Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows

R&D Meeting

February 28, 2017

Sumitomo Dainippon Pharma Co., Ltd.

Today's Agenda

1. Introduction
Masayo Tada President and CEO

2. Towards Sustainable Growth
Hiroshi Noguchi, Ph.D. Senior Executive Vice President and CSO

3. Psychiatry & Neurology Area, Respiratory Area: Pipeline Driving Sustainable Growth
Antony Loebel, M.D. Executive Officer, Head of Global Clinical Development
(Executive Vice President and CMO, Sunovion Pharmaceuticals Inc.)

4. New Challenge in Oncology Area: Making Meaningful Medicines
David J. Bearss, Ph.D. CEO, Tolero Pharmaceuticals, Inc.

5. Q&As

Introduction

Masayo Tada
President and CEO

Towards Sustainable Growth

Hiroshi Noguchi, Ph.D.
Senior Executive Vice President and CSO

Our Vision

- Aspire to be a globally active R&D-based company
- Contribute to medical care through leading-edge technologies

R&D Basic Strategy

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Early recovery from LATUDA Cliff: Focus on late-stage clinical studies

- **Be certain to obtain approval of late-stage development pipeline promptly**

For our future growth: Further activation in drug research

- **Discover first-in-class drugs or drugs with distinct characteristics**
  - Select and concentrate on focus therapeutic areas (Psychiatry & Neurology and Oncology), adopt business unit structure
  - Discover drugs by drawing upon our strengths
  - Ensure "POC First" principle and enhance translational research
  - Bring in cutting-edge technologies
  - Reinforce use of "outside" resources

R&D organizations & Personnel system

- **Management according to the development stage**
  - Early-stage: Venture approach, express abilities as an individual
  - Late-stage: Organizational power, cooperation
- **New personnel system (professional contributor: PC)**
  - Created PC1/PC2 positions based on individual expertise and achievements

Early Recovery from LATUDA Cliff

Performance Image after the 3rd MTBP

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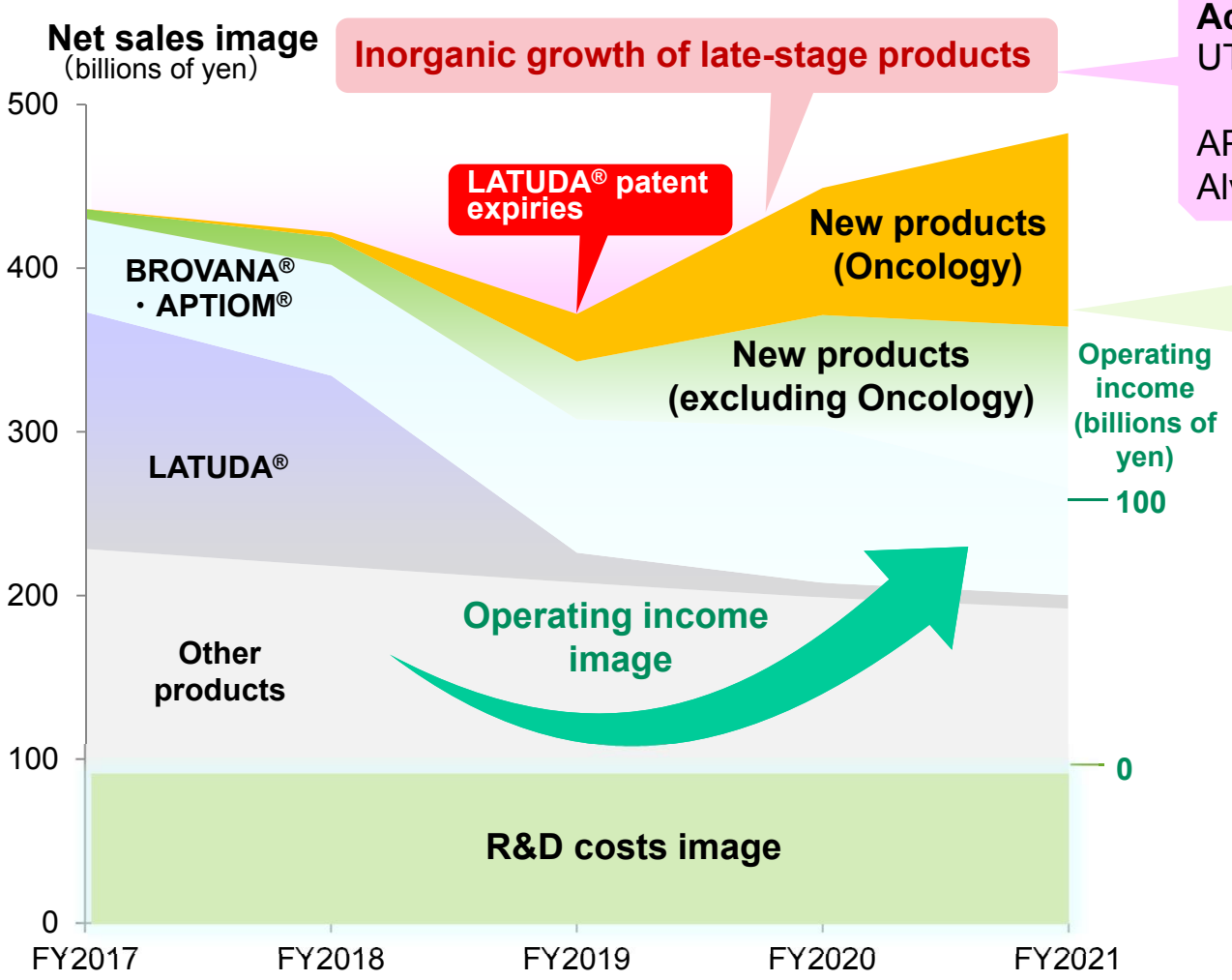
Drop expected in FY2019 as LATUDA® loses its exclusivity in North America.
Shooting for early recovery after FY2020 through launches and growth of late-stage products.



Acquired after May 2016

UTIBRON, SEEBRI, ARCAPTA	(U.S.)	Approved in U.S.
APL-130277	(Global)	Ph3 in U.S.
Alvocidib	(Global)	Ph2 in U.S.

Main products for launch (planned)

Oncology area

Napabucasin	(Japan and U.S.)
Amcasertib	(Japan and U.S.)
DSP-7888	(Japan and U.S.)

The other areas

SUN-101	(U.S.)
Dasotraline	(U.S.)
SB623	(U.S.)
Lurasidone	(Japan)
DSP-1747	(Japan)

(Created in May 2016)

Early Recovery from LATUDA Cliff

Key Late-stage Pipeline : Progress in FY2016

Compounds	Progress	Submission target
Napabucasin	• Gastric, Gastro-esophageal junction adenocarcinoma (combination): Completed recruitment for Phase 3 study • Colorectal, Pancreatic cancer (combination): Started recruitment for Phase 3 studies • CCTG announced results of CO.23 study (Colorectal / monotherapy): No significant difference was observed in OS between napabucasin and placebo, but napabucasin significantly improved OS in patients with high p-STAT3 expression.	FY2018 (Gastric, Gastro-esophageal junction adenocarcinoma)
Alvocidib	• Acquired through Tolero in January 2017 • Ongoing Phase 2 study for relapsed or refractory AML (combination / with biomarker)	FY2018 (at earliest)
Dasotraline	• ADHD (pediatric and adult): Significant improvement in the primary endpoint was observed in pediatric Phase 2/3 study. No Significant improvement in the primary endpoint was observed in adult Phase 3 study • BED: Significant improvement in the primary endpoint was observed in Phase 2/3 study	FY2017 (ADHD/ Pediatric and Adult)
Apomorphine Sublingual film (APL-130277)	• Acquired through Cynapsus in October 2016 • Ongoing Phase 3 study for OFF episodes associated with Parkinson's disease	FY2017
Glycopyrronium bromide (SUN-101)	• NDA for COPD accepted by the FDA in October 2016 (PDUFA date: May 29, 2017)	Filed
UTIBRON, SEEBRI, ARCAPTA	• In December 2016, acquired exclusive rights from Novartis for commercialization rights in the US of three products for COPD	(Approved)

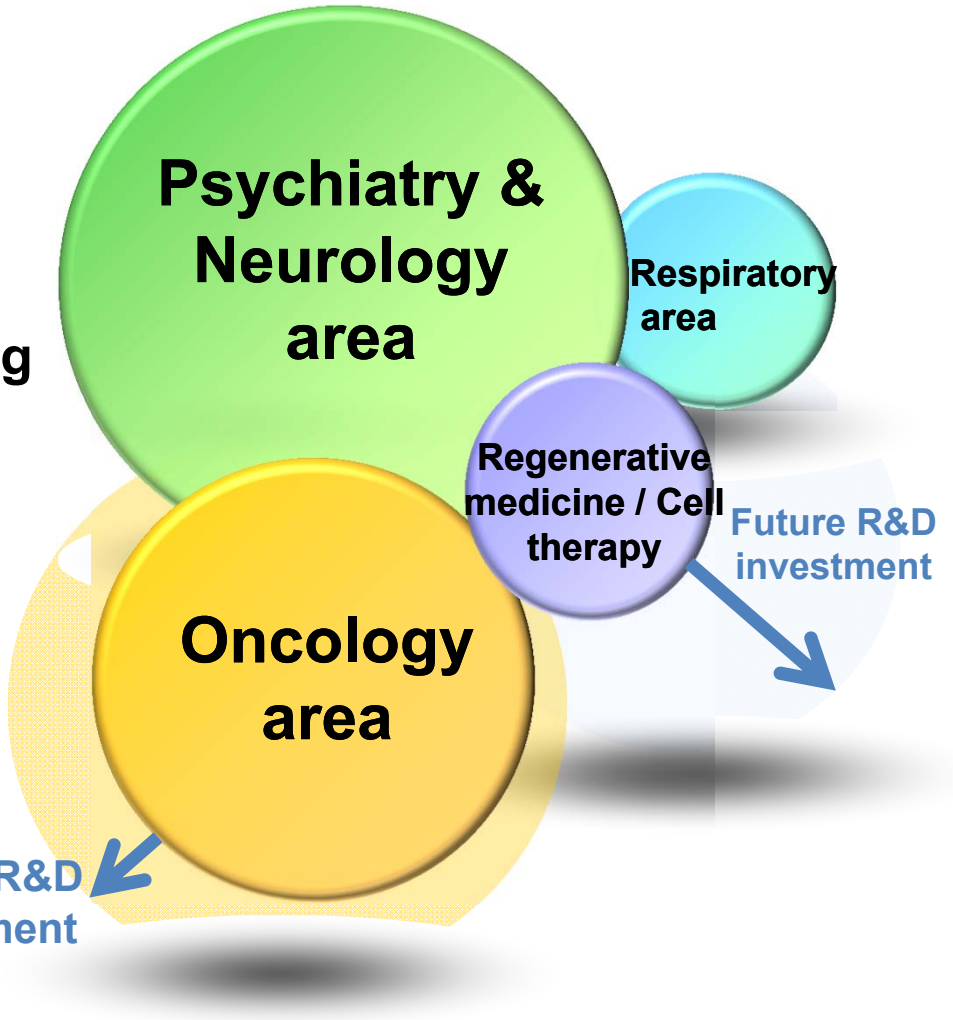
CCTG :Canadian Cancer Trials Group; previously known as NCIC-CTG, ADHD: Attention Deficit Hyperactivity Disorder, BED: Binge Eating Disorder
COPD: Chronic Obstructive Pulmonary Disease, Alvocidib is licensed from Sanofi.

Current Focus Areas & Future R&D Investment Strategy

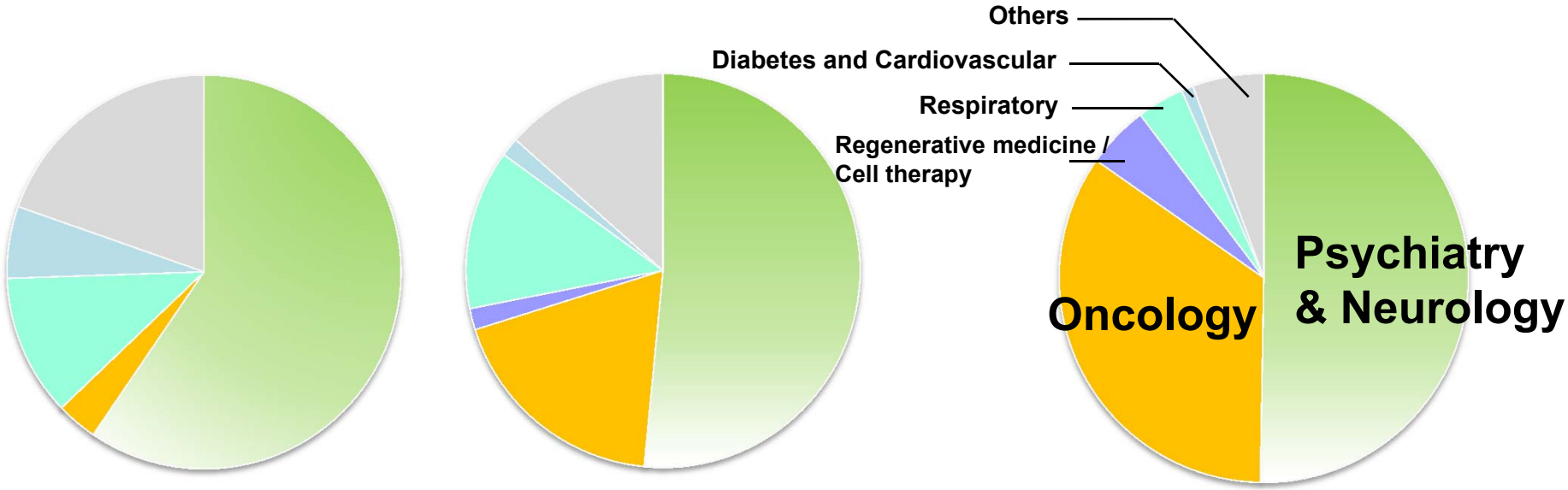
Prioritize

- Innovation
- Competitive advantages
- Marketability
- Growth potential

- **Take on the challenge of satisfying unmet medical needs**
  From “point“ to “plane“
- **Time axis**
  Addressing the needs of the time
  Rapid advances in Science & Technology
- **Own strengths**
  Past accomplishments & experiences
- **Toward the future**
  Growth areas



Trends in R&D Costs (direct) & Allocation to Areas



<FY2012 >

32.6 billion yen

<FY2015>

48.2 billion yen

<FY2016 (forecast)>

50.7 billion yen

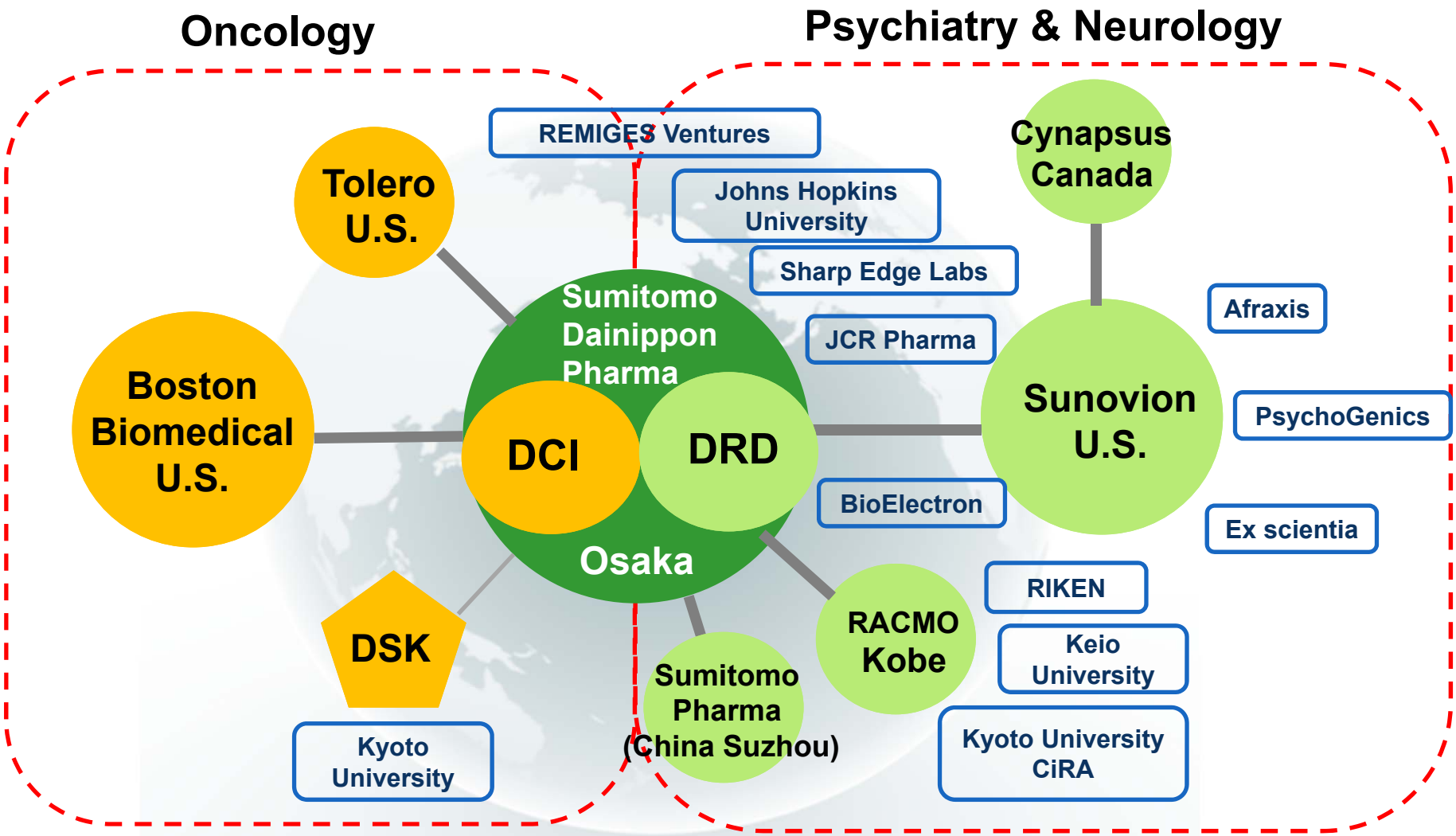
Focus investment on

Psychiatry & Neurology (including regenerative medicine / cell therapy)

Oncology

R&D Sites (including Alliances)

Hub & Spoke, Central & Satellite System



DCI: DSP Cancer Institute
DSK: Kyoto University and Sumitomo Dainippon Pharma Joint Research Project

DRD: Drug Research Division
RACMO: Regenerative & Cellular Medicine Office

Expansion from Psychiatry to Neurology

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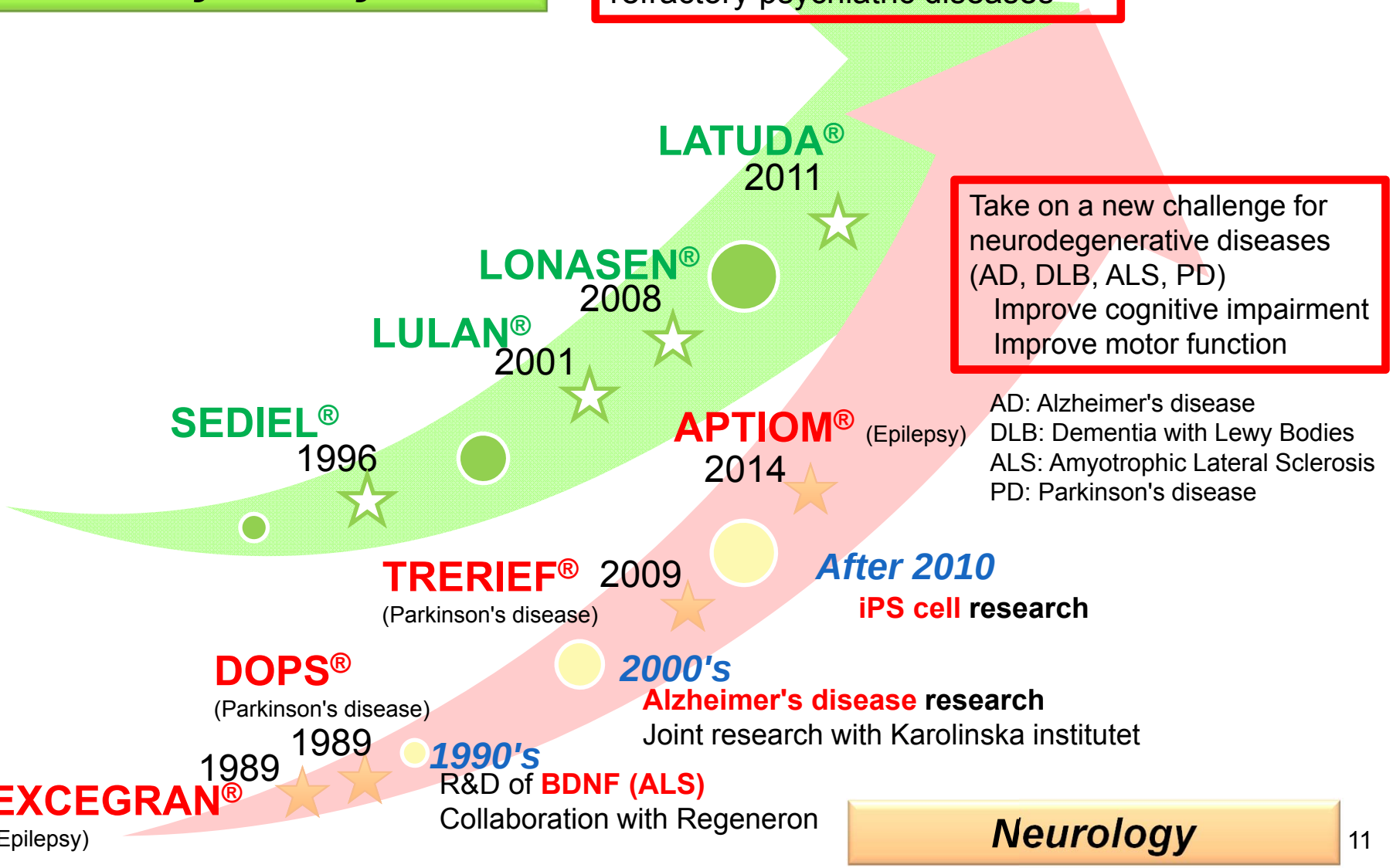
Psychiatry

Take on the challenge for refractory psychiatric diseases



Take on a new challenge for neurodegenerative diseases (AD, DLB, ALS, PD)
- Improve cognitive impairment
- Improve motor function

AD: Alzheimer's disease
DLB: Dementia with Lewy Bodies
ALS: Amyotrophic Lateral Sclerosis
PD: Parkinson's disease

Neurology

R&D Strategy: Fusion of Psychiatry & Neurology

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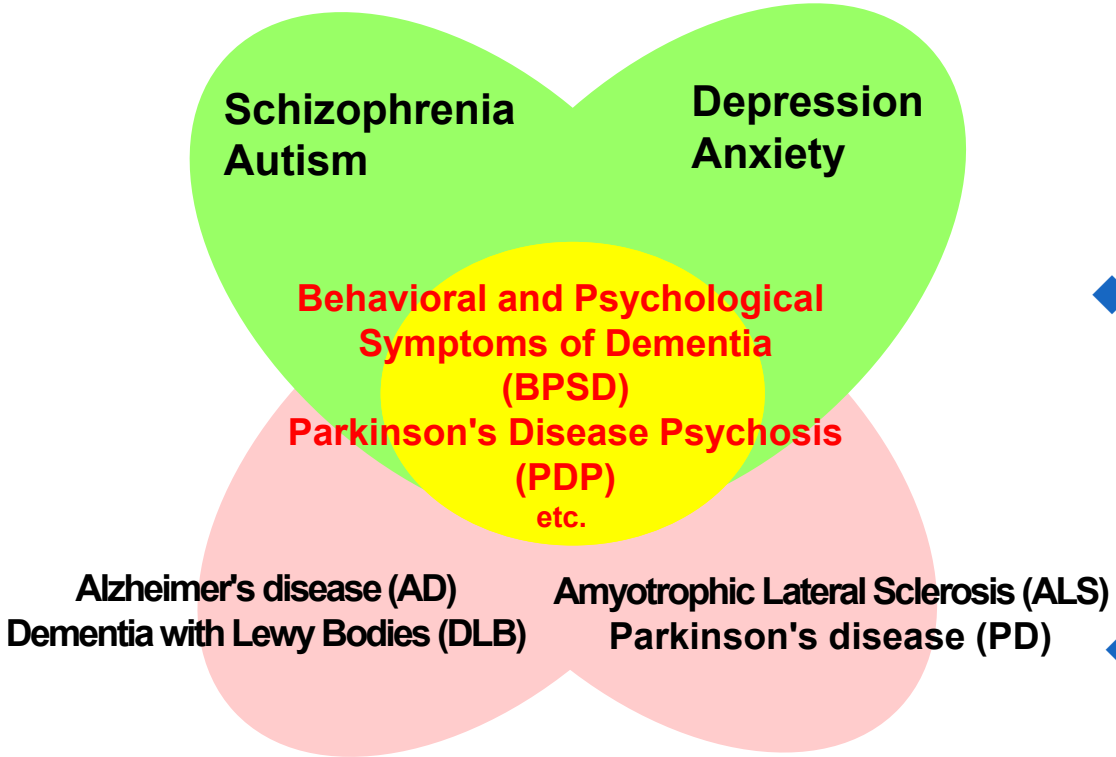
Psychiatry



Neurology

- **New indications for psychiatric drugs**
  - Expansion to associated or peripheral symptoms in neurodegenerative disease
    - BPSD
    - PDP
- **Expand to new indications from the originally specified disease**
  - From Orphan diseases to Common (segmented) diseases
- **Unique approach**
  - Phenotypic drug discovery (animal and cell)
  - Biomarkers (EEG, fMRI, PET)
  - Non-human primates

EEG: electroencephalogram
fMRI: functional nuclear magnetic resonance imaging
PET: positron emission tomography

Psychiatry & Neurology Area

Continual R&D Pipeline

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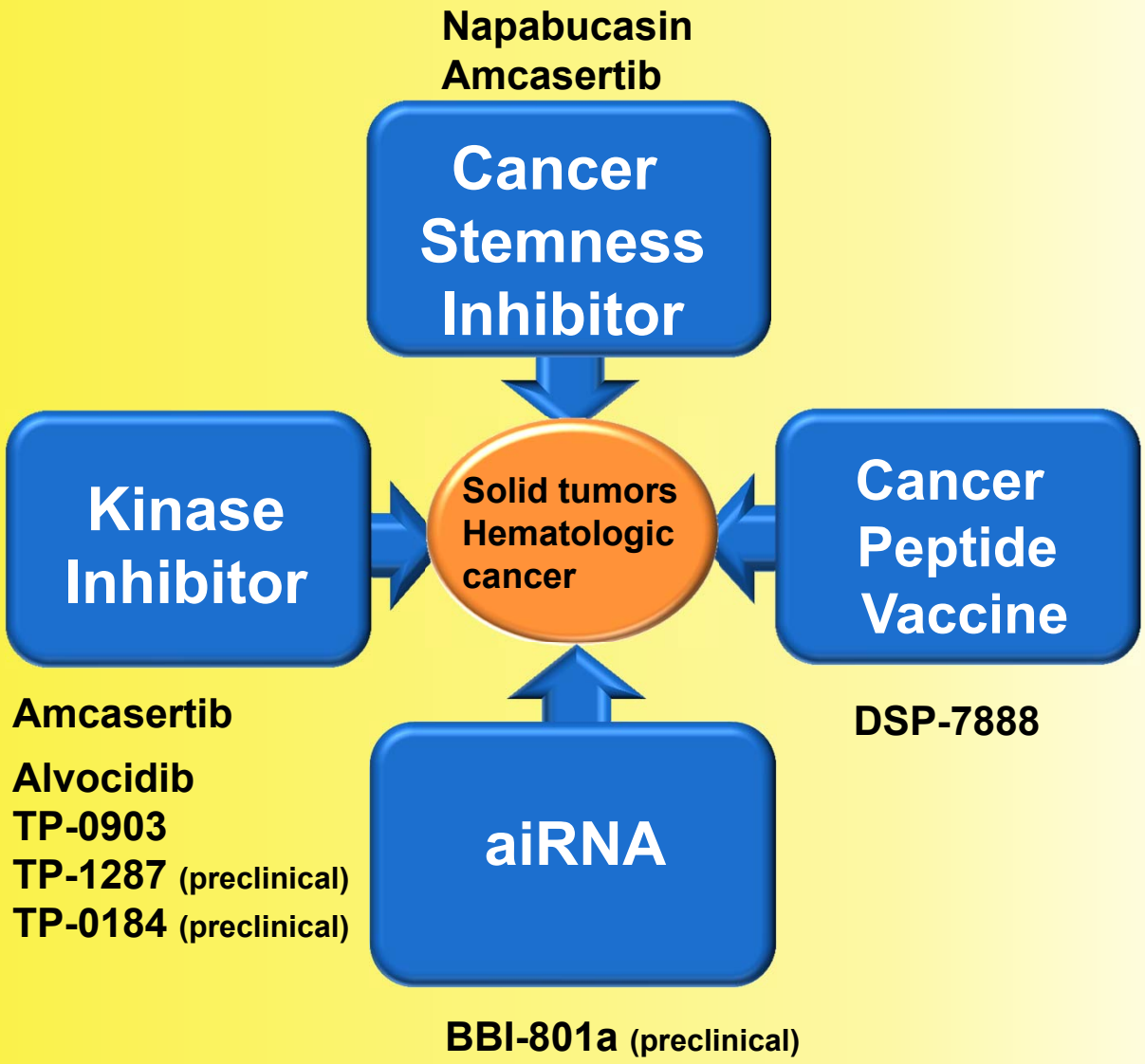
Area	Discovery/PC	Phase 1	Phase 2	Phase 3
Psychiatry	Early program (Neurotransmitter Monoamine system)	DSP-1200 Treatment-resistant depression	SEP-363856 PD psychosis, Schizophrenia	dasotraline ADHD, BED
		DSP-3748 CIAS		
		DSP-6745 PD psychosis		
Neurology	Early program (Core & Peripheral symptom Reduction neurodegenerative progress)	DSP-2230 Neuropathic pain	EPI589 PD, ALS	TRERIEF® Parkinsonism in DLB
				APL-130277 OFF episodes associated with PD
(Regenerative medicine / Cell therapy)	Early program (iPSC-RPE, iPSC-dopamine neuron, etc.)		SB623 Chronic stroke	

CIAS: Cognitive Impairments Associated with Schizophrenia
RPE: Retinal Pigment Epithelium

PD: Parkinson's Disease
ALS: Amyotrophic Lateral Sclerosis

ADHD: Attention Deficit Hyperactivity Disorder
BED: Binge Eating Disorder
DLB: Dementia with Lewy Bodies

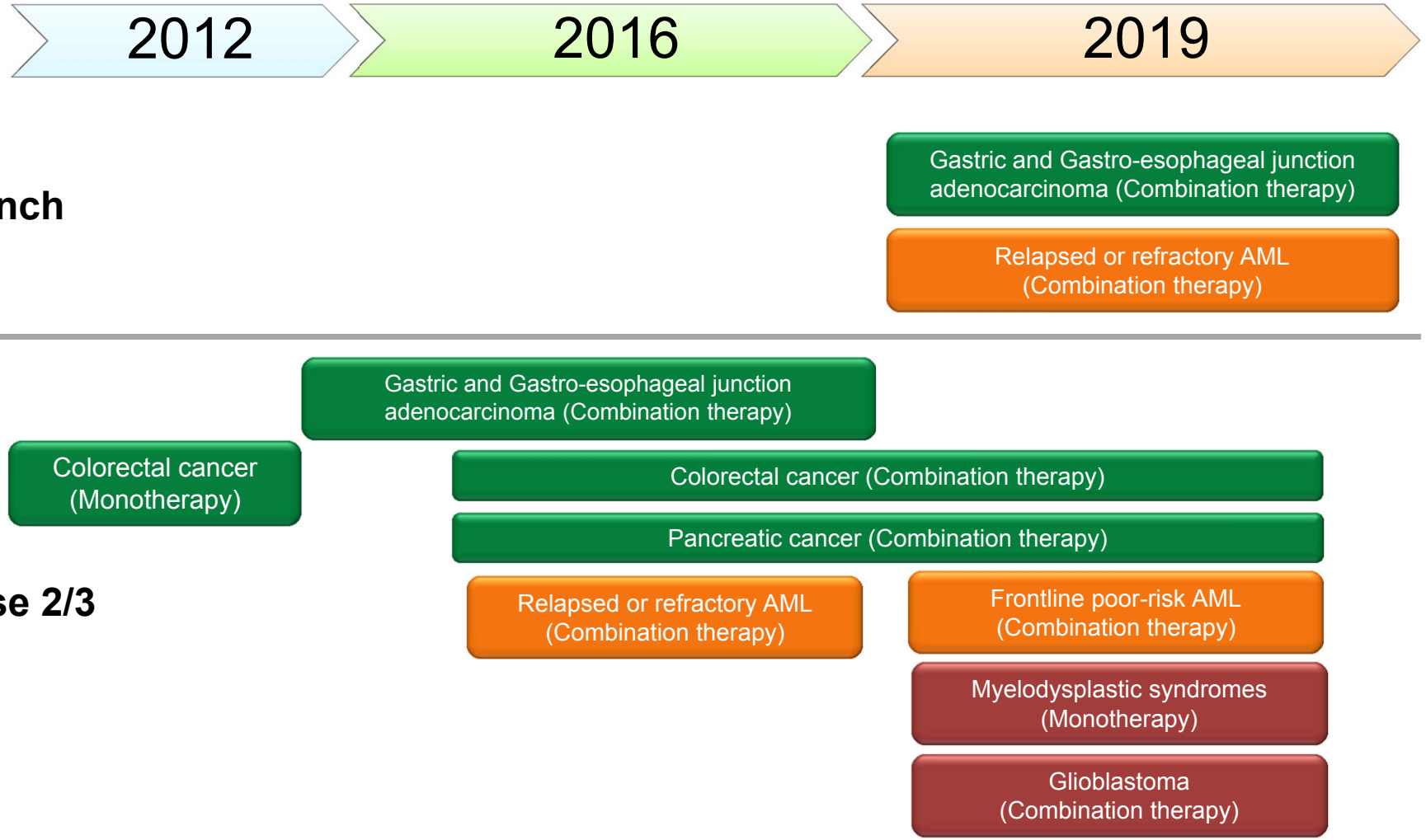
R&D strategy: Oncology



- Meet the needs of the times
- Take on the challenge of adopting innovative concepts and technology
- Fuse external knowledge, skills and culture with ours
  (Boston Biomedical, Tolero, Academia)

Oncology Area

Aim to Continual Approval & Launch



Napabucasin Clinical Development Status

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- **Cancer Stemness Inhibitor Napabucasin: Key late-stage clinical studies**
  - ✓ Gastric and Gastro-esophageal junction adenocarcinoma (combination): Phase 3 study ongoing, Completed LPI, Submission target FY2018
  - ✓ Colorectal cancer (combination): Phase 3 study ongoing
  - ✓ Pancreatic cancer (combination): Phase 3 study ongoing

- **Results of Phase 1b/2 study (BBI608-246) in colorectal cancer combination therapy with FOLFIRI, or FOLFIRI and bevacizumab (open label)**

  ➢ **Study Results :**

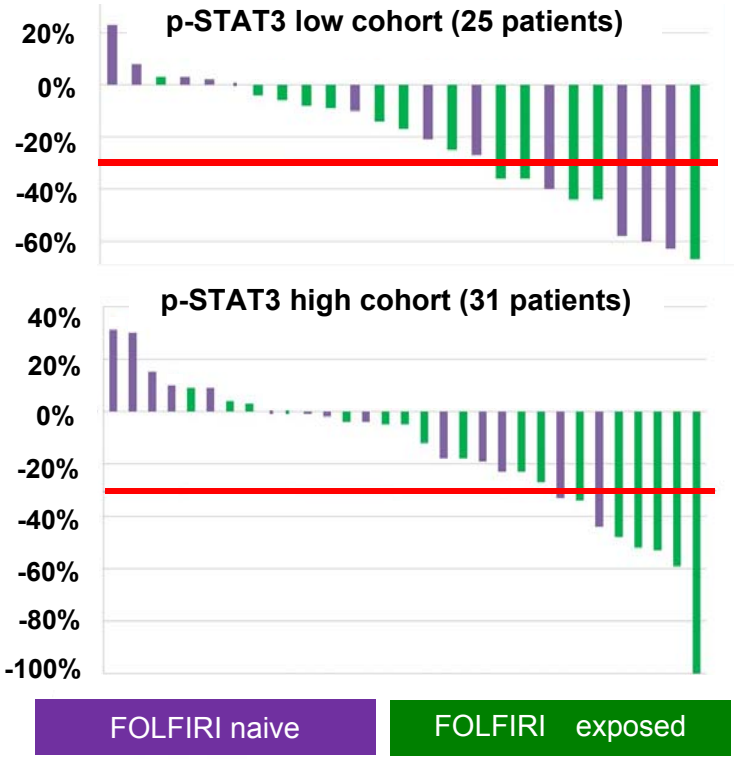
  ✓ Napabucasin showed signs of anti-cancer activity regardless of FOLFIRI-pretreatment or p-STAT3 status

(56 evaluable patients)

Subset	Disease control rate (DCR)	Overall response rate (ORR)
Evaluable 56 pts	88% (49/56 pts)	29% (16/56 pts) (1 pt achieving CR)
FOLFIRI naïve	93% (28/30 pts)	33% (10/30 pts)
FOLFIRI exposed	81% (21/26 pts)	23% (6/26 pts)
p-STAT3 low	92% (23/25 pts)	32% (8/25 pts)
p-STAT3 high	84% (26/31 pts)	26% (8/31 pts)

- LPI：Last Patient-in
- FOLFIRI (Combination with fluorouracil, leucovorin, irinotecan)

Percentage Change in target lesions (Best response)



Johanna C. Bendell, et al. *J Clin Oncol 35, 2017,* ASCO-GI 2017 (suppl 4S; abstract 593)

Cancer Peptide Vaccine (DSP-7888)

- **Characteristic: The peptide inducing WT1-specific CTL + peptide inducing helper T cells**
  Targeted disease: Solid tumors (Pediatric brain tumor),
  Hematologic malignancies (Myelodysplastic syndromes (MDS))

WT1: Wilms' tumor gene 1　　CTL：Cytotoxic T Lymphocyte

- **Phase 1 study for MDS**

➢ **Study Results :**

✓ Disease Control Rate was 66.7% in evaluable 12 patients

<u>Overall Survival in azacitidine failure higher-risk MDS patients</u>

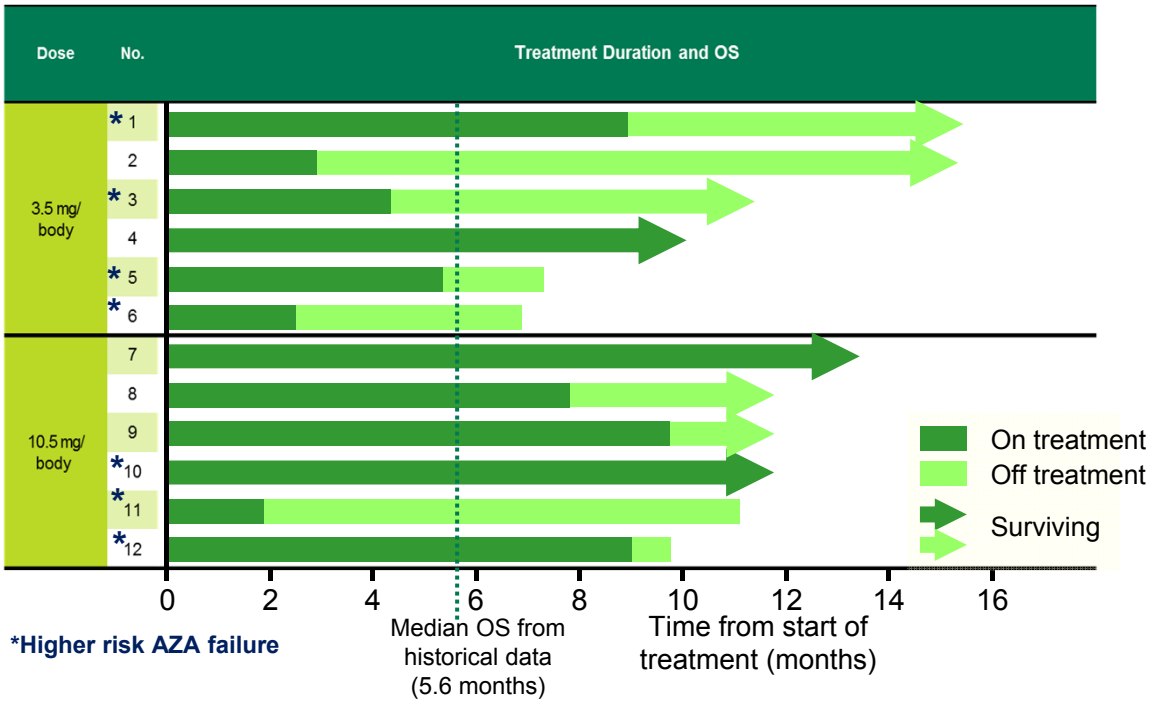
DSP-7888 (7 patients):
6.8 to 15.5 month[1)]

Historical data (435 patients):
Median 5.6 months[2)]

➢ **Future plans:**

✓ Phase 2/3 study will be initiated in FY 2017

Clinical Responses and Survival Outcomes of Individual Patients



1) Miyakoshi S et. al. ASH 2016(Abstract 4335)
2) Prebet T et. al. *J Clin Onclol* 2011;29:3322-7

Tolero's Pipeline & Discovery Capabilities

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➢ Tolero's pipeline

Development code	Generic name	Mechanism of action	Target indication	Development location	Development stage
–	Alvocidib	CDK9 inhibitor	Acute myeloid leukemia	U.S.	Phase 2 (Completed)
			Acute myeloid leukemia (Biomarker)	U.S.	Phase 2
			Myelodysplastic syndromes	U.S.	Preclinical
TP-0903	TBD	AXL receptor tyrosine kinase inhibitor	Solid tumors, Hematologic malignancies	U.S.	Phase 1
TP-1287	TBD	CDK9 inhibitor	TBD	U.S.	Preclinical
TP-0184	TBD	ALK2/BMPR Signaling Inhibitor	TBD	U.S.	Preclinical

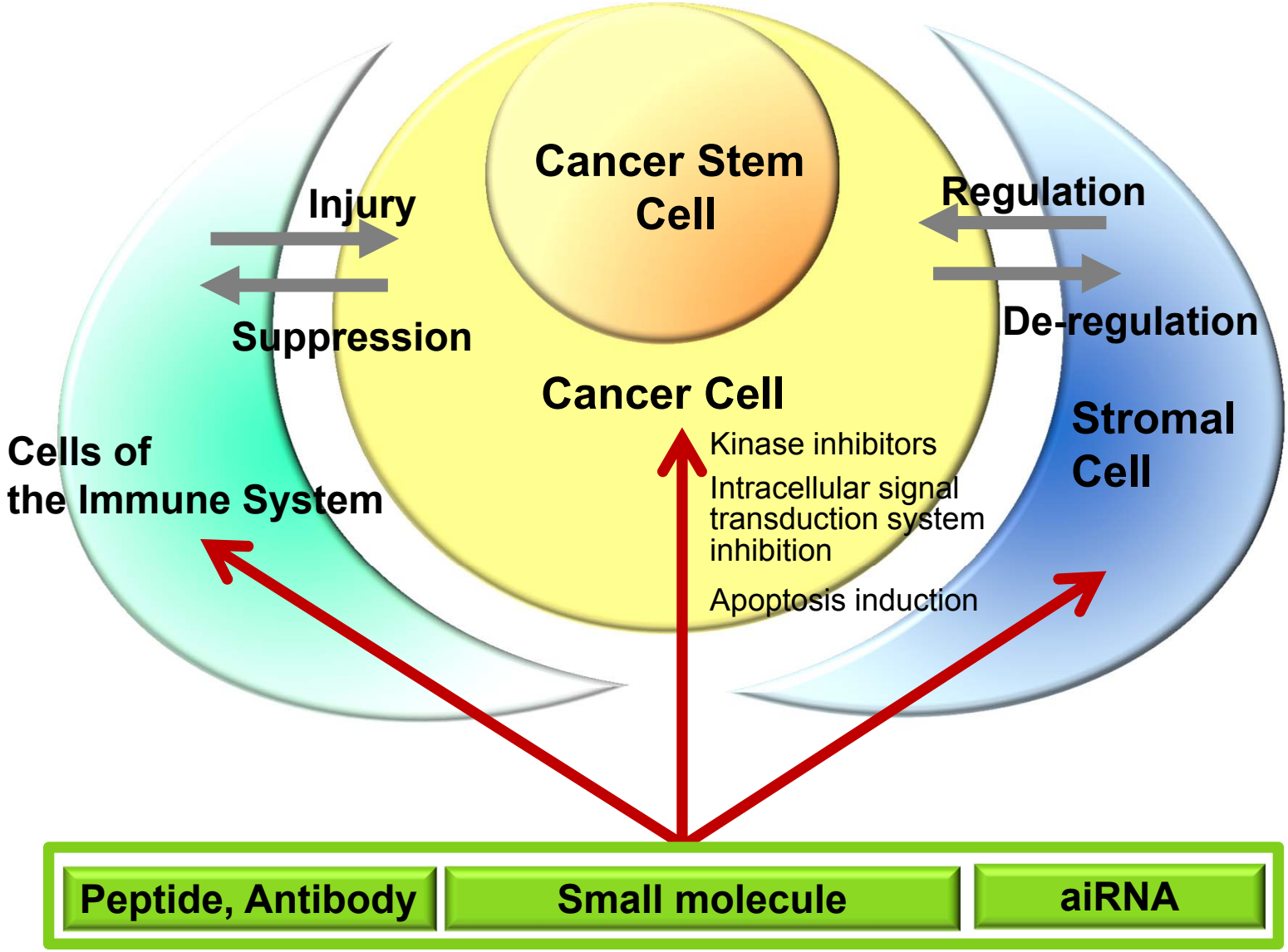
* In addition to the above list, Tolero possesses two compounds in the preclinical stage

➢ Tolero's drug discovery capabilities

- Experienced personnel who have been involved in drug discovery and clinical development targeting kinases for more than 10 years
- Unique evaluation system that assesses disease relevance and in-silico platform to discover disease-related kinases

Select target indication, such as hematologic malignancies, most relevant to targeted kinase

Cancer Drug Research: Outlook for the Future



Towards the Future

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- **Make achievements with limited R&D resources**
  - ✓ Selection and Concentration
  - ✓ Advancing the R&D system, Securing investment in early-stage programs
- **Continuously develop and reinforce our own science and technology platform (strength)**
  - ✓ In silico drug discovery, Disease iPS, Brain targeted DDS
  - ✓ Phenotypic screening system, Non-human primate system
- **Accelerate use of external resources**
  - ✓ Secure “drug seeds” through open innovation
  - ✓ Out-license of early assets
  - ✓ Cost sharing with partners through joint research or collaboration

Aspire to be a globally active R&D-based company, through leading-edge science and technologies

Ensure sustainable growth through the creation of new value

Topics

Psychiatry & Neurology and Respiratory Areas: Pipeline Driving Sustainable Growth

Dasotraline

Apomorphine Sublingual film (APL-130277)

Glycopyrronium bromide (SUN-101)

Antony Loebel, M.D
Executive Officer, Head of Global Clinical Development

Executive Vice President and CMO, Sunovion Pharmaceuticals Inc.

New Challenge in Oncology Area: Making Meaningful Medicines

Alvocidib

David J. Bearss, Ph.D
Chief Executive Officer
Tolero Pharmaceuticals, Inc.

Psychiatry & Neurology Area, Respiratory Area: Pipeline Driving Sustainable Growth

Antony Loebel, M.D.
Executive Officer, Head of Global Clinical Development
Executive Vice President and CMO, Sunovion Pharmaceuticals Inc.

Today's Agenda

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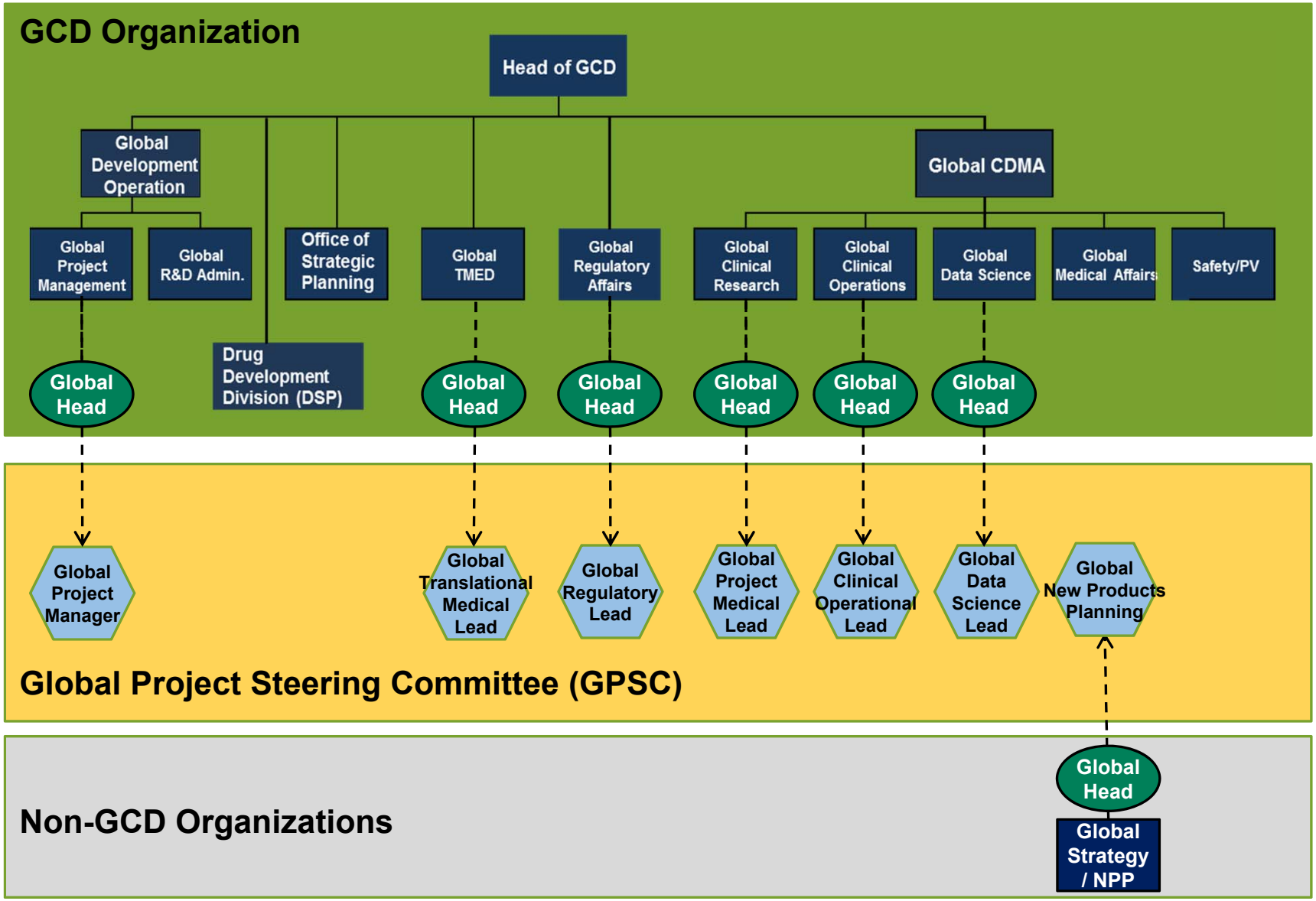
GCD OVERVIEW

PSYCHIATRY FRANCHISE

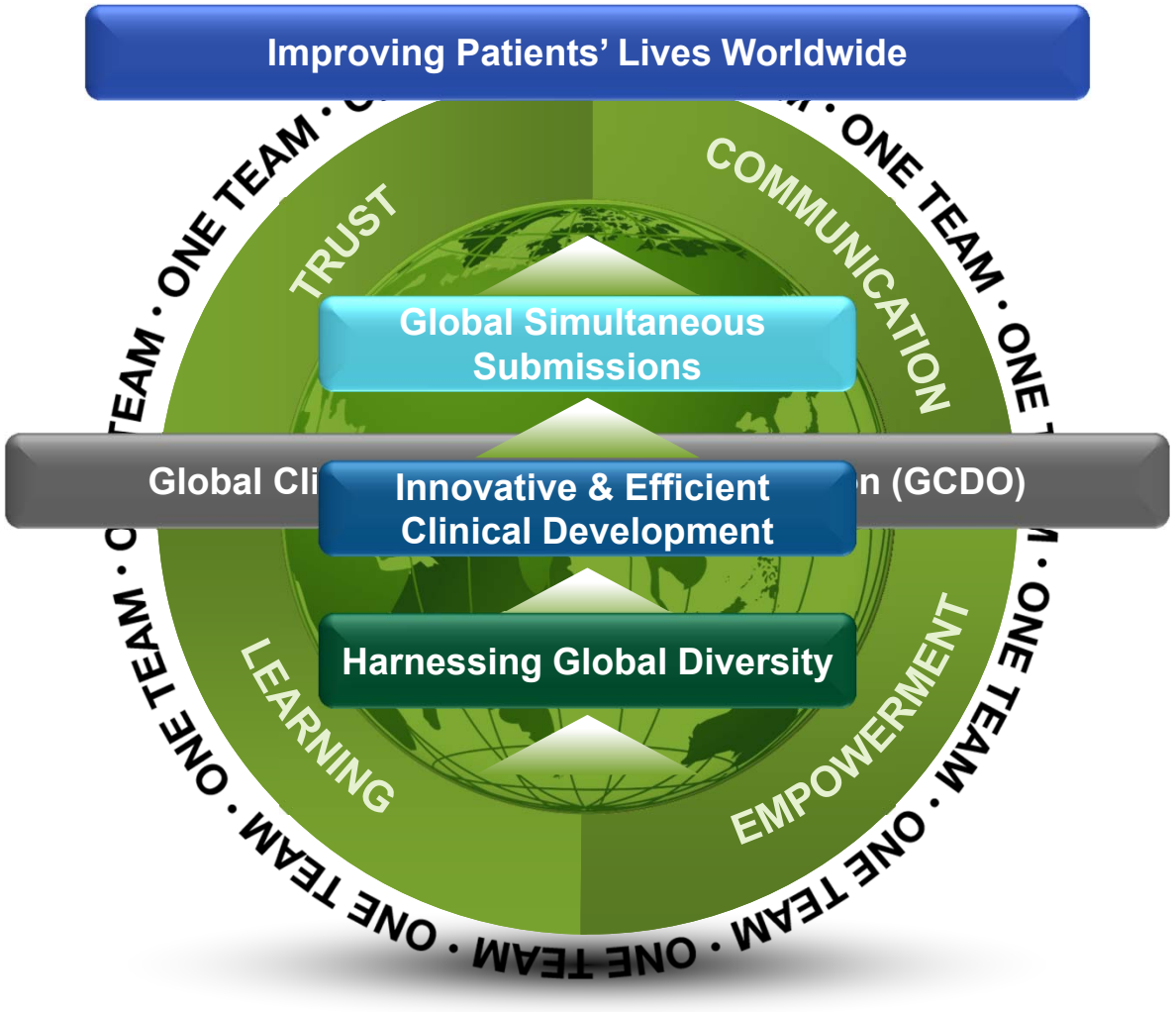
NEUROLOGY FRANCHISE

RESPIRATORY FRANCHISE

Global R&D Organization



Focus on One Team, Values, and Goals



Our Pipeline (as of January 27, 2017)

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Topics

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
LATUDA®	lurasidone hydrochloride	Schizophrenia	China				
		Schizophrenia	Japan				
		Bipolar I depression, Bipolar maintenance	Japan				
		Pediatric, adolescent Bipolar I disorder (new indication)	U.S.				
SEP-225289	dasotraline	Adult attention-deficit hyperactivity disorder (ADHD)	U.S.				
		Pediatric attention-deficit hyperactivity disorder (ADHD)	U.S.				※ Ph 2/3
		Binge eating disorder (BED)	U.S.				※ Ph 2/3
SEP-363856	TBD	Schizophrenia, Parkinson's disease psychosis	U.S.				
		Schizophrenia	Japan				
APTIOM®	eslicarbazepine acetate	Partial-onset seizures in children (4yr+) – adjunctive and monotherapy (new indication)	U.S.				
APL-130277	apomorphine hydrochloride Sublingual	OFF episodes associated with Parkinson's disease	U.S.				
SB623	TBD	Chronic Stroke	U.S.				
SUN-101/eFlow®	glycopyrronium bromide	Chronic obstructive pulmonary disease (COPD)	U.S.				

Other pipeline

LONASEN®	blonanserin	Schizophrenia (Submitted/China), (Pediatric usage) Schizophrenia (Ph3/Japan), (New formulation: Transdermal patch) Schizophrenia (Ph3/Japan)
TRERIEF®	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB) (Ph3/Japan)
EPI-743	vatiquinone	Leigh syndrome (Ph2/3 completed/Japan)
EPI-589	TBD	Parkinson's disease (Ph2/US), Amyotrophic lateral sclerosis (ALS) (Ph2/US)
DSP-1747	obeticholic acid	Nonalcoholic steatohepatitis (NASH) (Ph2/Japan)
DSP-6952	TBD	IBS with constipation, Chronic idiopathic constipation (Ph2/Japan)
DSP-2230	TBD	Neuropathic pain (Ph1)
DSP-3748	TBD	Cognitive Impairment Associated with Schizophrenia (Ph1)
DSP-1200	TBD	Treatment-resistant depression (Ph1)
DSP-6745	TBD	Parkinson's disease psychosis (Ph1)

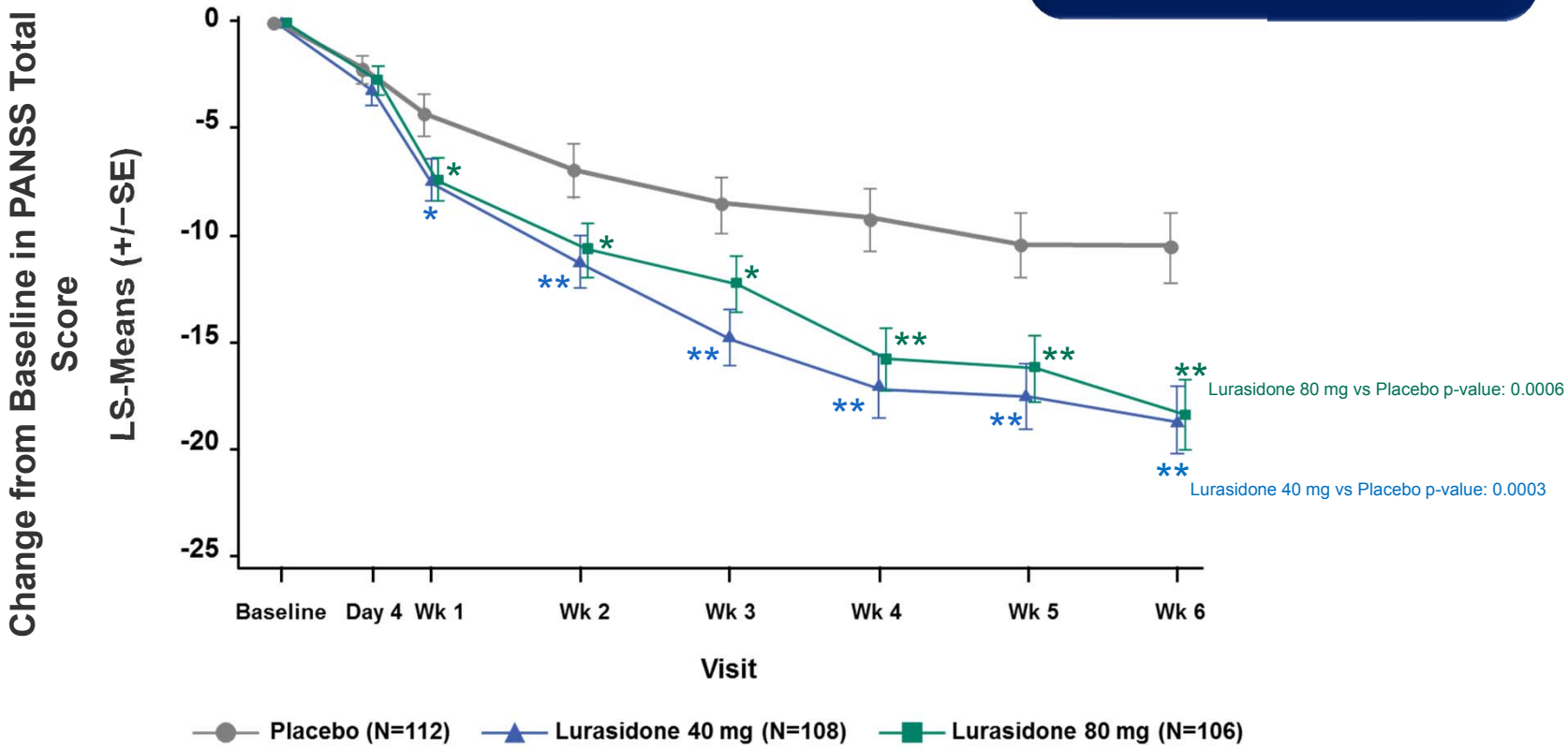

PSYCHIATRY FRANCHISE
FOCUSED ON
DIFFERENTIATED
THERAPIES FOR UNMET
NEEDS

LATUDA for Adolescents with Schizophrenia

Study Design (Study 301)

- Six-week, randomized, double-blind, placebo-controlled, parallel-group, fixed dose study (LATUDA 40 or 80 mg/day)
- Adolescents (ages 13-17 years) with schizophrenia

LATUDA now approved by FDA for treatment of adolescents with schizophrenia



	Placebo (N=112)	Lurasidone 40 mg (N=108)	Lurasidone 80 mg (N=106)
BL Mean	92.8	94.5	94.0
Effect Size at Week 6 LOCF (vs. Placebo)		0.51	0.48

*P<0.05; **P<0.01

LATUDA for Children & Adolescents with Bipolar Depression

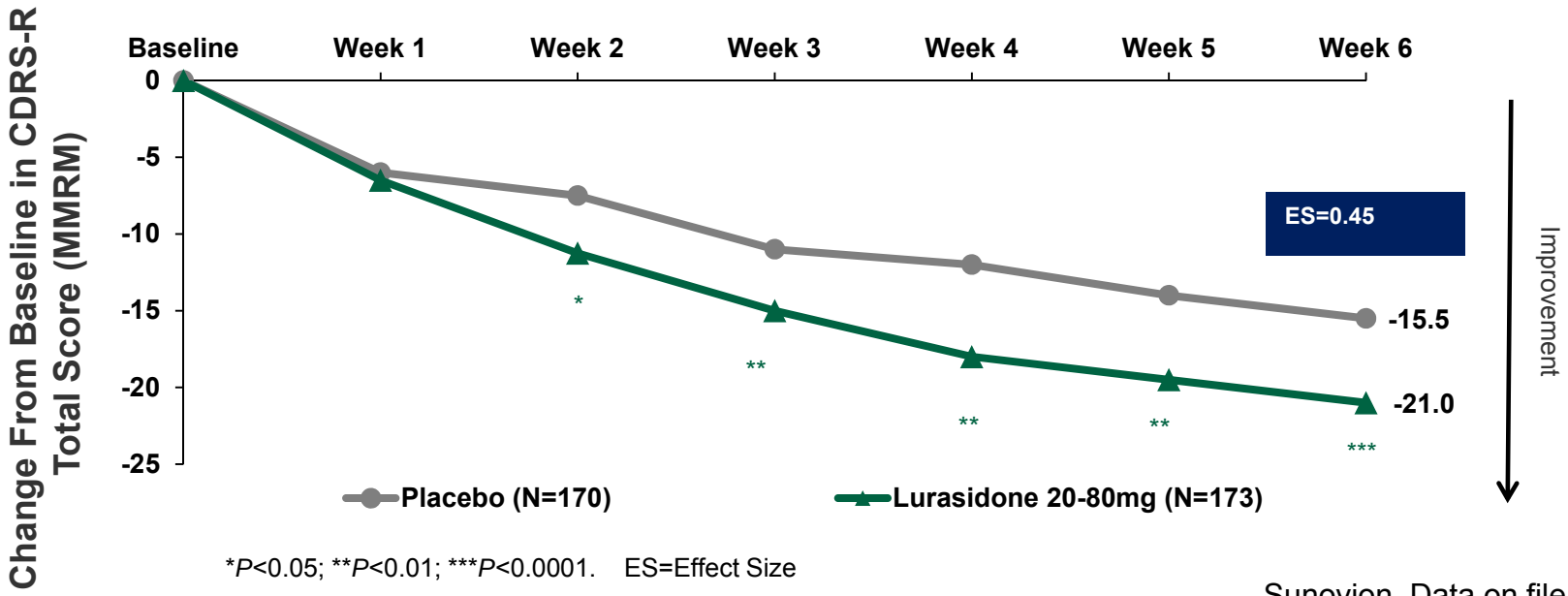
Study Design (Study 326)

- Six-week, randomized, double-blind, placebo-controlled, parallel-group, flexible dose study (LATUDA 20-80 mg/day)
- Children and adolescents (ages 10-17) with bipolar I disorder

Results

- Demonstrated statistically significant and clinically meaningful improvement versus placebo on primary and secondary endpoints
- LATUDA was generally well-tolerated with minimal effects on weight and metabolic parameters

Primary Efficacy Endpoint: Children Depression Rating Scale – Revised (CDRS-R) Total Score



*P<0.05; **P<0.01; ***P<0.0001. ES=Effect Size

Sunovion, Data on file

Opportunities in Multiple Indications

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Dasotraline (SEP-225289)

Attention-deficit hyperactivity disorder (ADHD)
Binge eating disorder (BED)

Attention Deficit Hyperactivity Disorder (ADHD)

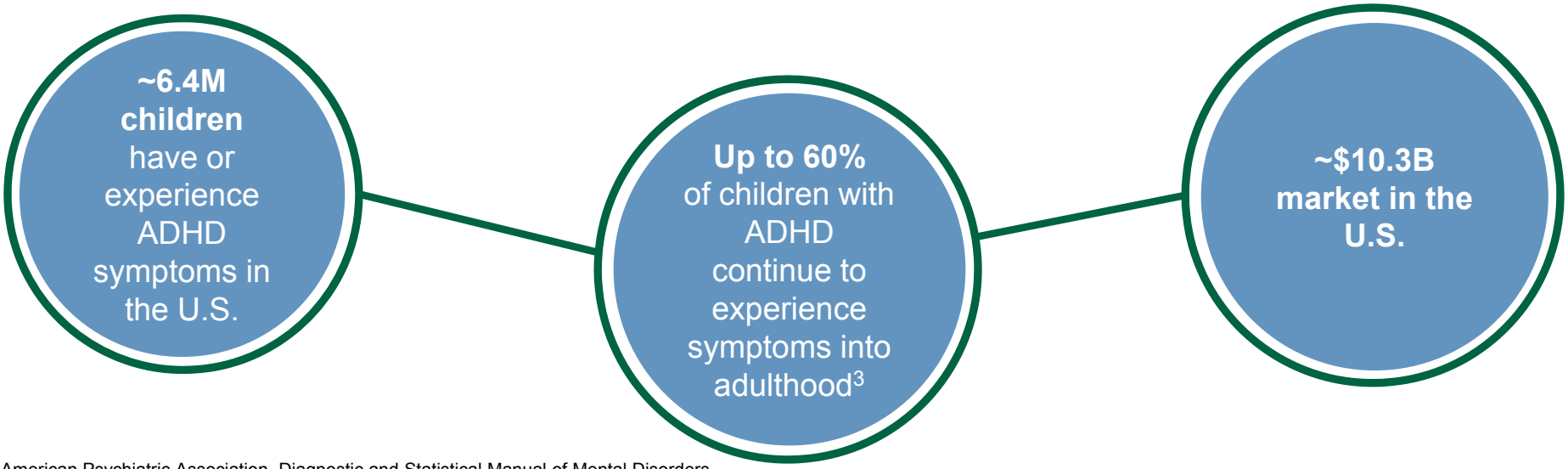
ADHD is a persistent pattern of ***inattention and/or hyperactivity-impulsivity*** that interferes with functioning and development.[1]

CHILDREN

Children with ADHD have poorer ***social relationships*** and more frequent and severe ***injuries*** than peers without ADHD.[2]

ADULTS

Symptoms impact ***social and occupational functioning***, leading to high levels of unemployment, workplace impairment and reduced productivity.[4, 5, 6]



[1] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders.
[2] Centers for Disease Control and Prevention. Data and Statistics.
[3] Innov Clin Neurosci. Our Current Understanding of Adult ADHD.
[4] Prim Care Companion J Clin Psychiatry. Assessing Adults With ADHD and Comorbidities.
[5] International Archives of Occupational and Environmental Health. The negative impact of attention-deficit/hyperactivity disorder on occupational health in adults and adolescents.
[6] WebMD. Attention Deficit Hyperactivity Disorder: ADHD in Adults.

About Dasotraline

Dasotraline is a long-lasting dopamine norepinephrine reuptake inhibitor (DNRI) with:

- Long duration of effect (tmax 10-12 hrs; t½ 47-77 hrs)
- Steady state achieved by 2 weeks
- Absence of wearing off and smoothness of effect
- Once-daily dosing
- Lower risk of abuse/diversion

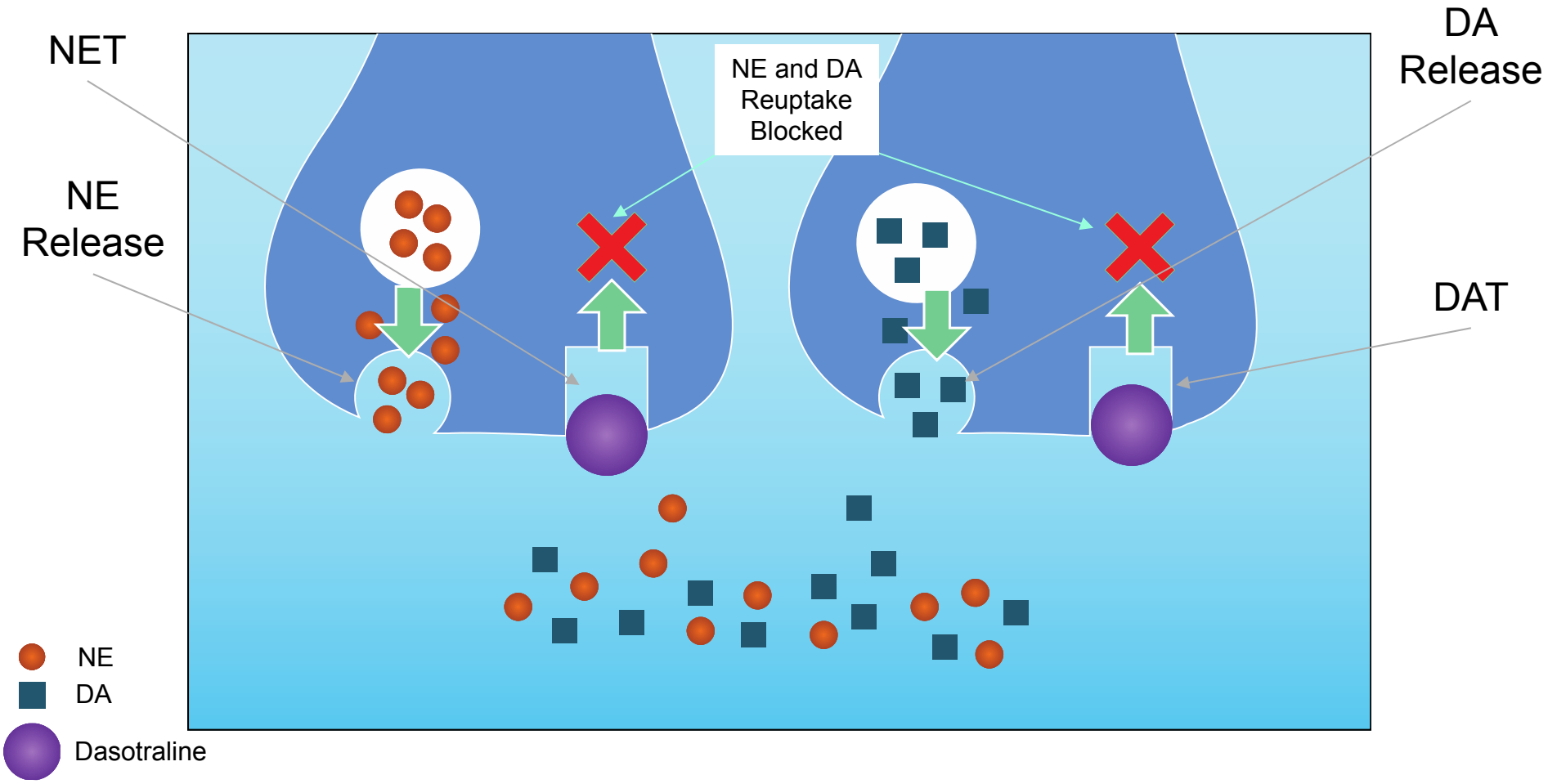
In development for the following indications:

- Attention deficit hyperactivity disorder (ADHD)
- Binge eating disorder (BED)

Dasotraline could offer an alternative treatment option for ADHD and BED

- Stimulants
  - Are most commonly prescribed therapeutic agents for ADHD
  - Are highly effective but there is a growing problem of abuse
  - Do not provide continuous 24 hour coverage of ADHD symptoms
- Non-stimulants
  - Are not associated with abuse potential
  - Are perceived to be less effective

Dasotraline: Mechanism of Action



NE = Norepinephrine
DA = Dopamine
NET = NE Transporter
DAT = DA Transporter

Dasotraline Efficacious in Children with ADHD

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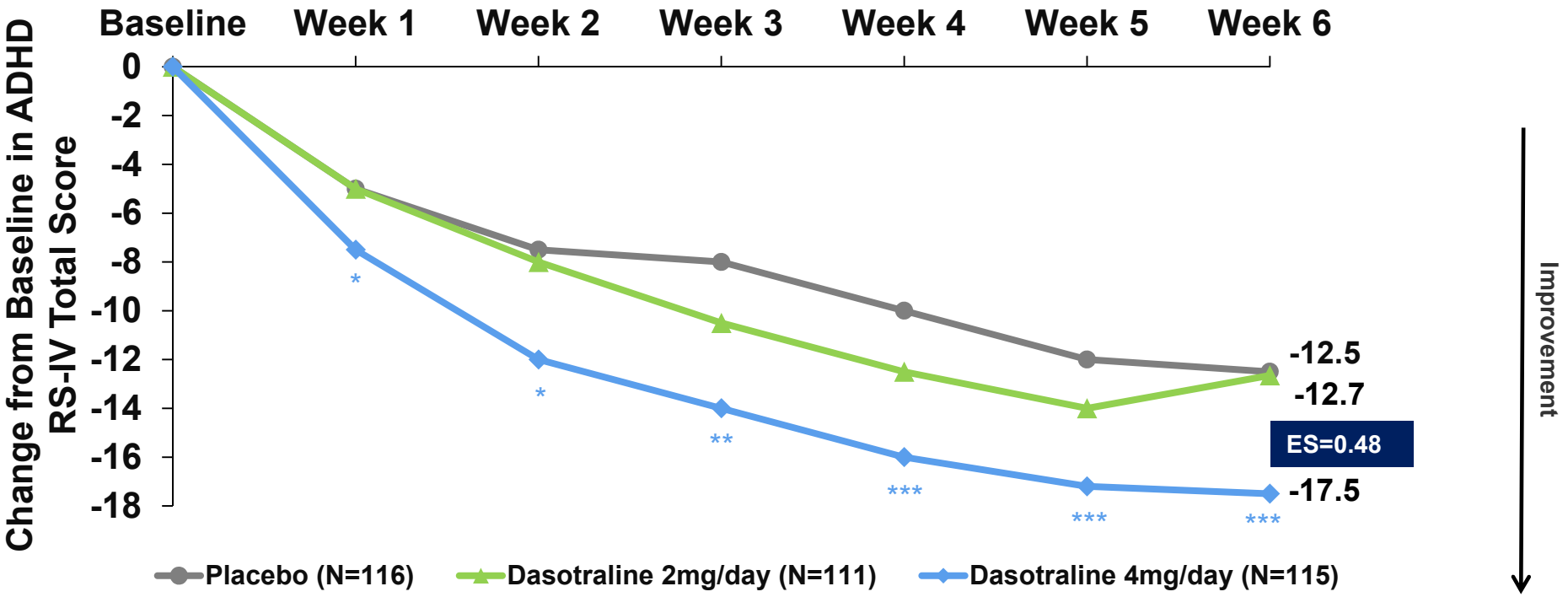
Study Design (SEP360-202)

- Six-week, double-blind, multi-center, placebo-controlled, parallel-group, fixed dose safety and efficacy trial in children ages 6-12 years

Results

- Study showed that the 4mg/per day dose demonstrated a statistically significant and clinically relevant difference compared to placebo (2mg/per day dose was not statistically significant)
- Dasotraline was generally well-tolerated



P values adjusted at week 6.
*P<0.05; **P<0.01; ***P<0.0001 ES=Effect Size

Sunovion, Data on file

Dasotraline Efficacious in Adults with ADHD

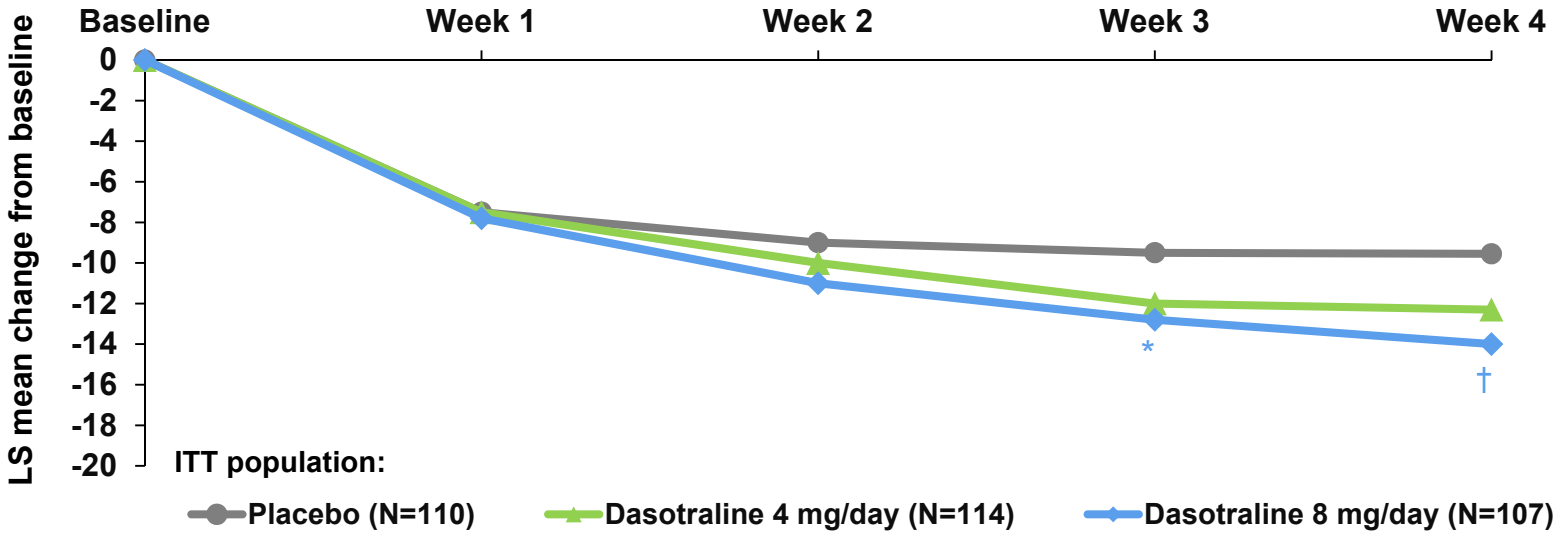
Study Design (SEP360-201)

- Four-week, randomized, double-blind, parallel-group, multi-center, placebo-controlled, fixed dose safety and efficacy trial in adults

Results

- Dasotraline 8 mg/day demonstrated statistically significant improvement compared to placebo on the primary efficacy endpoint
- Both dasotraline 4mg/per day and 8 mg/per day demonstrated a statistically significant and clinically relevant difference compared to placebo on the secondary endpoint
- Dasotraline was generally well-tolerated

ADHD RS-IV Total Score (MMRM) – Primary Endpoint LS Mean Change From Baseline



BL mean:	36.7	36.8	36.6

*P<0.05
†P<0.025
ADHD RS-IV, ADHD Rating Scale Version IV; BL, baseline; ITT, intent-to-treat; LS, least squares; MMRM, mixed-effects model for repeated measures

Koblan KS, et al; Neuropsychopharmacology 2015 40(12):2745-52.

Binge-Eating Disorder (BED)

BED is an eating disorder that is characterized by recurrent episodes of binge eating that occur ***at least once per week for three months*** and can lead to a number of psychological and physical problems. Binge eating involves two key features: ***eating a very large amount of food within a relatively short period of time*** (e.g. within two hours) and feeling ***a sense of loss of control while eating*** (e.g. feeling unable to stop yourself from eating).[1,2]

[1] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders.
[2] Mayo Clinic. Binge-Eating Disorder.
[3] Biological Psychiatry. The Prevalence and Correlates of Eating Disorders in the National Comorbidity Survey Replication.
[4] Current Psychiatry Reports. Epidemiology of Eating Disorders: Incidence, Prevalence and Mortality Rates.
[5] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders.
[6] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders.

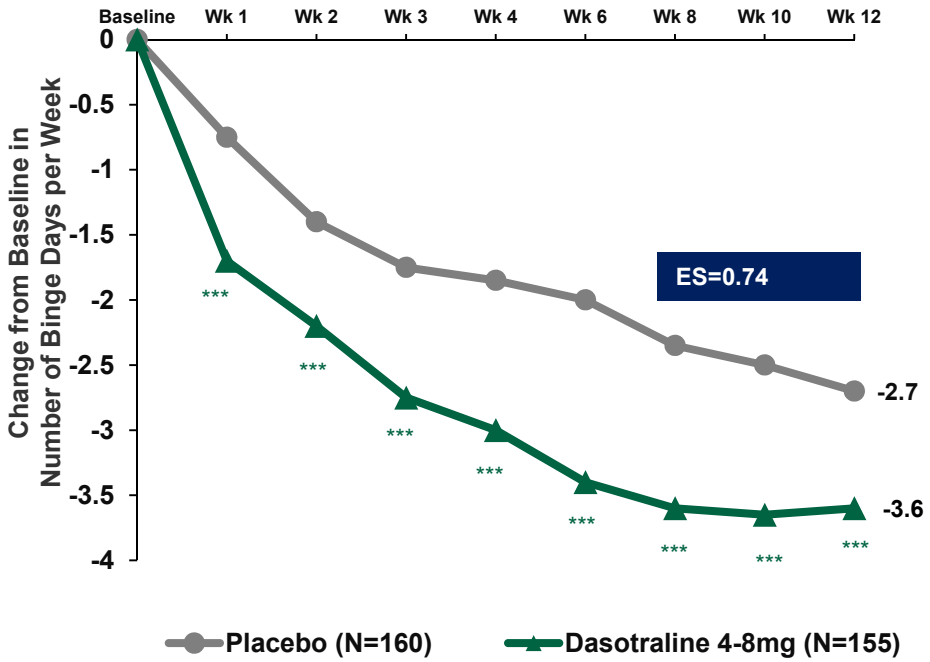
Dasotraline Demonstrates Efficacy in BED

Study Design (SEP360-221)

- Twelve- week, randomized, double-blind, parallel-group, multi-center, placebo-controlled, parallel-group, flexible-dose in adults with moderate to severe BED

Primary Endpoint

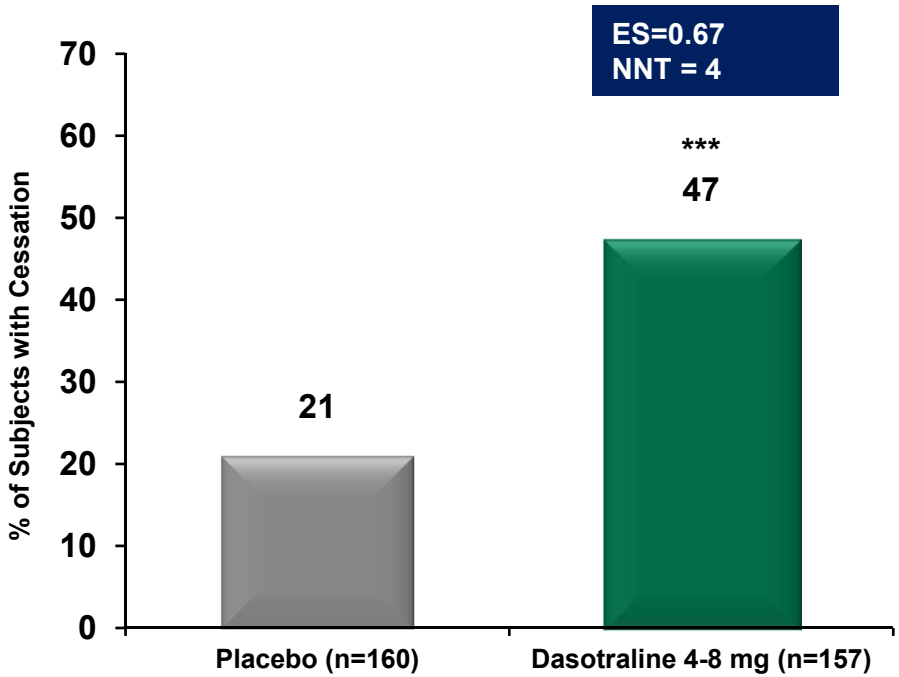
Number of Binge Days per Week



*** *P* <0.0001 ES=Effect Size

Key Secondary

Percentage of subjects with cessation of bingeing (28 days without bingeing) at week 12



***P<0.0001

Note: percentage is calculated based on number of subjects at the visit as denominator

Sunovion, Data on file

The Dasotraline Program Continues To Advance

Study	Timing	Results
Adult ADHD – only one positive study required		
201	December 2013	***Positive study in ADHD***
301	October 2016	NS – provides supporting evidence
Pediatric ADHD – two positive studies required		
202	August 2016	***Positive study in Peds ADHD***
305	March 2017 (expected)	Ongoing – results expected March 2017 Completes ADHD submission package
BED		
221	November 2016	***Positive study in BED***
321	Planned study to start March 2017	Replication study

- Plan to submit ADHD (adult & pediatric) NDA in Q2 FY2017
- Plan to submit sNDA for BED in FY2018

Psychiatry Franchise

Opportunities in Multiple Indications

Sumitomo Dainippon Pharma

SEP-363856

Schizophrenia
Parkinson's disease psychosis

SEP-363856 Overview

Overview

- Investigational psychotropic agent with non-dopamine D_2 mechanism of action
- Identified by Sunovion researchers in collaboration with PsychoGenics Inc, using its proprietary in vivo SmartCube systems biology drug discovery platform

Indication

- Being studied for patients with ***schizophrenia*** and ***Parkinson's disease psychosis***

Global Phase 2 clinical development program initiated in December 2016

- SEP361-201: 4-week, double-blind, randomized, parallel-group, placebo controlled, flexibly-dosed, multicenter study
  - To evaluate the efficacy and safety of SEP-363856 in acutely psychotic adult subjects with schizophrenia (global) [NCT02969382]
- SEP361-202: 26-week open-label study
  - Safety and tolerability extension study of SEP-363856 in adult subjects with schizophrenia (global) [NCT02970929]
- SEP361-203: Randomized, parallel group, multicenter study
  - To evaluate the efficacy, safety and tolerability of SEP-363856 in subjects with Parkinson's disease psychosis (U.S. only) [NCT02969369]

NEUROLOGY FRANCHISE OPPORTUNITIES INCLUDE EPILEPSY, PARKINSON'S DISEASE AND STROKE

About APTIOM

APTIOM (eslicarbazepine acetate):

- Voltage-gated sodium channel blocker
- Member of the dibenzazepine carboxamide family of antiepileptic drugs (AEDs), an established class of medicines

APTIOM is approved by the U.S. Food and Drug Administration for adults with partial-onset seizures as:

- Monotherapy (August 27, 2015)
- Adjunctive therapy (November 8, 2013)

Key attributes include:

- Once-daily dosing (not an extended release)
- Crushability
- Not classified as a controlled substance

APTIOM Pediatric Indication for POS

Pursuing an expansion of the indication for APTIOM for the treatment of partial-onset seizures as monotherapy or adjunctive therapy in patients 4 years of age and older

- Submission based on recent FDA guidance that allows extrapolation of data

- Submission will also include:
  - Pediatric data from three trials conducted by our partner BIAL in Europe
  - Pharmacokinetic analyses to support a proposed dosing regimen for children ages 4-17 years

Addresses an unmet need and represents a opportunity for APTIOM

sNDA submission anticipated Q4 FY2016

Innovative Near-Term Potential Therapy

Sumitomo Dainippon Pharma

Apomorphine sublingual film (APL-130277)

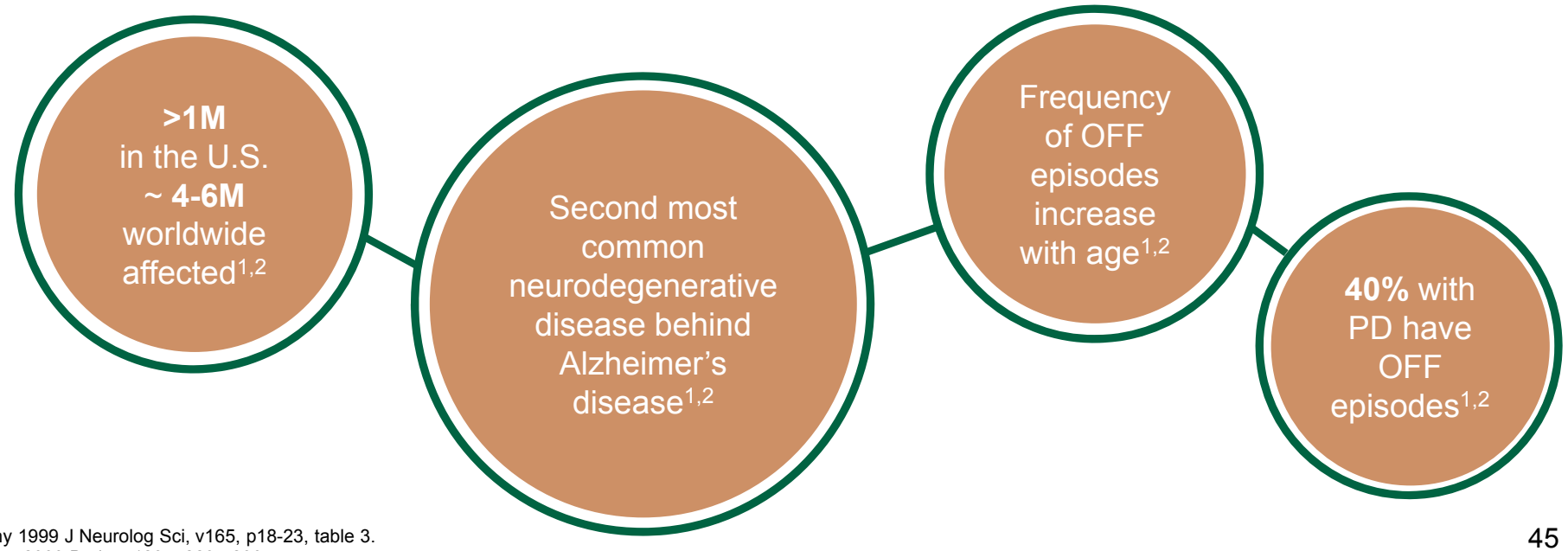
OFF episodes associated with Parkinson's disease

Parkinson's Disease (PD) and OFF Episodes

PD is a chronic, progressive neurodegenerative disease characterized by motor symptoms, rigidity and impaired movement. ***OFF episodes*** are periods of ***loss of function*** (motor and non-motor) experienced by PD patients and can occur ***one to six times daily***, impairing mobility and ***ability to maintain normal activities***.[1,2]

Types of OFF episodes

- Early morning OFF – patient wakens in OFF state
- Delayed ON – levodopa effects take longer than normal to take effect
- End-of-dose wearing-off – the effects of levodopa wear off prior to next scheduled dose
- Erratic or unpredictable OFF – episode at times not related to dose timing



[1]Denny 1999 J Neurolog Sci, v165, p18-23, table 3.
[2]Schrag 2000 Brain v 123, p2297-2305

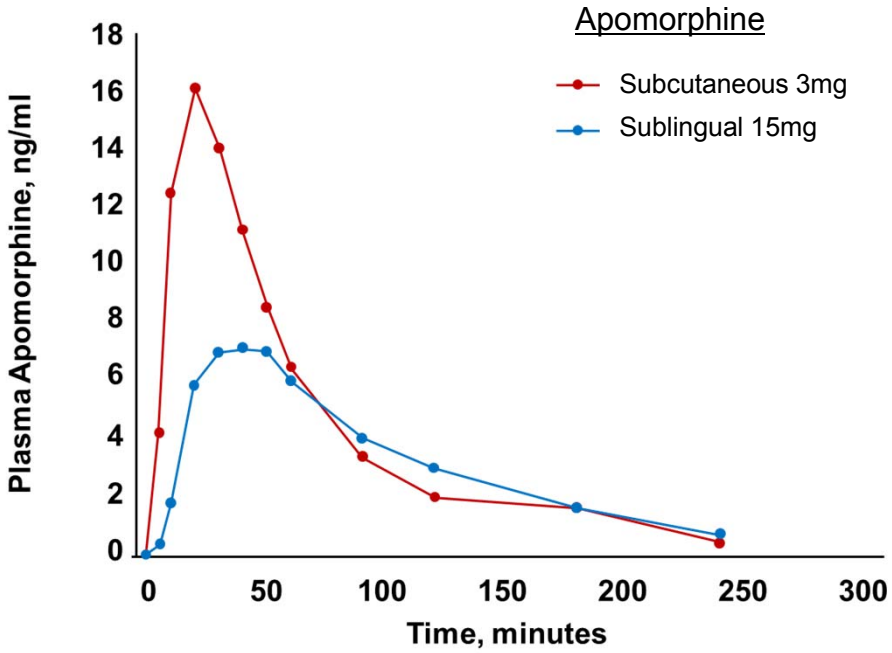
About APL-130277 (sublingual)

Designed to be a fast-acting, easy-to-use thin film for the on-demand management of OFF episodes associated with PD

- Novel formulation of apomorphine
- Broad dose range (10 mg – 35 mg being tested)
- Has been studied in all types of OFF episodes, including morning OFF

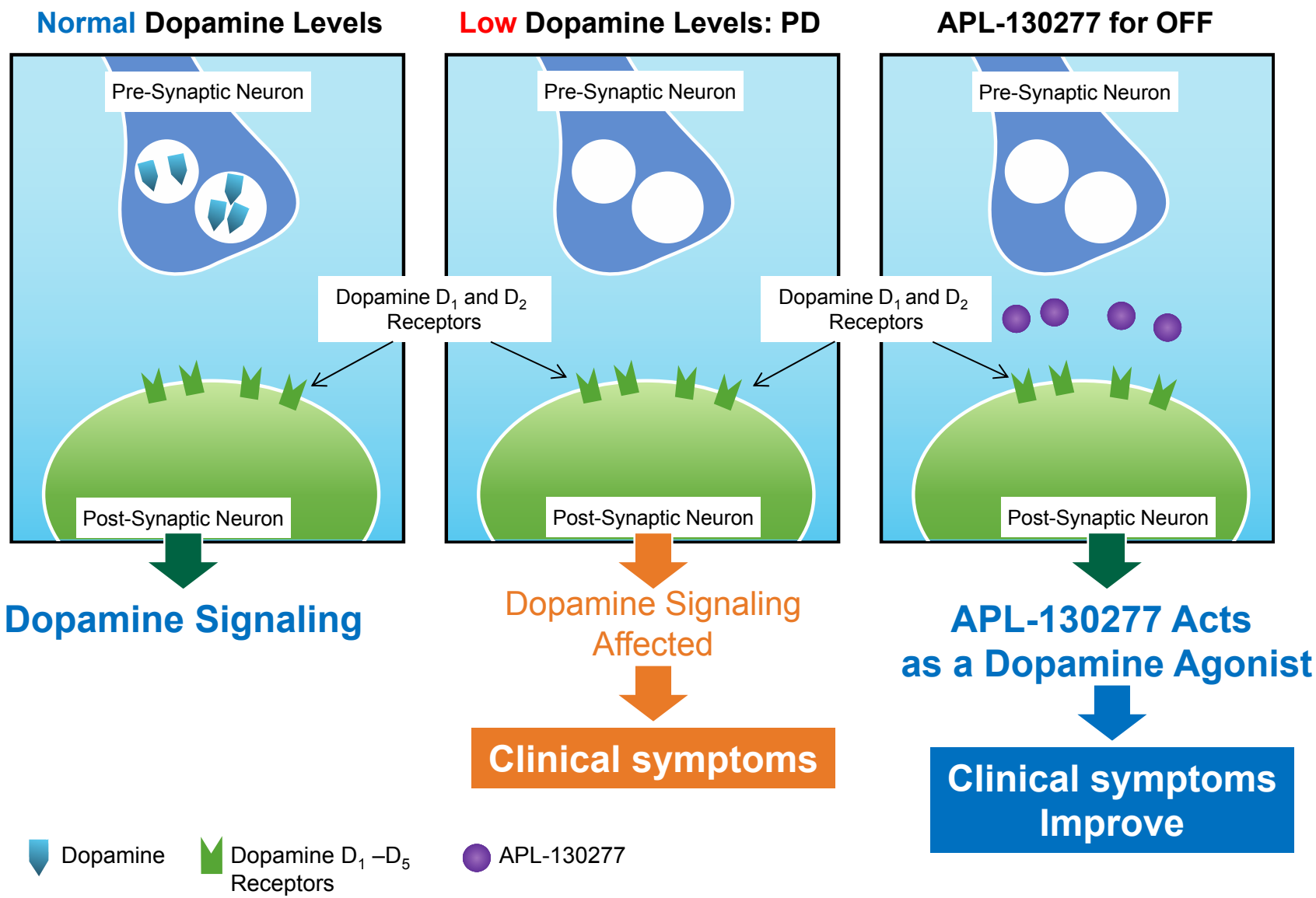
Single dose pharmacokinetic profile

- Tolerability: blunted peak may relate to low incidence nausea, vomiting, hypotension and possibly low risk QT prolongation
- Efficacy: slow decline in [C] from peak may allow persistence of efficacy
  - In Phase 2 study, approximately 50% of subjects remained “ON” at 90 minutes



Sunovion, Data on file, Study CTH-103

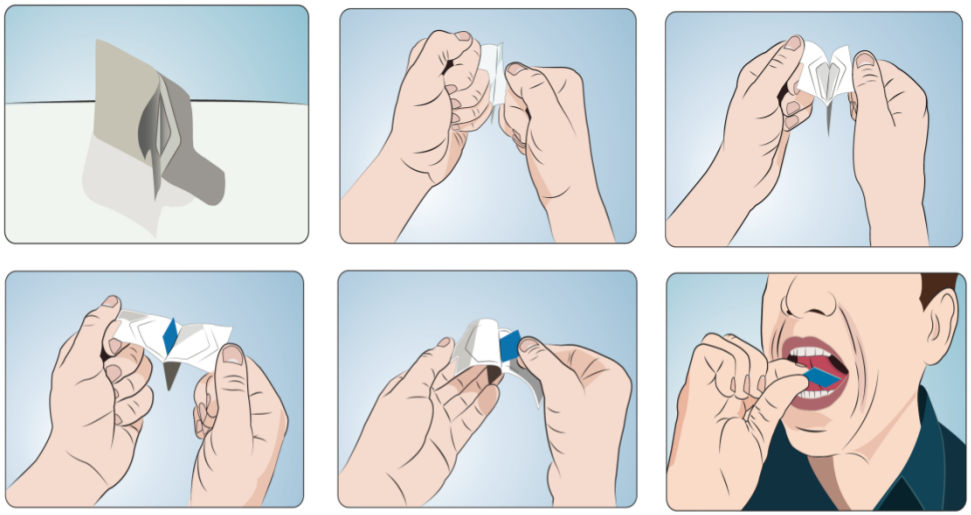
APL-130277: Mechanism of Action

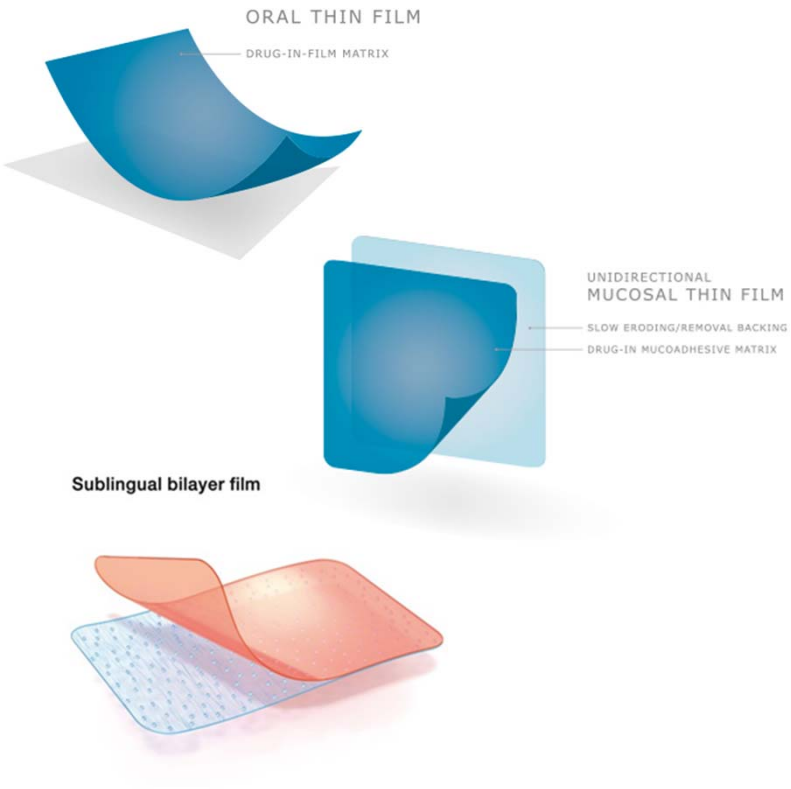


Administration Of APL-130277

Sublingual (under-the-tongue) administration of apomorphine

- Designed to be a convenient, well-tolerated, safe and effective option
- May help avoid issues with injectable subcutaneous apomorphine

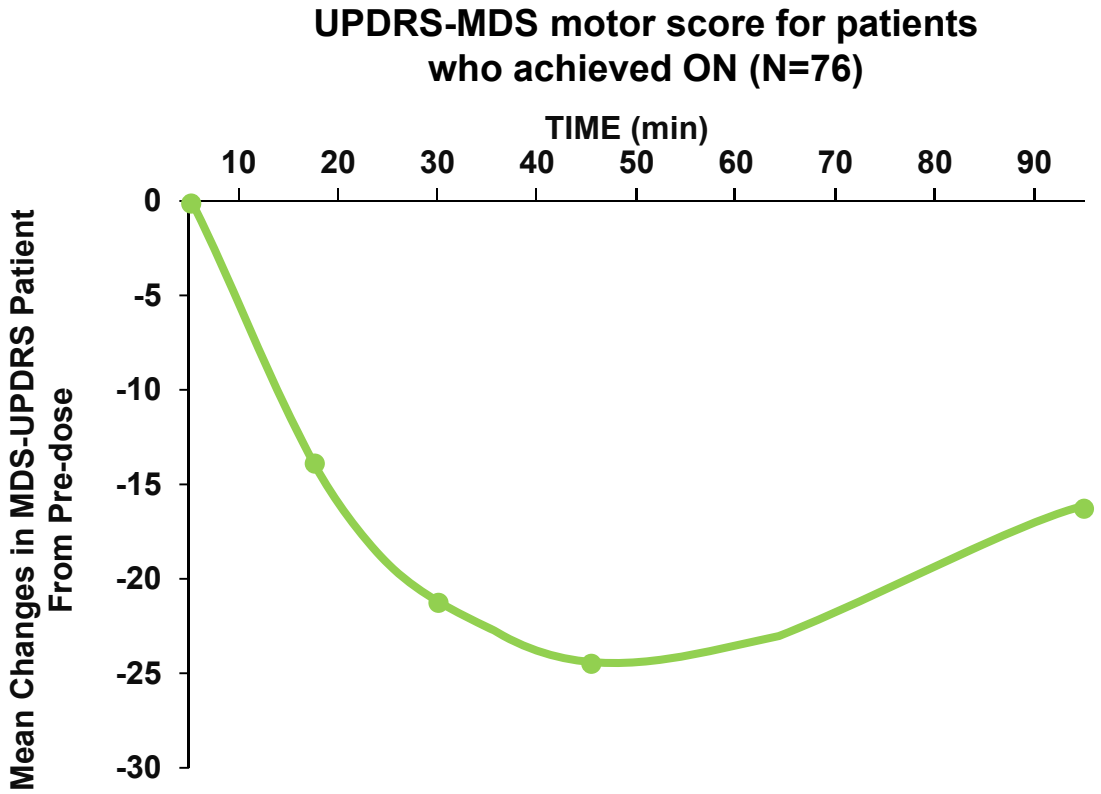




Study CTH-300 Preliminary Titration Results

Open label titration phase study results

- The mean time to full ON as reported by study staff was 22 minutes
- All five doses of APL-130277 (10, 15, 20, 25 and 30 mg) converted patients from the OFF state to a full ON state once titrated to their appropriate dose. Over half of the patients needed the lowest two doses (10 and 15 mg) and 80% used 20 mg or less
- The mean dose required to convert patients to ON was 18.4 mg



Sunovion, Data on file

Neurology Franchise

APL-130277 Clinical Development Program

Sumitomo Dainippon Pharma

CTH-300

- **U.S. double-blind Phase 3 efficacy and safety study**
- Completion is expected in the first half of FY2017

CTH-302

- **European registration has been initiated**
- **Open-label, active comparator study with subcutaneous apomorphine**
- Up to 80 patients randomized in a 4-week open label crossover study
- Primary endpoint is patient preference and quality of life
- The use of an antiemetic should be limited during the study

Regenerative Medicine / Cell Therapy

Sumitomo Dainippon Pharma

SB623

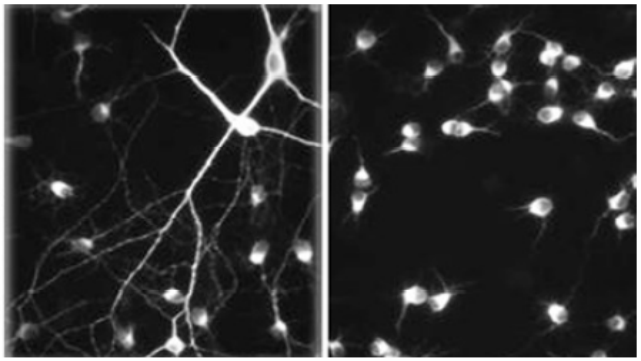
Chronic stroke

SB623 Overview

Investigational treatment for chronic ischemic stroke

Stem Cells Engineered to Secrete Nerve Growth Factors

25 days tissue culture



SB623 poly-Lysine control

Stereotactic Implantation of Stem Cells Into Brain

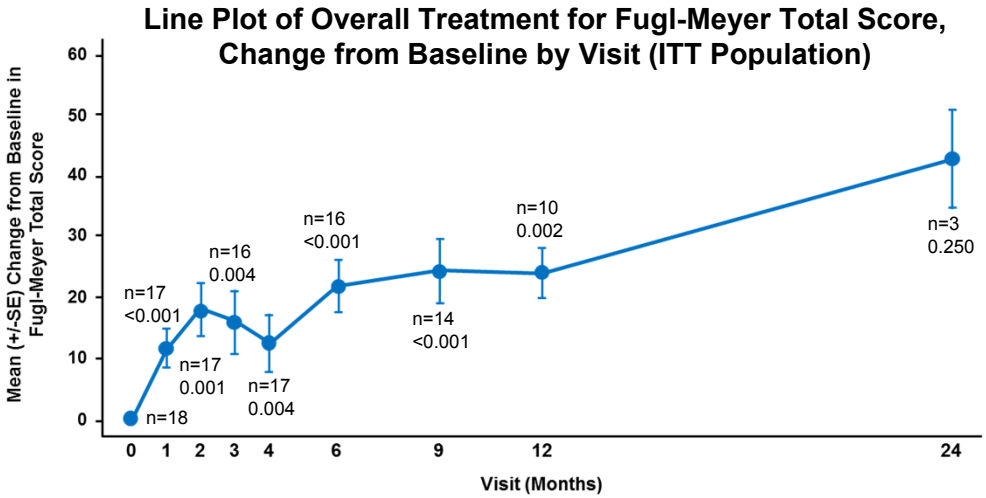
Early Data Supports Ongoing Development

Important Phase 1/2a findings published in *Stroke*

Original Contribution

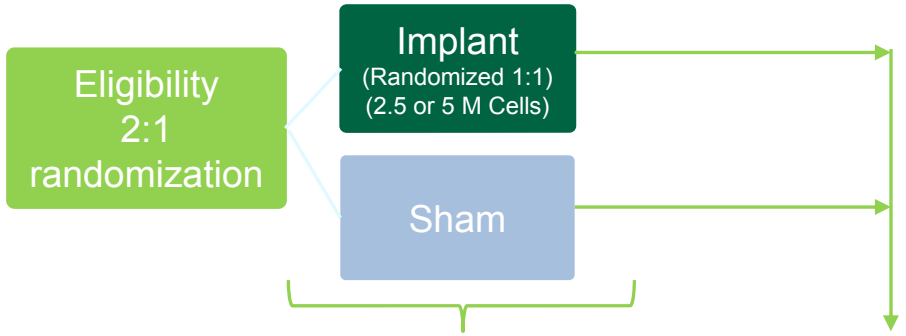
Clinical Outcomes of Transplanted Modified Bone Marrow–Derived Mesenchymal Stem Cells in Stroke: A Phase 1/2a Study

Gary K. Steinberg, MD, PhD; Douglas Kondziolka, MD; Lawrence R. Wechsler, MD; L. Dade Lunsford, MD; Maria L. Coburn, BA; Julia B. Billigen, RN, BS; Anthony S. Kim, MD, MAS; Jeremiah N. Johnson, MD; Damien Bates, MD, PhD; Bill King, MS; Casey Case, PhD; Michael McGrogan, PhD; Ernest W. Yankee, PhD; Neil E. Schwartz, MD, PhD

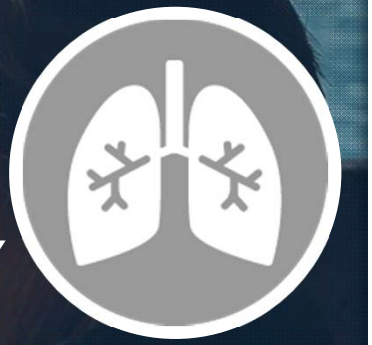


Source: Post-text figure 14.2.4.5
Abbreviations: ITT=intent-to-treat; SE=standard error
Note: p-values were based upon the Wilcoxon Signed Rank test.

Ongoing Phase 2b study design



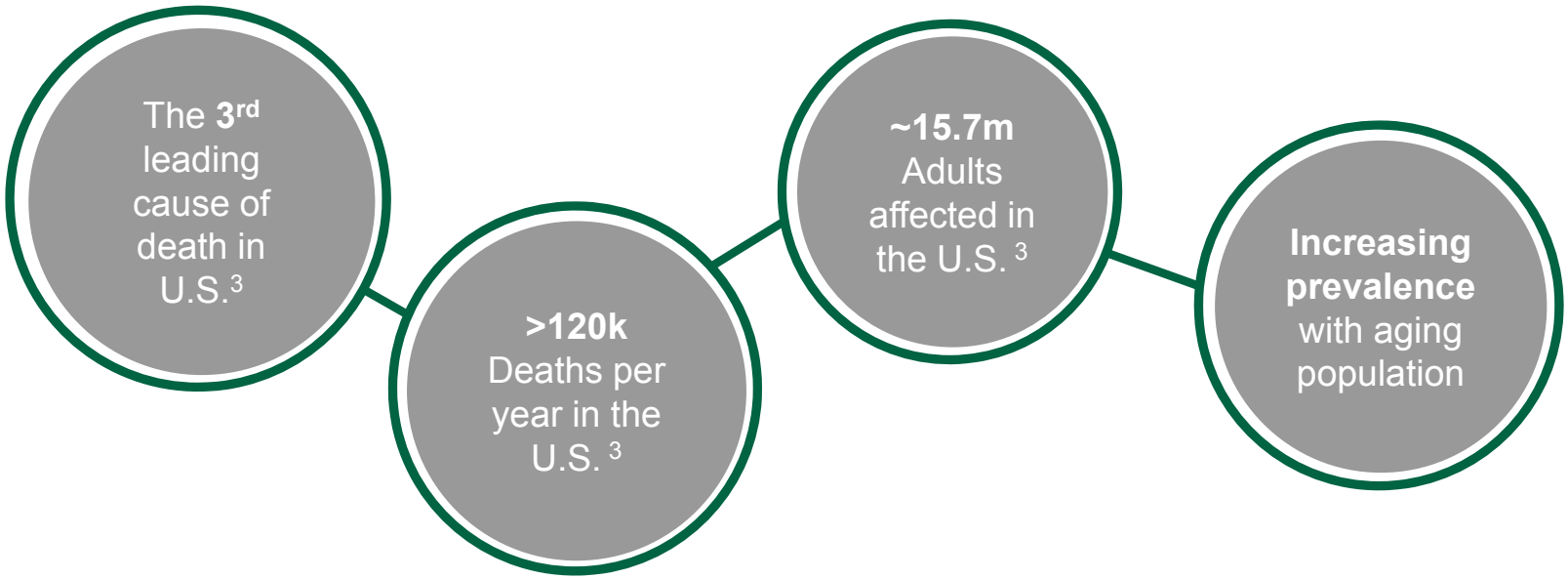
RESPIRATORY FRANCHISE FOCUSED ON CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)



- *Sunovion now has the broadest COPD portfolio in the U.S.*
- *Treatment options for people at all stages of COPD*
- *Flexibility to choose handheld or nebulized products*

Chronic Obstructive Pulmonary Disease (COPD)

COPD is a serious and ***progressive respiratory disease*** that develops slowly and causes worsening ***obstruction of airflow*** to the lungs over time,[1] potentially limiting the ability to perform ***routine activities***.[2] Symptoms of COPD include coughing, wheezing, ***shortness of breath***, excess production of mucus in the lungs, the inability to breathe deeply and the ***feeling of being unable to breathe***.[3]



[1]National Heart, Lung and Blood Institute. What is COPD?
[2]FDA. Glaxo Appendices.
[3]MMWR: Morbidity and Mortality Weekly Report. Employment and Activity Limitations Among Adults with Chronic Obstructive Pulmonary Disease.

Respiratory Franchise

Portfolio Options For Patients On COPD Disease Continuum

Sumitomo Dainippon Pharma

Disease Severity →

New COPD Patients	Patients Symptomatic on LAMA or LABA	Patients Symptomatic on LABA/ICS	Patients who would benefit from nebulized medication	BROVANA add-on for uncontrolled patients
 OR 			**SUN-101 / eFlow®**  Investigational	NEBULIZE WITH Brovana® 15 mcg (arformoterol tartrate) Inhalation Solution

Full trade names are: Seebri™ Neohaler®, Utibron™ Neohaler® and Arcapta® Neohaler®

ARCAPTA and are registered trademarks of Novartis AG, used under license

SEEBRI and are trademarks of Novartis AG, used under license

UTIBRON and are trademarks of Novartis AG, used under license

eFlow® device technology licensed from PARI Pharma GmbH

Near-Term Portfolio Growth Expected

SUN-101/eFlow® (glycopyrronium bromide)

Chronic obstructive pulmonary disease (COPD)

SUN-101/eFlow is an investigational product under review with the FDA
eFlow® device technology licensed from PARI Pharma GmbH

About SUN-101/eFlow®

SUN-101/eFlow® is comprised of:

- SUN-101 (glycopyrronium bromide), an investigational, nebulized long-acting muscarinic antagonist (LAMA)
- eFlow®, PARI's innovative investigational closed-system nebulizer customized to deliver SUN-101

SUN-101/eFlow® is being reviewed by the U.S. Food and Drug Administration (FDA) for the long-term, maintenance treatment of airflow obstruction in patients with COPD

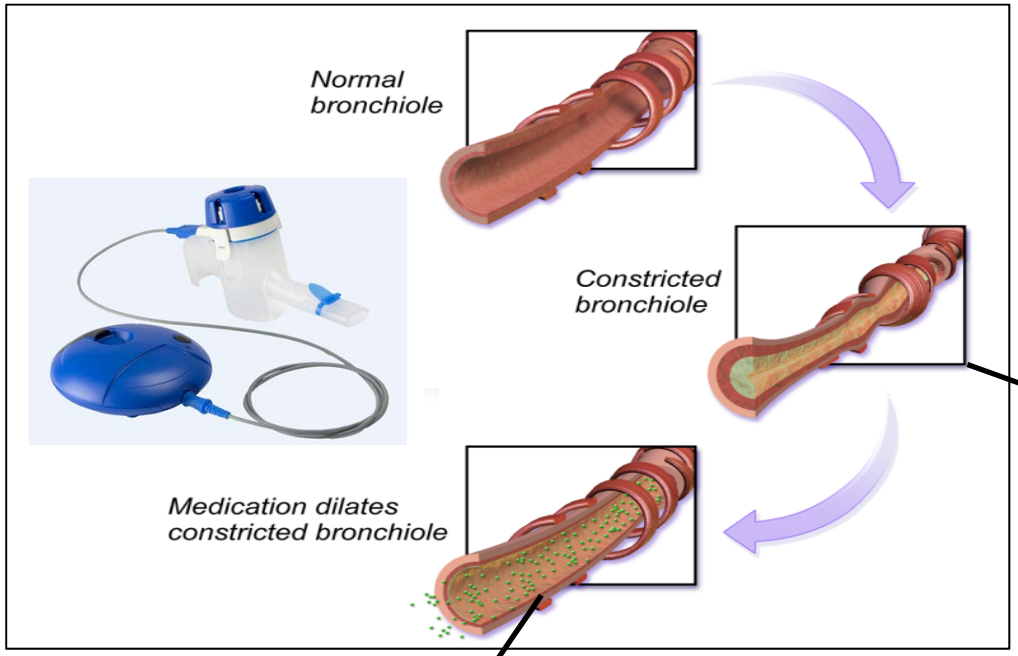
- If approved, it would represent the first available nebulized LAMA for patients with COPD
- May 29, 2017 PDUFA action date

Key attributes include:

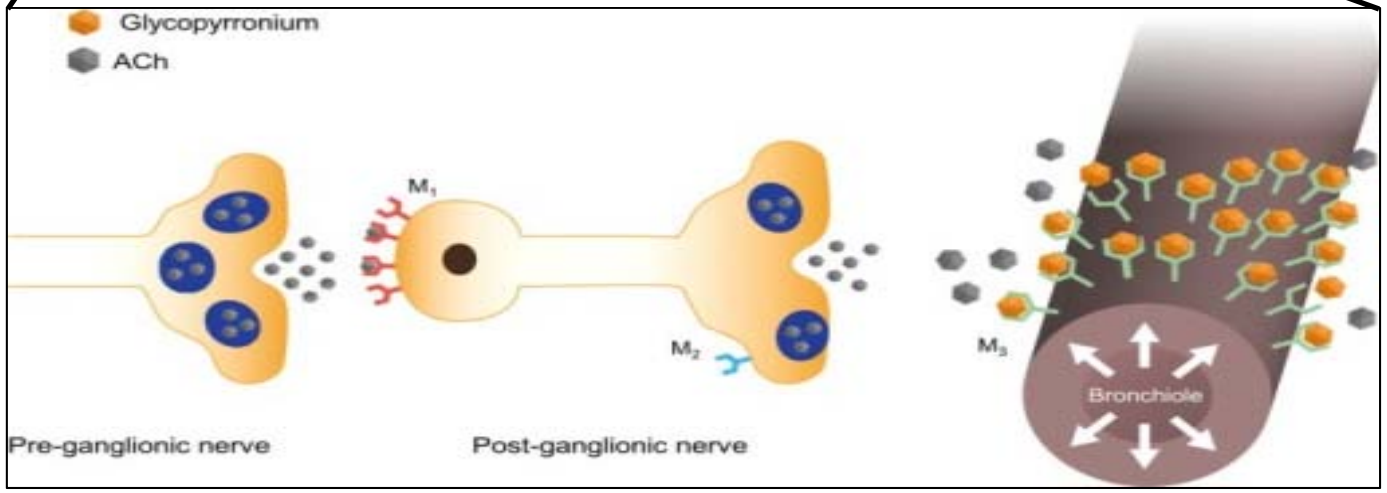
- Time for administration is two to three minutes (standard jet nebulizer typically takes up to ten minutes)
- Portable, handheld, electronic system
- Ability for patient to breathe normally

eFlow® device technology licensed from PARI Pharma GmbH

LAMA Mechanism of Action



Long-acting muscarinic antagonist (LAMA) therapies work by blocking M_3 receptors on smooth muscle to produce bronchodilation



Product Demonstration

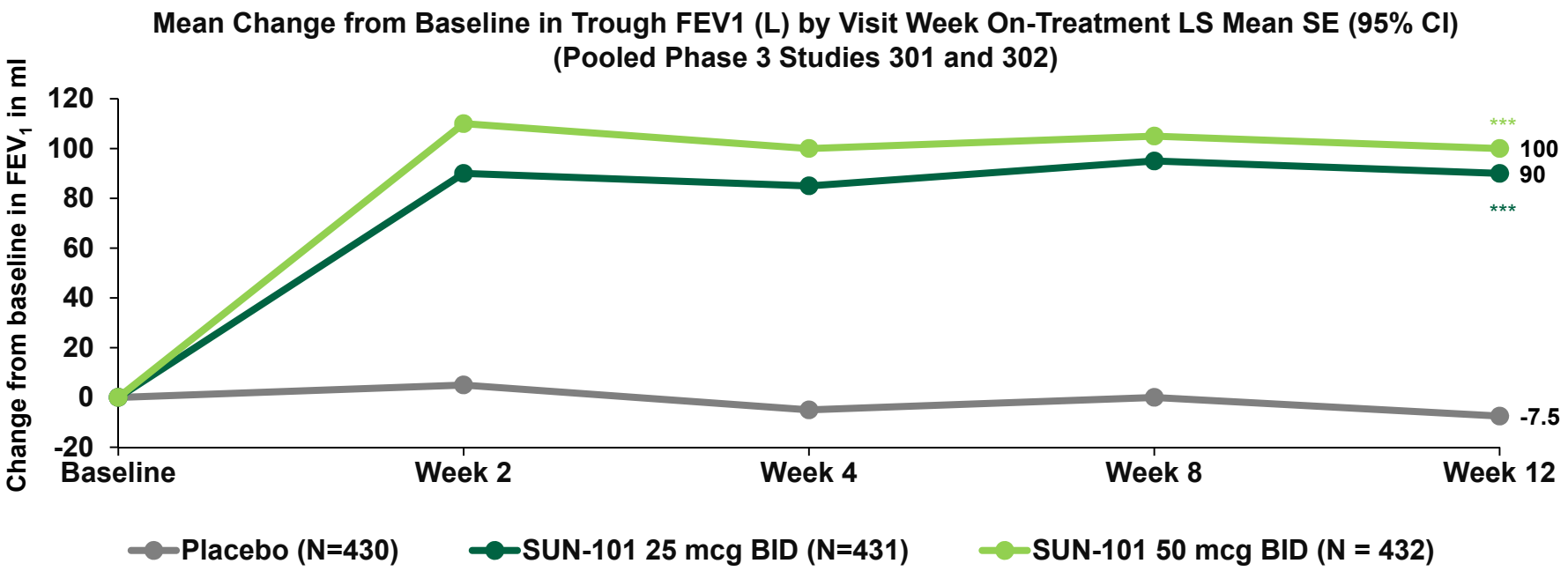
GOLDEN-3 and -4 Topline Data

Study Design (SUN101-301 and SUN101-302)

- Overview: Phase 3, 12-week, randomized, double-blind, placebo-controlled, parallel-group, multicenter
- Objective: Establish efficacy and safety by comparing SUN-101 twice daily dosing with placebo in adults with moderate-to-very severe COPD
- Enrolled patients: 1294 (GOLDEN-3 and GOLDEN-4 studies) of at least 40 years of age. Included patients with LABA background therapy (30%); and patients with cardiovascular risk factors (65%)
- Primary endpoint: Change from baseline in trough FEV_1 at the end of treatment (week 12)

Study Results

- Efficacy: Statistically significant and clinically important improvements in the primary endpoint in both 25 mcg BID and 50 mcg BID dose groups
- Safety: SUN-101 is safe and generally well tolerated



***P<0.0001.

Sunovion, Data on file

Upcoming Milestones

Pipeline Progress	FY2016	FY2017	FY2018
PSYCHIATRY FRANCHISE			
LATUDA pediatric bipolar depression sNDA expected submission		✓	
LATUDA pediatric bipolar depression sNDA expected PDUFA action date		✓	
Dasotraline ADHD NDA expected submission		✓	
Dasotraline ADHD NDA expected PDUFA action date			✓
Dasotraline ADHD expected launch			✓
Dasotraline BED NDA expected submission			✓
NEUROLOGY FRANCHISE			
APTIOM pediatric sNDA expected submission	✓		
APTIOM pediatric sNDA expected PDUFA action date		✓	
APL-130277 Ph 3 data		✓	
APL-130277 NDA expected submission		✓	
APL-130277 expected PDUFA action date			✓
APL-130277 expected launch			✓
TRERIEF (zonisamide) Parkinson's in Dementia with Lewy Bodies sNDA expected submission (Japan)		✓	
RESPIRATORY FRANCHISE			
Launch UTIBRON Neohaler		✓	
Launch SEEBRI Neohaler		✓	
Promote ARCAPTA Neohaler		✓	
SUN-101/eFlow PDUFA action date		✓	
SUN-101/eFlow expected launch		✓	

New Challenge in Oncology Area; Making Meaningful Medicines

David J. Bearss, Ph.D.
CEO, Tolero Pharmaceuticals, Inc.

Company Purpose

Tolero is committed to developing Meaningful Medicines to improve and extend the lives of patients with serious diseases

Experienced Management Team

Sumitomo Dainippon Pharma

Name/Title	Experience
David Bearss, PhD Chief Executive Officer	▪ Founder, CSO at Montigen Pharmaceuticals ▪ CSO at Supergen (Nasdaq: SUPG) ▪ Co-director of the Center for Investigational Therapeutics at the Huntsman Cancer Institute
Dallin Anderson, MBA President	▪ Founder, Chairman, CEO and President at Montigen Pharmaceuticals ▪ SVP of Business Development at Supergen (Nasdaq: SUPG) ▪ MBA, Harvard
David Sampson, CPA Chief Financial Officer	▪ Vice President of Finance and Principle Accounting Officer, Fusion-io, Inc. ▪ Vice President of Finance, Ancestry.com, Inc. ▪ Audit Senior Manager, Ernst & Young
Steve Weitman, MD, PhD Chief Medical Officer	▪ Physician and Director of the Institute for Drug Development, UTHSC-San Antonio ▪ CMO and SVP at Ilex Oncology ▪ Led team for FDA approval of Clofarabine
Michael McCullar, PhD, MBA Chief Operating Officer	▪ SVP of Business Development, Astex Pharmaceuticals (Acq. by Otsuka Pharmaceuticals) ▪ Vice President of Strategy and Development, SuperGen, led approval of Dacogen in US, acquisitions of Montigen Pharmaceuticals and Astex Therapeutics, LLC
Katsumi Tanaka, MBA Chief Strategy Officer	▪ Senior Officer, Business Development, Sumitomo Dainippon Pharma ▪ Led licensing collaborations with Intercept Pharmaceuticals, SanBio and Edison Pharmaceuticals at Sumitomo Dainippon Pharma
Steve Warner, PhD Vice President, Discovery & Development	▪ Translational Genomics Research Institute ▪ Manager, Discovery Biology at Supergen (Nasdaq: SUPG) ▪ Senior Manager, Drug Discovery at the Huntsman Cancer Institute
Michael Bernstein, MPH Vice President, Regulatory Affairs	▪ 11 years at the FDA as Project Manager, Administrative Assistant to the Division Director and Executive Secretary to the PCNS and PDAC ▪ Senior Director of Regulatory Affairs at Ilex Oncology ▪ Career to date includes over 20 INDs/CTXs and 9 NDAs/BLAs/MAAs submissions

Tolero Pipeline

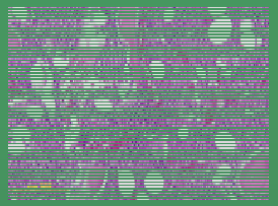
- Lead program, alvocidib, is a late-stage CDK9 inhibitor with a novel biomarker-based approach to hematological cancers
  - CDK9 regulates the transcription of proteins such as MCL1, which are involved with cancer
  - Significant clinical experience in over 400 patients
  - Potential to dramatically improve patient outcomes in AML
  - Additional opportunities in MDS and solid tumors

Program	Mechanism of action	Target indication	Pre-clinical	Phase 1	Phase 2	Phase 3
Alvocidib	CDK9 inhibitor	Biomarker-Defined R/R AML				
		Biomarker-Defined MDS				
		Frontline AML (Combination therapy with 7+3)				
TP-0903	Axl Kinase Inhibitor	TBD				
TP-1287	Oral CDK9 Inhibitor	TBD				
TP-0184	ALK2/BMPR Signaling Inhibitor	TBD				

CDK9: Cyclin-dependent kinase 9
MCL1: Myeloid Cell Leukemia 1
R/R: Relapsed or refractory
AML: Acute myeloid leukemia
MDS: Myelodysplastic syndromes

Tolero's Meaningful Medicine Approach

AML



- Rapidly progressive disease
- Heterogeneous with tumors harboring multiple different mutations
- No single driver mutation has been identified for the majority of patients
- Patients are older (typically >60 years) and are very sick, limiting the use of toxic therapies

TOLERO PHARMACEUTICALS
Sumitomo Dainippon Pharma Global Oncology

Meaningful Medicine

Alvocidib + NOXA Biomarker

R

- ACM
- CM

R: Randomize
ACM: alvocidib + cytarabine + mitoxantrone
CM: cytarabine + mitoxantrone

High Unmet Medical Needs in AML

- Current standard of care
  - Frontline treatment of AML (naive) : 7+3 regimen
  - Relapsed or refractory (R/R) AML : No standard regimen

naive AML

Non-elderly

About 7,000 in US

Systemic Therapy(Induction)	utilization
7+3 (cytarabine, daunorubicin)	36.9%
7+3 (cytarabine, idarubicin)	29.2%
5+2 (cytarabine, idarubicin)	6.5%
azacitidine	6.0%
5+2 (cytarabine, daunorubicin)	3.5%

CR rate : 54.7%

Elderly

About 10,000 pts in US

Systemic Therapy(Induction)	utilization
azacitidine	31.1%
decitabine	14.3%
7+3 (cytarabine, daunorubicin)	13.6%
7+3 (cytarabine, idarubicin)	9.4%
LoDAC	7.4%

CR rate : 30.3%

R/R AML

About 4,000 pts in US

Systemic Therapy(First relapse)	utilization
FLAG-ida	19.5%
HiDAC	13.6%
7+3 (cytarabine, daunorubicin)	12.8%
azacitidine	10.1%
MEC	9.0%

CR rate : 31.7% (first relapse)

About 5,000 pts in US

Systemic Therapy(First relapse)	utilization
azacitidine	25.8%
Investigational drug (clinical trial)	16.2%
decitabine	10.9%
LoDAC	8.2%
7+3+7 (cytarabine, daunorubicin, etoposide)	5.9%

CR rate : 21.1% (first relapse)

Source : CancerMPact (Synix Inc. / Kantar Health)

CR: Complete remission

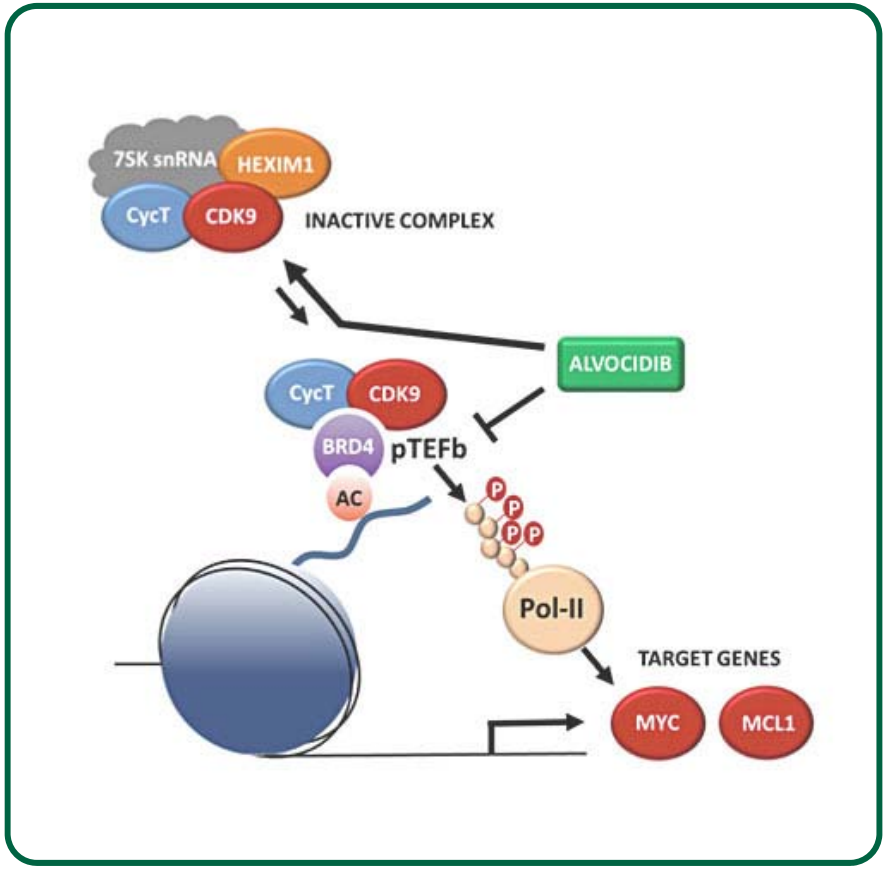
Alvocidib Can Be a Meaningful Medicine

- Potential to improve the rate of complete remissions in patients with AML
  - Consistent and promising activity in both frontline and relapsed or refractory AML
  - Significant clinical experience in over 400 patients with AML
- Biomarker enables identification of patients likely to respond to alvocidib
- Potent inhibitor of CDK9 which regulates the transcription of many important proteins such as MCL1, which are involved with cancer

Alvocidib Disrupts Super Enhancer Activity via CDK9 Inhibition

Sumitomo Dainippon Pharma

- Alvocidib is a potent inhibitor of CDK9
- Alvocidib downregulates transcription of super enhancer-regulated genes, such as c-Myc and MCL1
- MCL1 is an important survival factor in many forms of cancer including AML



Alvocidib in AML

- The complex nature of AML suggests combination therapy would be more effective than single agents

- Investigators at the National Cancer Institute (NCI) identified alvocidib as an encouraging novel agent to be used in combination AML therapy
  - Alvocidib targets key pathways involved with AML – differentiated from cytotoxic therapies
  - Synergistic when used in Timed Sequential Therapy (TST)

- Alvocidib has consistently shown encouraging activity in multiple AML studies as part of the regimen

ACM: alvocidib, cytarabine, mitoxantrone

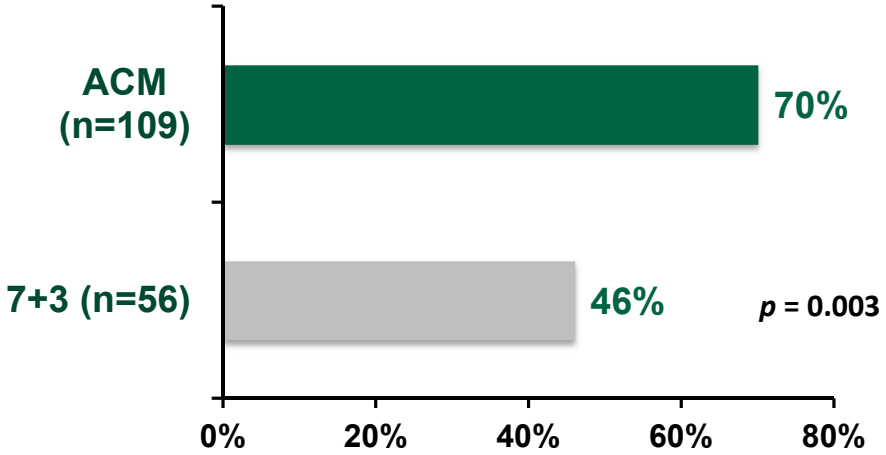
Phase 2 Study Results (Efficacy) (Conducted by NCI)

Sumitomo Dainippon Pharma

Positive randomized Phase 2 study in naive poor-risk AML patients

- Most patients had secondary AML or other poor-risk features
- ACM demonstrated a statistically significant improvement in CR rate Over 7+3 (standard of care)

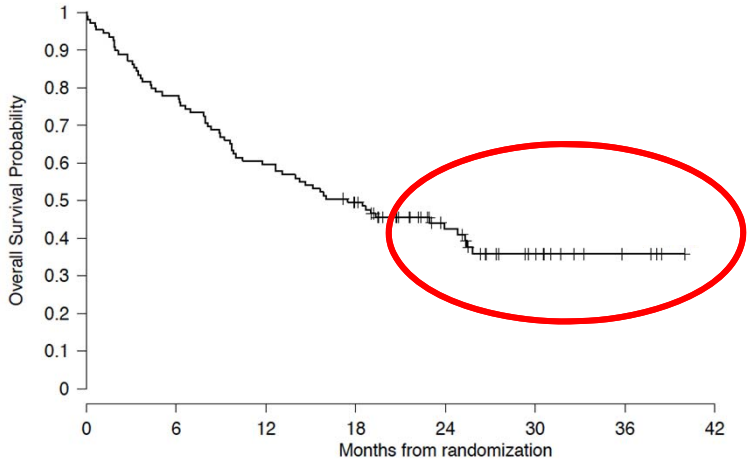
CR Rate: ACM vs. 7+3



ACM advantage was consistent across subgroups including adverse cytogenetics, FLT3, secondary AML

- Survival plateaued in a high proportion of ACM-treated patients

Survival of ACM-Treated Patients



Joshua F. Zeidner, et al. haematologica 2015; 100: 1172

Alvocidib

Phase 2 Study Results (Safety) (Conducted by NCI)

Sumitomo Dainippon Pharma

- ACM demonstrated similar tolerability as control therapy

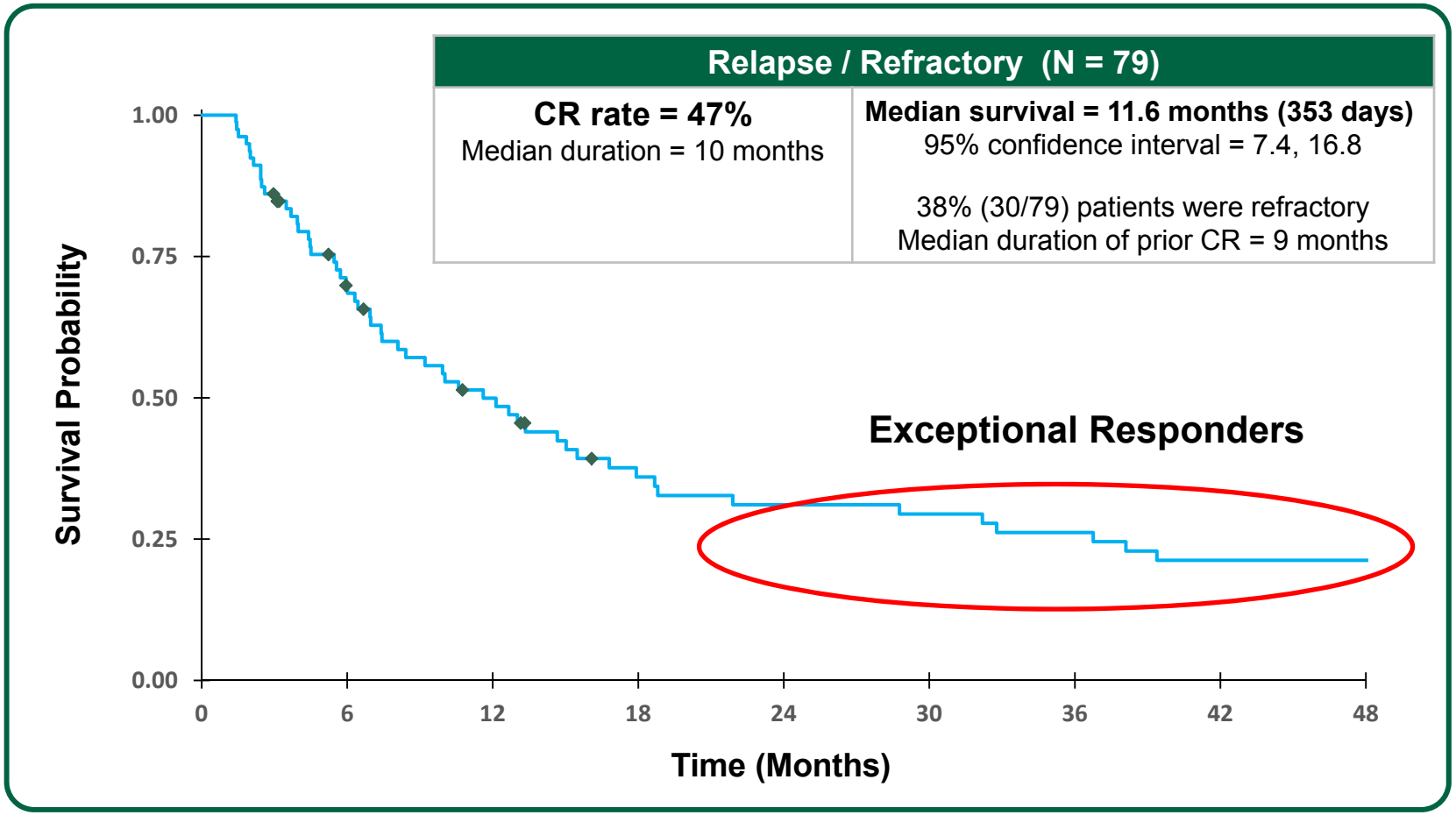
  - **naive poor-risk AML patients**

Grade ≧3 toxicity	ACM（n=109）	7+3（n=56）	p
Tumor lysis syndrome	9 (8%)	4 (7%)	>0.99
Myocardial dysfunction	8 (7%)	3 (5%)	0.75
GI toxicity	12 (11%)	5 (9%)	0.79
Hepatic dysfunction	23 (21%)	13 (23%)	0.84
Infection	38 (35%)	21 (38%)	0.74
Pulmonary toxicity	8 (7%)	4 (7%)	>0.99
Renal toxicity	3 (3%)	1 (2%)	>0.99
Thromboembolic events	3 (3%)	1 (2%)	>0.99
Febrile neutropenia events	52 (48%)	25 (45%)	0.74

Joshua F. Zeidner, et al. *haematologica 2015*; 100: 1172.

Phase 1 & 2 Study Results (Pooled Analysis)

Phase 1 & 2 R/R AML studies overall survival – pooled analysis



Tolero, Data on file

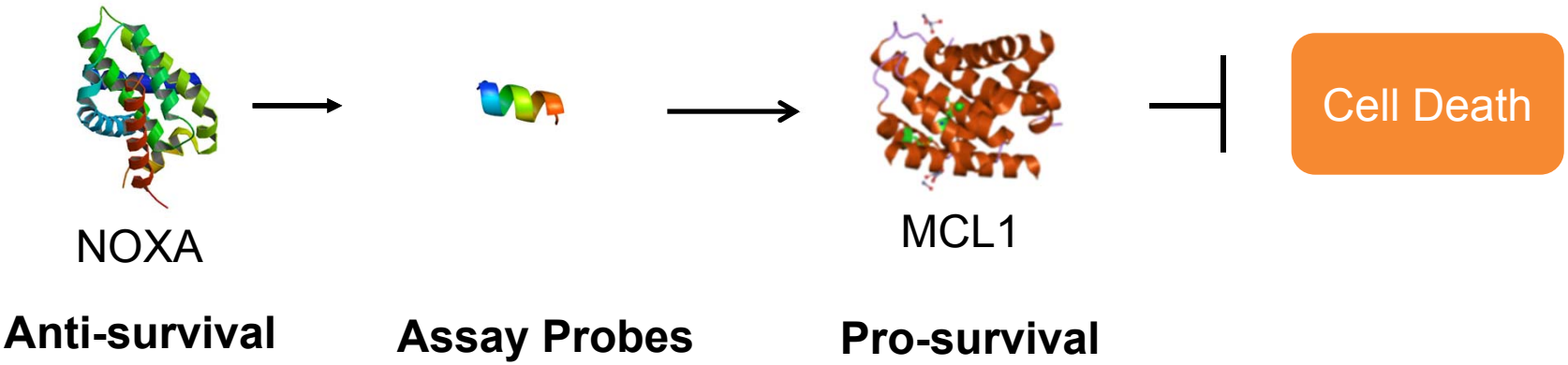
Alvocidib in MCL1-Dependent Malignancies

Sumitomo Dainippon Pharma

- Alvocidib's primary pharmacology is related to potent inhibition of CDK9
- CDK9 is a central signaling protein in the super enhancer complex
- By inhibiting CDK9, alvocidib can disrupt super enhancer-driven expression of MCL1
- The ability of alvocidib to prevent the expression of MCL1 may provide a novel approach to targeting MCL1-dependent malignancies

Functional Approach to Determine MCL1 Dependency

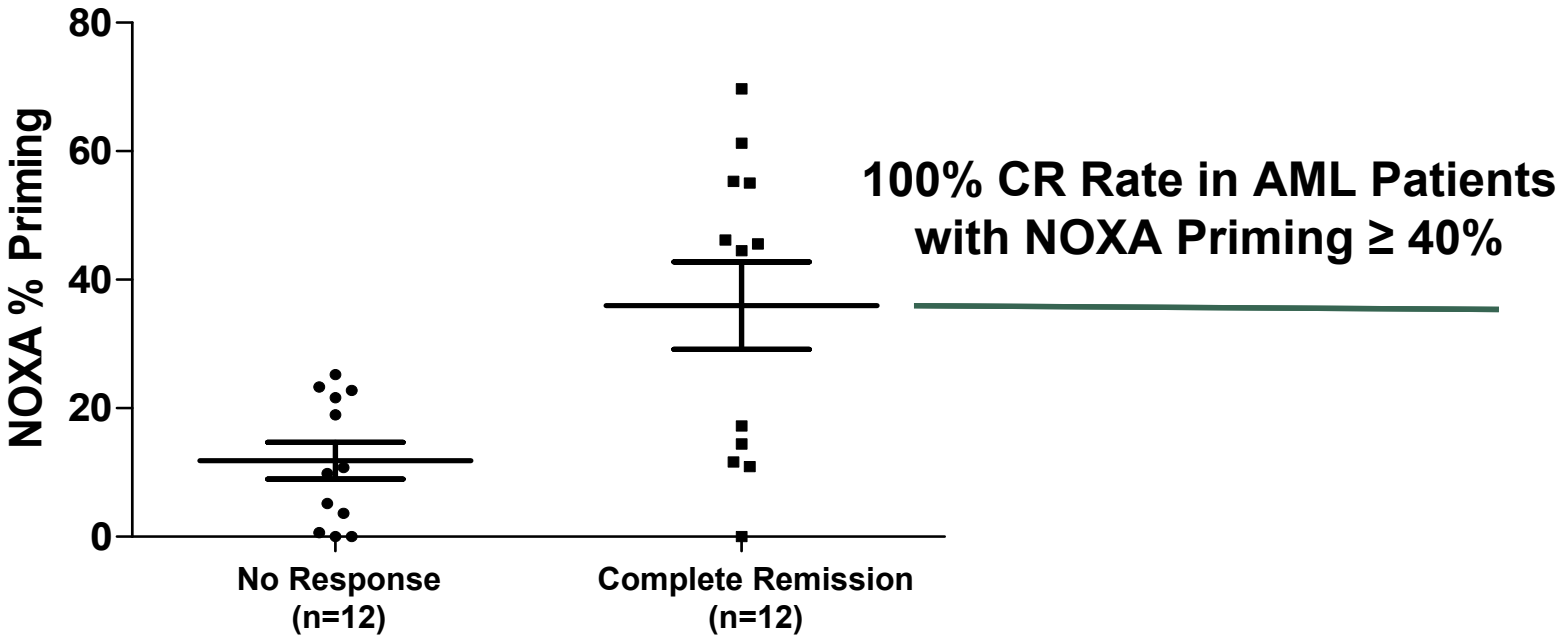
- MOA of alvocidib can be leveraged into an assay platform to identify sensitive patients
- MCL1 is a key survival signal well documented in AML
- NOXA is anti-survival protein inhibiting MCL1
- NOXA priming is a functional measurement of MCL1 dependence in AML



Results from NOXA Priming Validation Set

Sumitomo Dainippon Pharma

High NOXA priming is predictive of alvocidib sensitivity in AML patients



NOXA priming in CR and NR (No Response) pre-treatment bone marrow samples from AML patients treated with the ACM regimen

NOXA priming did not predict response in patients treated with 7+3

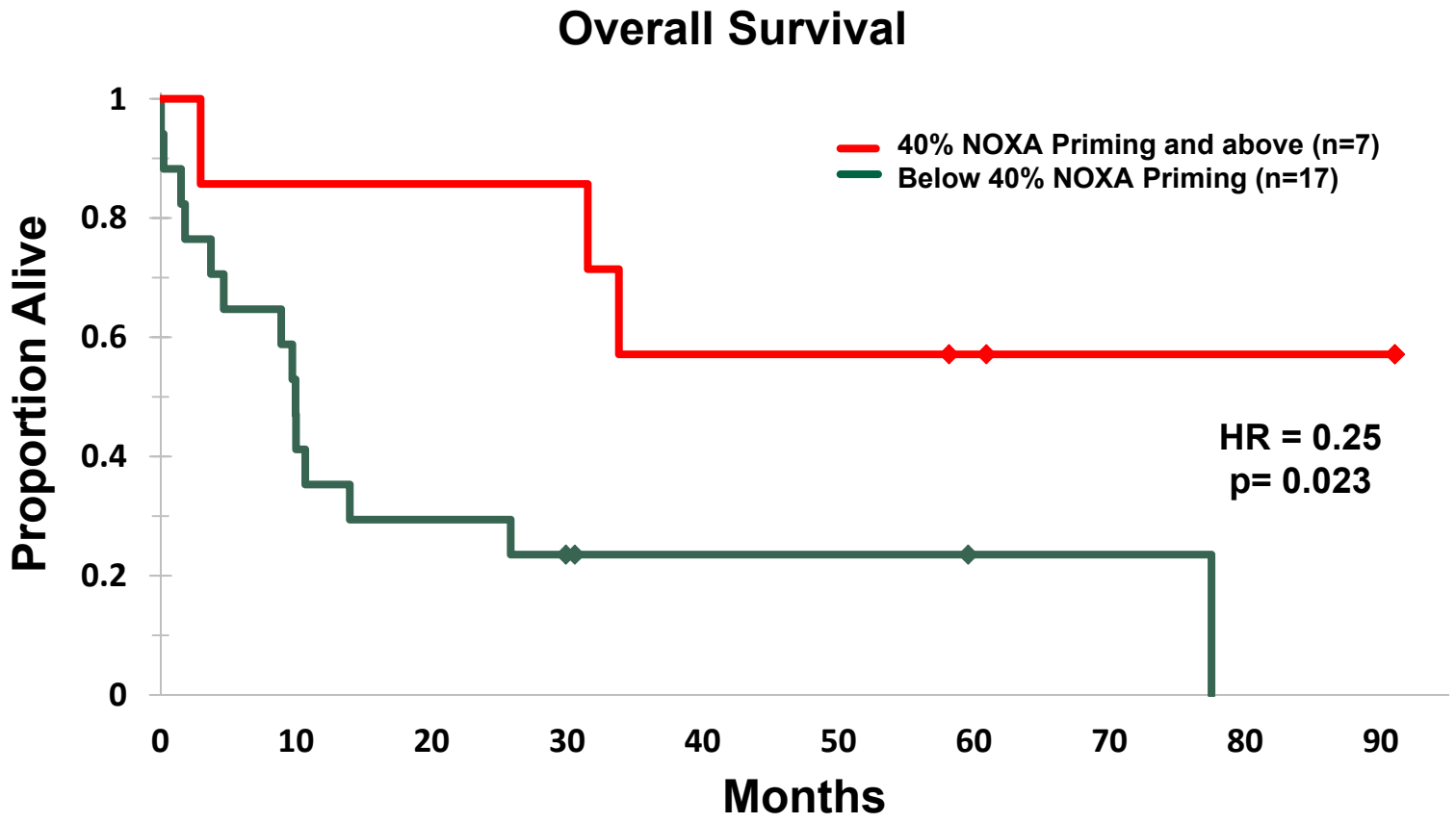
25% of AML patients are positive for the biomarker

E.J. Dettman, et al. AACR 2015 (Abstract 3400)

Overall Survival in ACM-Treated AML Patients

Sumitomo Dainippon Pharma

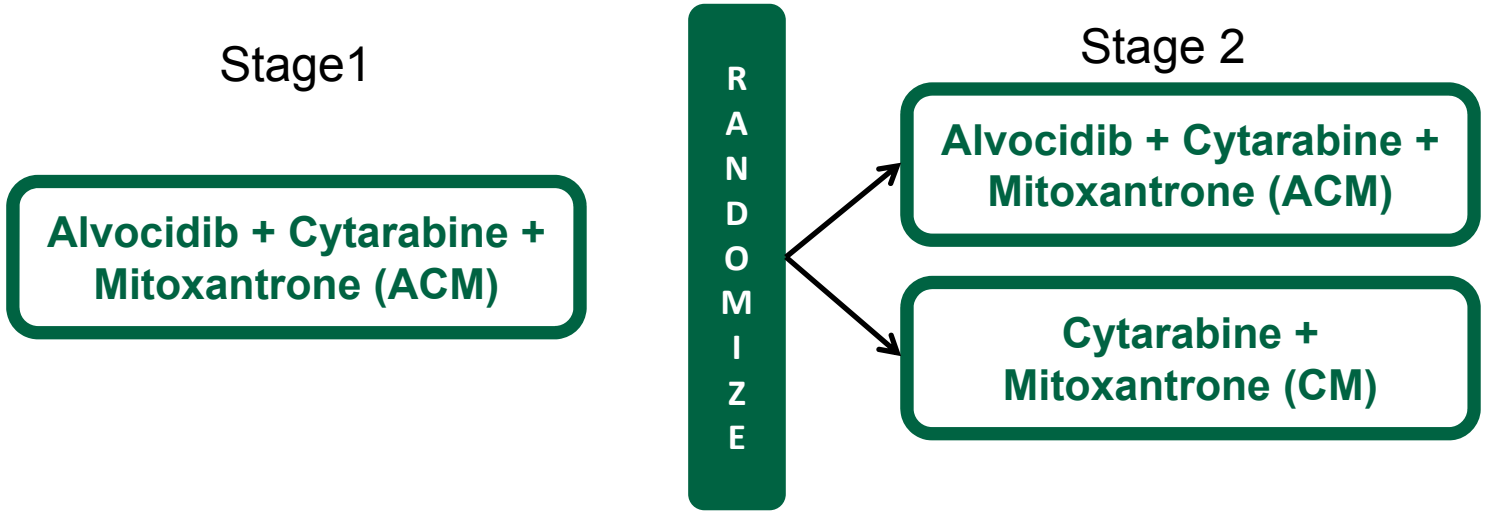
ACM-treated AML patients with NOXA priming greater than 40% demonstrated greater survival



E.J. Dettman, et al. AACR 2015 (Abstract 3400)

Phase 2 Study Design (Biomarker)

- **Biomarker-driven Phase 2 AML Study:**
  - Two-stage Phase 2 study; Open-label, randomized study to asses the clinical response to ACM compared to AM treatment in relapsed or refractory AML patients (18-65 years) with MCL1 positive patients
    * MCL1 positive patients: Method of measuring using biomarker (NOXA priming)
  - Primary endpoint: Complete remission rate
  - Secondary endpoint: Overall survival rate, etc.
  - Study Start Date : December 2015



ClinicalTrials.gov, NCT02520011

Alvocidib

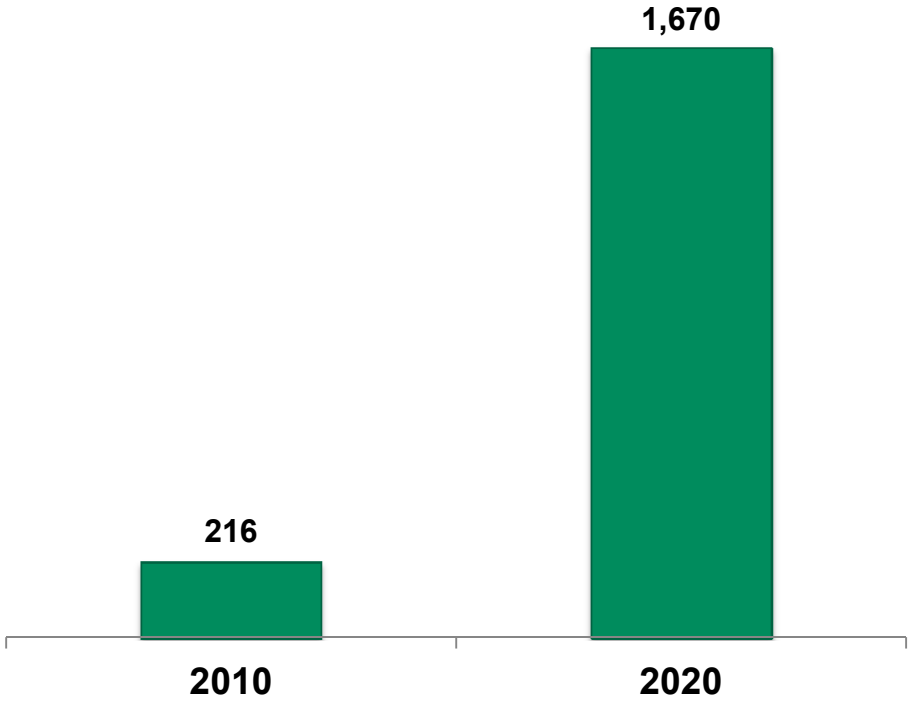
Positive FDA Guidance

- FDA agreed that a single, randomized trial in patients with relapse or refractory AML, with CR rate as the primary endpoint, would support NDA
  - Statistical significance on CR rate will support accelerated approval
  - Tolero expects to have data from the biomarker-driven Phase 2 study which would support an NDA filing in FY2018
    - Tolero plans to consult this strategy with the FDA based on stage 1 data of Phase 2
- Tolero will perform a confirmatory study with OS as the primary endpoint
  - Confirmatory study may be done in a different patient population such as frontline AML
  - Tolero expects to have the confirmatory study underway in 2018
- Analysis of OS will include patients who have received a stem cell transplant, censoring only those patients alive at the time of the final analysis
  - Primary analysis of OS regardless of transplant, with a sensitivity analysis censored for transplant. This approach is advantageous, as it will favor treatments that attain a high CR rate

AML Market Positioned for Rapid Growth

- AML therapies have remained unchanged for decades
- As evidenced in other liquid tumors, therapies offering new mechanisms should experience rapid adoption
- Frontline AML and relapsed or refractory AML addresses 75,000 patients in the major markets

AML Market to Experience Rapid Growth (Revenue, $M, G8 Countries)



Source: *the*pharmaletter, 20-12-2011

TP-0903

Tolero Pipeline

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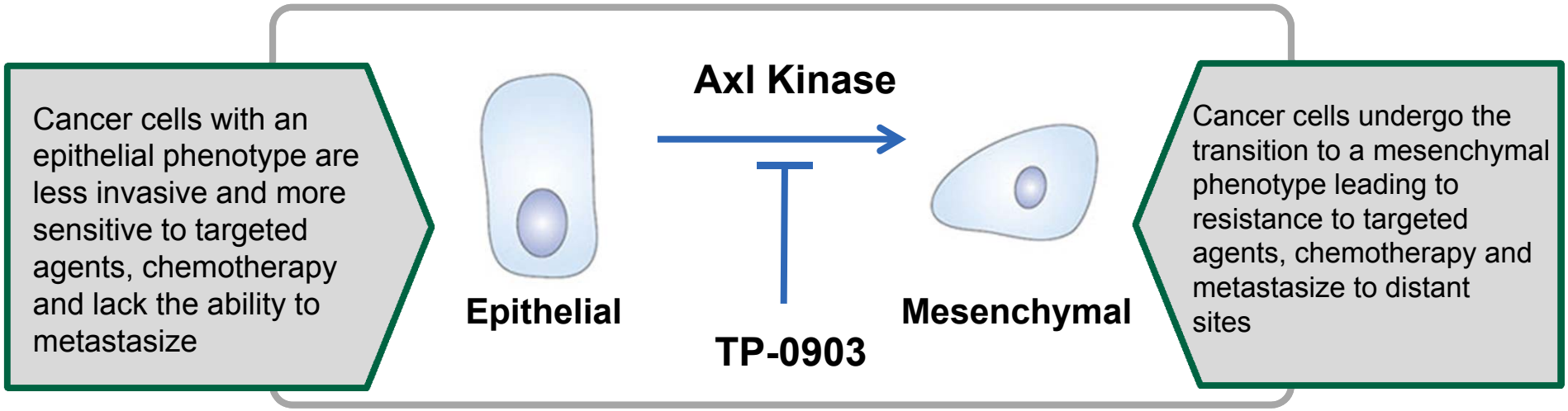
Program	Mechanism of action	Target indication	Pre-clinical	Phase 1	Phase 2	Phase 3
Alvocidib	CDK9 inhibitor	Biomarker-Defined R/R AML				
		Biomarker-Defined MDS				
		Frontline AML (Combination therapy with 7+3)				
TP-0903	Axl Kinase Inhibitor	TBD				
TP-1287	Oral CDK9 Inhibitor	TBD				
TP-0184	ALK2/BMPR Signaling Inhibitor	TBD				

TP-0903: Axl Kinase Inhibitor

TP-0903 blocks the mesenchymal phenotype in cancer cells



Hallmarks of a Mesenchymal Phenotype

Drug Resistance	Escape From Immune Surveillance	Resist Endogenous Differentiation Signals

TP-0903: Program Summary

- Phase 1 study enrolling
- TP-0903 is a first in class inhibitor of AXL
- Inhibition of AXL targets several key cancer pathways through inhibition of the mesenchymal phenotype
  - Restores sensitivity to targeted therapies
  - Synergistic with PD-L1 inhibition
- Favorable drug-like properties and pharmaceutical profile
- Multiple tumor types to explore for development in major indications

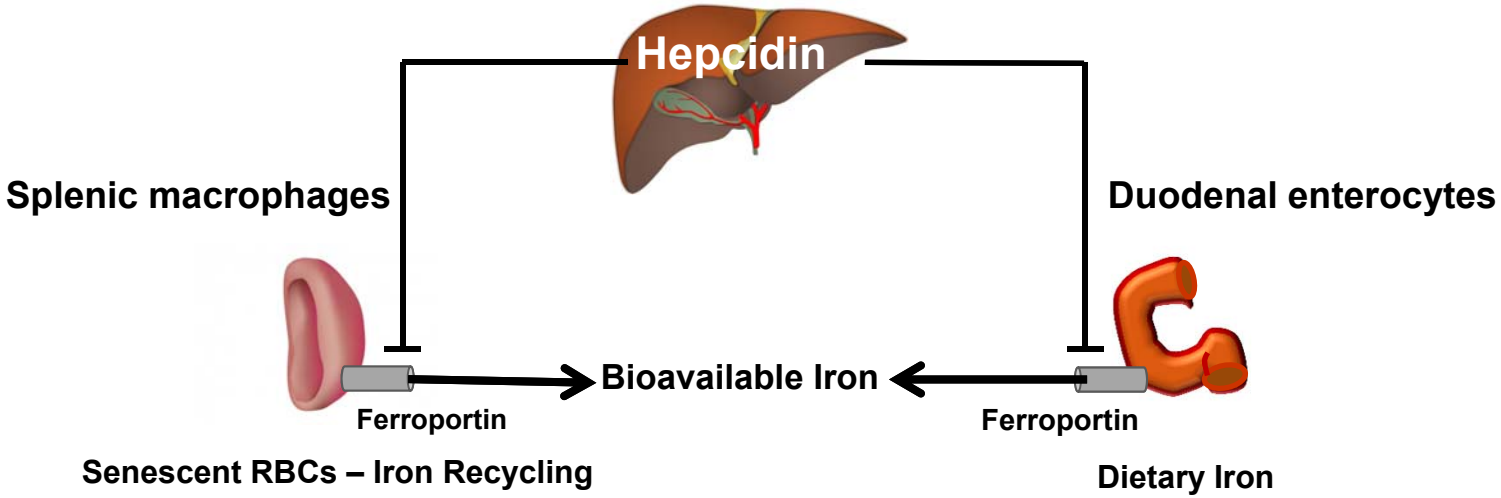
TP-0184

Tolero Pipeline

Sumitomo Dainippon Pharma

Program	Mechanism of action	Target indication	Pre-clinical	Phase 1	Phase 2	Phase 3
Alvocidib	CDK9 inhibitor	Biomarker-Defined R/R AML				
		Biomarker-Defined MDS				
		Frontline AML (Combination therapy with 7+3)				
TP-0903	Axl Kinase Inhibitor	TBD				
TP-1287	Oral CDK9 Inhibitor	TBD				
TP-0184	ALK2/BMPR Signaling Inhibitor	TBD				

Hepcidin – A Master Regulator of Iron Levels in the Blood



- Hepcidin is a peptide liver hormone that binds to the iron export pump, ferroportin, and sequesters iron making it unavailable to support erythropoiesis
- Hepcidin becomes up regulated during inflammation resulting in functional iron deficiency
- Hepcidin-lowering agents represent a novel approach to treating anemia of chronic disease

TP-0184: ALK2/BMPR Signaling Inhibitor

Sumitomo Dainippon Pharma

- TP-0184 demonstrates anti-anemia in vivo activity
  - Downregulates circulating hepcidin levels
  - Increases serum iron in inflammatory models
  - Improves hemoglobin levels in models of anemia
  - Concentrates in the liver, its target site of action
- Multiple pathways of development
  - Cancer – supportive care
  - Anemia of chronic disease/inflammation
- Expected Differentiation:
  ALK2/BMPR targeting activity allows for an anti-anemia through oral delivery of a small molecule
- Selected as a lead candidate to enter IND track
- Good pharmaceutical properties and wide therapeutic window

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Innovation today, healthier tomorrows