

Update on Clinical Programs and R&D Pipeline

Nov 2, 2023

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Agenda



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Anil Raghavan



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Siu-Long Yao



03 SCD-153

Vikram Ramanathan



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Nitin Damle



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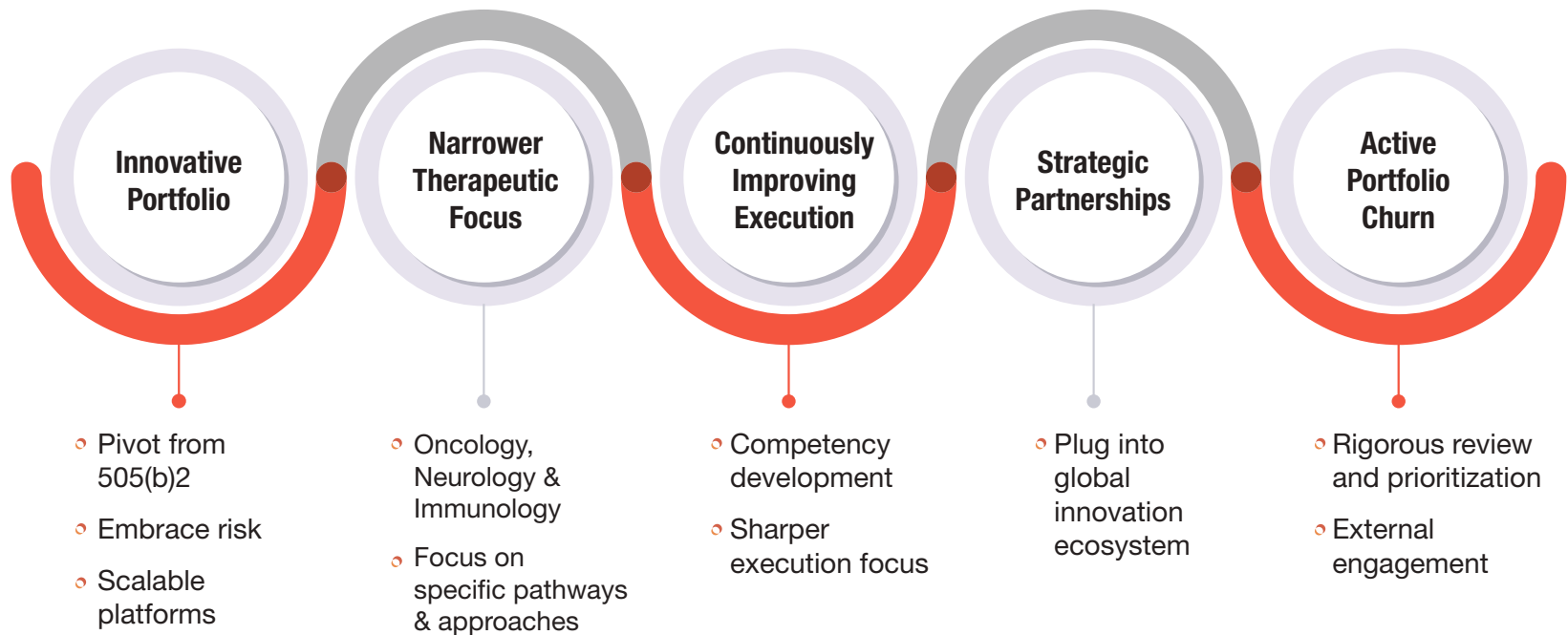
Chetan Rajpara

Strategic overview

Anil Raghavan

Maturing portfolio & operating model

Cost competitive translation with global access to science



- In-house competencies and infrastructure to prosecute an idea from 'bench to bedside' with an ability to scale across modalities
- 3 NDAs approved by the USFDA and commercialized by partners, contributing significant 'non dilutive' cash to support the portfolio and operating model build-up
- Robust pipeline with 3 NCEs under clinical development in 6 indications including two 'first-in-class' opportunities

Year 2024 promises several value inflection points



High-yield assets set to read out clinical PoCs and proceed to pivotal programs

- Key catalytic events coming up every quarter during next year

**Q1
2024**

Vodobatinib PD

PROSEK Interim
analysis readout

**Q2
2024**

SCD-153

Phase 1 SAD
study results

Vibozilimod*

Atopic dermatitis
Phase 2 study
enrollment
completion

**Q3
2024**

Vodobatinib PD

PROSEK full data
readout

**Q4
2024**

SBO-154

IND submission

Vibozilimod*

Atopic dermatitis
Interim analysis and
topline results

SCD-153

Phase 1 MAD study
initiation

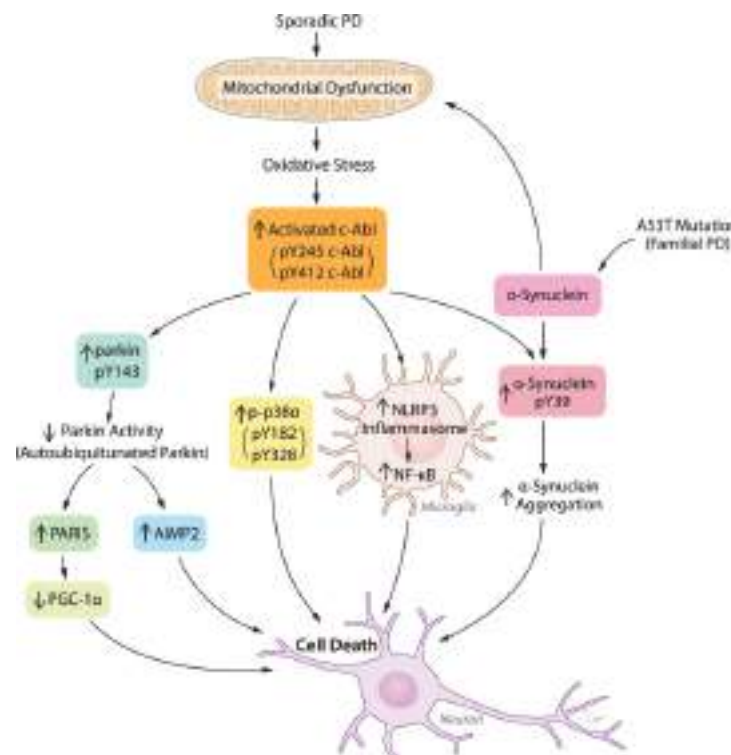
Vodobatinib reached Phase 2 enrollment target

PROSEEK read out to provide definitive PoC for the cAbl hypothesis and oxidative stress response modulation as an approach for neuroprotection



Phase 2 study of Abl tyrosine kinase inhibition with Vodobatinib

- One of the largest Phase 2 study ongoing for early PD patients (pre L-Dopa)
 - Study met enrollment target, 504 evaluable patients**
 - Treatment duration of 40 weeks followed by 40 weeks' extension study
 - Data from interim analysis expected in March 2024
- Geared up for post PROSEEK outcome
 - State of readiness for initiation of Phase 3 study
 - Engaging partners for potential collaboration

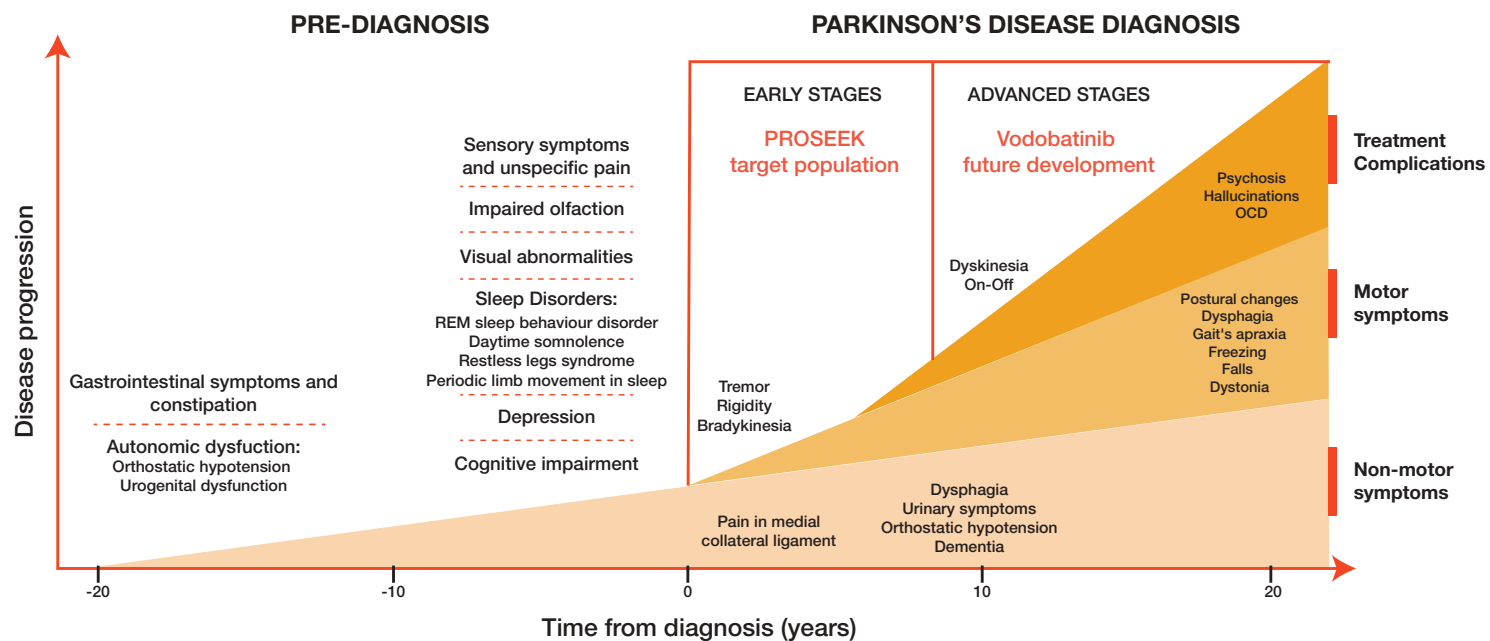


Oxidative stress in PD and related
 α -synucleinopathies¹

PROSEEK opens up a broad opportunity set

Unlocks significant value for SPARC with potential use across PD progression and in disorders driven by α -synuclein

- Potential to combine with symptomatic therapies in PD
- Potential for early interventions in precursor conditions
- PROSEEK offers a powerful PoC for the pathway in diseases driven by α -synuclein
- Key disorders having α -synuclein aggregation as a pivotal process include PD, MSA & DLB



Vodobatinib can emerge as the protective backbone across the continuum of care for synucleopathies and other neurodegenerative disorders resulting from misfolded proteins

Optionality beyond PROSEEK

SPARC pipeline includes multiple high value assets with platform potential

- SPARC's immunology program will provide additional efficacy and safety data points in 2024
- Oncology offers a potential hedge and anchor for future portfolio build across modalities
- Additional bets to understand underlying mechanisms in neurodegenerative diseases - UK DRI collaboration

Immunology

- Led by 3rd generation S1PR1 agonist, Vibozilimod with potential to be best-in-class asset in Dermatology – Clinical PoC in 2024
- SCD-153 program to explore a novel pathway with a topical agent for Alopecia Areata – Safety PoC in 2024
- Potential additional indications

Oncology

- Vodobatinib in CML – Recalibrating to a changing regulatory and market landscape
- MUC-1 program – A differentiated targeting approach which can become a pipeline in itself beyond the first ADC
- UCSF collaboration for Small Molecule Drug Conjugates in mPC
- Strong preclinical interest in antibody mediated delivery, RNA targeted therapeutics, & collateral lethality

Additional shots on goal & enabling competencies differentiate SPARC's risk profile

Immunology program focused on autoimmune disorders in dermatology

Opportunity to become safer oral alternative to the current SoC; offers a path to build an immunology franchise

Vibozilimod

- Two Phase 2b studies recruiting patients in Psoriasis and Atopic Dermatitis; lead indication Atopic Dermatitis
- Provides an alternate mechanism to IL-4/IL-13 antibodies and JAK inhibitors
- Studies being expanded to Europe and Canada

SCD-153

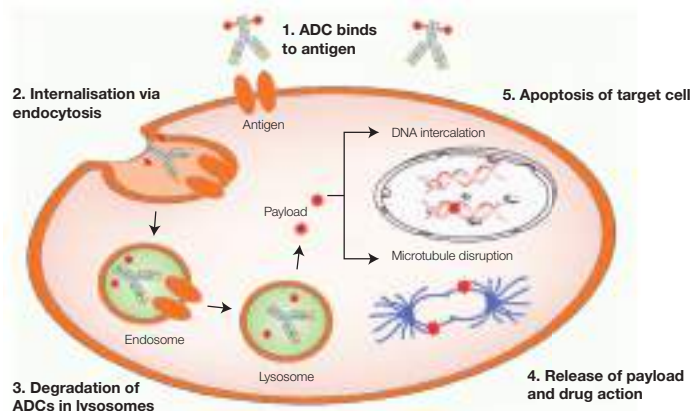
- Topical application may potentially provide a safer alternative to currently approved JAK inhibitors for treatment of AA
- Phase 1 study initiated for AA
- Preclinical evaluation ongoing in other autoimmune diseases of epidermis

Oncology pipeline with multiple near-term clinical options...

...backed up by an active preclinical effort involving multiple targets and modalities

- Vodobatinib for CML (SCO-088) writes down the PROSEK risk
 - Validated target; efficacy established in patients
 - Being developed under Frontrunner program of the USFDA; potential to move in earlier lines of treatment

Cell-targeting by ADC¹



- Antibody and small molecule ligands targeted delivery of payloads across modalities is a key focus for SPARC oncology
- MUC-1 antibody provides a differentiated platform to build pipeline of assets targeting a defined subset of patients across multiple tumors
- Key elements of the MUC-1 α/β hypothesis validated. First program on track; expected to enter clinic in 2024
- Additional constructs with other payloads and augmented targeting are being evaluated in preclinical setting
- Preclinical PoC established for Small Molecule Drug Conjugate
- Emerging preclinical interest in novel synthetic lethality pairings and RNA therapeutics

1. Adapted from: Antibody-drug conjugates for cancer Cindy C et al. Lancet 2019;394:793-804

Rigorous translational focus

Focused on patient needs, developability considerations & asset appropriateness



- Rigorous portfolio review process – Kill early, kill cheap, kill completely
- Large proportion of programs focusing on novel biology (potential first-in-class). Continued development of best-in-class assets for validated targets to balance the risk

SPARC expects additional non-dilutive cash flows from its commercial/partnered assets



ELEPSIA & XELPROS

- Strong uptake post launch
- Commercialization disrupted due to import alert at partner's manufacturing site
- Identified alternate manufacturing site for tech transfer

SEZABY

- Licensed to SPI Inc.
- Safeguarding interests of patients and caregivers
 - Filed PIL with USFDA
 - Sent cease & desist letters to companies marketing unapproved products in the US market
 - Robust supply chain development

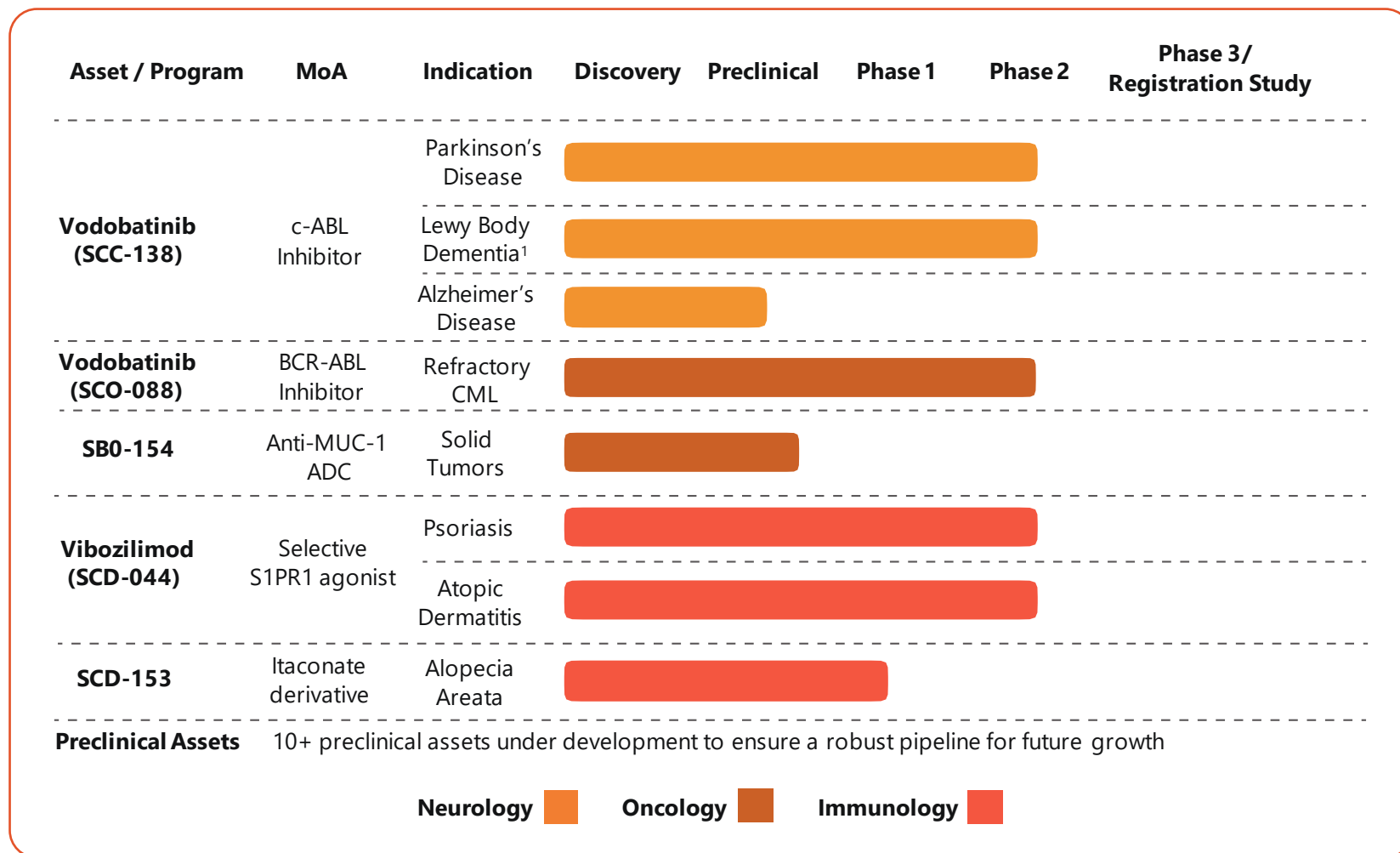
PDP-716

- USFDA issued CRL to PDP-716 NDA due to inspection findings at a third-party API manufacturing facility
- No additional clinical data or trials requested
- Identified alternate API partner

VIBOZILIMOD

- SPARC eligible to receive regulatory & sales milestones and royalty on sales
- Option to monetize royalty for immediate fund requirements

Pipeline overview



Bexirestrant deprioritized based on commercial assessment and change in treatment landscape

Key priorities for next year

Execution focus is the objective

Clinical studies

- PROSEEK completion and data readout
- Vodobatinib Phase 3 study initiation for PD
- SCD-153 Phase 2 study initiation
- Vibozilimod enrollment completion for Atopic Dermatitis study

Regulatory filing

- Elepsia site transfer
- PDP-716 re-filing
- EoP2 meeting with USFDA for Vodobatinib in neurodegenerative disorders
- SBO-154 IND filing

Strategic priorities

- Resourcing to ensure smooth operations
- In-licensing of potential opportunities
- Capabilities and resource building

Clinical programs

Siu-Long Yao

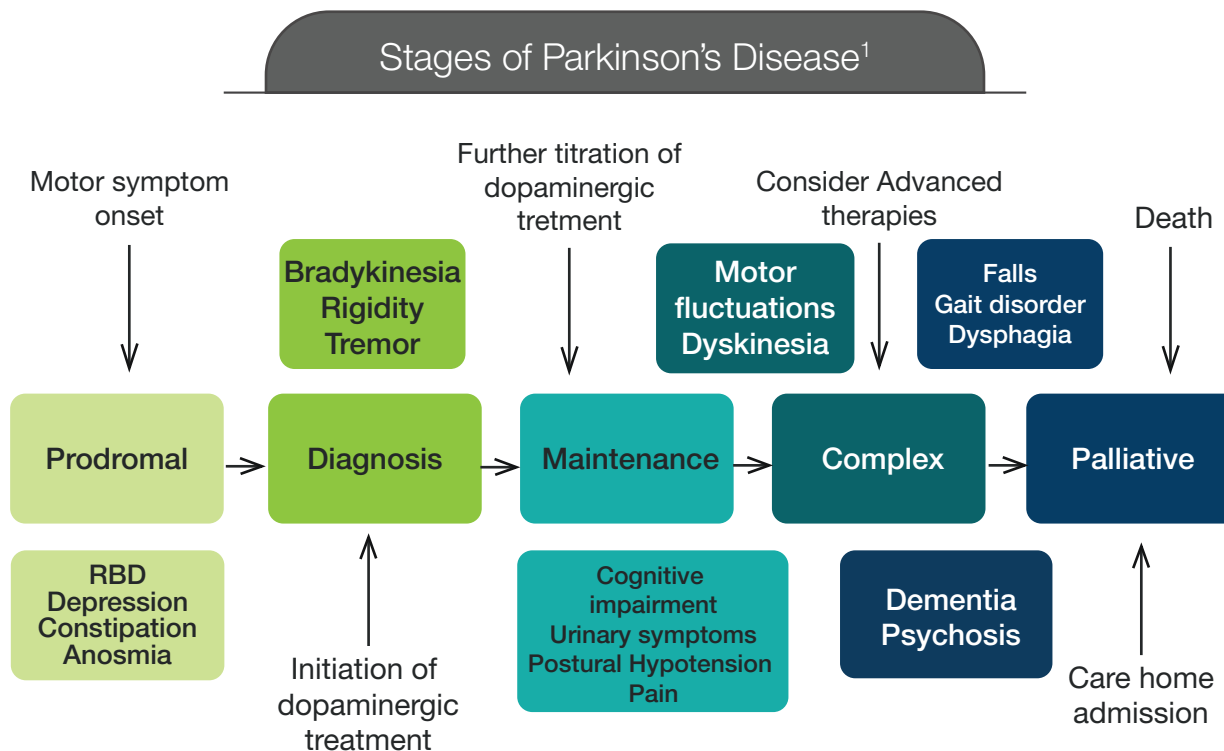
**Vodobatinib (SCC-138) for
neurodegenerative diseases**

Siu-Long Yao

Parkinson's disease epidemiology

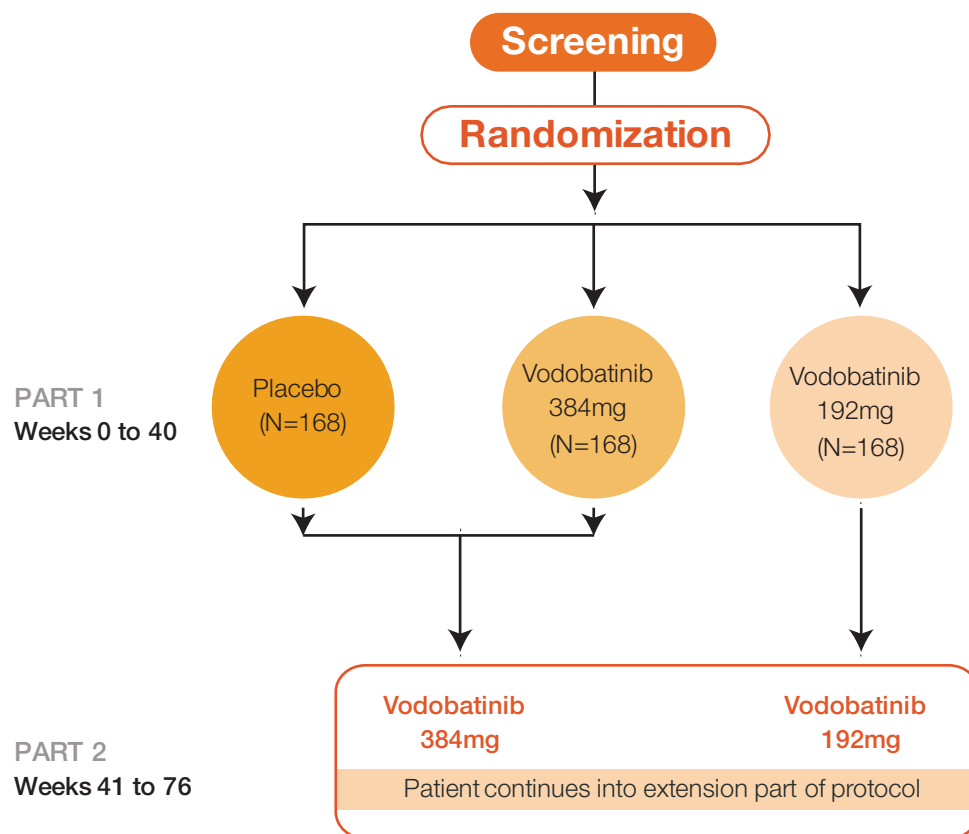
PD affects ~7 mn people globally; expected to grow above 14 mn by 2040

- PD population outgrowing overall population (2-4% growth in PD vs. 1% global population growth)
- DMTs can make significant impact to the lives of PD patients by changing the trajectory of disease



1. Update on the diagnosis and management of Parkinson's disease. Kobylecki C. Clinical Medicine. 2020 Jul;20(4):393.
IQVIA-SPARC-Vodabatinib Opportunity Assessment in PD-Final Readout-September 2020
Source: IQVIA analysis; population and growth rate: Census, Eurostat, INSEE, World Bank, Parkinson's Foundation, Savica et al, JAMA Neurology, 2017
DMT: Disease Modifying Therapy

Enrollment target met



Part 1

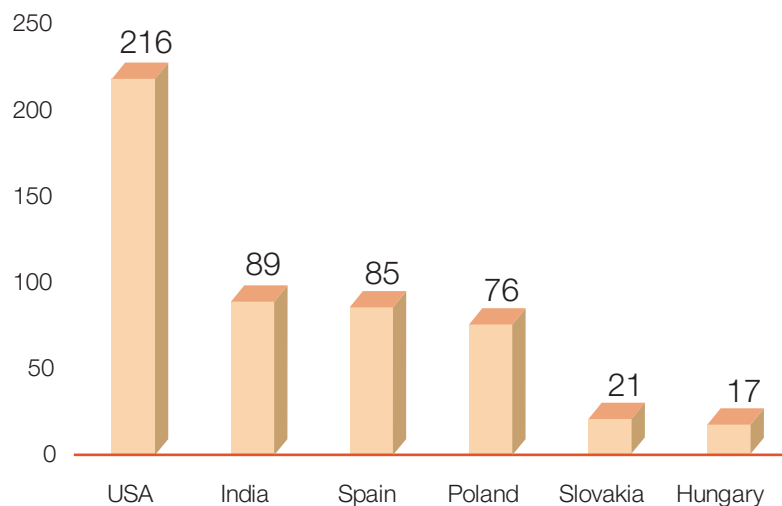
- Data from interim analysis expected to be available by March 2024

Part 2

- Study initiated in Q4 2021
- ~87% of eligible patients enrolled in Part 2
- Continuing treatment for additional 9 months
- Continues to evaluate patients until May 2025

No significant cardiac events reported in the patients recruited

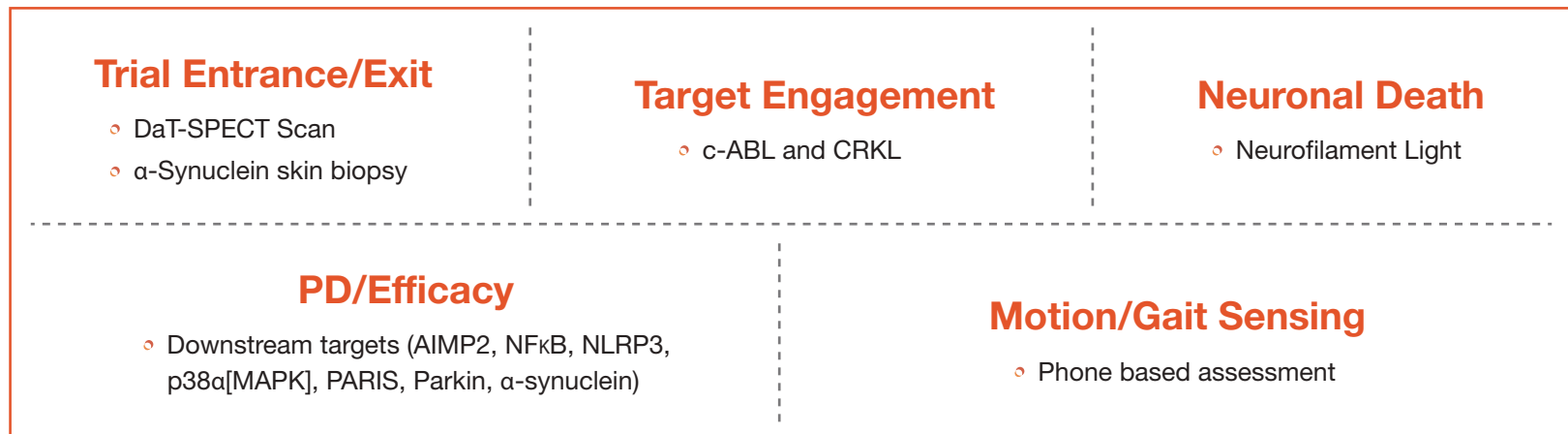
Number of patients randomized



- Over 40% patients enrolled from the US
- Grade 3/4 events reported in 6.1% patients
- GI and rash were the most common AEs reported
- No changes in study protocol recommended by DSMB throughout the conduct of the study
 - 6 DSMB reviews conducted

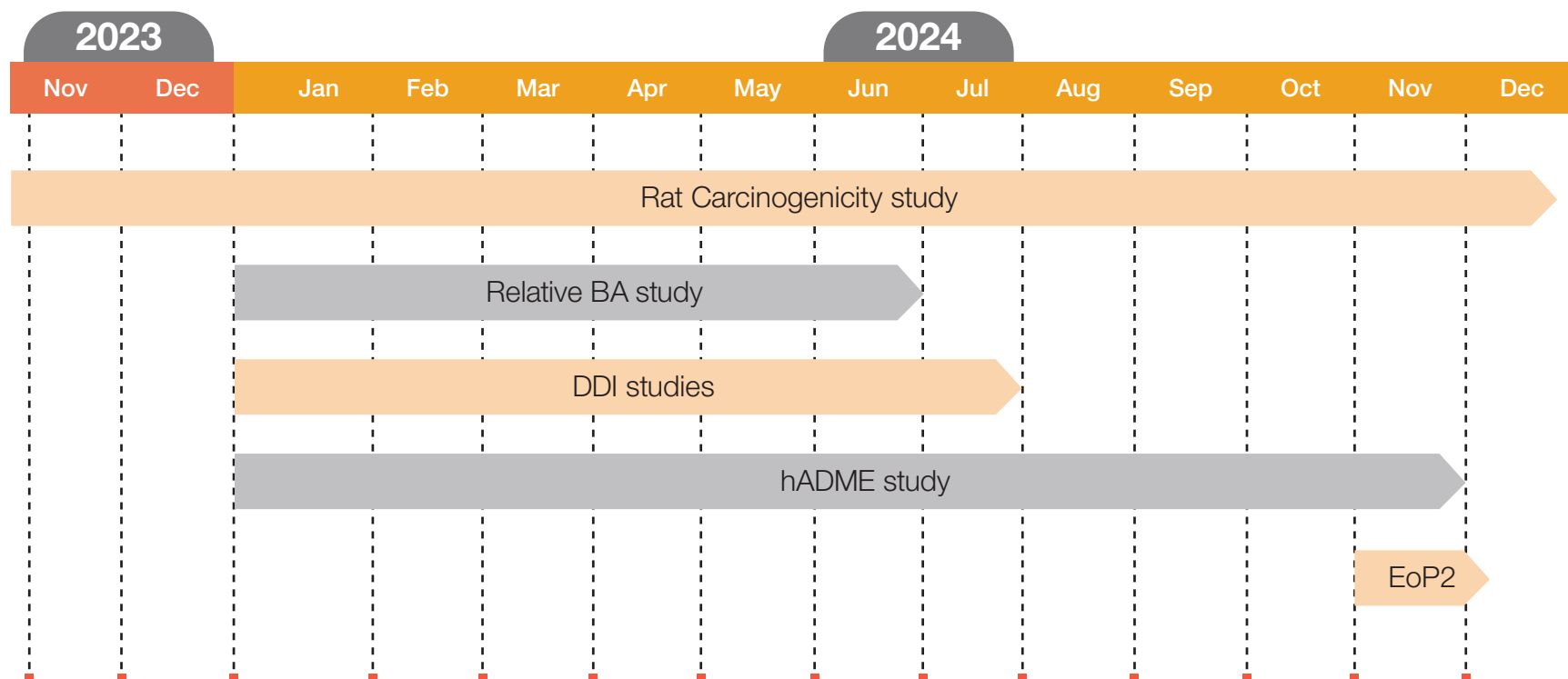
Biomarkers under evaluation

- Target biomarker cohort enrolment – 150 total (random assignment)
- Further randomization to placebo, low dose, or high dose Vodobatinib – 50 assigned to each arm
- Exploratory samples (CSF, plasma, serum) at baseline, 8 & 40 weeks (EOT)



Vodobatinib development

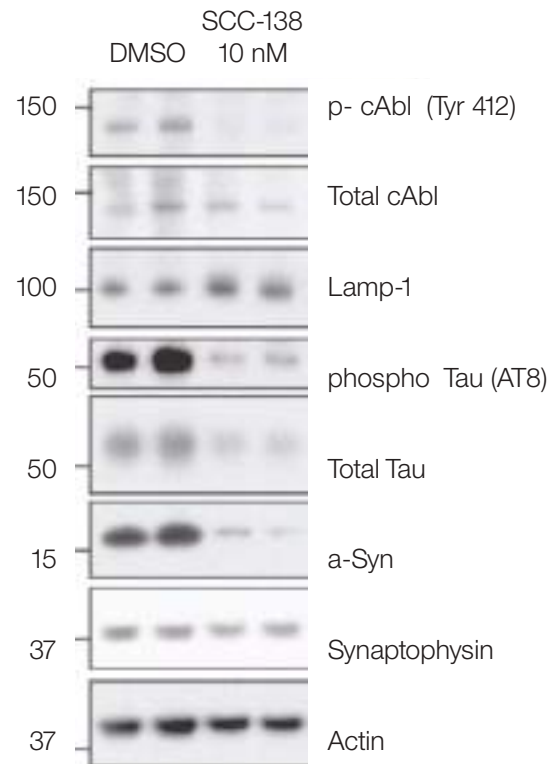
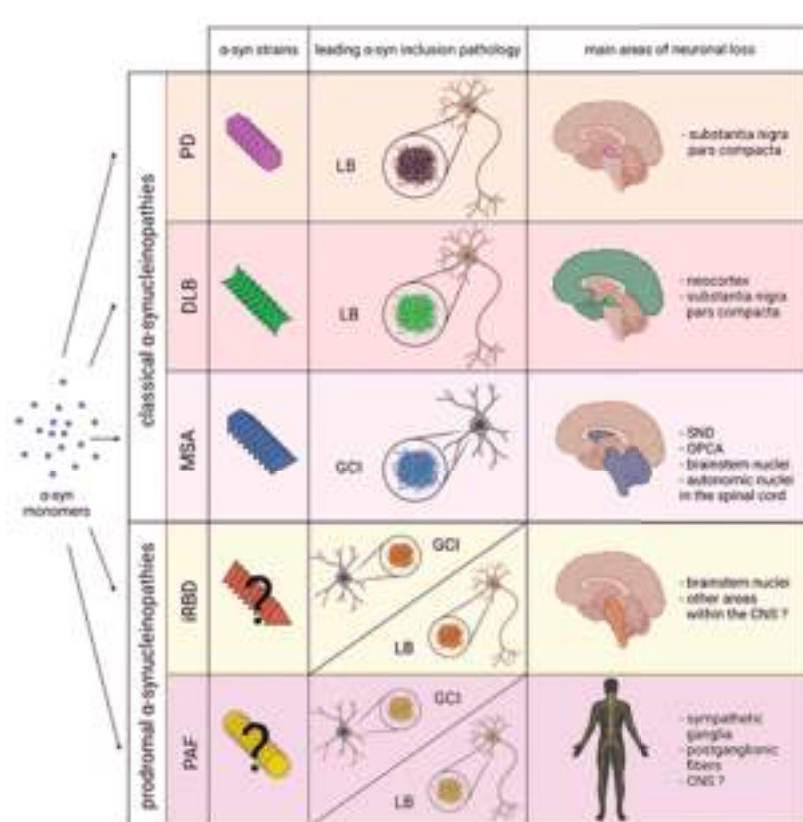
Activities running in parallel before EoP2 meeting with FDA



EoP2 meeting with FDA planned in Nov 2024

Opportunities beyond Parkinson's disease

Vodobatinib reduces the intracellular load of potentially toxic proteins in iPSC - induced neurons



Vodobatinib downregulates key proteins associated with development of synucleopathies and tauopathies*

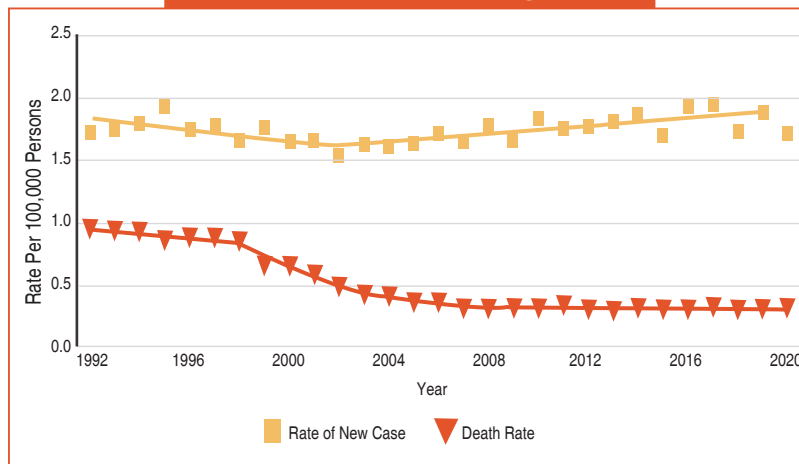
**Vodobatinib (SC0-088) for
chronic myeloid leukemia**

Siu-Long Yao

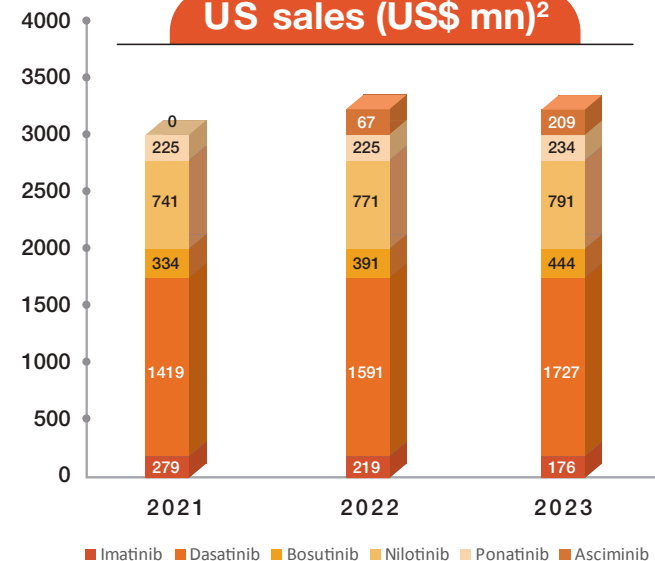
Chronic myeloid leukemia

Use of 2nd and 3rd generation agents increasing

US epidemiology¹



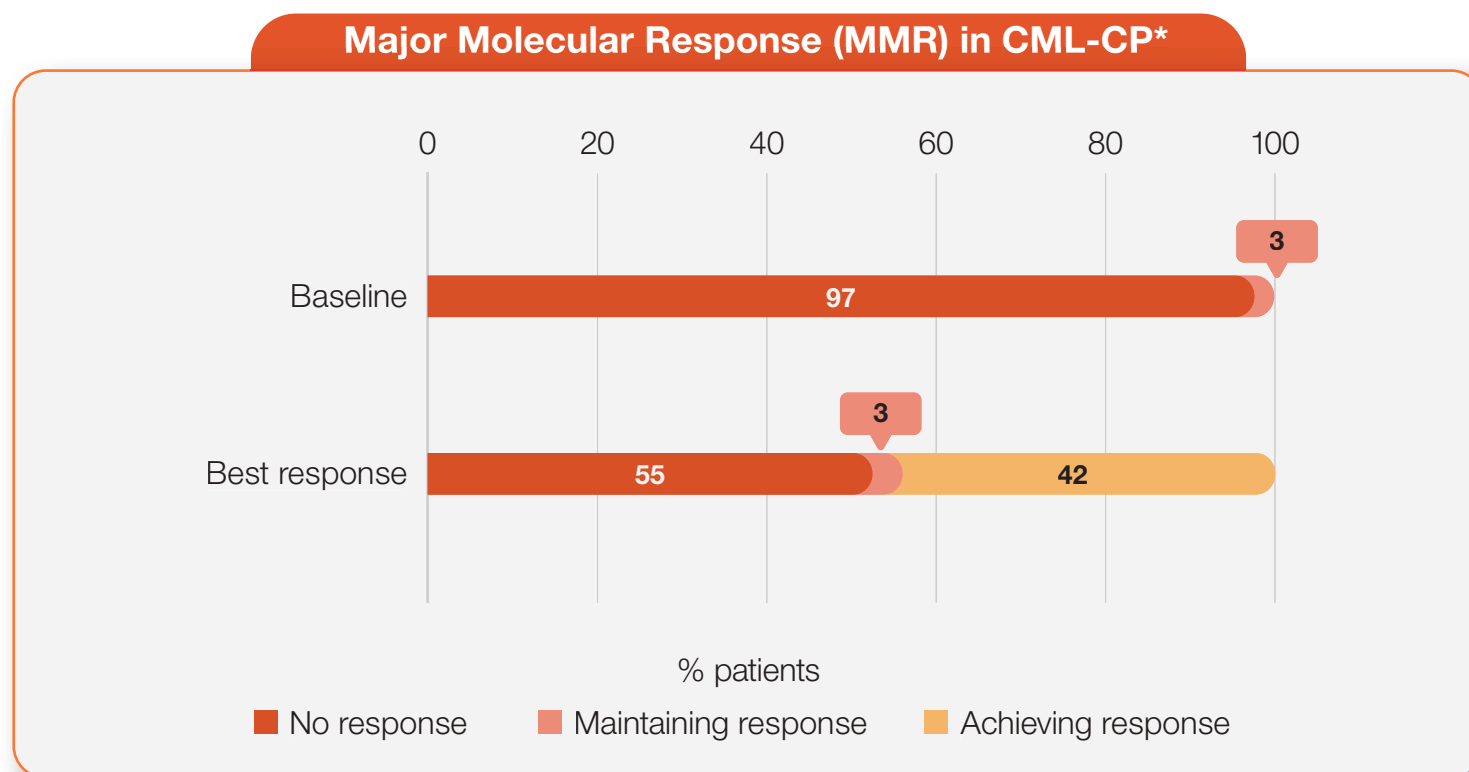
US sales (US\$ mn)²



- The prevalence of CML is estimated to grow primarily attributed to prolonged survival and access to TKIs
- The current value market is over US\$ 3.5 bn

Vodobatinib (SCO-088) Phase 1/2 study results

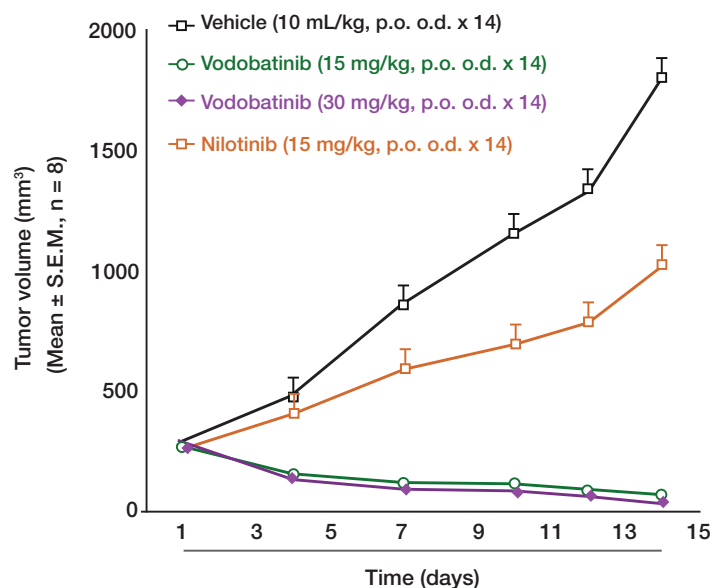
Patients continue to benefit over a long period of time



- Over 1/3rd patients on study drug beyond 3 years
- Median duration on study drug being 32.3 months (range: 0.3 – 73.4 months)

Preclinical data confirms superiority of Vodobatinib over 2nd generation TKI

Anti-leukemic activity in Ba/F3-WT xenografts

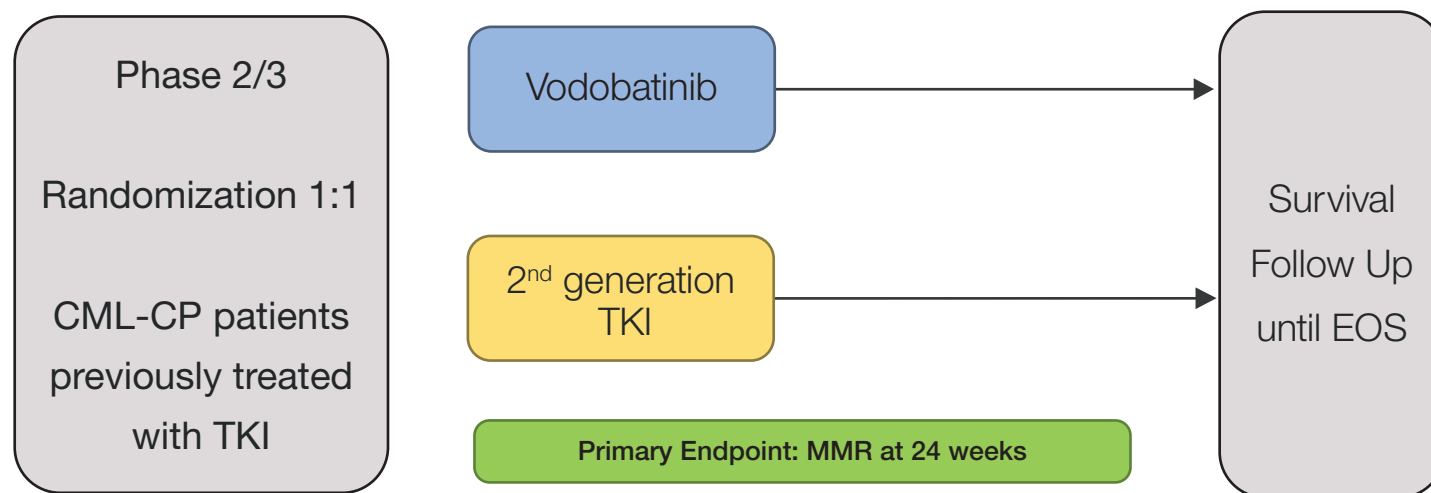


- Vodobatinib demonstrated better growth inhibition (GI₅₀) over nilotinib in Ba/F3 BCR::ABL1 wildtype (WT) and its resistant mutants *in-vitro*
- Vodobatinib has better antitumor activity over nilotinib *in-vivo*

Vodobatinib (SCO-088) registration plan alignment with FDA

Vodobatinib being developed under project Frontrunner

- Frontrunner is a program launched to make newer disease modifying therapies in earlier lines of treatment instead of late line setting
- Registration path
 - Randomized control study in earlier line of treatment: Phase 3 study in patients failing >1 TKI may be acceptable for approval
 - Clinical spend expected to increase; due to cost of comparator drug



**Vibozilimod for
autoimmune disorders**

Siu-Long Yao

Vibozilimod (SCD-044)

Targeting fragmented dermatology market

- Highly selective S1PR1 agonist
- Leading agent in the class under development for Psoriasis and Atopic Dermatitis

Psoriasis

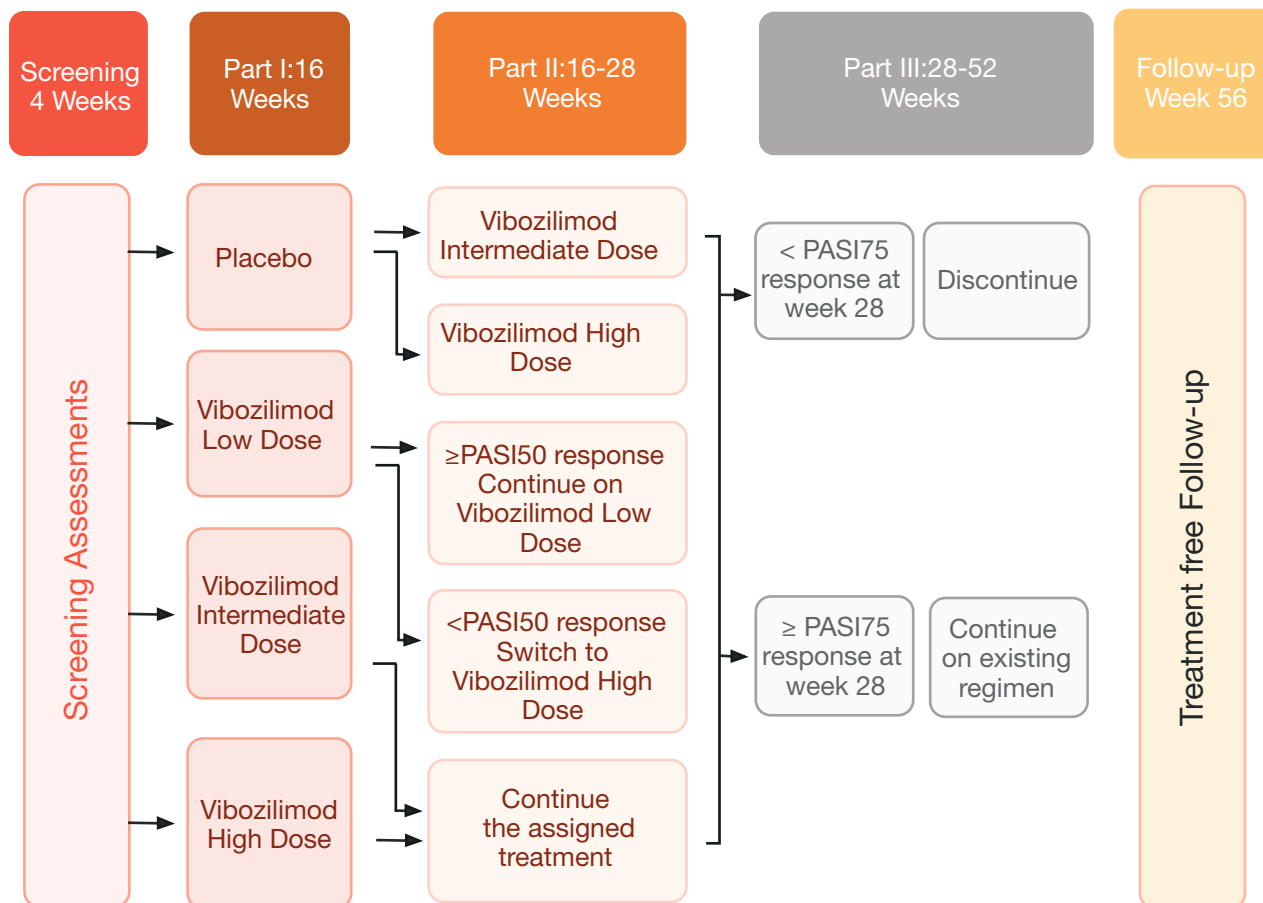
- US Prevalence ~ 8 mn
- Dominated by biologics (injectables), limited oral agents being developed for moderate to severe disease
- Biosimilars yet to take majority share of patients

Atopic Dermatitis

- US prevalence ~ 18 mn
- Systemic therapy primarily for moderate to severe disease
- Usage of JAK inhibitors limited primarily due to black box warning and AE profile

Vibozilimod (SCD-044) for Psoriasis

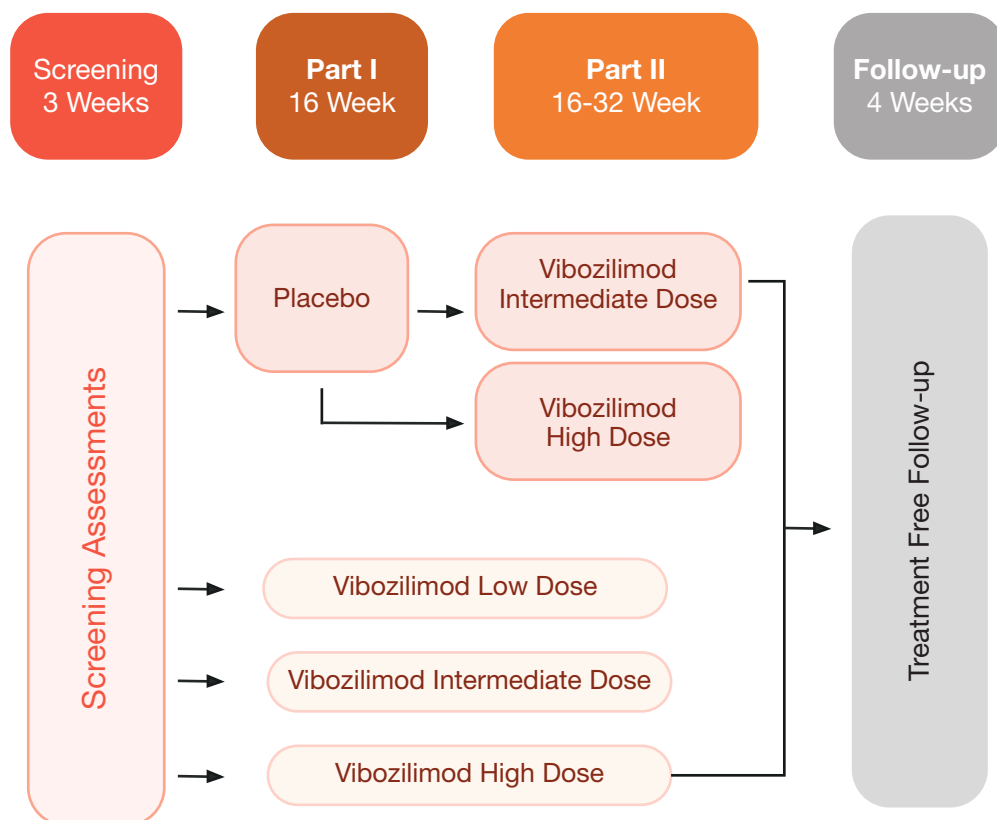
Phase 2 Study design



- Study open in the US, Latin America and Europe
- 15 sites in the US
- 3 sites in Europe
- Primary endpoint – Proportion of patients with PASI75 response at week 16

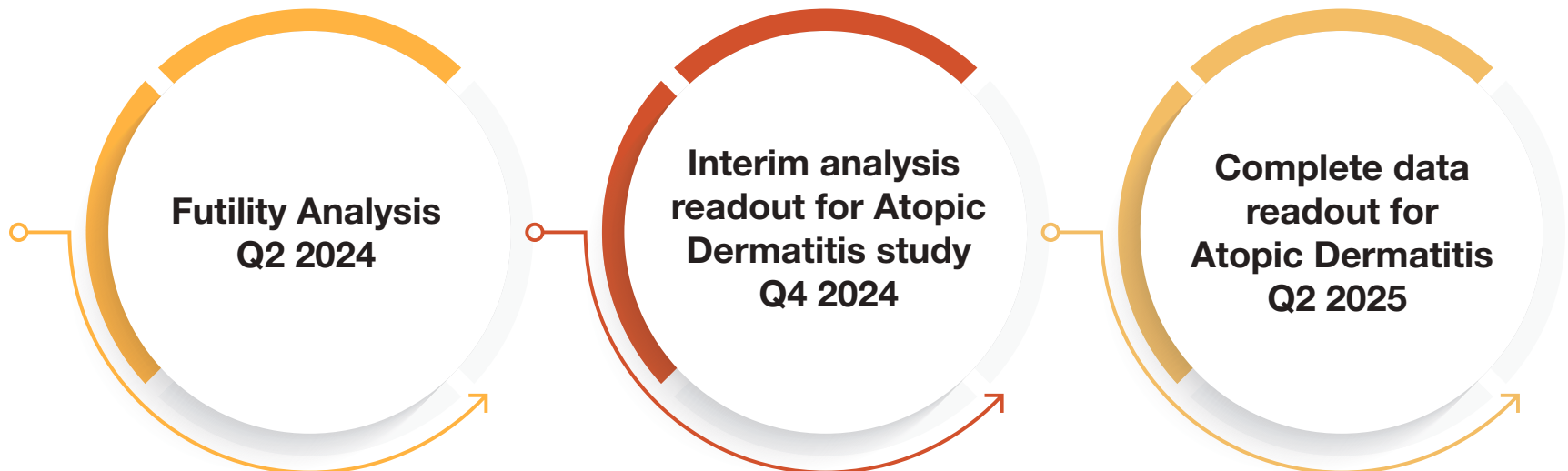
Vibozilimod (SCD-044) for Atopic Dermatitis

Phase 2 Study design



- Study open in the US, Latin America and Europe
- 18 sites in the US
- 15 sites in Europe
- Primary endpoint – Proportion of patients with EASI75 response at week 16

Next steps



**SCD-153 for
Alopecia Areata**

Vikram Ramanathan

Alopecia Areata: Autoimmune disease that causes hair loss

Current treatment approaches are limited

Clinical manifestations of Alopecia Areata¹

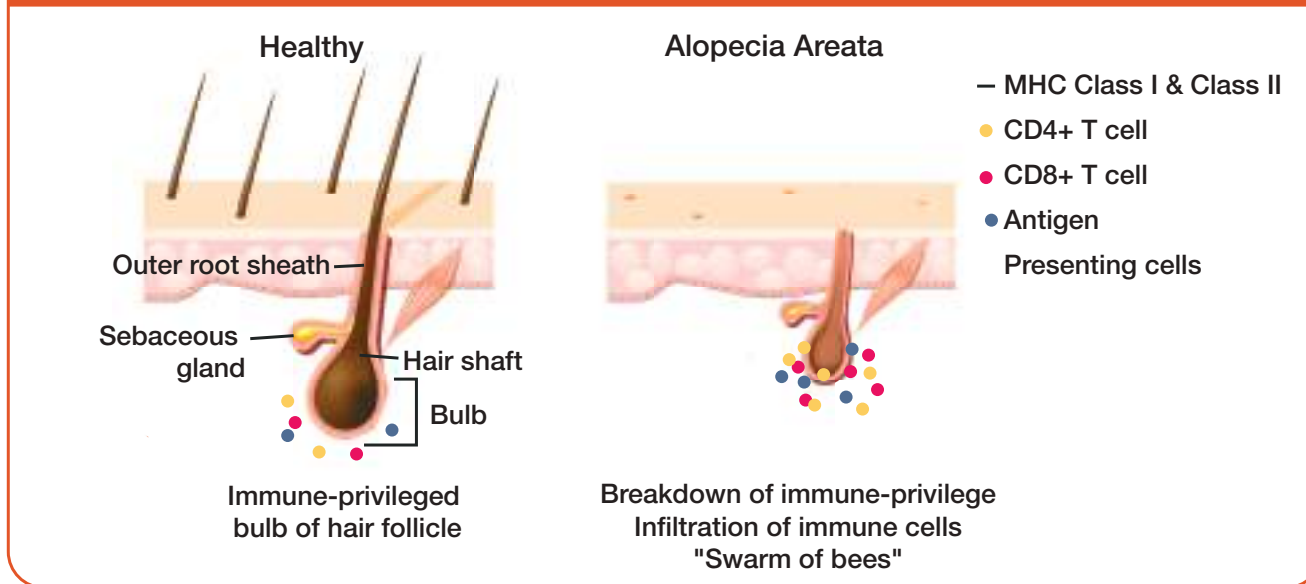


- Estimated 6.7 mn people in the US and 160 mn people worldwide have AA²
- ~ 50% can experience spontaneous hair regrowth within one year, the majority often relapse

- Current treatments are inadequate
 - Approved JAK1 inhibitors carry black box warning
 - Steroids cause serious AEs: systemic immuno-suppression, muscle wasting, growth retardation in pediatric population

Novel topical drug for treatment of Alopecia Areata

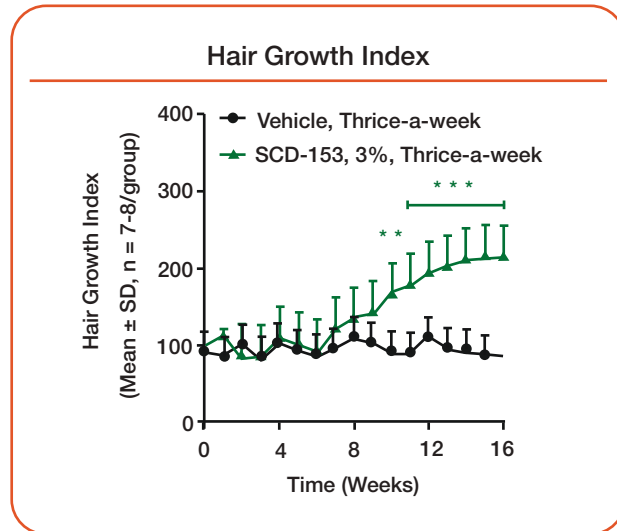
SCD-153 blocks key inflammatory cytokines implicated in AA¹



- SCD-153 inhibits inflammatory chemokines, cytokines and decreases pathogenic CD8+ T cells at base of hair follicle; restores immune privilege at hair follicle
- Being topical treatment should reduce systemic exposure thereby reducing systemic side effects

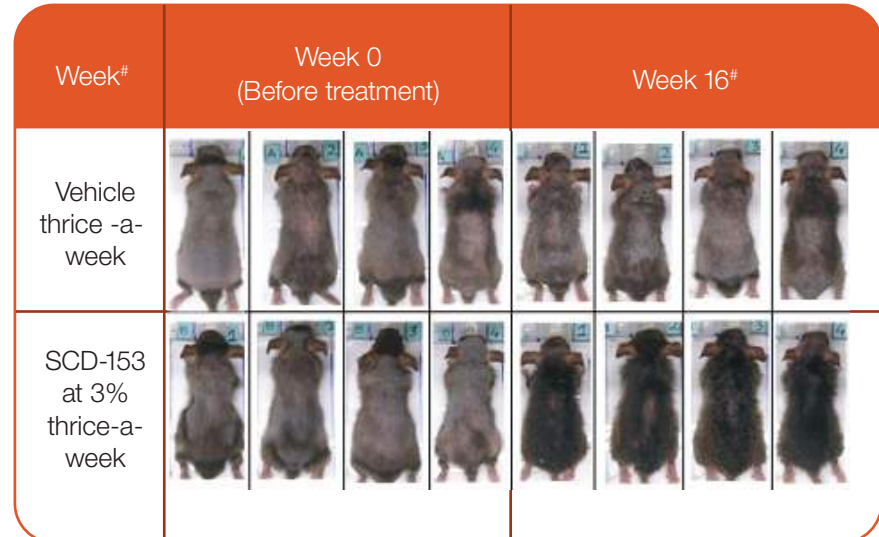
SCD-153 has demonstrated promising preclinical data

Hair growth in mouse Alopecia Areata model



n=7; 85–100% alopecia; >45 weeks age
Spontaneous severe C3H/HeJ AA mouse model

Data are represented as mean ± SD; two-way ANOVA followed by Bonferroni's multiple comparisons test (* p < 0.05 vs Vehicle)



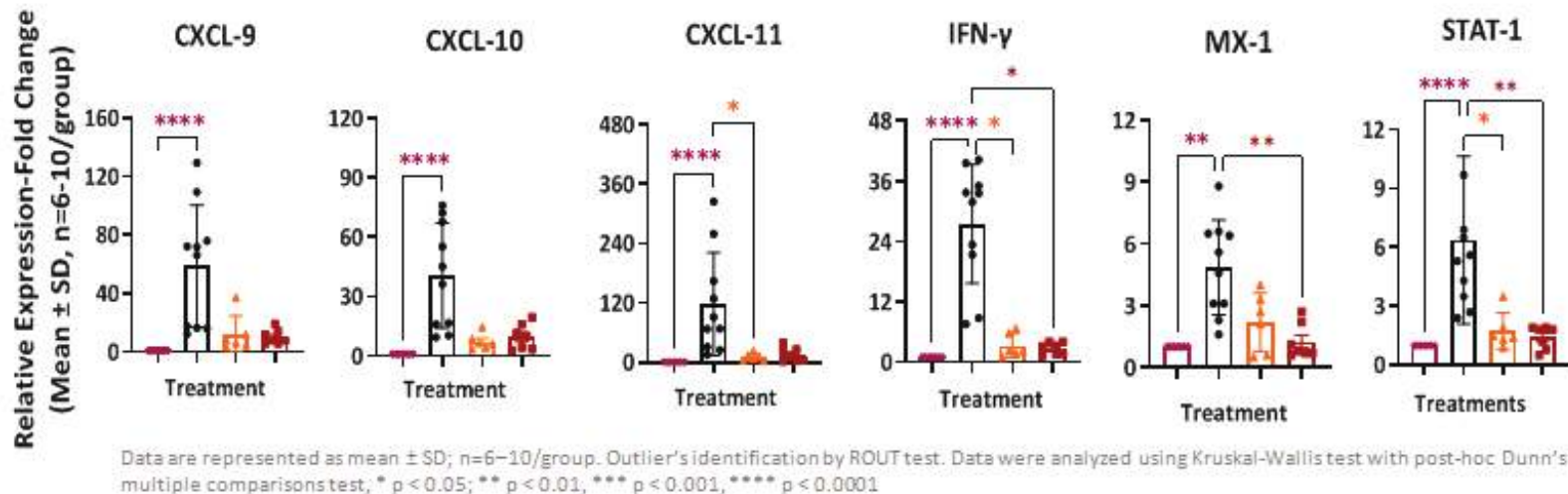
n=4

#n=1 from each group has completed Week 14

- SCD-153 demonstrates single agent activity
- It also showed suppression of inflammatory markers in skin
- Potential to use in combination with other agents

SCD-153 inhibited IFN signature gene expression in skin of AA diseased mice

qPCR analysis of AA diseased skin

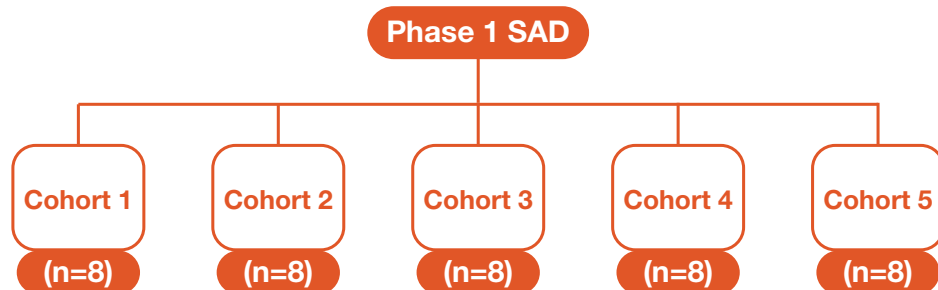


- ◆ Naive (Healthy) ● Vehicle, Thrice-a-week ▲ SCD-153, 3%, Thrice-a-week ■ SCD-153, 3%, Twice-a-week
- Significant reduction in IFN signature genes in treated skin at different administered doses was observed
- Suppressed inflammatory markers in skin

SCD-153 Phase 1 study

A Randomized, Double-Blind, Vehicle-Controlled, Study to Evaluate the Safety, Tolerability and Pharmacokinetics of topically applied SCD-153 in Healthy Volunteers

IND Approved by DCGI



- Phase 1 SAD study initiated in India
- 5 dose levels
- Cohorts administered active drug and placebo

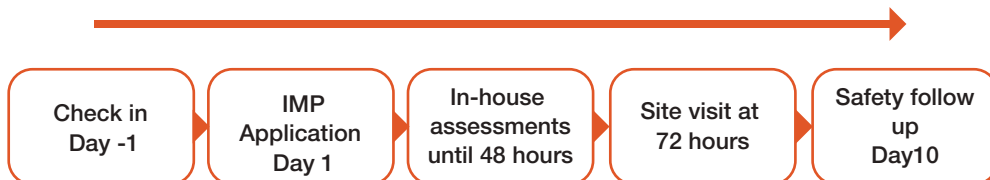
Primary Objective:

- To evaluate the safety and local tolerability

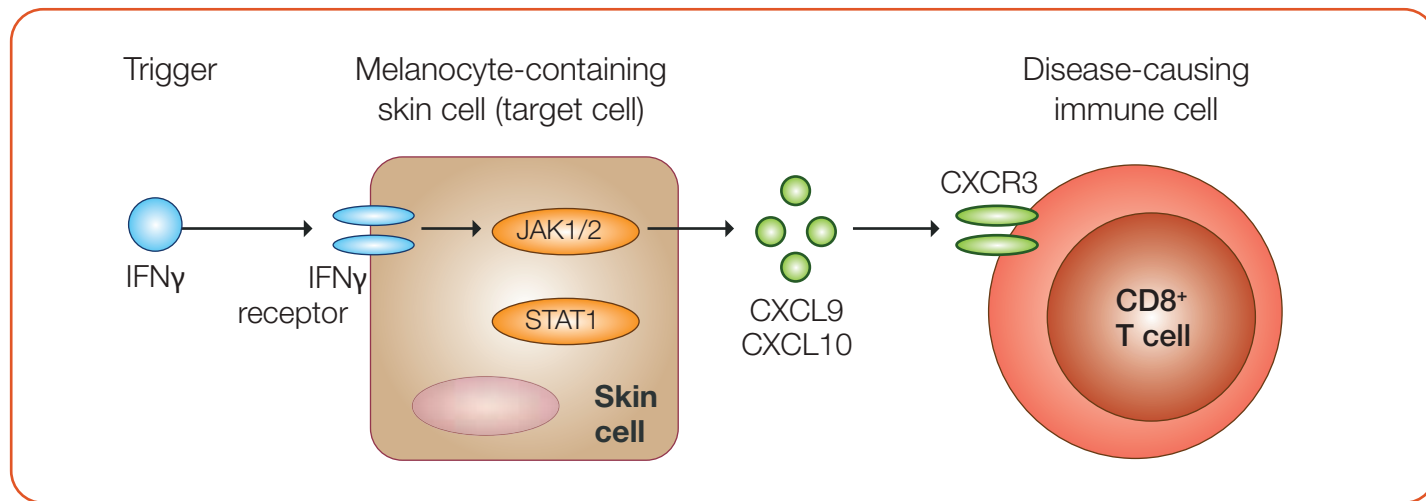
Secondary Objective:

- To evaluate the plasma pharmacokinetics of SCD-153 and its metabolite

Study Flow Chart



SCD-153: potential to expand in other epidermal diseases



- IFN γ induces CXCL9, CXCL10 & CXCL11 in vitiligious skin. These chemokines recruit pathogenic CD8+ T cells to the pigment-containing melanocyte in the epidermis
- CD8+ T cells release cytokines that destroy the melanocytes causing depigmentation
- In-vitro* studies have shown that SCD-153 inhibits:
 - Expression of CXCL9, 10 and 11 in stimulated human keratinocytes
 - IFN γ secretion from stimulated murine CD8+ T cells

**SBO-154 for multiple
cancer indications**

Nitin Damle

Antibody drug conjugates

Large market expected to reach ~ 25 bn by 2038



12 FDA
Approved ADCs

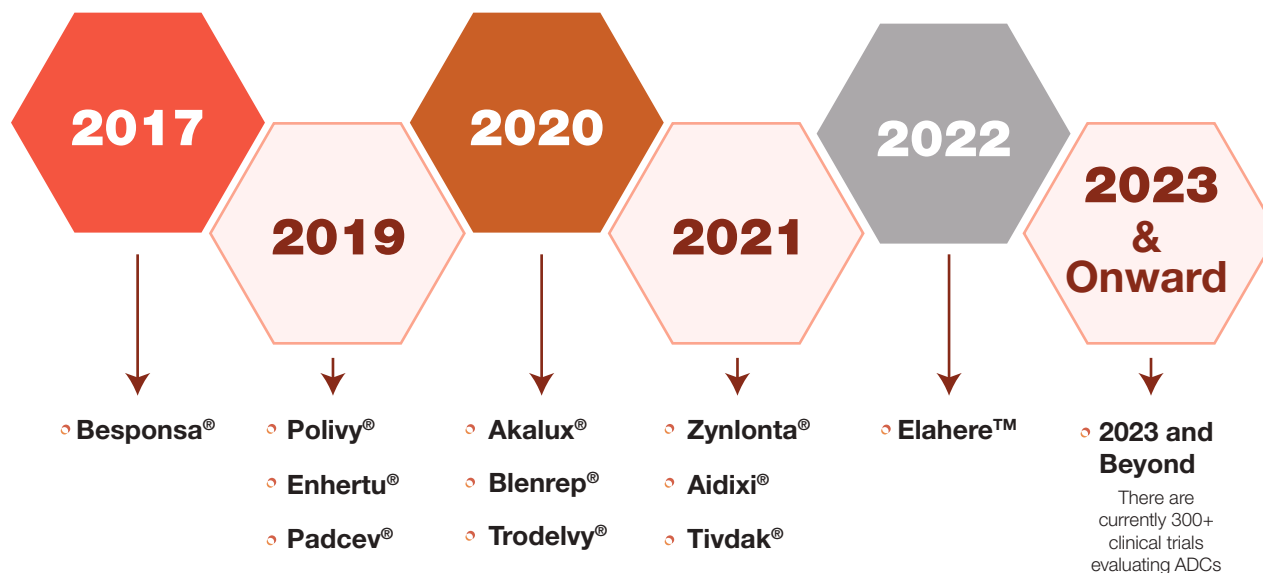


US\$ 25.34 Bn
Projected ADC market
by 2028



24.19% CAGR
from 2023 to 2028

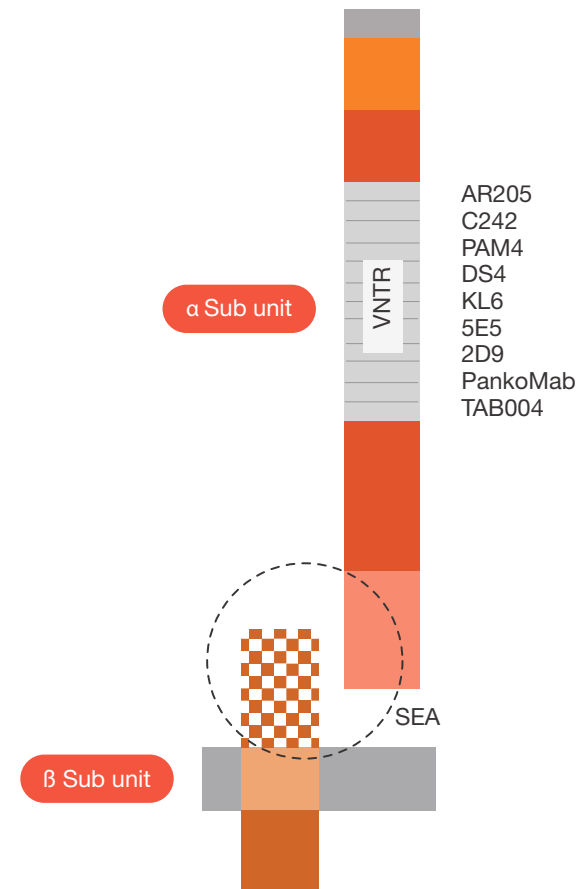
Approved ADCs



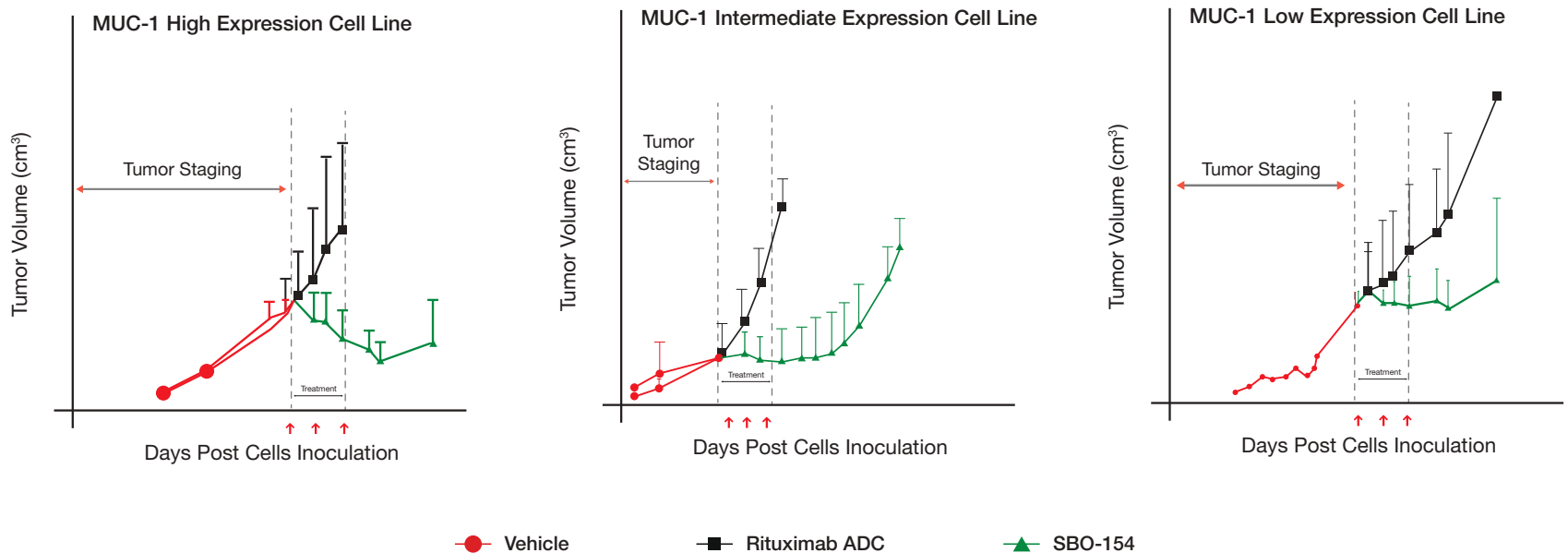
SBO-154 (Anti-MUC-1 ADC)

Novel antigen & approach to target MUC1-SEA domain, with an opportunity to therapeutically address multiple cancer indications

- Tumor agnostic opportunity in-licensed from Biomodifying LLC
- SEA targeting hypothesis validated
- Preclinical PoC of anti-tumor efficacy of anti-MUC-1-SEA targeted ADC established
- So far, no directly competing agents targeting MUC1-SEA in clinical development



SBO-154: Efficacy demonstrated in large established tumors



SBO-154 causes regression of large established tumors with high MUC-1 SEA expression

SBO-154 development update

INTERACT meeting granted by FDA

- INTERACT Meeting (Initial Targeted Engagement for Regulatory Advice on CBER CDER Products) Request
 - Meeting to seek early advice from the FDA to validate preclinical developmental strategy for the IND-enablement of the product and serve as a prelude to Pre-IND meeting prior to IND filing
- FDA response anticipated in November 2023

Financial update

Chetan Rajpara

Financial summary

Year	FY19	FY20	FY21	FY22	FY23	Q1FY24
USD INR	69.95	70.91	74.23	74.49	80.37	82.17
INR Cr						
Total Income	196	87	258	144	250	34
Total Expenses	342	399	410	347	472	129
Profit/(Loss) after Tax	-145	-312	-151	-203	-223	-95
USD Mn						
Total Income	28.1	12.2	34.8	19.3	31.1	4.2
Total Expenses	48.9	56.3	55.2	46.6	58.8	15.8
Profit/(Loss) after Tax	-20.8	-44.1	-20.4	-27.3	-27.7	-11.6

- Out-licensed SEZABY to SPI Inc. in Q4 2022 and received an upfront sum of US\$ 10mn. In addition, SPARC is eligible to receive regulatory and sales linked milestone payments and tiered royalties on sales
- Received ₹703 Cr (US\$ 93mn) in Jan-2023 against the conversion of warrants. With this, the entire proceed of the Preferential Issue (i.e. ₹1,112 Cr) stands received
- Cash and cash equivalent as of September 30, 2023 was ₹363 Cr (US\$ 44mn)
- The Company has
 - (a) Sanctioned bank facilities for ₹175 Cr (US\$ 21mn)
 - (b) Line of credit from the parent company for ₹250 Cr (US\$ 30mn) in place. Utilization of limits as of September 30, 2023 is NIL
- Obtained shareholders' approval in Aug-2023 AGM for raising a sum up to ₹1,800 Cr (US\$ 220mn) by way of fresh issuance



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