



SPARC/Sec/SE/2022-23/060

October 13, 2022

National Stock Exchange of India Ltd.,
Exchange Plaza, 5th Floor,
Plot No. C/1, G Block,
Bandra Kurla Complex,
Bandra (East), Mumbai – 400 051.

BSE Limited,
Market Operations Dept.
P. J. Towers,
Dalal Street,
Mumbai - 400 001.

Ref: Scrip Code: NSE: SPARC; BSE: 532872

Dear Sir/Madam,

Sub: Investor Presentation: Update on Clinical Programs and R&D Pipeline

Pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 and further to our letter dated September 29, 2022 bearing reference no. SPARC/Sec/SE/2022-23/056, we enclose herewith a copy of the Investor Presentation on the above mentioned subject, which is self-explanatory.

This is for your information and dissemination.

Yours faithfully,

For **Sun Pharma Advanced Research Company Ltd.**

Dinesh Lahoti
Company Secretary and Compliance Officer
ICSI Membership No. A22471

Encl: As above

The title is centered within a large, abstract graphic. It consists of a large orange circle with a pattern of fine, curved lines radiating from its center. This circle overlaps with a smaller, solid yellow circle positioned to its right and slightly below. The background is white with faint, light gray wavy lines and a pattern of small, light orange dots at the bottom.

Update on Clinical Programs and R&D Pipeline

13th October 2022

BSE:532872
NSE: SPARC
BLOOMBERG: SPADV@IN
REUTERS: SPRC.BO
CIN:L73100GJ2006PLC047837

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Agenda

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Anil Raghavan

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Nitin Damle

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Vikram Ramanathan

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Financial Update

Chetan Rajpara

Built a robust R&D organization

Innovating from India for the world, SPARC offers operating model validation

Successful track record of development and commercialization



2

USFDA approved drugs (Xelpros™, Elepsia™)



2

NDA submitted to USFDA in FY23



1

NDA targeted for submission in H2 FY23

Clinical pipeline targeting high-value opportunities



3

NCEs targeting 6 clinical indications in development



USD 20Bn+

Combined peak sales potential for NCEs currently under clinical development

Through an innovation-focused R&D platform



10+

Preclinical programs in R&D pipeline covering 3 therapy areas



2

IND filings targeted by FY24

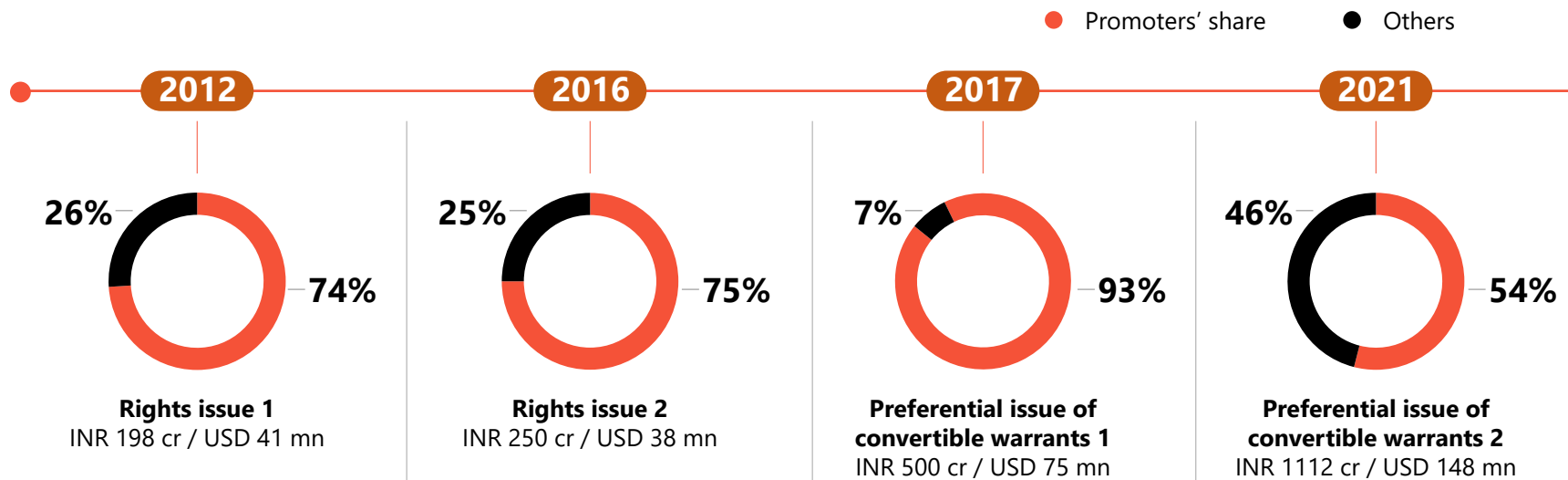


11

Partnerships with academic centers and commercial entities¹

Attractive portfolio built using a cost-efficient structure

Over 50% funded through non-dilutive revenue generated



USD 523 mn

Total investment till FY22

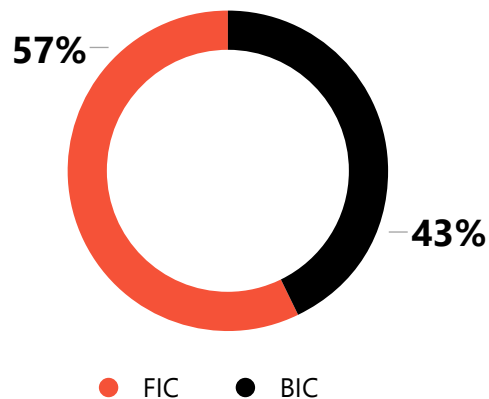
USD 277 mn

Revenues re-invested till FY22

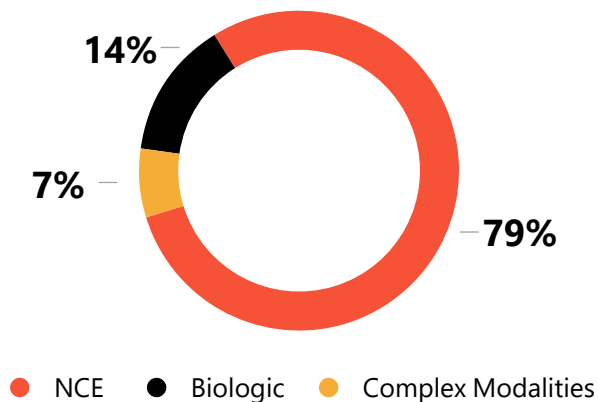
Our strategy to address unmet clinical need has transformed

With a focus on novel biology as opposed to fast follower approach

Asset Distribution by Class



Asset Distribution by type



- Increasing proportion of programs focusing on novel biology (potential first-in-class)
- Investments in new modalities/complex platforms is now translating to tangible programs
- Continued development of best-in-class assets for validated targets
- Collaboration with external innovators as a key tenet of strategy to access early science

First-in-class innovation in three therapy areas

With 70% of the preclinical pipeline targeting novel hypotheses

Areas of interest



Neurology

- Restoring cellular function in the CNS to modify disease-course by:
 - Modulating oxidative stress response
 - Improving autophagic flux
 - Preventing misfolded protein aggregation



Oncology

- Modality-agnostic, tumor-targeted strategies to address indications that have limited treatment options



Immunology

- Pursuing novel targets in immune cells and inflamed tissues to modulate inflammatory conditions

Lead FIC Program

SCC-138

- Internally developed NCE - vodobatinib
- Selective c-ABL inhibitor with good brain penetration and superior safety for Parkinson's Disease (PD)
- Currently in a Phase 2 clinical study

SBO-154

- In-licensed anti-MUC-1 antibodies from Biomodifying LLC
- Developed antibody-drug conjugate asset for solid tumors
- Currently in IND-enabling preclinical development

SCD-153

- Collaboration with Johns Hopkins University
- NCE targeting a novel pathway to address alopecia areata
- Currently in IND-enabling preclinical development

Expected cash inflow from warrants conversion

Cash runway till FY24, with potential extension from milestones and royalties



Cash inflow from warrants conversion by Dec'22

USD 93 mn

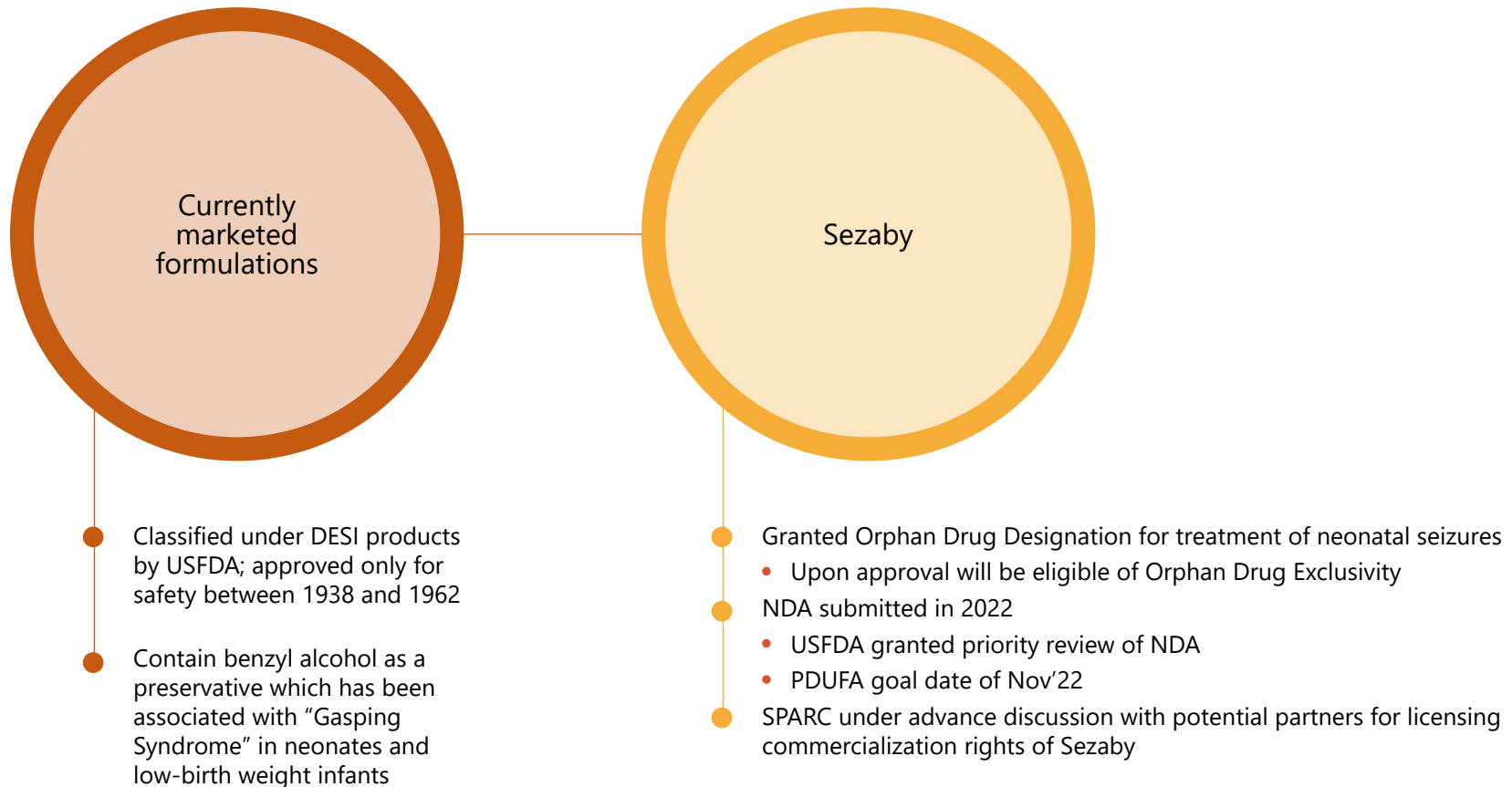
Expected cash burn

USD 30 mn USD 30 mn USD 30 mn

Cash runway excluding milestones and royalties

USD 93 mn

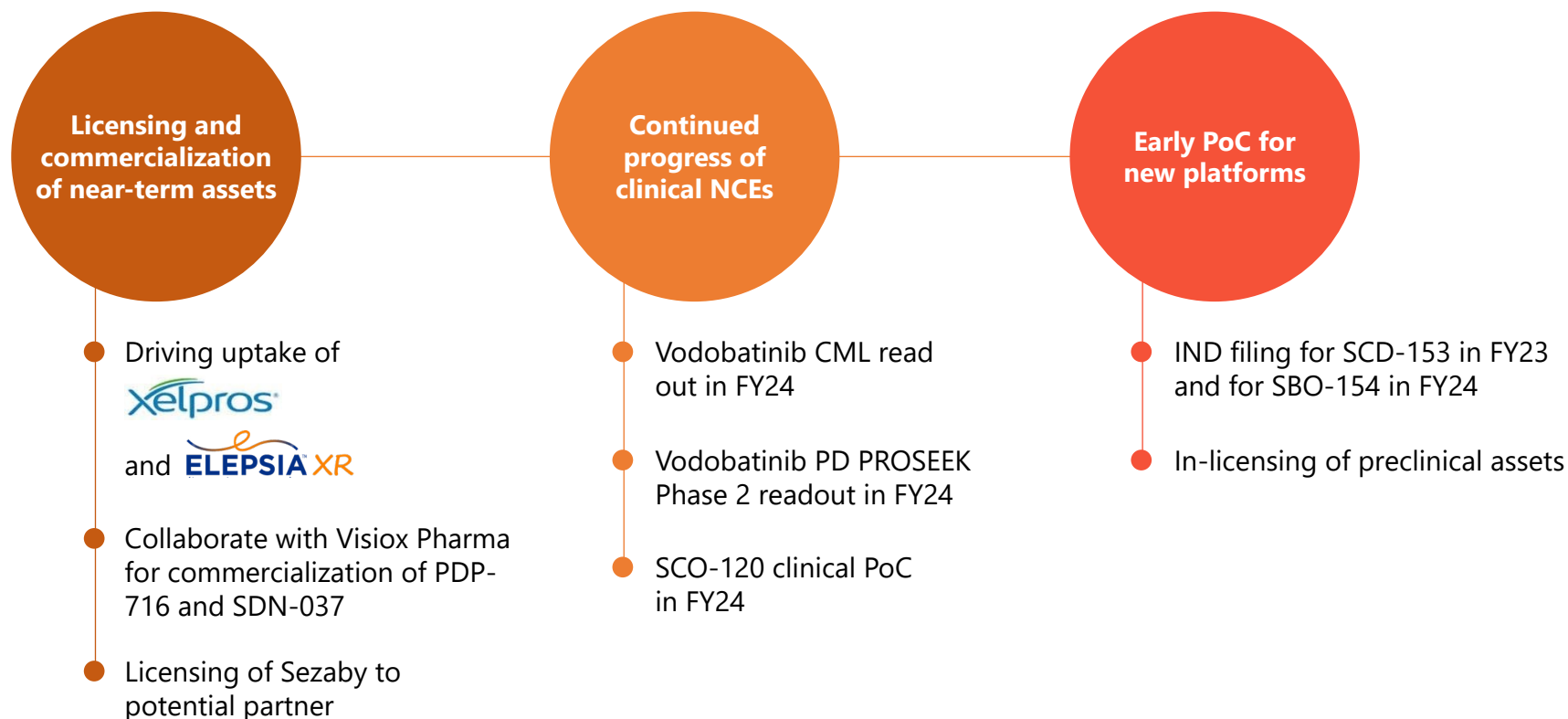
Sezaby*: benzyl alcohol-free phenobarbital injection for neonatal seizures



Sezaby as a trade name is conditionally accepted by the USFDA

Several high-yield assets graduating to next set of data events in the short term

Sharp execution focus to deliver key updates in the next 18-24 months



Pipeline overview & key upcoming milestones



Asset / Program	MoA	Indication	Discovery	Preclinical	Phase 1	Phase 2	Phase 3/ Registration Study	Upcoming Catalyst	Partner
Vodobatinib (SCC-138)	c-ABL Inhibitor	Parkinson's Disease						PoC data from PROSEK study in FY24	
		Lewy Body Dementia ¹						PoC data in FY24	
		Alzheimer's Disease							
Vodobatinib (SCO-088)	BCR-ABL Inhibitor	Refractory CML						Pivotal data in FY24	
SCO-120	Selective ER α Receptor Degradar	Metastatic Breast Cancer						Phase 1 data in FY24	
SB0-154	Anti-MUC-1 ADC	Multiple Tumors						IND filing targeted in FY24	
Vibozilimod (SCD-044)	Selective S1PR1 agonist	Psoriasis							
		Atopic Dermatitis							
SCD-153	Undisclosed	Alopecia Areata						IND filing targeted in FY23	

Preclinical Assets 10+ preclinical assets under development to ensure a robust pipeline for future growth

Neurology **Oncology** **Immunology**

Clinical Programs

Siu-Long Yao

**Vodobatinib in CML
(SCO-088)**

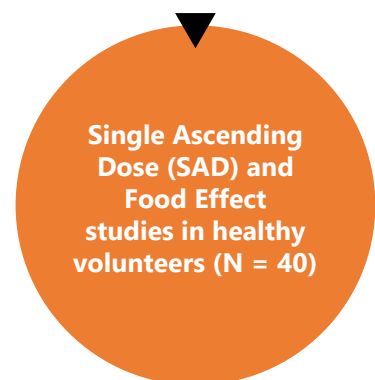
**A safer, last-line
option for heavily
pre-treated patients**

Vodobatinib for CML (SCO-088)

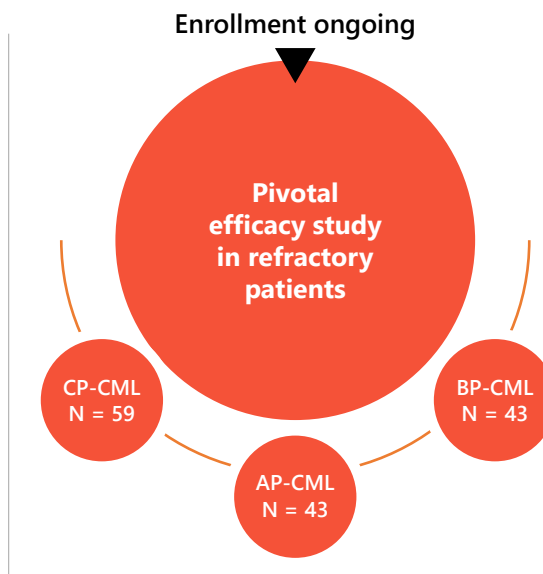
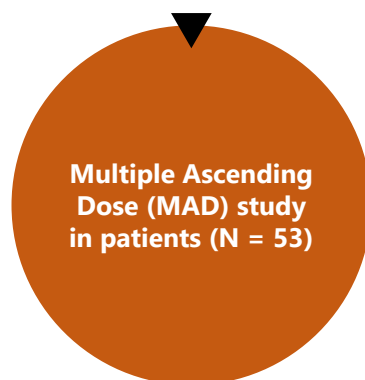
Potent and selective inhibitor of BCR-ABL1

Clinical study design

Healthy volunteer study



Patient studies



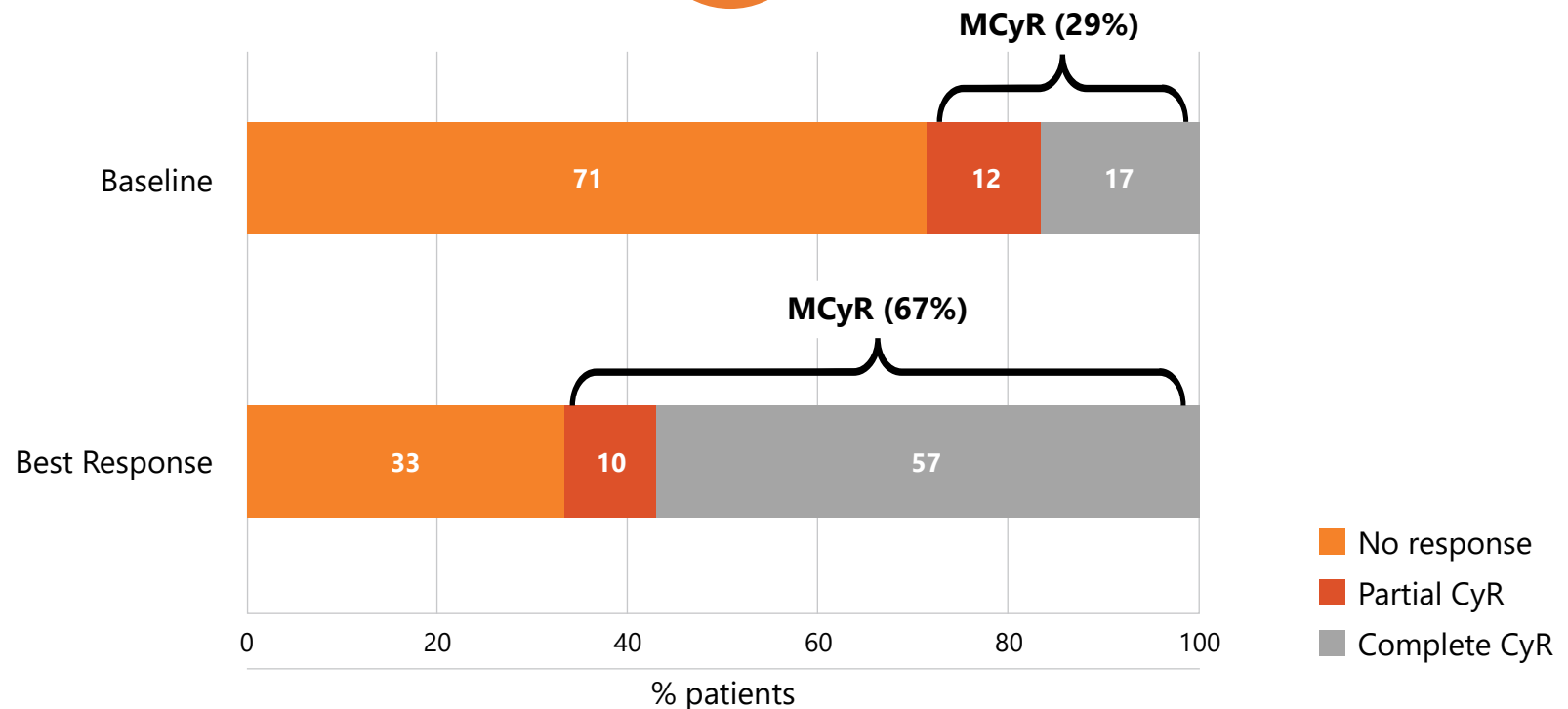
- Single arm study, Ph+ CML patients refractory and/or intolerant to ≥ 3 TKIs including ponatinib
- Participating countries: USA, Belgium, France, Italy, Spain, Romania, Hungary, Singapore, UK, Korea

Vodobatinib (SCO-088) MAD study outcome

Major Cytogenetic Response (MCyR) rate more than doubles in CP-CML patients treated with vodobatinib

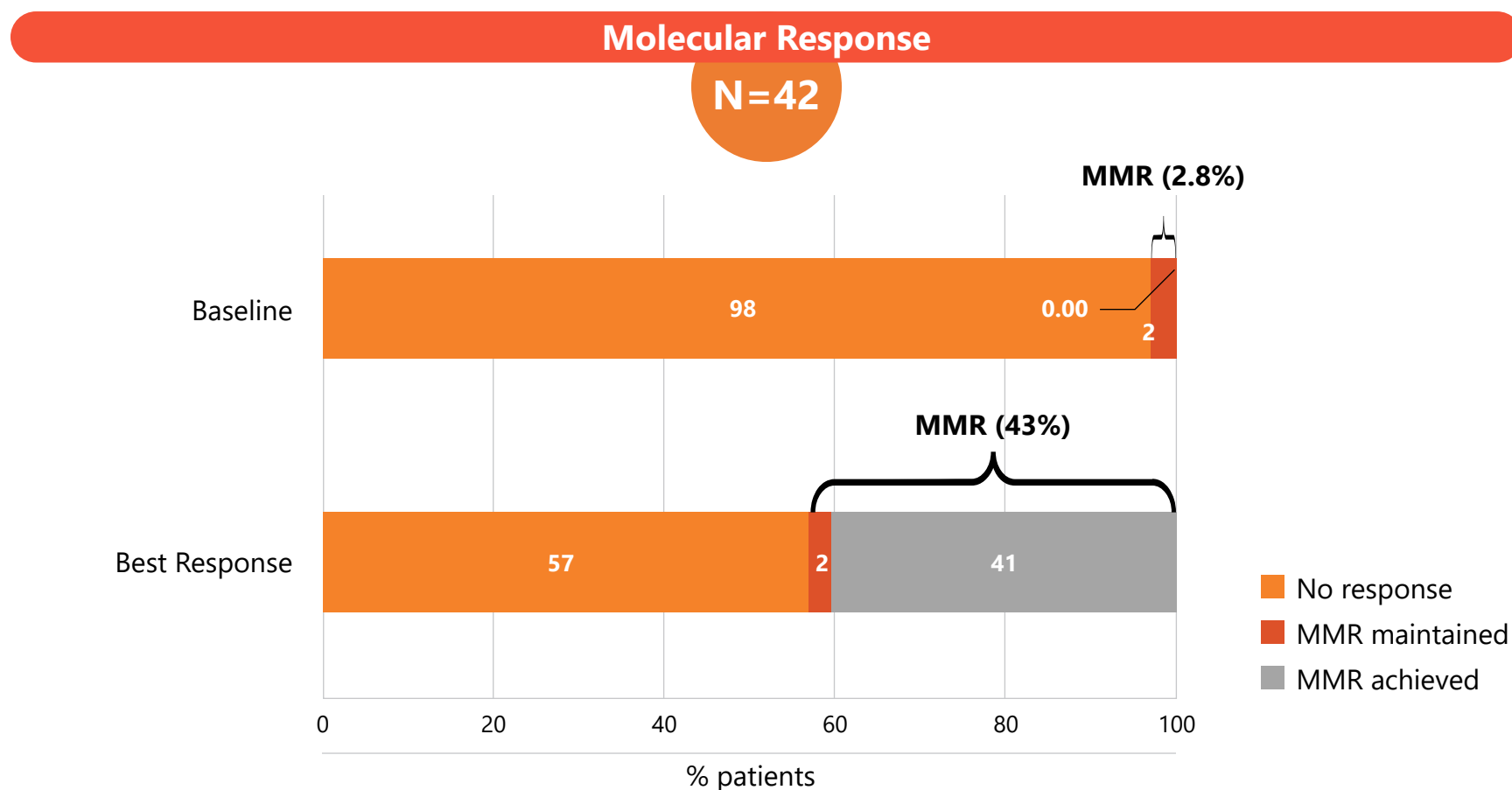
Cytogenetic Response

N=42



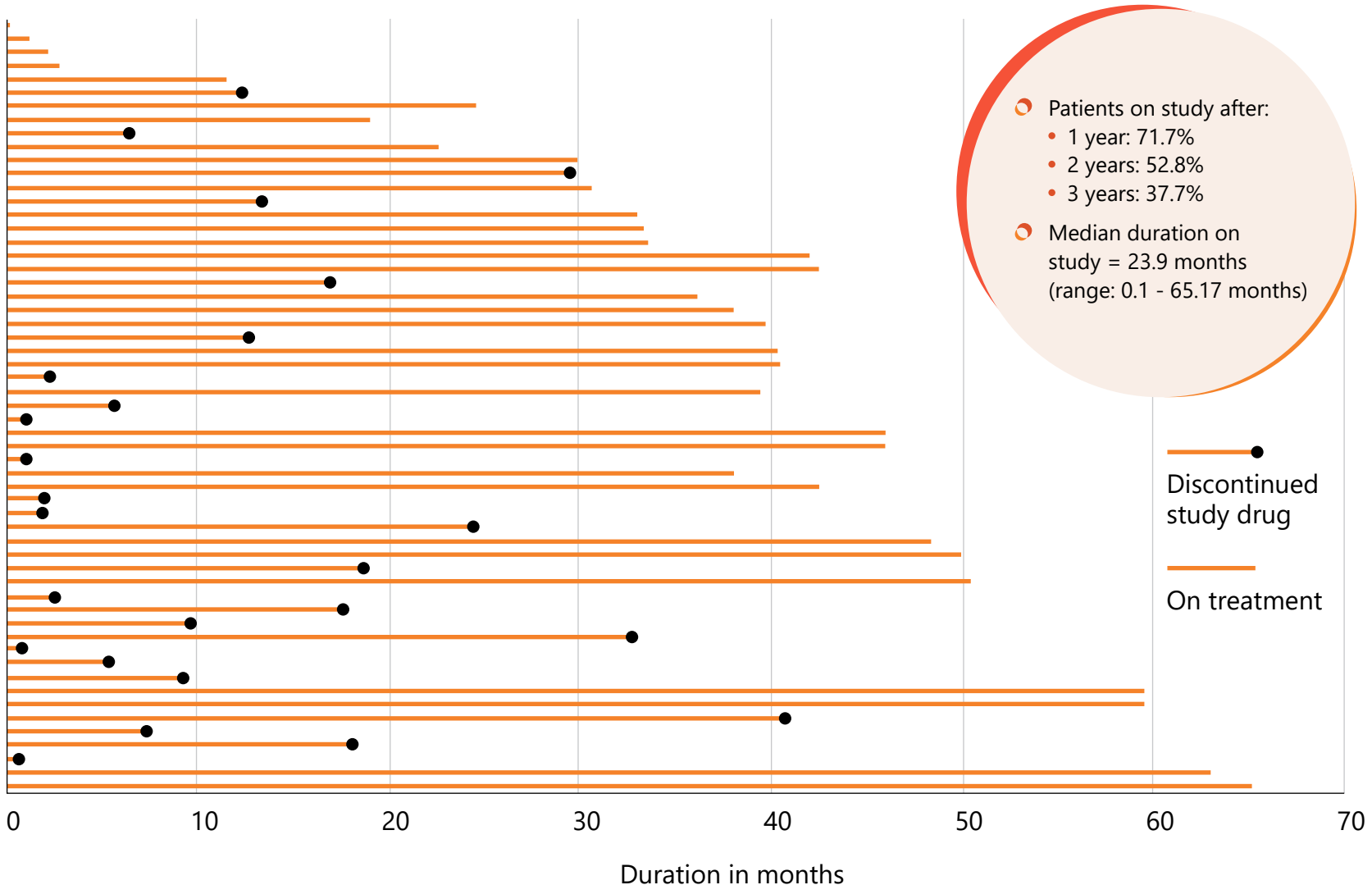
Vodobatinib (SCO-088) MAD study outcome

Twenty-fold improvement in Major Molecular Response (MMR) rate in CP-CML patients treated with vodobatinib



Vodobatinib (SCO-088) MAD study outcome

Excellent efficacy and safety



Next steps

Additional data to be presented at upcoming clinical conferences: the 2022 ESH John Goldman Conference and the 2022 ASH Annual Meeting

Pivotal study readout in FY24

**Vodobatinib for
Neurodegenerative
diseases
(SCC-138)**

**A potential first-
in-class disease
modifying therapy
targeting c-Abl**

c-Abl: a critical component of neurodegeneration

Substantiated by multiple research groups

- Ubiquitous expression in nucleated cells
 - Expressed in all parts of the CNS (brain and spinal column, and peripheral neuronal tissue)

- Pivotal role in promoting neurodegeneration
 - Under oxidative stress, c-Abl is activated and phosphorylates a number of key substrates that bring about programmed death of oxidatively-stressed neurons

c-Abl and Parkinson's Disease: Mechanisms and Therapeutic Potential

Saurav Brahmachari^{a,b,f,1}, Senthilkumar S. Karuppagounder^{a,b,f,1}, Preston Ge^{a,b,f,1}, Saebom Lee^{a,b}, Valina L. Dawson^{a,b,c,d,f,*}, Ted M. Dawson^{a,b,d,e,f,*} and Han Seok Ko^{a,d,g,*}

Activation of tyrosine kinase c-Abl contributes to α -synuclein-induced neurodegeneration

Saurav Brahmachari, ... , Ted M. Dawson, Han Seok Ko

c-Abl Inhibitors Enable Insights into the Pathophysiology and Neuroprotection in Parkinson's Disease

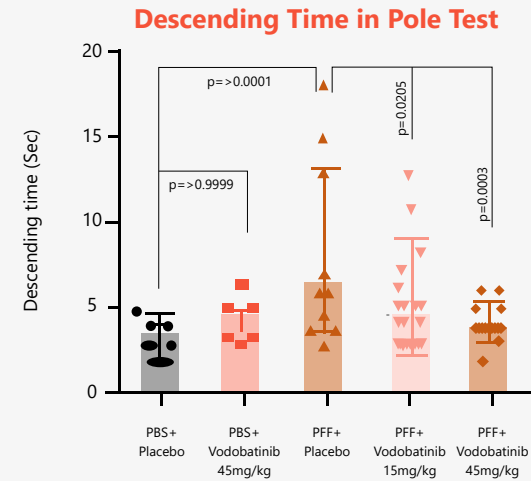
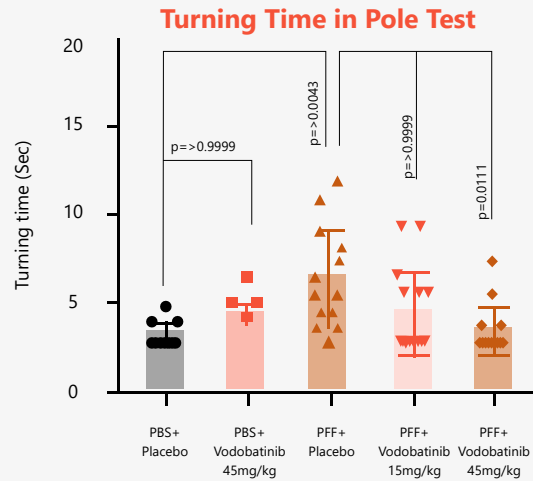
Dan Lindholm^{1,2*}, Dan D. Pham^{1,2}, Annunziata Cascone¹, Ove Eriksson¹, Krister Wennerberg³ and Mart Saarma⁴

c-Abl phosphorylates α -synuclein and regulates its degradation: implication for α -synuclein clearance and contribution to the pathogenesis of Parkinson's disease

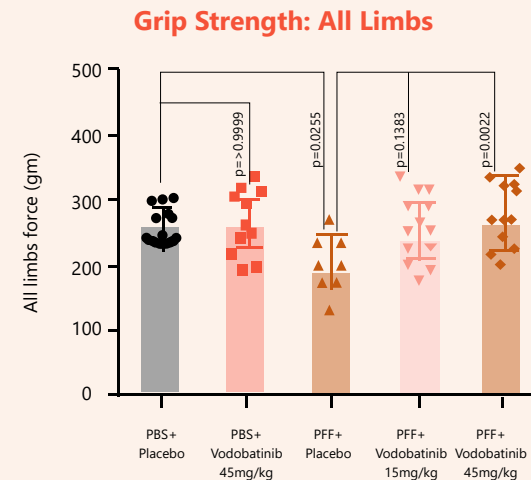
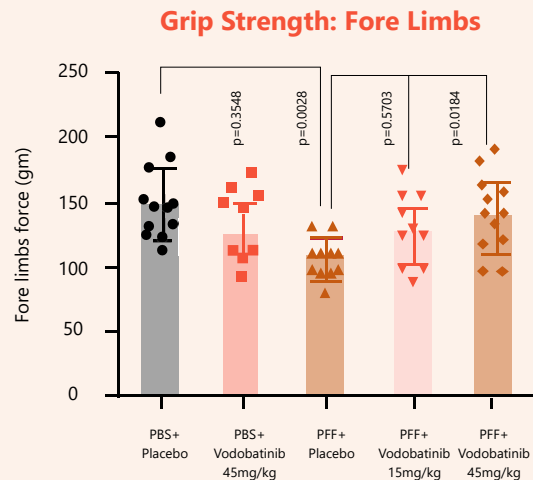
Anne-Laure Mahul-Mellier¹, Bruno Fauvet¹, Amanda Gysbers², Igor Dikiy⁴, Abid Oueslati¹, Sandrine Georgeon², Allan J. Lamontanara², Alejandro Bisquertt⁵, David Ellezer¹, Eliezer Masliah⁵, Glenda Halliday³, Oliver Hantsche² and Hilal A. Lashuel^{1,*}

Vodobatinib improved motor and cognitive function in the PFF-induced mouse model¹

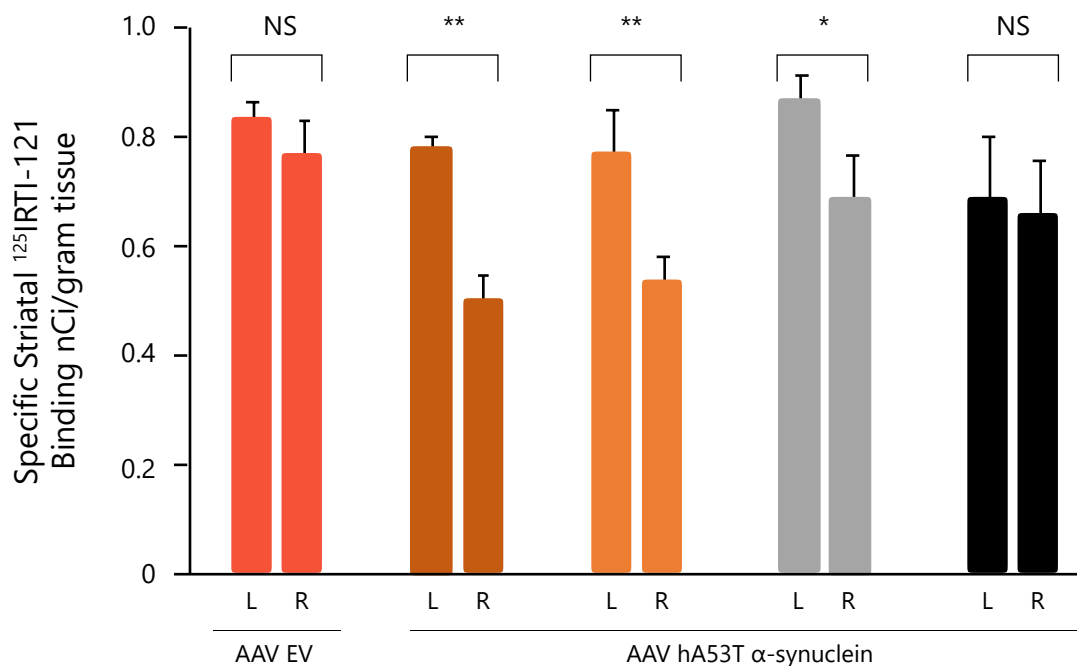
Vodobatinib at 45 mg/kg improves PFF-induced movement disorder-related deficits in Turning Time and Descending Time in the Pole test



Vodobatinib treatment improves PFF-induced deficits in Grip Strength



Vodobatinib protects dopaminergic neurons in the AAV mutant α -synuclein (hA53T) rat model – dopamine transporter expression

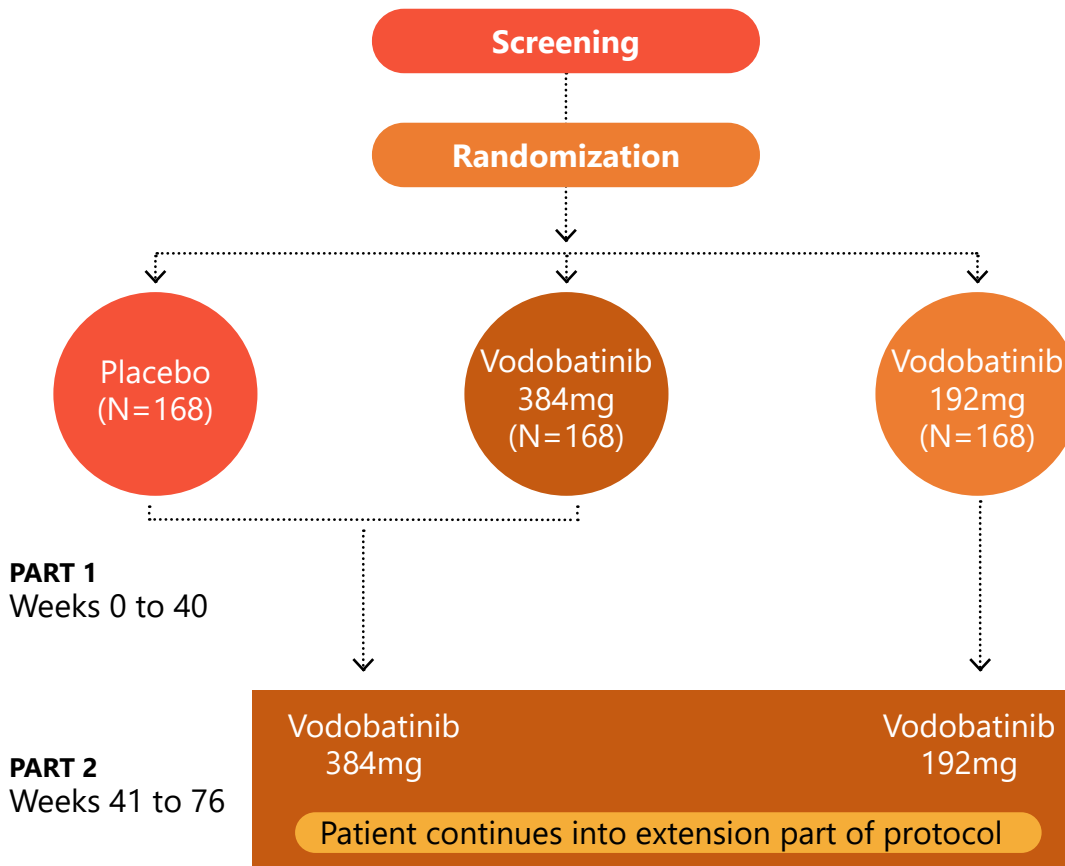


- Vodobatinib treatment protects against dopaminergic neuronal loss measured by radiolabeled ¹²⁵I labeled RTI-121 binding in the striatum
 - Comparison of un-operated left hemisphere (L) and operated right hemisphere (R, injected with & expressing the AAV) shows that 45 mg/kg dose provides protection of dopaminergic neurons

■ Vehicle ■ Vehicle ■ Vodobatinib 15mg/kg
■ Vodobatinib 30mg/kg ■ Vodobatinib 45mg/kg

Vodobatinib for PD (SCC-138)

Recruitment on track to achieve enrollment target in PROSEEK



PROSEEK

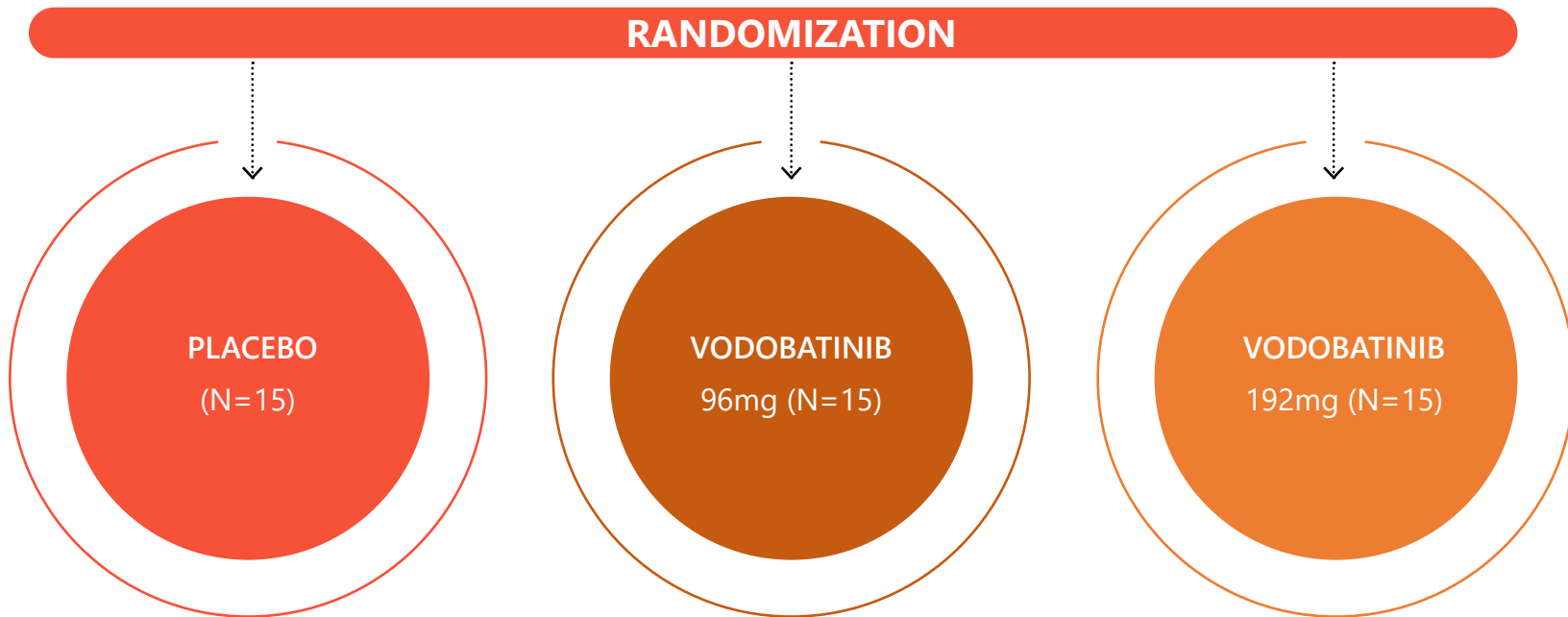
- 77 sites across US, Europe and India functional; recruitment ongoing to complete enrollment in FY23
- Over 70% patients randomized (N=349)*

Extension study

- Patients enrolled to establish long-term safety and tolerability

Opportunities beyond PD: Lewy Body Dementia

Recruitment ongoing in an investigator-initiated clinical trial at Georgetown University



- Recruitment ongoing in a 12-week Phase 2 study in collaboration with Georgetown University
- 50% patients randomized
- Safety and tolerability being evaluated as a primary outcome
- Concentration of LBD-related plasma and CSF biomarkers form the set of secondary outcome measures

Next steps



Parkinson's Disease

Complete recruitment in PROSEEK

PROSEEK study readout in FY24



Lewy-Body Dementia

Complete recruitment by FY24 in the Georgetown University study

Study readout in FY24

**Vibozilimod (SCD-044) –
A selective S1PR1 agonist**

**A safer
alternative to
JAK inhibitors**

Vibozilimod (SCD-044) for Psoriasis and Atopic Dermatitis

An opportunity to improve oral standard-of-care in dermatology

Vibozilimod is a Best-in-Class S1PR1 modulator with excellent safety

S1PR1 Modulator Landscape

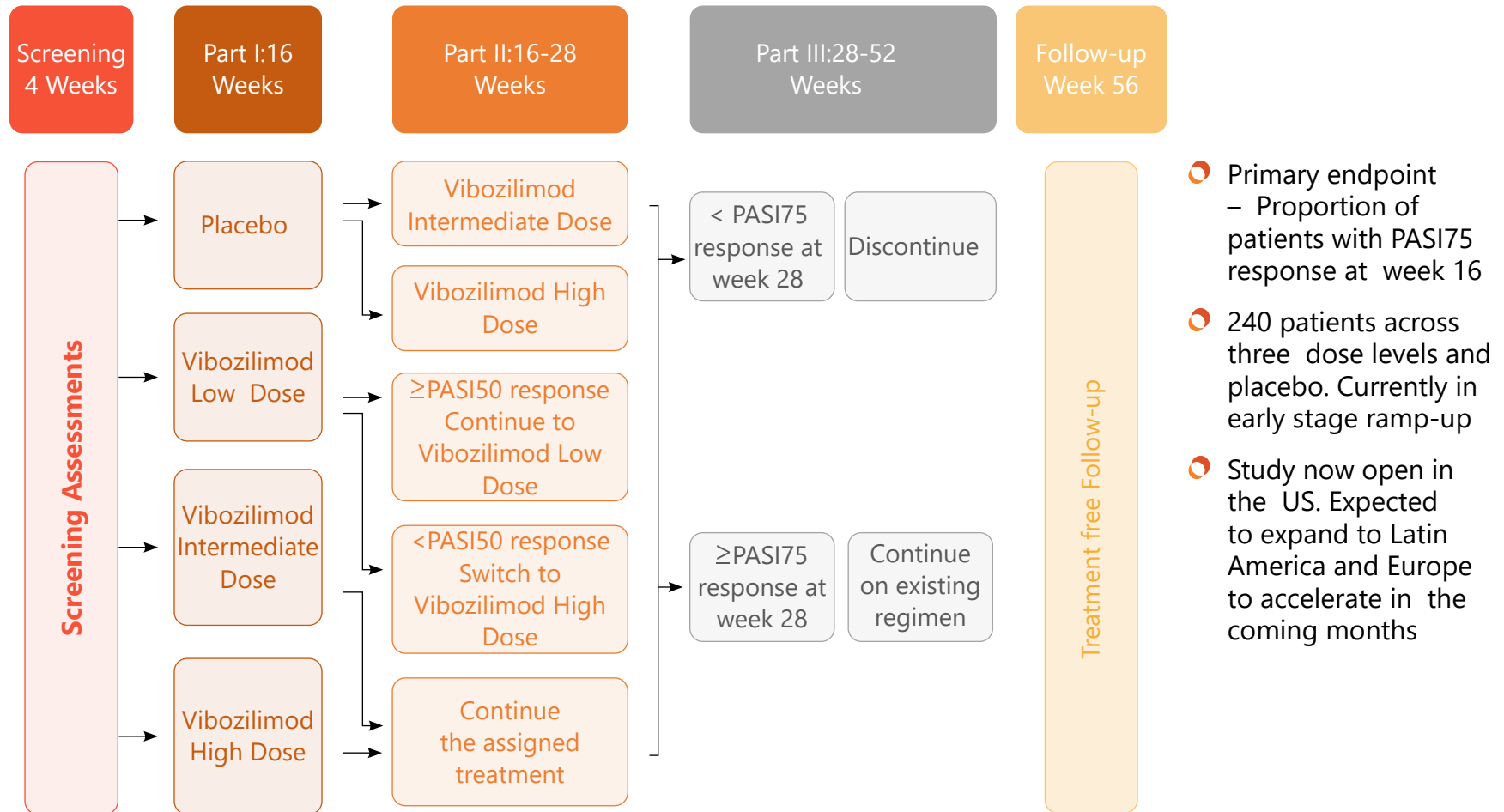
- Fingolimod is the first-in-class S1PR agonist approved, but not suitable for some indications because of safety concerns
- Multiple S1PR1 modulators are approved (siponimod and ozanimod) for non-dermatology indications; vibozilimod has opportunity to lead the field in dermatology
- Recent safety concerns related to JAK inhibitors increase the significance of S1PR1 agonists as a 'class alternative' in several autoimmune disorders, particularly in dermatology

Vibozilimod (SCD-044)

- Developed in collaboration with a French biotech company, Bioprojet. SPARC in-licensed Bioprojet's share of IP in 2019
- Highly-selective for S1PR1 over S1PR2 and S1PR3, which can be associated with serious side effects
- Established preclinical and early clinical validation
- Currently targeting atopic dermatitis, psoriasis and other autoimmune disorders
- Potential synergy with other mechanisms in IBD – like IL-23 blockade

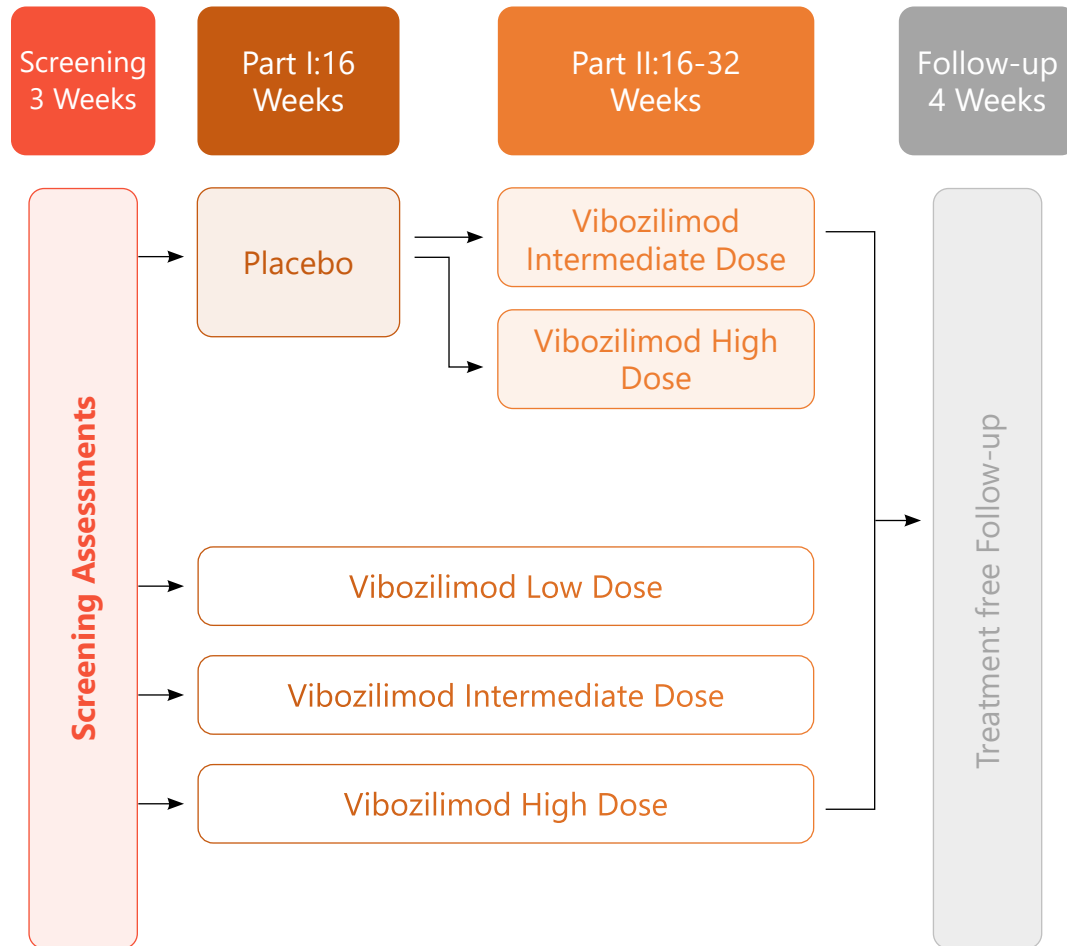
Vibozilimod (SCD-044) for Psoriasis

Phase 2 study design



Vibozilimod (SCD-044) for Atopic Dermatitis

Phase 2 study design



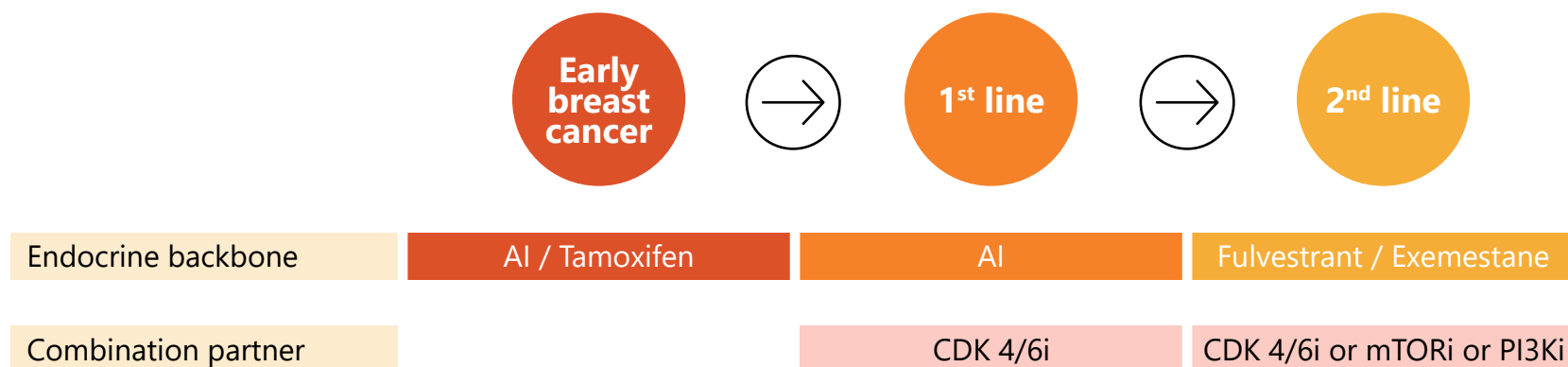
- Primary endpoint – Proportion of patients with EASI-75 response at week 16
- 240 Patients across three dose levels and placebo. Currently in early stage ramp-up
- Study now open in the US. Expected to expand to Latin America and Europe to accelerate in the coming months

**SCO-120 for HR⁺/
HER2⁻ MBC**

**An oral SERD with
brain penetration**

Current treatment paradigm

Dominated by endocrine therapy except in patients with visceral disease



- Fulvestrant is currently the only SERD available for patients failing 1L setting
 - It is limited by intramuscular (IM) administration and its inability to address mutations
 - Elacestrant phase 3 study met its co-primary endpoints of improved PFS in patients with wild type and mutant disease in 2nd line patients.
- CDK4/6i has emerged as the gold standard in 1L but requires an endocrine backbone
 - SERDs in development have the potential to become that backbone

SCO-120: Oral SERD for HR⁺/HER2⁻ MBC




Clinical study design

	Single Ascending Dose (Part A)	Food Effect (Part B)	Multiple Ascending Dose (Part C)
Phase 1 Healthy Volunteer Study Design	Double blind, placebo controlled, single oral dose	Open label, two period, cross over, single dose, fast/fed study	Double blind, placebo controlled, once daily, 14 day repeat dose

Multiple Ascending Dose study		
Phase 1 Patient study	HR ⁺ /HER2 ⁻ metastatic breast cancer patients that have failed at least 1 prior endocrine therapy and no more than 3 prior chemotherapy treatments	
Dose escalation (MTD/RP2D, safety) (N~44)	→ MTD/RP2D reached	→ Dose expansion (Safety & Preliminary efficacy) (N~105) <ul style="list-style-type: none"> ○ Part a: ESR1 mutations ○ Part b: Resistant to AI ± CDK4/6i ○ Part c: Resistant to AI & Ful+ CDK4/6i ○ Part d: Secondary brain metastases to breast cancer

Next steps




MAD in patients study completion and read out in FY24

Phase 2 initiation in FY24

Target NDA submission in FY27

Biologics

Nitin Damle



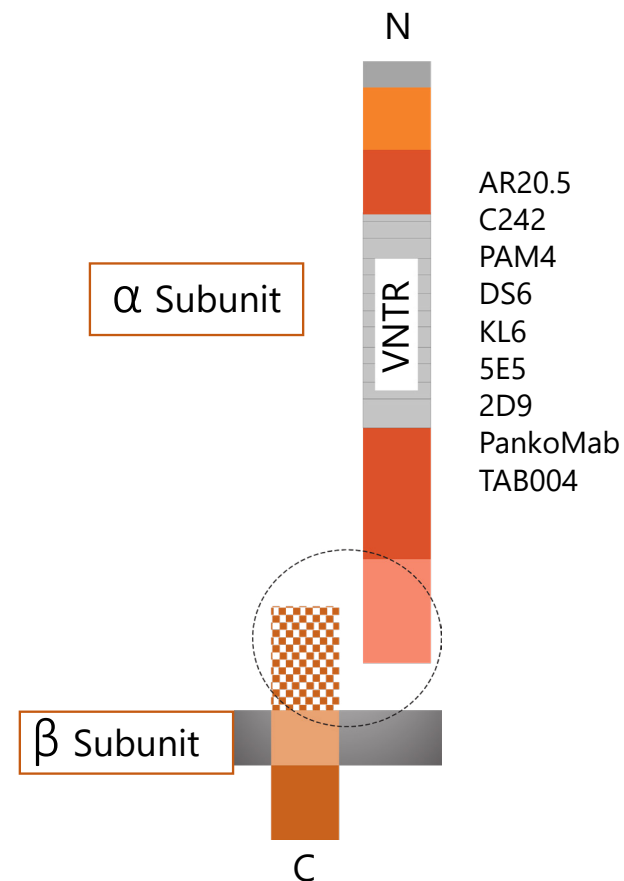
**SBO-154
(Anti-MUC-1 ADC)**

Targeting
an antigen
expressed in a
wide spectrum
of tumors

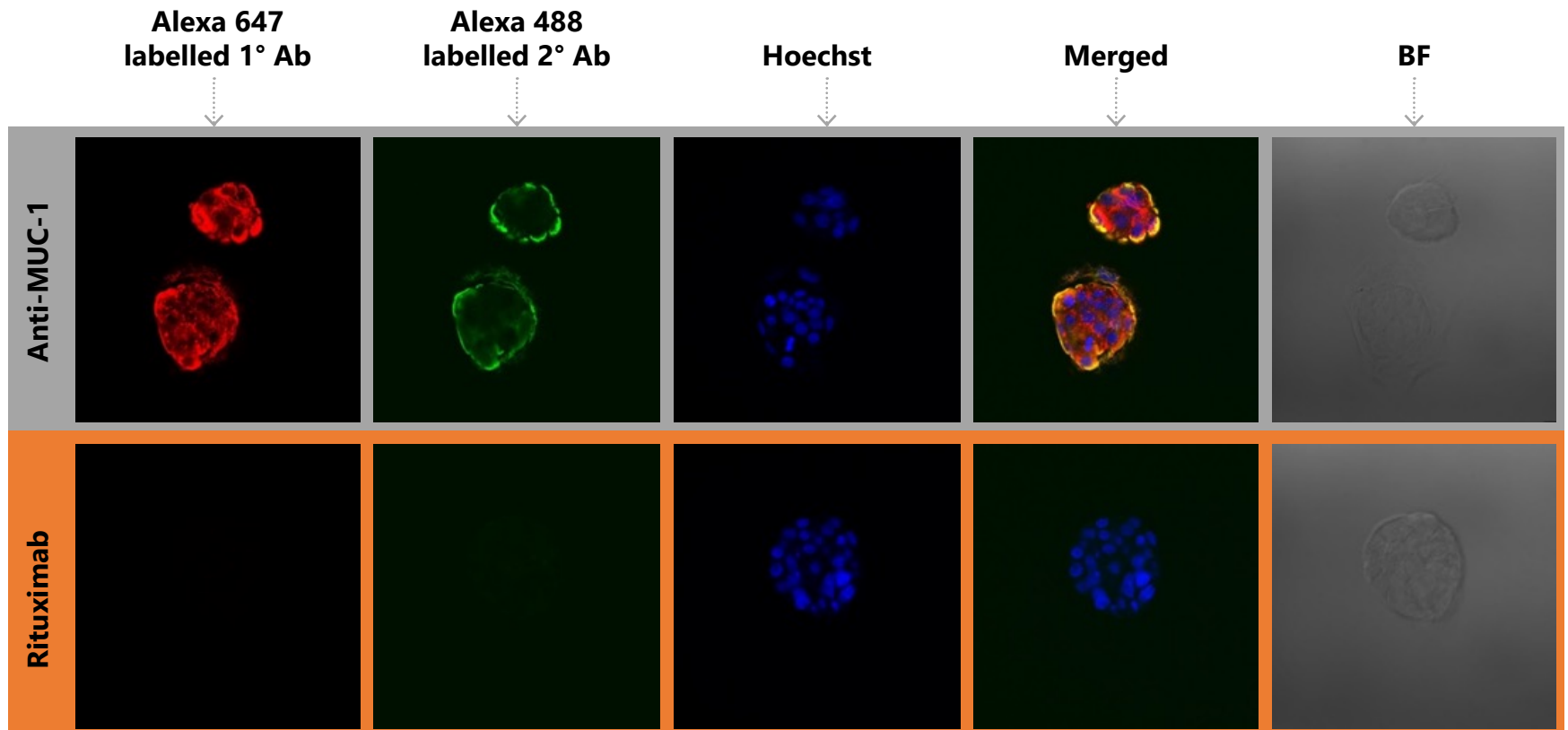
SBO-154: Anti-MUC-1 ADC

Novel approach to target α/β complex, with an opportunity to target multiple tumor types

- Tumor agnostic opportunity in-licensed from Biomodifying LLC*
- MUC-1 expressed extensively in majority of tumors
- Preclinical PoC of anti-tumour efficacy of anti-MUC-1 targeted ADC established
- Most anti-MUC-1 mAbs under development target VNTR in the MUC-1 α
 - Circulating MUC-1 α in plasma and in peritumoral space block meaningful tumor targeting by MUC1 α -targeted therapies
 - Primary reason for the lack of efficacy
- No directly competing agents targeting α/β junction
- Potential to be an anchor for other constructs like bi-specific/multi-specific antibodies, naked mAb, etc.



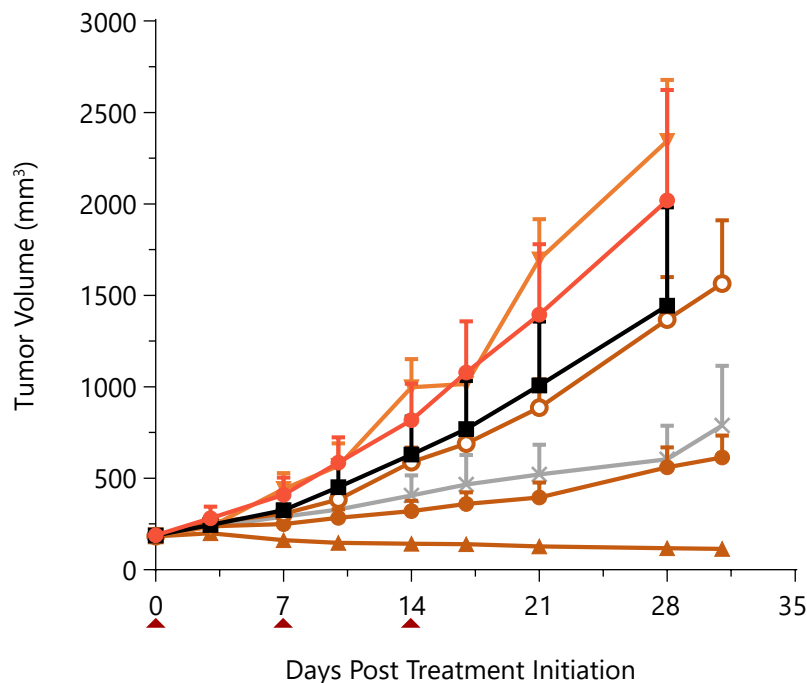
Anti-MUC-1 mAbs* internalize in pancreatic carcinoma cells



Red fluorescence is associated with anti-MUC-1 antibody, green fluorescence is associated with anti-human Fc- γ antibody & Hoechst dye stains nucleus and is blue in colour

SBO-154 strongly inhibits growth of MUC-1 expressing tumors

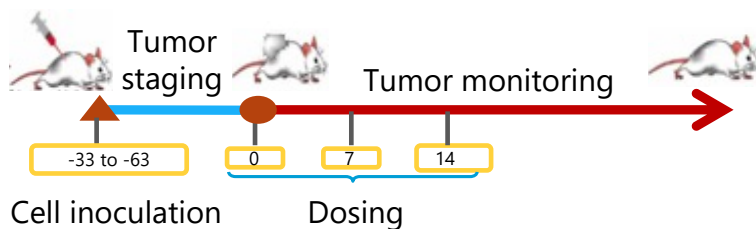
Established in subcutaneous pancreatic carcinoma xenografts



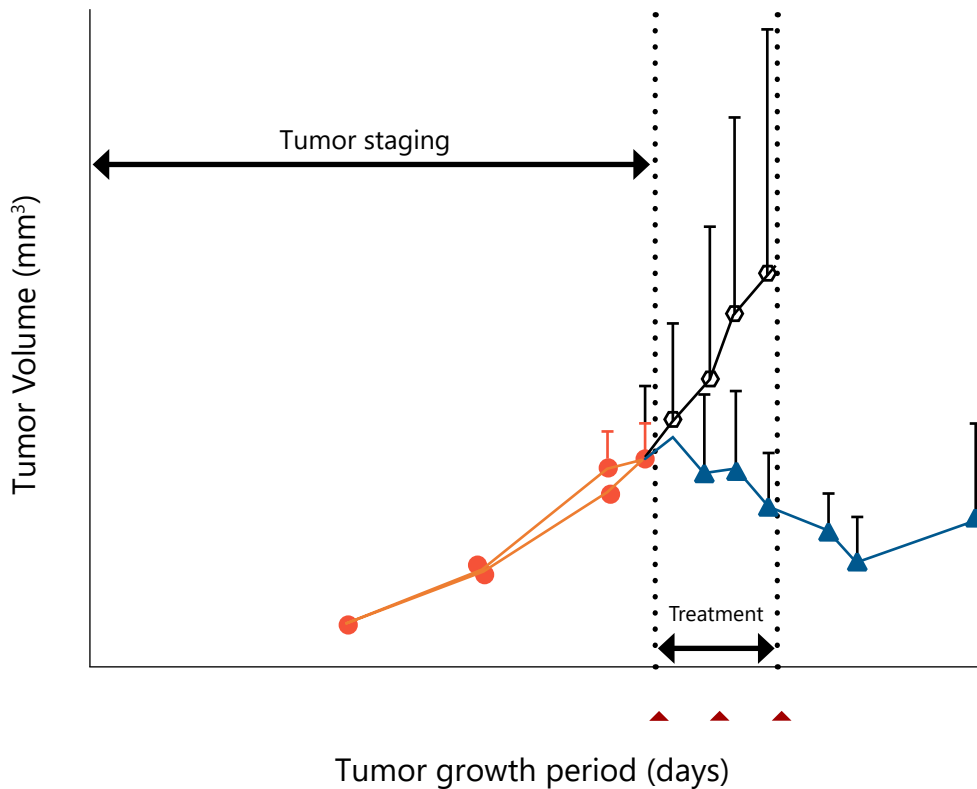
Regimen: Q7D x 3, i.p.

- Free Payload
- Vehicle, 10ml/kg
- Rituximab-DC
- SBO-154, low dose
- Nab-PTX
- SBO-154, medium dose
- SBO-154, high dose

- Dose-dependent efficacy observed with SBO-154, with sustained regression observed at high-dose
- Rituximab-drug conjugate and paclitaxel do not show similar activity



SBO-154 causes regression of large tumor mass xenografts of a pancreatic carcinoma cell line



Treatment: ip Q7Dx3

- Vehicle
- Rituximab-DC
- SBO-154

- Large tumor study is used to determine cytoreductive potential
- SBO-154 but not isotype matched control (rituximab-DC) causes significant regression of large established pancreatic tumor xenografts

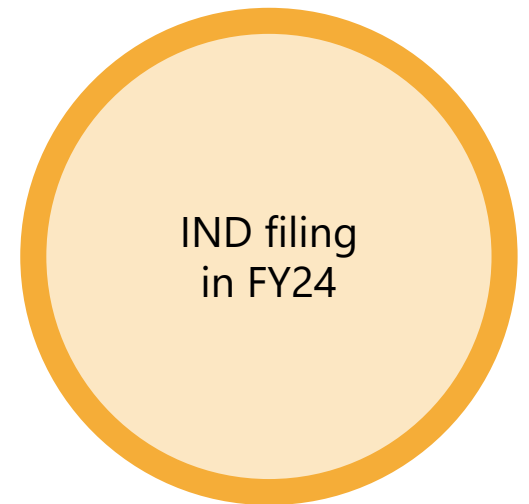
Next steps

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IND enabling tox studies completion

A large circle with a dark orange border and a light beige fill. The text "Pre-IND meeting" is centered inside.

Pre-IND meeting

A large circle with a yellow-orange border and a light beige fill. The text "IND filing in FY24" is centered inside.

IND filing in FY24

Preclinical NCE Program

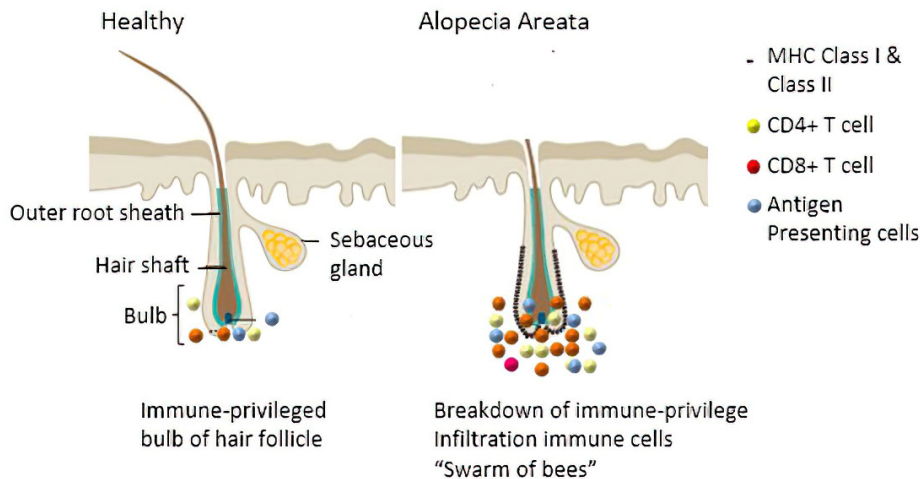
Vikram Ramanathan

**SCD-153 for
Alopecia Areata**

**A potential
first-in-class
opportunity in
an autoimmune
disease with
significant
unmet need**

Alopecia Areata – Autoimmune disease causing hair loss

Hair follicles lose immune privilege and they move into Telogen (resting) phase



Alopecia Areata is characterized by

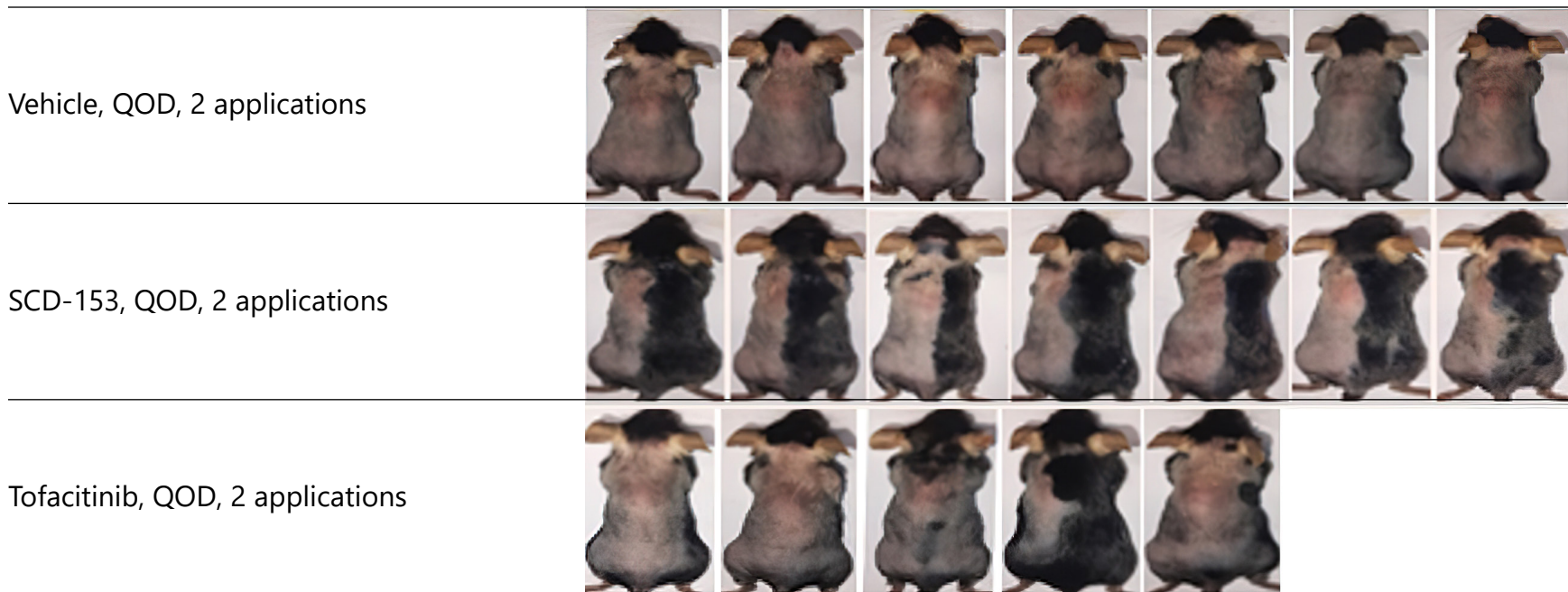
- Rapid progression of hair follicle from anagen (growing) phase to catagen (transition) phase to telogen (resting) phase
- Collapse in immune privilege in hair follicle bulb
 - CD4⁺ and CD8⁺ T cells infiltrate and damage the hair bulb
 - NKG2D positive CD8⁺ T cells are the major effectors of hair follicle damage
 - Alters normal hair growth cycle and causes hair to fall out
- However, the hair follicle structure and stem cells are preserved, suggesting potential for hair growth

Clinical manifestations of Alopecia Areata



SCD-153 stimulates hair growth in animal models

C57BL/6 telogen - anagen alopecia model

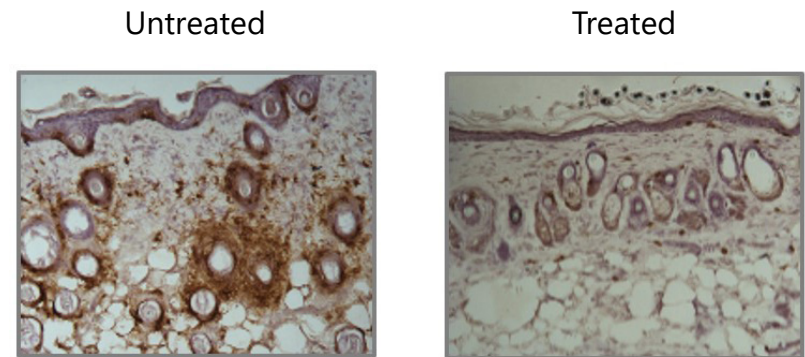


Female mice, 8.5 weeks, Dorsal hair clipped. Treated on right side, left side is untreated. QOD: every other day

- SCD-153 stimulates robust hair growth after 2 doses given on alternate days
- Promotes re-entry into anagen possibly via activation of stem cells at the base of the hair follicle

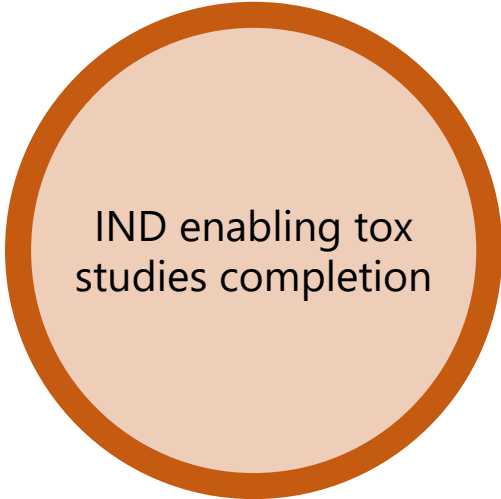
SCD-153 stimulates hair growth in animal models

C3H/HeJ alopecia areata immune disease model




- Robust hair growth in a disease model
- Decrease in CD8⁺ immunostaining proximal to hair follicles. Reduction in “swarm of bees”
- Decrease in gamma-interferon and CTL gene signature

Next steps

A large orange circle with a thick border, containing the text "IND enabling tox studies completion".

IND enabling tox studies completion

A large orange circle with a thick border, containing the text "IND filing in FY23".

IND filing in FY23

Financial Update

Chetan Rajpara

Financial summary



Year	FY18	FY19	FY20	FY21	FY22	Q1FY23
USD/INR	64.46	69.95	70.91	74.23	74.49	77.16
						INR Cr
Total Income	83	196	87	258	144	29
Total Expenses	329	342	399	410	347	111
Exceptional Item	49	-	-	-	0	0
Profit / (Loss) after Tax	(197)	(145)	(312)	(151)	(203)	(82)
						USD Mn
Total Income	12.9	28.1	12.2	34.8	19.3	3.7
Total Expenses	51.1	48.9	56.3	55.2	46.6	14.4
Exceptional Item	7.6	-	-	-	-	-
Profit / (Loss) after Tax	(30.6)	(20.8)	(44.1)	(20.4)	(27.3)	(10.7)

Cash and liquidity

- Issued convertible warrants for Rs. 1,112 Cr (~USD 148 Mn) in July 2021 by way of preferential issue
- Received Rs. 409 Cr (~USD 55 Mn) being 25% payable on application & upon conversion of warrants
- Balance Rs. 703 Cr (~USD 93 Mn) to be received by Dec 2022 upon conversion of warrants by investors
- Line of credit from parent company Rs. 250 Cr (~USD 31 Mn) and bank facility for Rs. 245 Cr (~USD 31 Mn) in place, of which Rs. 183 Cr (~USD 23 Mn) is utilized as on Sept 30, 2022
- Obtained shareholders' fresh approval in Sep 2022 for raising additional sum up to Rs. 1,800 Cr (~USD 225 Mn) by way of issuance of fresh equity or debt



THANK YOU

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