the requirements from user's view point



※ METI : Ministry of Economy, Trade and Industry
NPO : Non-profitable organization

Duchenne-type and Becker-type Muscular Dystrophy

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Type	Duchenne	Becker
Cause	Dystrophin protein	
	Deficient	incomplete expression (quality, quantity)
Mutation	Out-of-frame	In-frame

ENA® Oligonucleotide-induced exon skipping would save Duchenne type patients by changing to Becker type.

3rd wave (Nucleic acids)

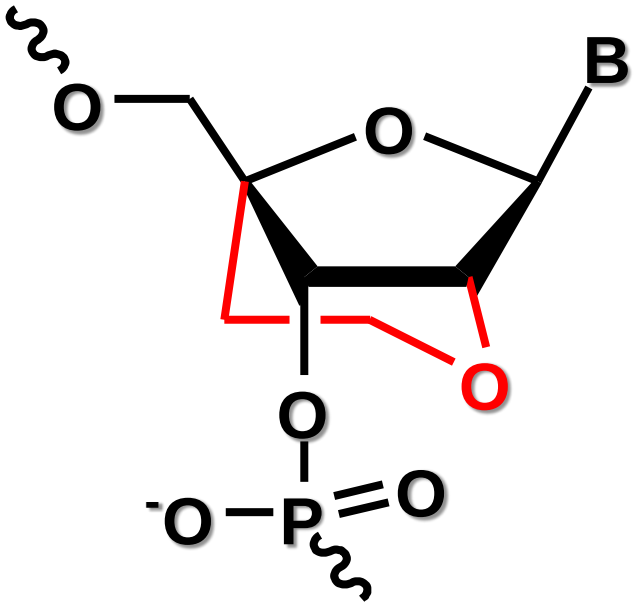
ENA®Oligonucleotides

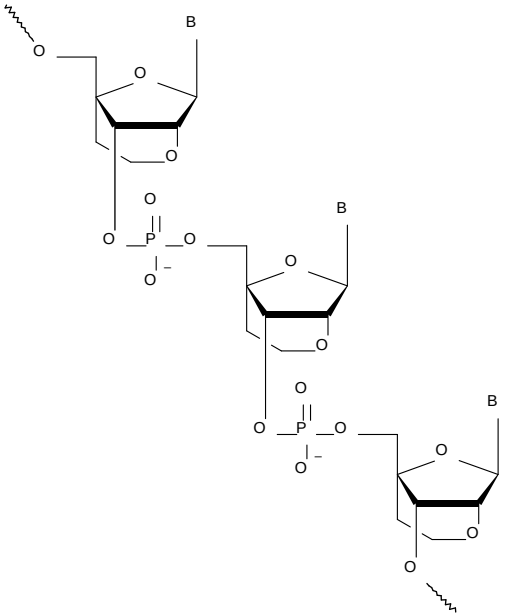
Daiichi-Sankyo

ENA: 2'-*O*,4'-*C*-Ethylene-bridged Nucleic Acids

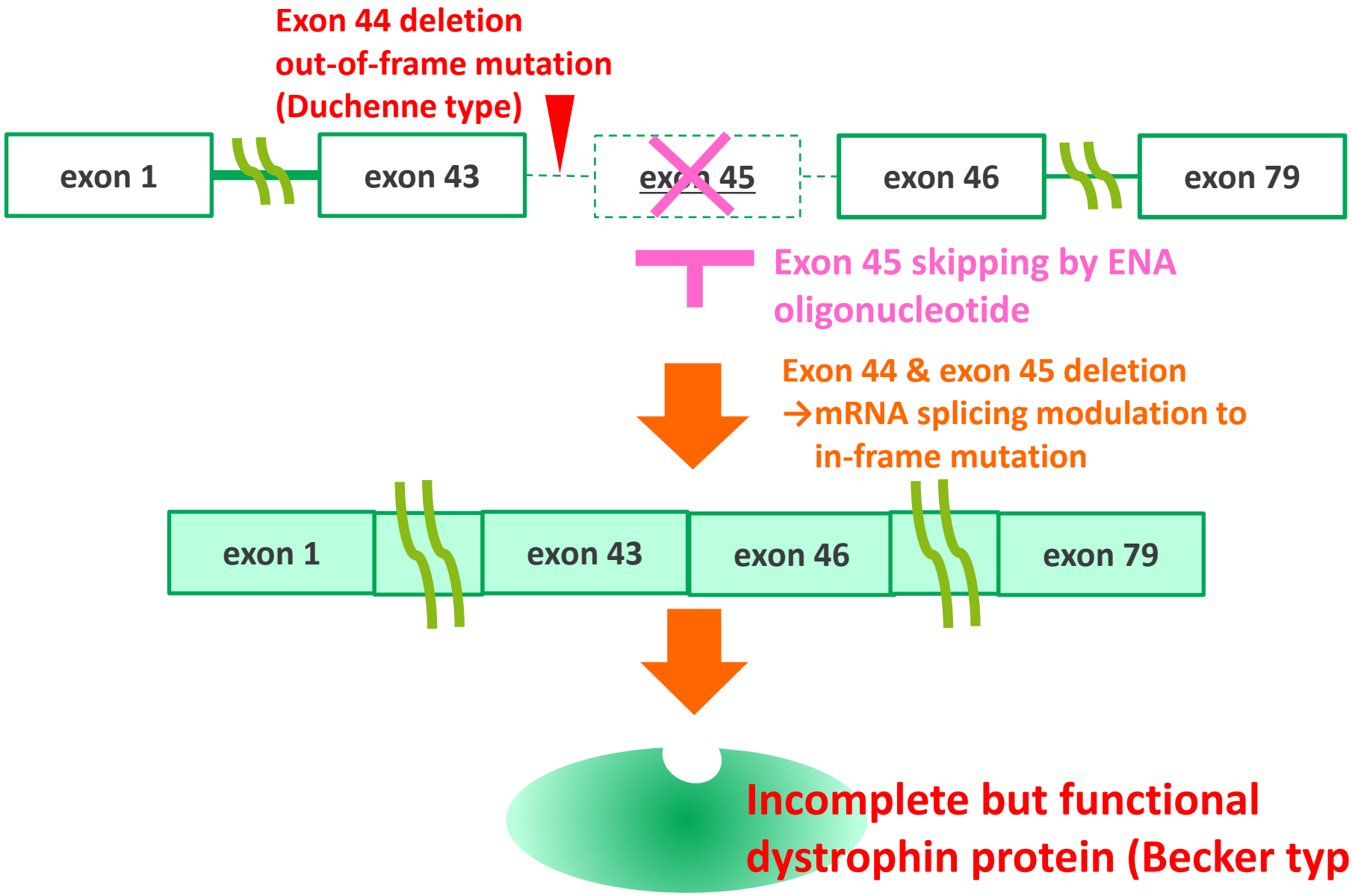
- High affinity
- Highly resistant to nucleases
- In vivo antisense activity was observed in diabetic mice model*

**Koizumi et al., Oligonucleotides, 16: 253-262 (2006)*





Concept of ENA® Oligonucleotide-induced exon skipping



New business model for open development

Academia/
Industry/Financier

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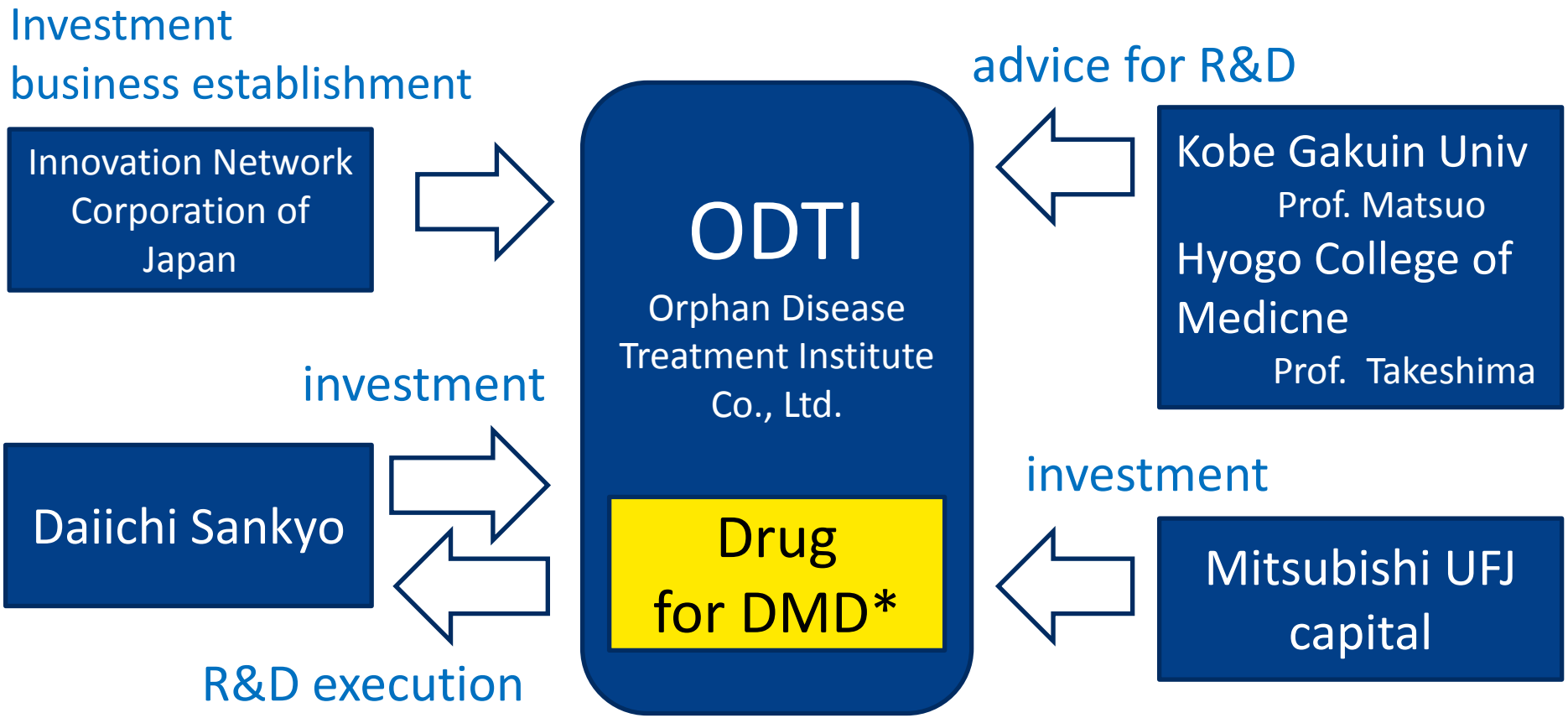
DS has interest in research and development for Orphan Disease, in order to achieve this we have structured new business model



* Duchenne Muscular Dystrophy

Passion for Innovation.
Compassion for Patients.™

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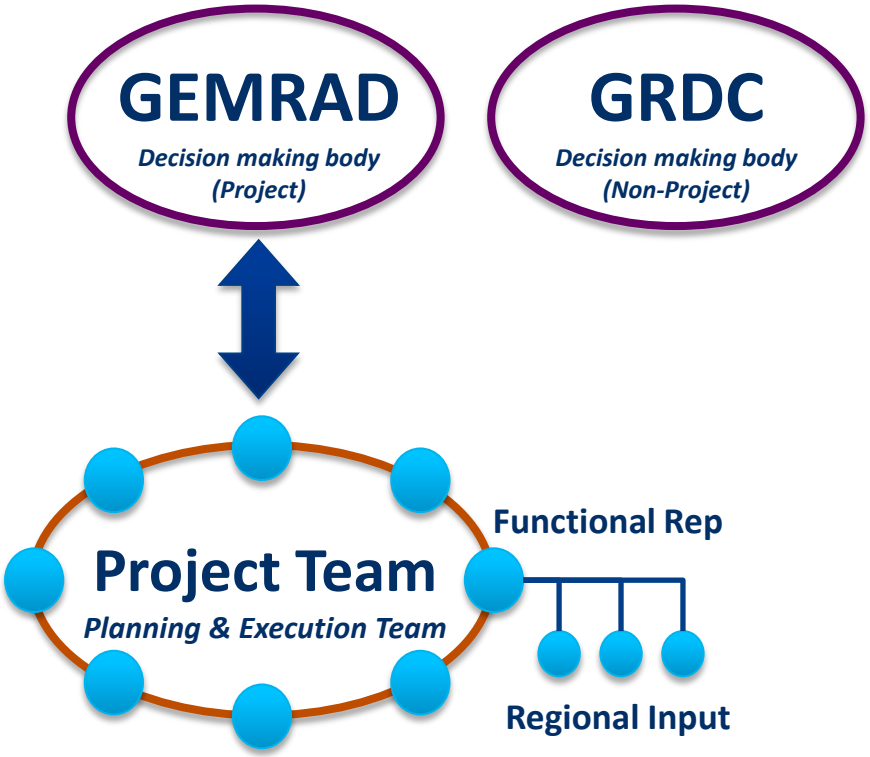
Global Development at Daiichi Sankyo

Mahmoud Ghazzi, MD PhD
Global Head of Development

Daiichi-Sankyo Global Development

Governance



Structure (Matrix)

Functions*	Global Functional Cmts	JP	Asia	EU	N. Am
	Clinical				
	Regulatory				
	Project M.				
	TMCP				
	BioStat				
	Clin. Ops				

Global Development **governance and structure is designed to deliver quality new medicines, efficiently and quickly**

** Not a complete list, for illustration only*

An Example of DS Development Capability:
Edoxaban Phase 3 Global Program

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Engage AF TIMI 48

6 continents
46 countries
1,393 study site
21,105 Subjects

Giugliano et al. N Engl J Med 2013

Hokusai VTE

6 continents
37 countries
439 study sites
8,292 Subjects

The Hokusai-VTE Investigators. N Engl J Med 2013

Edoxaban project enrolled over 30,000 patients in phase 3 trials and was submitted to JP, US, EU, Switzerland, Brazil, Taiwan and South Korea

Targets for Approval and Launch

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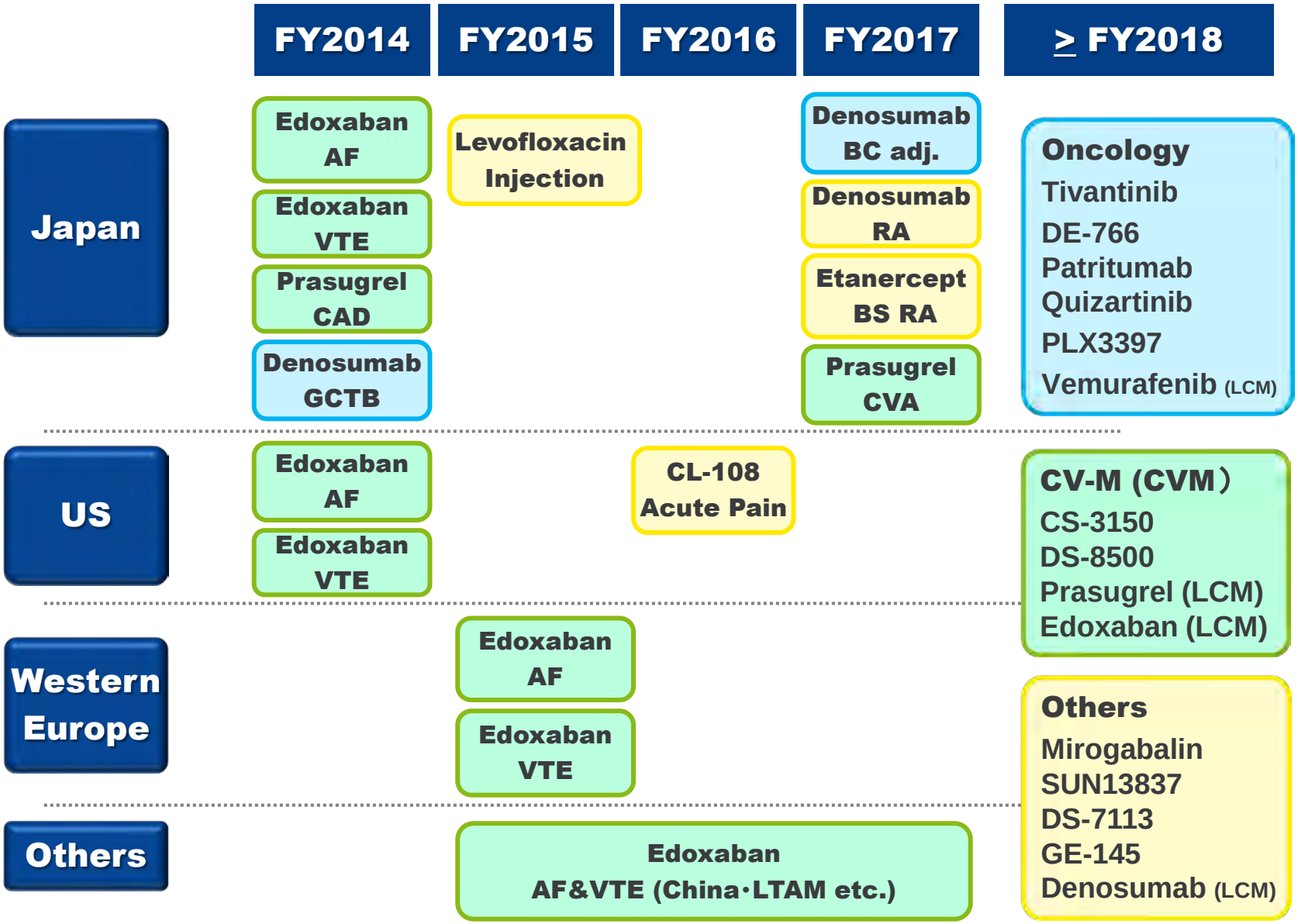

Late Stage Development Update

- Edoxaban for Atrial Fibrillation and Venus Thrombo-Embolism
- Mirogabalin (DS-5565) for Neuropathic Pain and Fibromyalgia
- CL-108 for Pain management
- Quizartinib a FLT3 inhibitor for Acute Myeloid Leukemia
- PLX3397 a CSF1R/KIT/FLT3 inhibitor for Pigmented Villonodular Synovitis (PVNS)

Late Stage Pipeline:
Edoxaban

Edoxaban: Competitive advantage

- Oral, highly selective, direct, and reversible Factor Xa inhibitor
- Unique combination of both once-daily convenience and superior safety for atrial fibrillation and VTE
- The only NOAC with three approved major indications in Japan: AF, VTE and DVT-OS

AF : Atrial Fibrillation; VTE : Venous Thromboembolism;
DVT-OS : Deep Vein Thrombosis - Orthopedic Surgery

Edoxaban: Regulatory Update

Target Indications	Schedule
Prevention of stroke and systemic embolic events in patients with atrial fibrillation Engage AF TIMI 48	**Japan:** Approved in Sep 2014 **US:** Filed in Jan 2014, Advisory committee (AF indication) in Oct 2014 PDUFA date in Jan 2015 **EU:** Filed in Jan 2014 **Other:** Filed in Switzerland, Brazil, Taiwan and South Korea
Treatment and prevention of recurrence of venous thromboembolic event in patients with DVT/PE* Hokusai VTE	
Prevention of venous thromboembolism in patients undergoing major orthopedic procedures of the lower limb (DVT-OS) STARS	**Japan:** Launched in Jul 2011

AF : Atrial Fibrillation
DVT: Deep Vein Thrombosis
PE : Pulmonary Embolism

Commitment to Edoxaban Life Cycle Management:

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Generating supportive data related to AF and VTE

- Safety of edoxaban in patients with AF undergoing planned electrical cardioversion (On-going)
- Safety of edoxaban in patients with AF following PCI with stenting (under evaluation)
- VTE in patients with cancer for whom long term treatment with LMWH is intended (under evaluation)

Reversal agent programs (Multiple)

- Perosphere, PER977 (small molecule)
- Portola, Andexanet Alfa (recombinant proteins)
- CSL Behring, Beriplex®/Kcentra® (4-factor prothrombin complex concentrate)

Pediatric Development

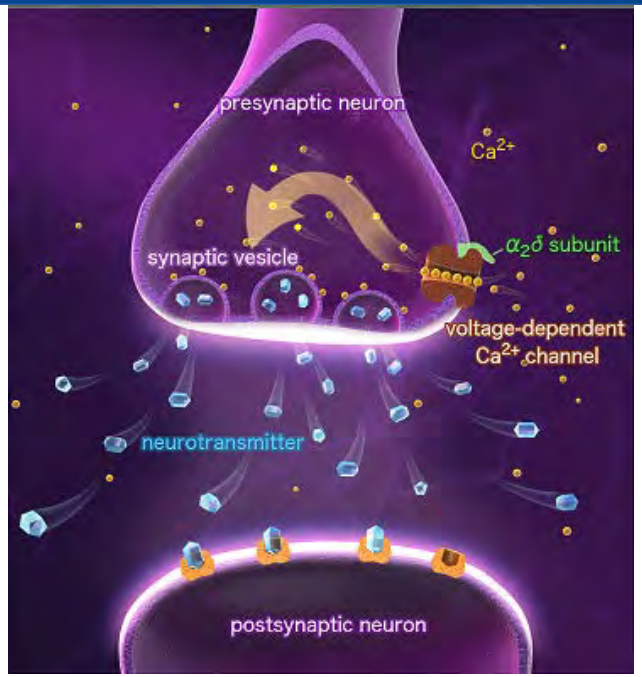
Late Stage Pipeline: Mirogabalin

- Phase 2 (U201) Study Results
- Broad Global Development Strategy

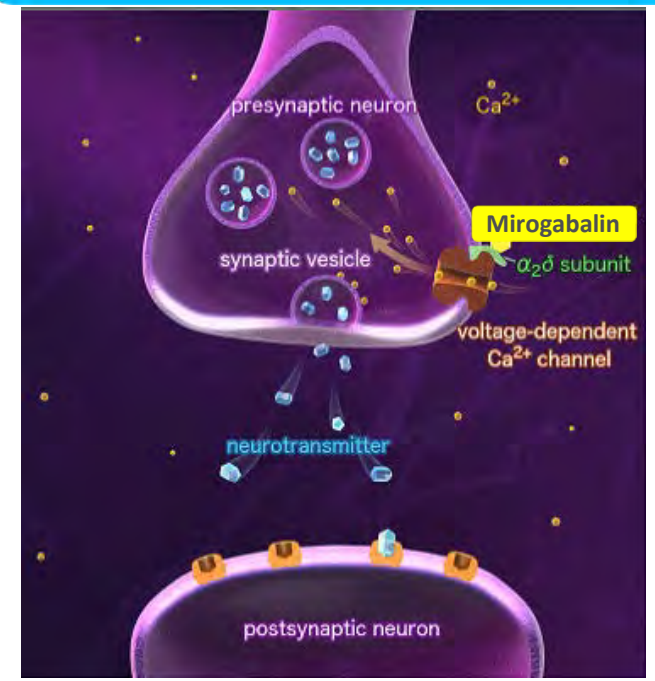
Mode of Action

- In neuropathic pain, neurons respond to stimuli with excessive $Ca^{2}+$ influx and release of neurotransmitters
- Mirogabalin binding to presynaptic α2δ subunits inhibits $Ca^{2}+$ influx and neurotransmitter release

Pain state

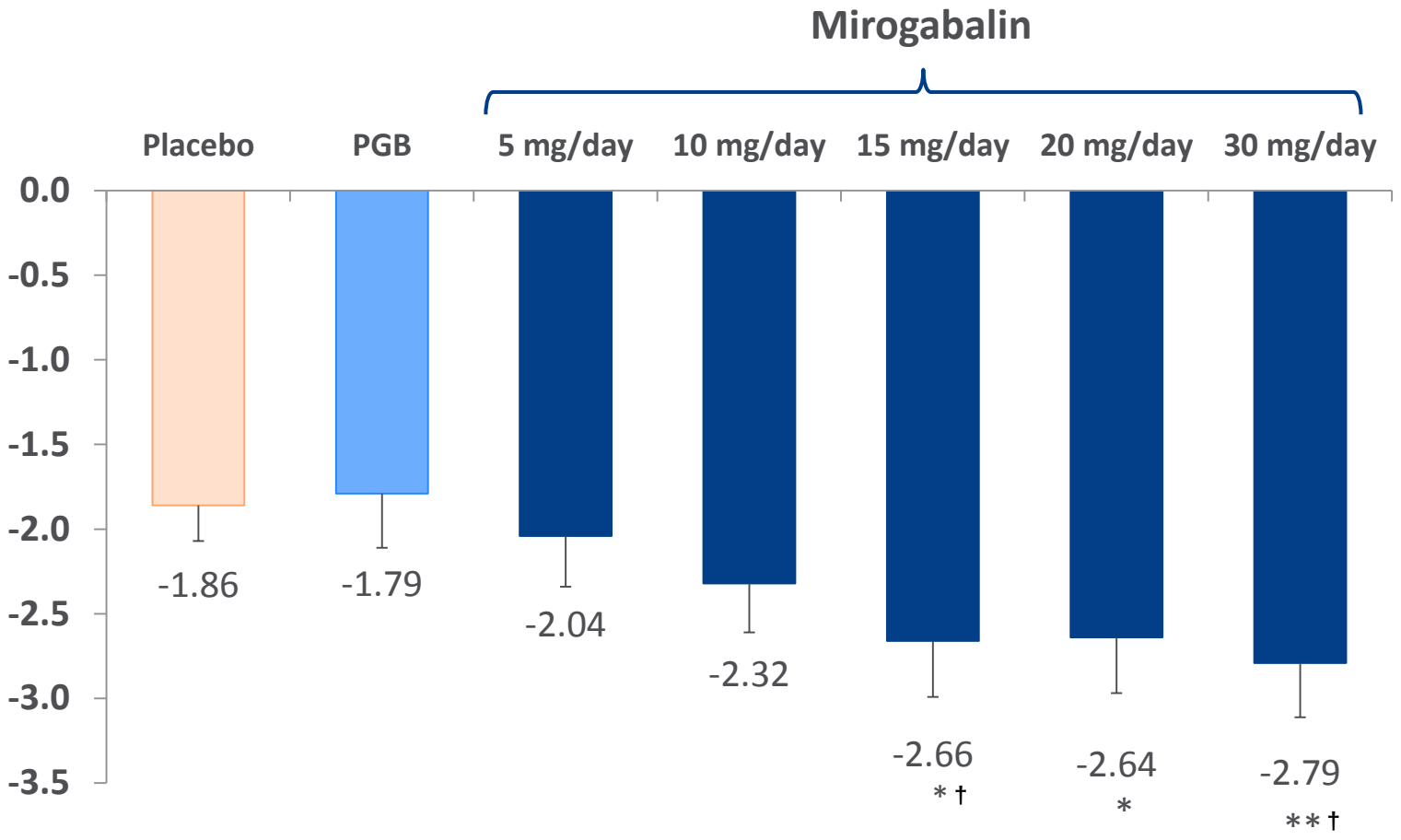


Pain state + Mirogabalin



U201 Phase 2 Study Results

ADPS Change from Baseline at Week 5



***p<0.05, **p<0.01 vs placebo (LOCF); †p< 0.05 vs pregabalin (LOCF), ADPS (average daily pain score)**

(*Vinik et al, Diabetes Care, Sep 2014)*

Mirogabalin:
Broad Global Development Strategy

Daiichi-Sankyo

- **Development program in three indications**
  - **Focus on Fibromyalgia (FM)** in West and future consideration for Japan

    (Fibromyalgia: a chronic condition of widespread pain, debilitating fatigue, sleep disturbance, and joint stiffness)

  - **Focus on Peripheral Neuropathic Pain** (DPNP and PHN) indication in Japan and Asia

- **Program Status: Phase 3**
  - **Fibromyalgia: on-going, FPI: Nov. 2014**
  - **Broad Neuropathic Pain: FPI: Jan. 2015**

DPNP: Diabetic peripheral neuropathic pain; PHN: Post herpetic neuralgia

Late Stage Pipeline:
Quizartinib (Ambit AC 220)

Quizartinib (AC220):
Ph3 for Acute Myeloid Leukemia (AML)

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Target Indication:

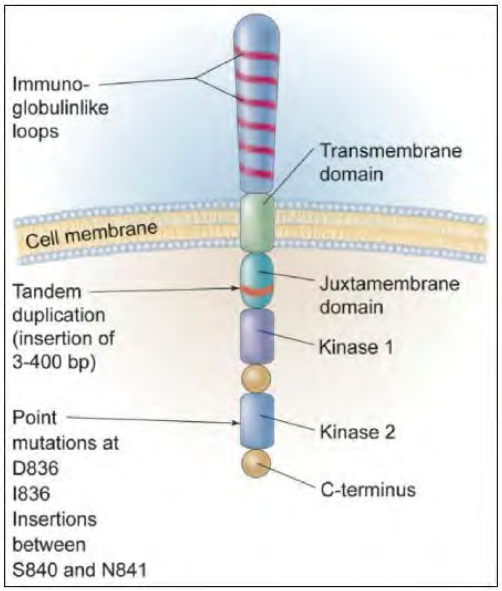
Relapsed or refractory FLT3-ITD positive AML patients.

Mechanism of Action:

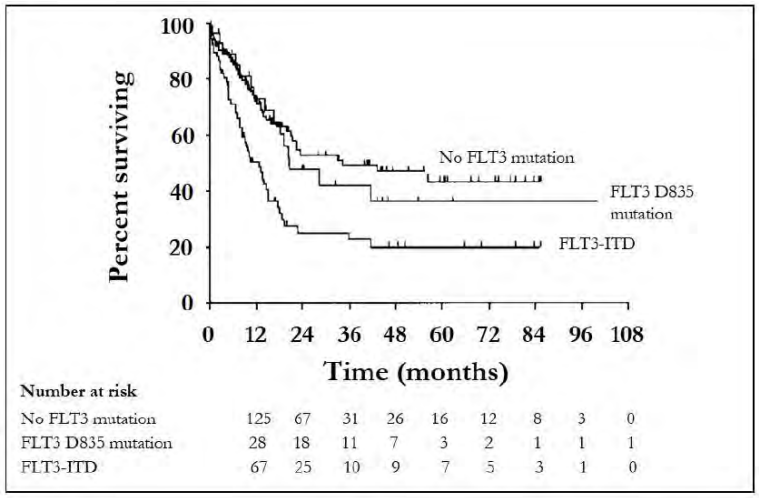
Potent and selective inhibitor of FLT3, a validated target in AML

Unmet Medical Need:

- AML accounts for ~36% of all new leukemia cases
- Five-year survival 23%
- No new treatments approved in the last 30 years.
- Fast Track review granted



FLT3 receptor tyrosine kinase. *Litzow, Blood 2005*



Fröbling. S. et al., 2002

Quizartinib: Effect in FLT3-ITD(+) AML

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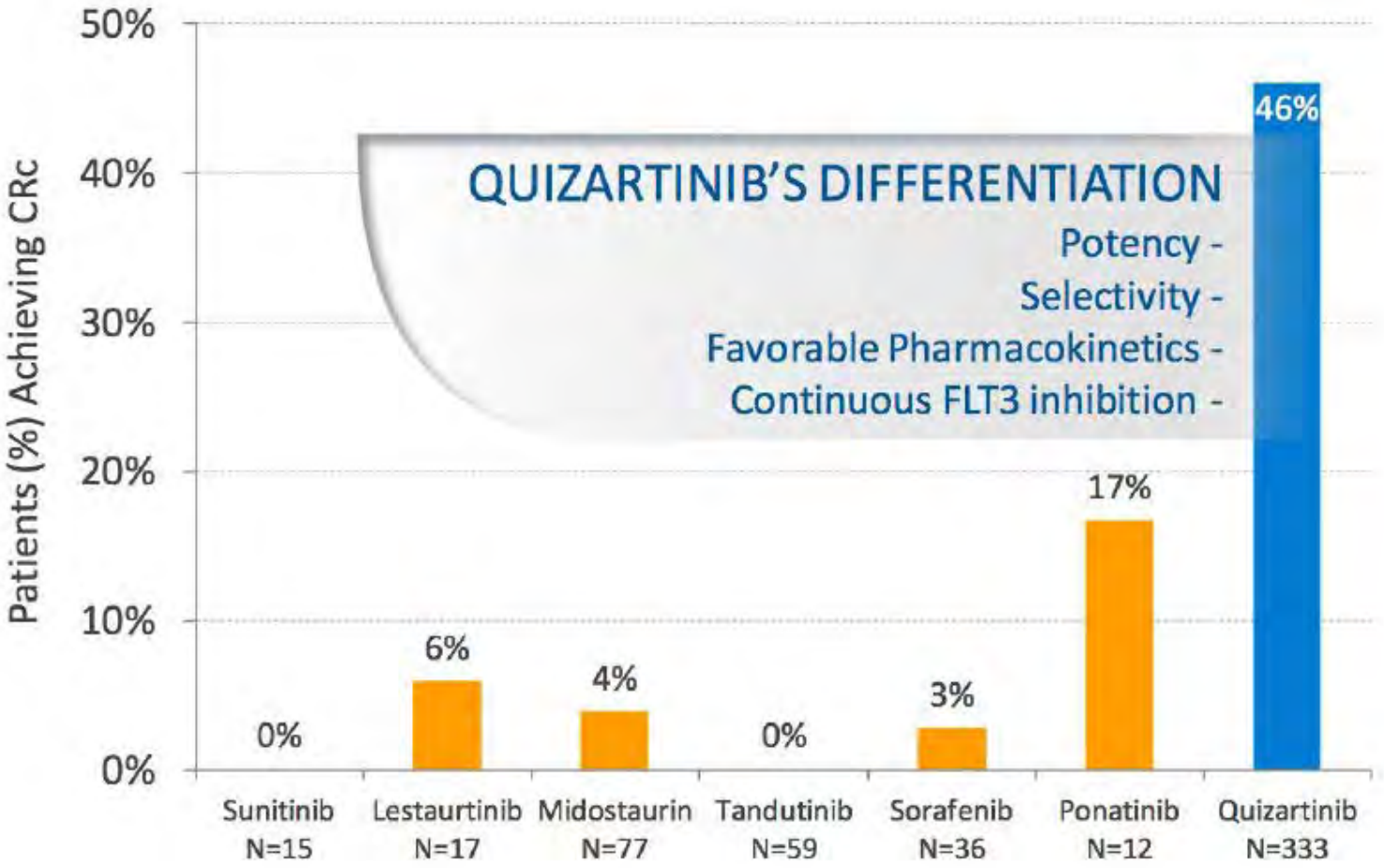
Response Rate for FLT3 Inhibitors Observed in Clinical Trials of AML

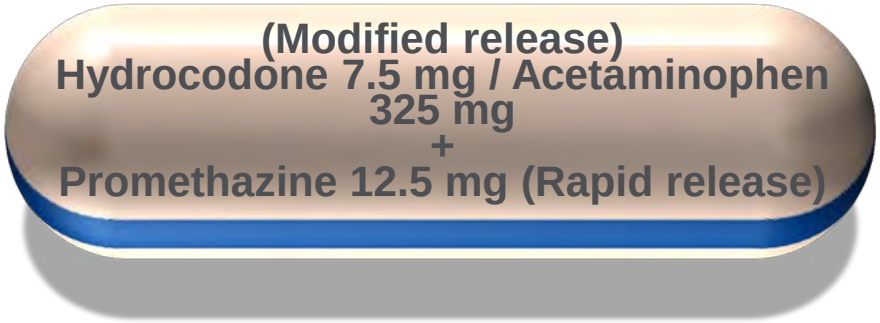


Ambit Presentation & Knapper, S., 2011

Late Stage Pipeline
Hydrocodone combination CL-108

CL-108: Hydrocodone combination

Pain relief with less Opioid-Induced Nausea and Vomiting



Novel, fixed-dose, bi-layered tablet provides anti-emetic activity prior to hydrocodone effect

- **Exclusive license for commercialization in US from Charleston Laboratories Inc.***
- **Indication: Opioid Induced Nausea and Vomiting (OINV)**
- **Ph3 studies: treatment of moderate to severe acute pain as well as the reduction of OINV**
- **NDA: Targeted for FY2015**

** Charleston Laboratories, Inc., privately held and located in Jupiter, Florida, is a specialty pharmaceutical company focused on the research and development of novel pain products*

Late Stage Pipeline:

PLX3397: Pigmented Villonodular Synovitis (PVNS)

PLX3397: for the treatment of Pigmented Villonodular Synovitis (PVNS)

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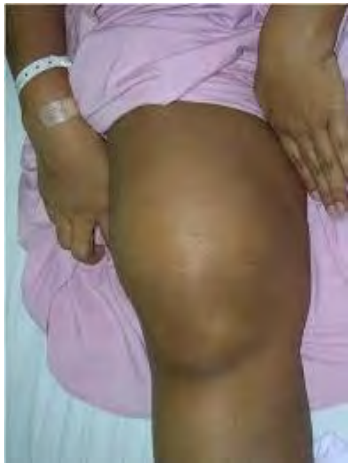
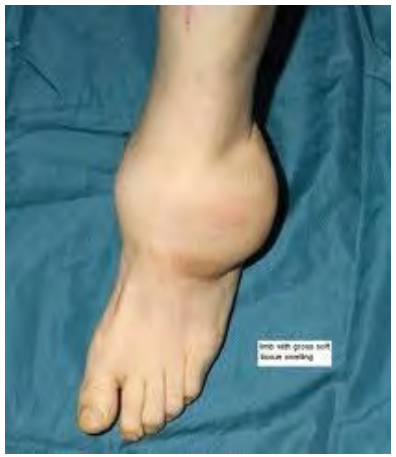
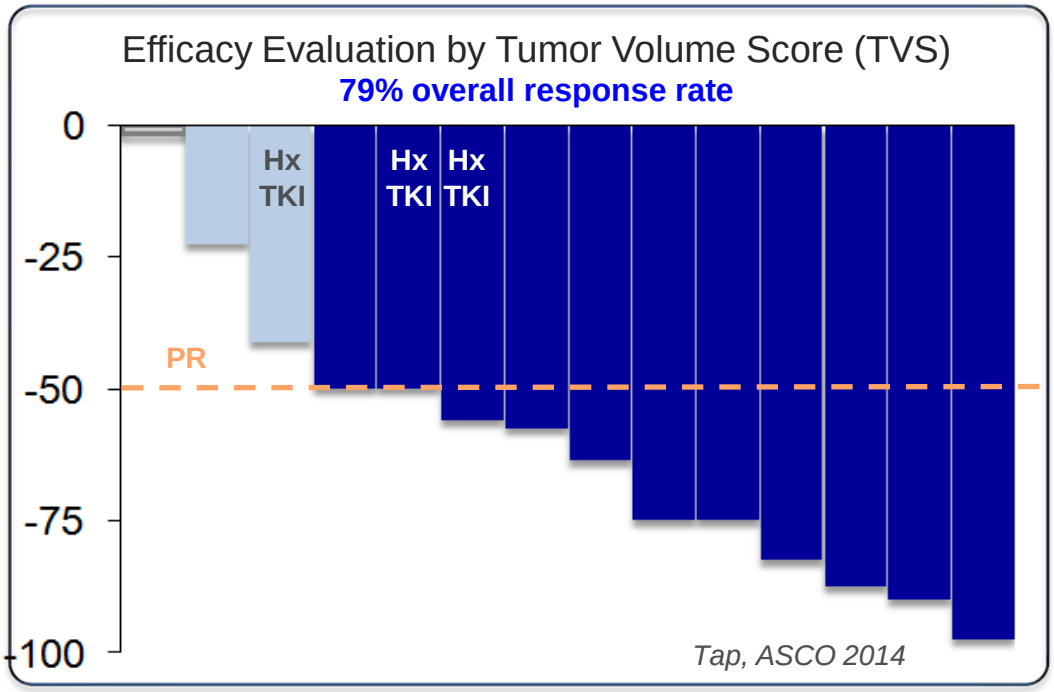
- ***PVNS:***
  A painful and motion limiting joint disease characterized by inflammation and overgrowth of the joint lining.
- ***MOA:***
  PLX3397 targets the CSF1 Receptor blocking tumor-produced cytokines action on CSF1
- ***Unmet Medical Need:***
  No systemic therapies available.
- ***Clinical Study Status:***
  - **Phase 1 ongoing, and preliminary data presented at ASCO June 2014**
  - **Phase 3 in planning**







Global Development Summary

Daiichi-Sankyo development is a global and capable organization with proven record of delivery of large scale projects

There is an exciting list of phase 3 projects with a mix of best-in-class and first-in-class mechanisms

Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

Closing Remarks – Our Culture

DS R&D Culture