

SPARC/Sec/SE/2024-25/058

December 19, 2024

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,

P. J. Towers,

Dalal Street,

Mumbai - 400 001.

Scrip Code: 532872

Market Operations Dept.

Scrip Symbol: SPARC

Dear Sir/Madam,

Sub: Investor Presentation

Further to our letter SPARC/Sec/SE/2024-25/056 dated December 14, 2024 and pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, we enclosed herewith the investor presentation to be held today i.e. December 19, 2024 at 4:00 PM (IST), which we shall be uploading on our website after sending this letter to you.

This conference call will be reachable through an audio dial-in.

Audio conference Partic	pants can dial-in	on the number below:
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To participate in the conference call, please dial in the number provided above couple of minutes ahead of the scheduled start time. The operator will provide instructions on asking questions before the call.

Management presentation: The presentation pertaining to this discussion can be accessed through the link given below on the date of audio conference.

https://links.ccwebcast.com/?EventId=SPA191224

This is for your information and dissemination.



Yours faithfully,

For Sun Pharma Advanced Research Company Ltd.

Kajal Damania Company Secretary and Compliance Officer

Encl: As above





December, 19 2024

BSE:532872

NSE: SPARC

BLOOMBERG: SPADV@IN

REUTERS: SPRC.BO

CIN: L73100GJ2006PLC047837



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Agenda



SHORT-TERM
OPPORTUNITIES:
IMMUNOLOGY

MUDGAL KOTHEKAR

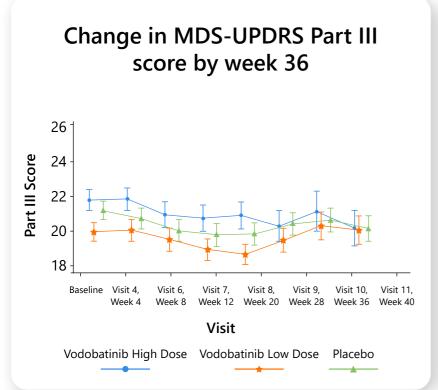


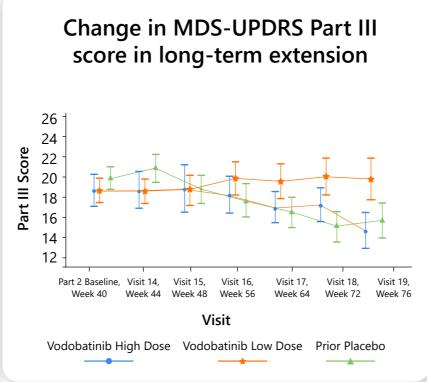


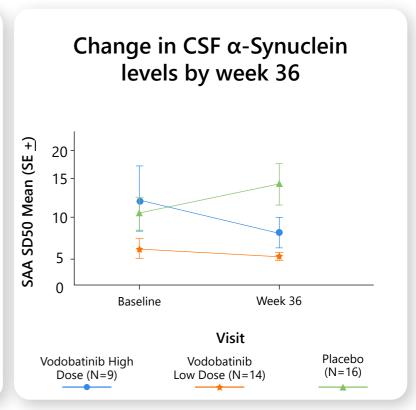
PROSEEK data analysis completed

Full data set confirms IA findings

- Study did not meet primary endpoint
 - The placebo response in PROSEEK appears to be an outlier compared to historical data
- Target CSF concentrations of Vodobatinib were achieved in both dosing arms
- Plasma PK consistent with earlier studies and expectations
- Biomarker data showed mixed and inconclusive trends





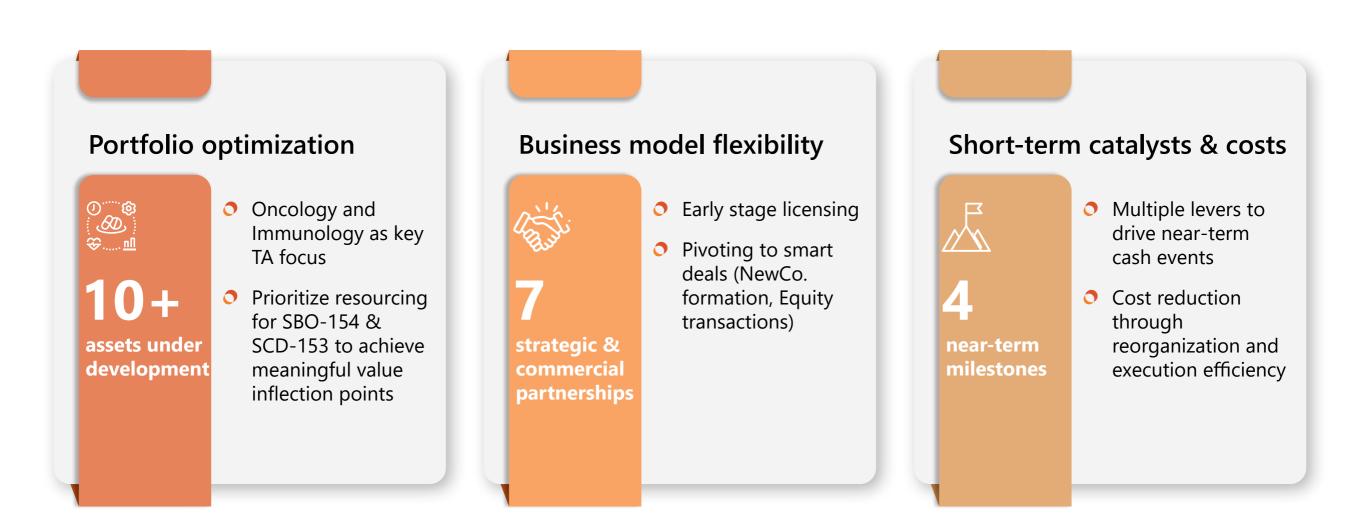


SPARC will discuss results with scientific advisory board and publish the results



Turning the page - Post PROSEEK priorities

Focus on medium-term clinical PoCs and cash flow

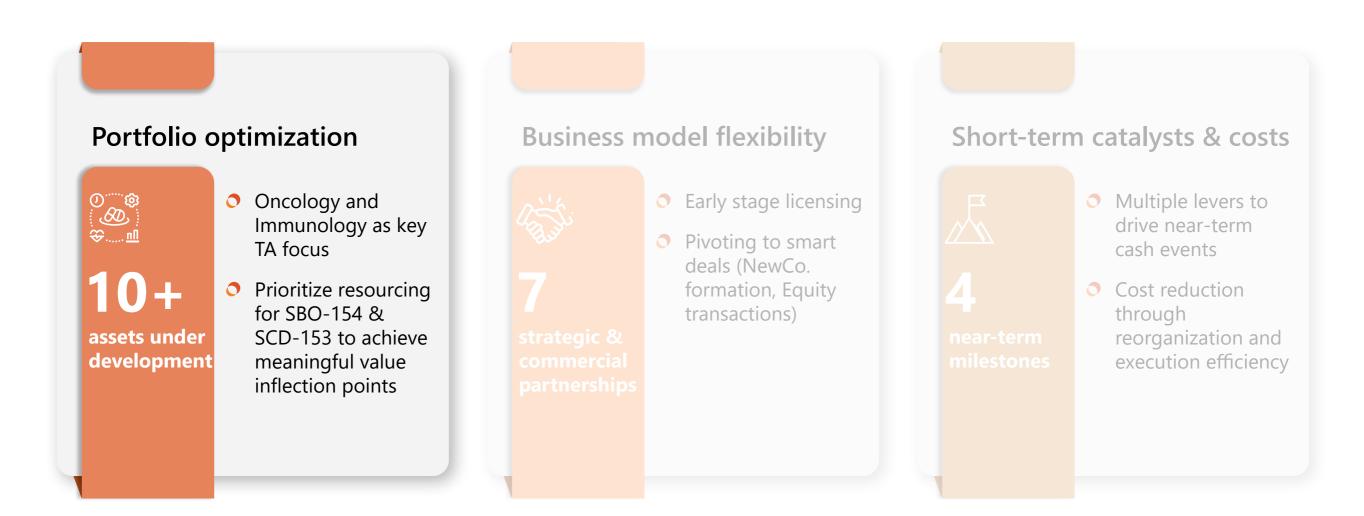


SCD-153 and SBO-154 can become productive platforms upon successful translation



Turning the page - Post PROSEEK priorities

Focus on medium-term clinical PoCs and cash flow



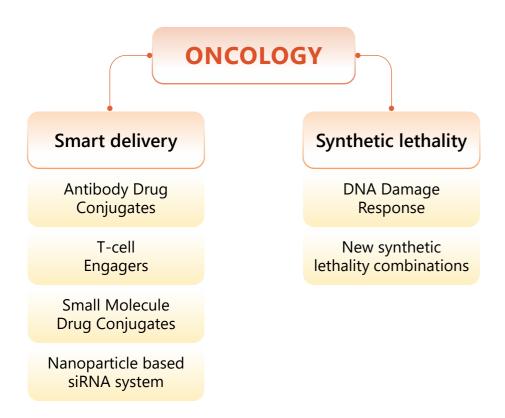
SCD-153 and SBO-154 can become productive platforms upon successful translation



Narrowing therapeutic area focus

ONCOLOGY

Smart delivery of chemotherapeutics or immune activators using targeting mAbs or small molecule ligands



 Targeting novel antigens and delivery platforms to deliver therapeutic agents

IMMUNOLOGY

Topical delivery of novel agents providing potentially safer treatment options to patients



- Focus on dermatological indications with a potential to work both as monotherapy and in combination with other complementary mechanisms
 - Targeting novel mechanisms for treatment of AA, Vitiligo and other chronic inflammatory dermatological conditions having limited treatment options
 - Developing topical agents to achieve optimal concentration at the site of action without the toxicity challenges associated with systemic agents



Potential first-in-class assets as anchors

Prioritized resourcing for SBO-154 and SCD-153

SBO-154

- Delivers proven
 payload with a novel
 epitope of tumor
 targeting antibody and
 a validated linker
- Key elements of the hypothesis validated in preclinical studies

SCD-153

- Topical agent for treatment of AA and Vitiligo
- Low potential for systemic AEs confirmed in Phase 1a study in healthy volunteers

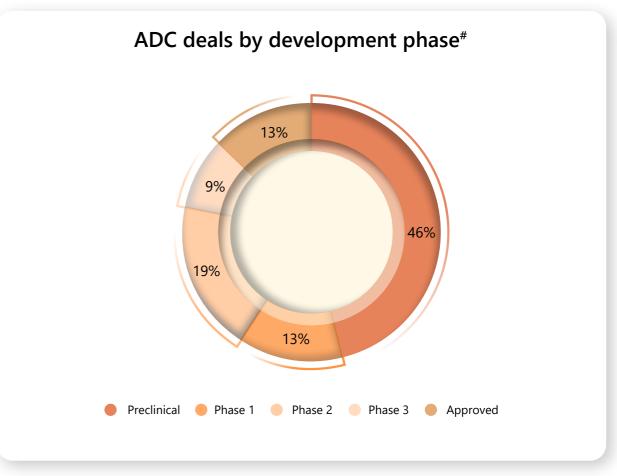
Both products offer significant product extensions once the primary tenets of the hypothesis get clinically validated



SBO-154 leverages the broad success of the modality

15 ADCs approved by USFDA



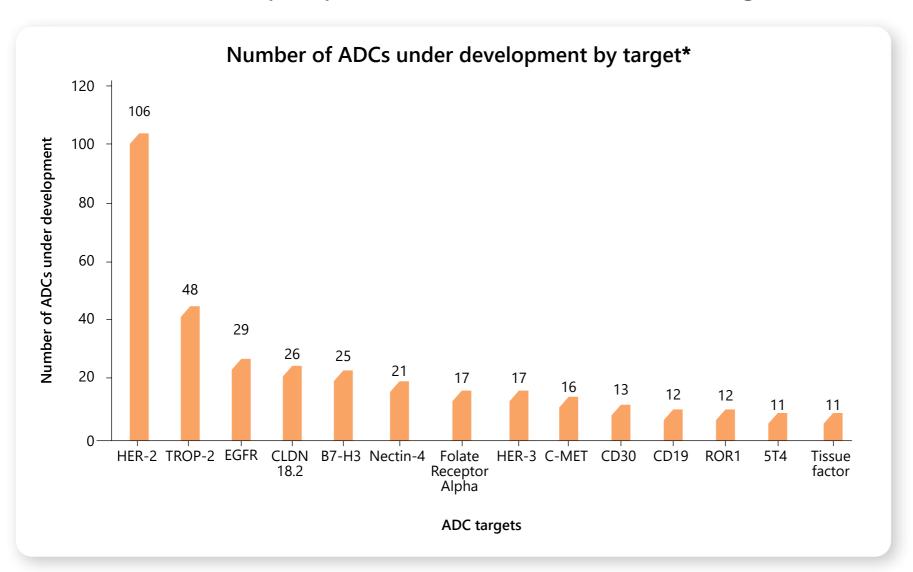


- Notable progress in the development of new ADCs in oncology, making up 9% of the oncology pipeline in 2023
- ADCs have transformed the treatment landscape with their ability to deliver payloads with precision directly to tumor cells providing better cell kill and avoiding off-target side-effects
- Advanced linker technology allows use of both covalent and non-covalent methods to retain the conjugates in circulation while permitting antibody function and cellular internalization



SBO-154 offers a distinctive advantage in dynamic ADC space

Binds to a novel epitope of a cancer associated antigen



ADC field centered around select antigens

~65% of pipeline assets targeting 5 antigens

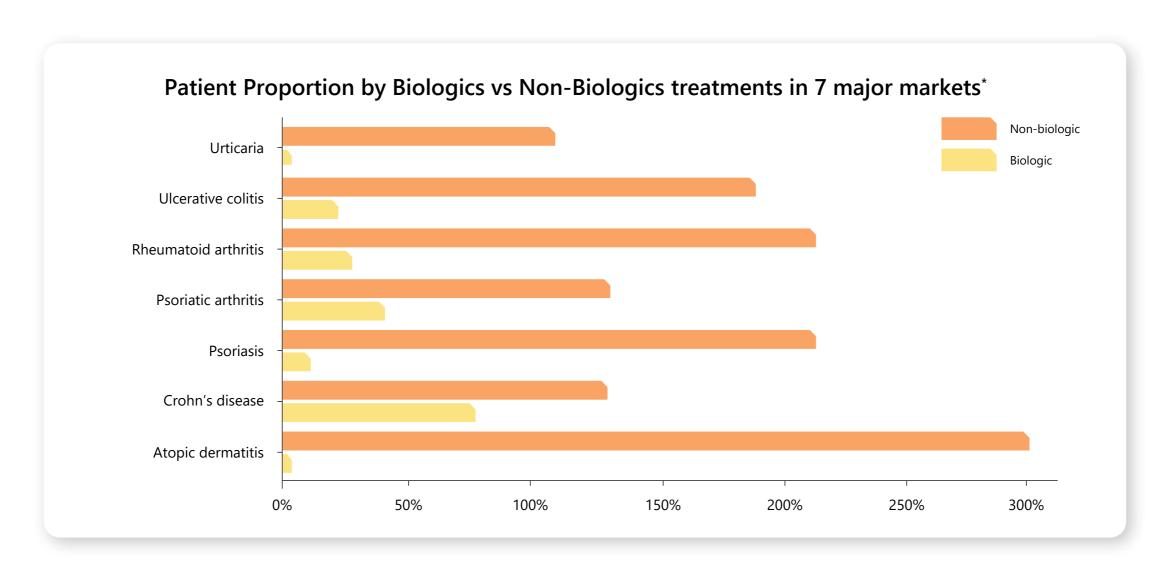
MUC1-SEA domain is an unexplored ADC target

- MUC1 expression confirmed across multiple tumor types providing development opportunities to target several patient sub-types
- SBO-154 has successfully established SEA binding hypothesis in preclinical studies and can be used for multiple constructs using different payloads and linkers



SCD-153 expands pathway & modality options

Addressing the need for safer and convenient alternatives in Immunology

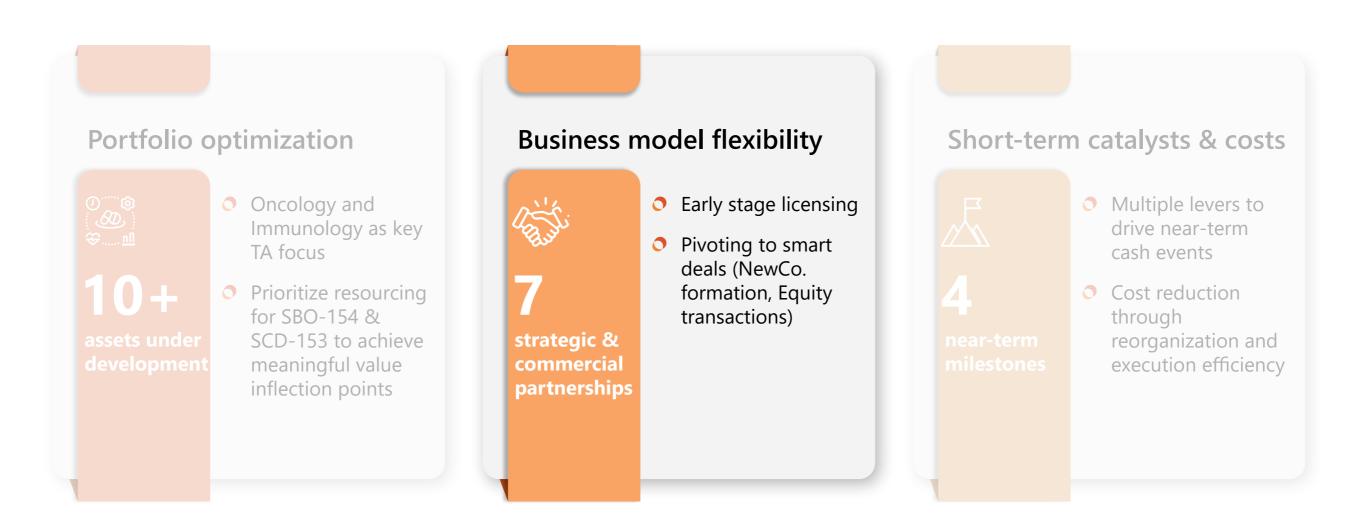


- Expensive biologic treatments are reserved for more severe patients who constitute a much smaller proportion of treated patients
- Adverse events associated with current oral SoC for dermatological indications warrant a different modality for reduced side effects
- The field is expected to evolve towards use of mechanistically independent combinations enhancing effectiveness and provide more comprehensive management of disease



Turning the page - Post PROSEEK priorities

Focus on medium-term clinical PoCs and cash flow



SCD-153 and SBO-154 can become productive platforms upon successful translation



Business model flexibility to advance assets and leverage capabilities

EXPAND PARTNERING INTENT

- Openness to explore partnering options at multiple inflection points including IND
- Explore preclinical program/ platform collaborations

EXPLORE NEW STRUCTURES

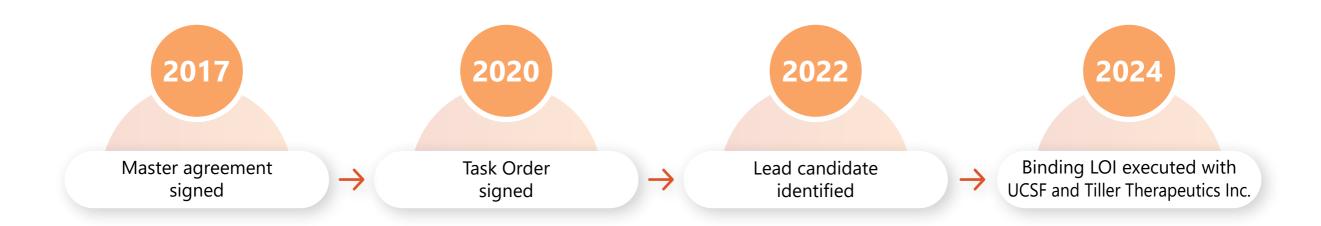
- Beyond traditional licensing arrangements including asset specific NewCos and potential spin-outs
- Opportunities to leverage capability based partnering

Our collaboration with the UCSF and the formation of Tiller Therapeutics illustrates this approach



Case in point - A NewCo. to advance Joint IP

Developed in collaboration with UCSF



- Research collaboration with the University of California San Francisco (UCSF) for development of oncology assets
- Fast-track development
 - Lead compound identified within 2 years of initiation of the project
 - Terms finalization and LOI execution within 6 months of NewCo (Tiller Therapeutics) formation



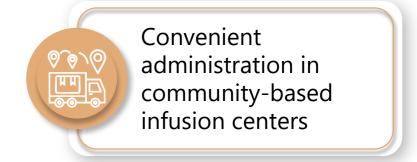
SCO-155 enables preferential delivery using a small molecule ligand

Offers potential advantages over RLTs

- SCO-155 is a Small Molecule Drug Conjugate (SMDC) delivering cytotoxic agent targeting prostate-specific membrane antigen (PSMA) as a potential treatment for metastatic Castration Resistant Prostate Cancer (mCRPC)
- PSMA is specifically and highly expressed in prostate cancer
- Opportunities with PSMA directed SMDCs







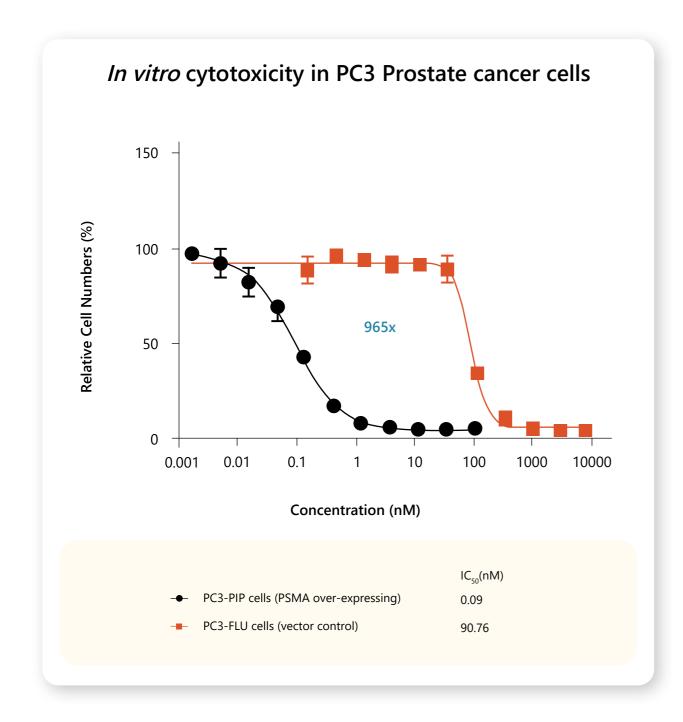
SCO-155 has potential to become standard of care for treatment of Prostate Cancer

15



SCO-155 improves the therapeutic window

Preclinical PoC established



In vivo efficacy in Prostate Cancer PC3 Xenograft model 2000 1500 Tumor volume (mm³) 1000 500 SCO-155 treated 0 10 15 20 25 **Days after Treatment** PC3-FLU cells (vector control) PC3-PIP cells (PSMA over-- SCO-155 60 µg/kg expressing) - SCO-155 60 µg/kg PC3-FLU cells (vector PC3-PIP cells (PSMA overcontrol) - Vehicle expressing) - Vehicle

SCO-155 showed selective killing of PSMA overexpressing prostrate cancer cells *in vitro* with around 1000x selectivity over PSMA null cells

SCO-155 showed selective tumor growth inhibition of PSMA over-expressing tumors *in vivo*



Tiller Therapeutics explores smart delivery with a novel approach

SMDCs leveraging synthetic ligands of cancer specific antigens

SPARC and UCSF have signed binding LOI with Tiller Therapeutics Inc. (Tiller) granting exclusive worldwide license to Tiller for preclinical oncology asset along with associated IP

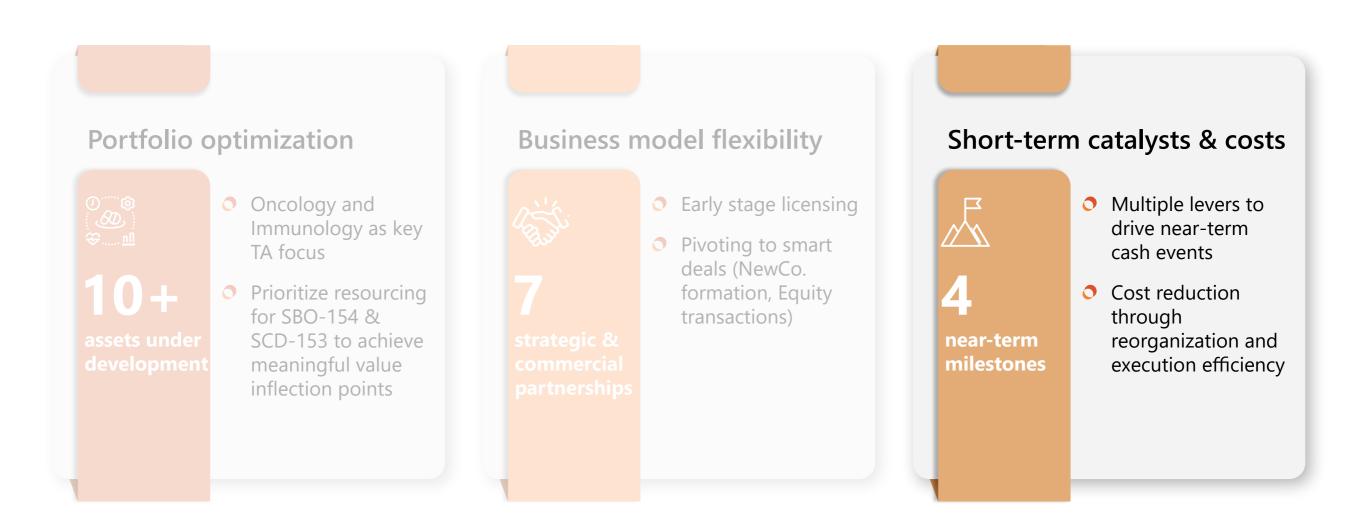


- Upon grant of license, SPARC will receive 55% equity stake in the fully diluted securities of Tiller. The equity will be issued to SPARC in two tranches within 6 months of execution of license agreement
- IND filing expected in FY26



Turning the page - Post PROSEEK priorities

Focus on medium-term clinical PoCs and cash flow



SCD-153 and SBO-154 can become productive platforms upon successful translation



Focus on near-term catalysts & cost efficiency

PURSUE PROGRAMS WITH CASH VISIBILITY

 Execute on short-term catalysts which can provide non-dilutive capital to reduce external funding

Opportunities with a spectrum of probabilities of success, which will be resolved mostly by end of this financial year

OPTIMIZE CASH BURN

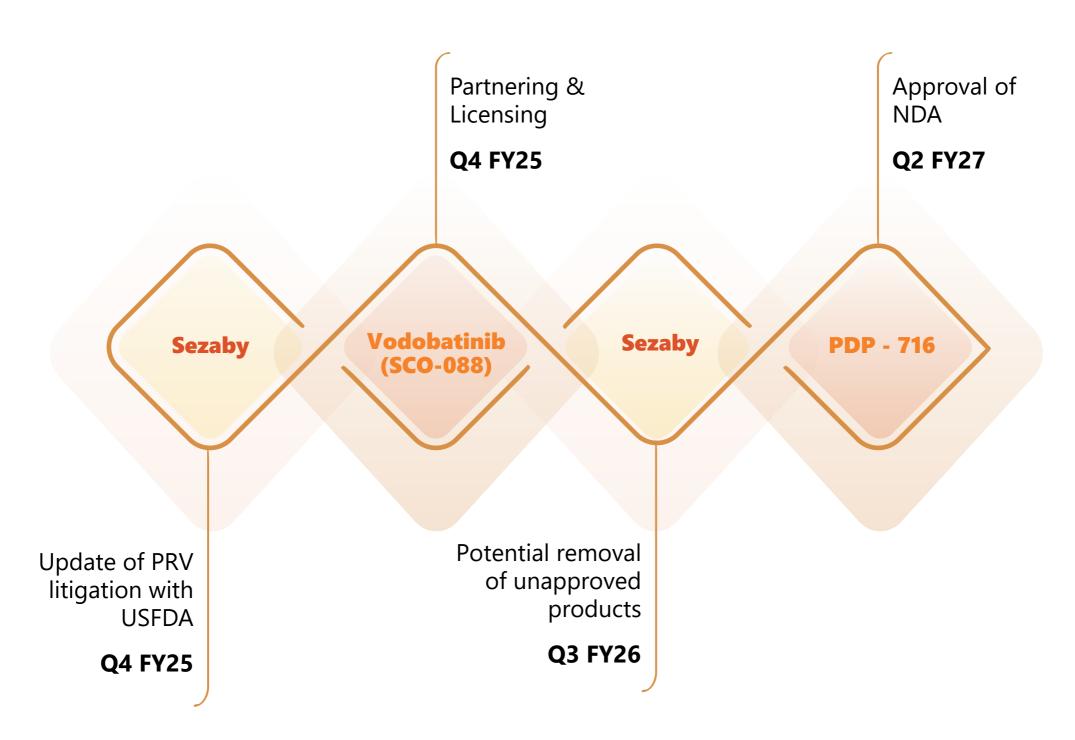
 Reduce cash burn through better alignment of objectives and cost

Clinical capability base and execution cost targeted for optimization



Near-term cash generating milestones

Delivering on actionable drivers of identified milestones is a top operational priority





Sezaby's eligibility for PRDV

Exploring all available options to ensure PRDV resolution

- USFDA denied SPARC PRDV based on its interpretation of PRDV statute and its requirements
- SPARC believes the agency's interpretation led to an unfair denial of PRDV
- SPARC is committed to exploring all available remedies including litigation in search of a final resolution







SPARC approached US District Court for the District of Columbia



Court opinion

In-person meeting with USFDA for sharing its position and seeking a review of decision

USFDA did not provide any feedback. SPARC sued USFDA for resolution of matter

Priority review vouchers have recently been traded for value in excess of \$100 mn

Ipsen announces sale of Priority Review Voucher for \$158m

* 27 August 2024

Acadia Pharmaceuticals Enters Into an Agreement to Sell its Rare Pediatric Disease Priority Review Voucher for \$150 Million

November 06, 2024 04:05 PM Eastern Standard Time

If granted, PRV can provide an income in excess of \$100 mn for SPARC

PRDV: Pediatric Rare Disease Review Voucher



Enforcing Sezaby's orphan drug exclusivity

Unapproved phenobarbital injectable formulations may cause serious adverse events in neonates

- Sezaby is the only approved phenobarbital injectable formulation by the USFDA
- USFDA stated in a recent guidance that excipients with known toxicity should not be used in neonates (e.g.propylene glycol, benzyl alcohol)
- Unapproved phenobarbital injectable formulations currently marketed contain propylene glycol and benzyl alcohol that presents specific safety concerns for neonates



Communication with USFDA

- Filed Citizen's Petition with USFDA. National coalition of Infant Health provided support to Citizen Petition
- Ongoing communication with the USFDA for acting on manufacturers' unapproved injectable formulations



Engaged manufacturers of unapproved injectable formulation

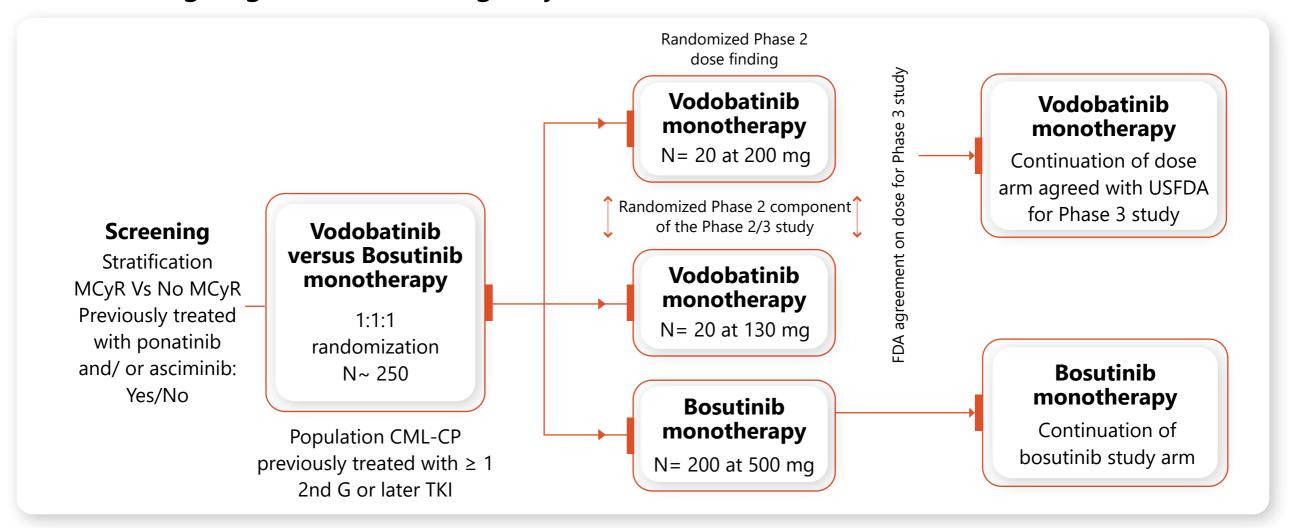
- Sent notification letters to voluntarily withdraw the unapproved injectable formulation
- Sent cease & desist letters

Significant efforts ongoing to potentially secure the removal of unapproved injectable formulations from the market



Vodobatinib in Chronic Myelogenous Leukemia

Phase 3 design agreed with the agency



Registration path

- Significant activity in last line CML patients demonstrated in Phase 2 study
- Registration study requirement was reset by USFDA; aligned with new requirements
- State of readiness for initiation of Phase 3

Licensing

- Initial outreach completed through an Investment banker
- Expected to close by end of FY25, however, CML being niche area, licensing process may require longer time



Vibozilimod Phase 2 outcomes later this year

Both studies achieved enrolment closure in Q2 FY25

S@LARES-AD-7

- 240 patients across three dose levels and placebo
- Primary endpoint Proportion of patients with EASI-75 response at week 16
- Enrolment completed: Jul 2024; 250 patients enrolled
- Topline (16-week) results: Q4 FY25

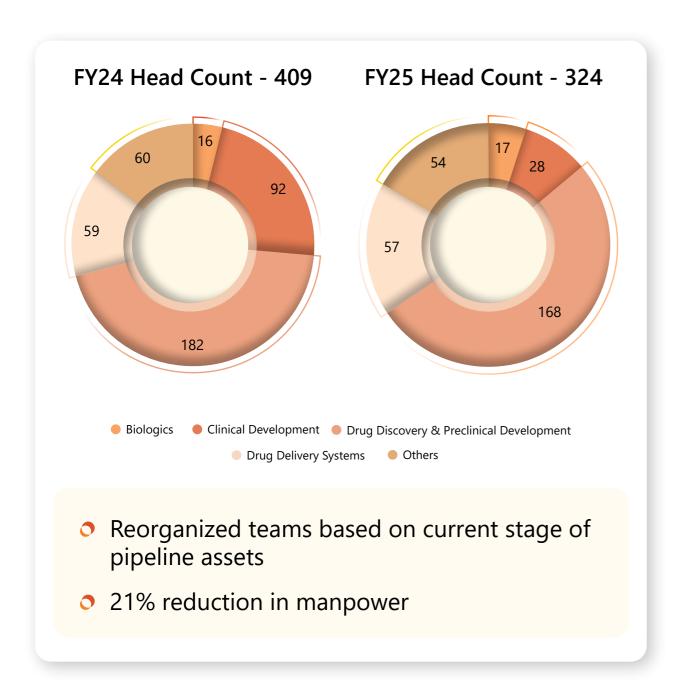
S@LARES-PsO-7

- 240 patients across three dose levels and placebo
- Primary endpoint Proportion of patients with PASI-75 response at week 16
- Enrolment completed: Aug 2024;263 patients enrolled
- Topline (16-week) results: Q1 FY26



Leaner organization to drive cost optimization

Manpower expense expected to be reduced by ~30%



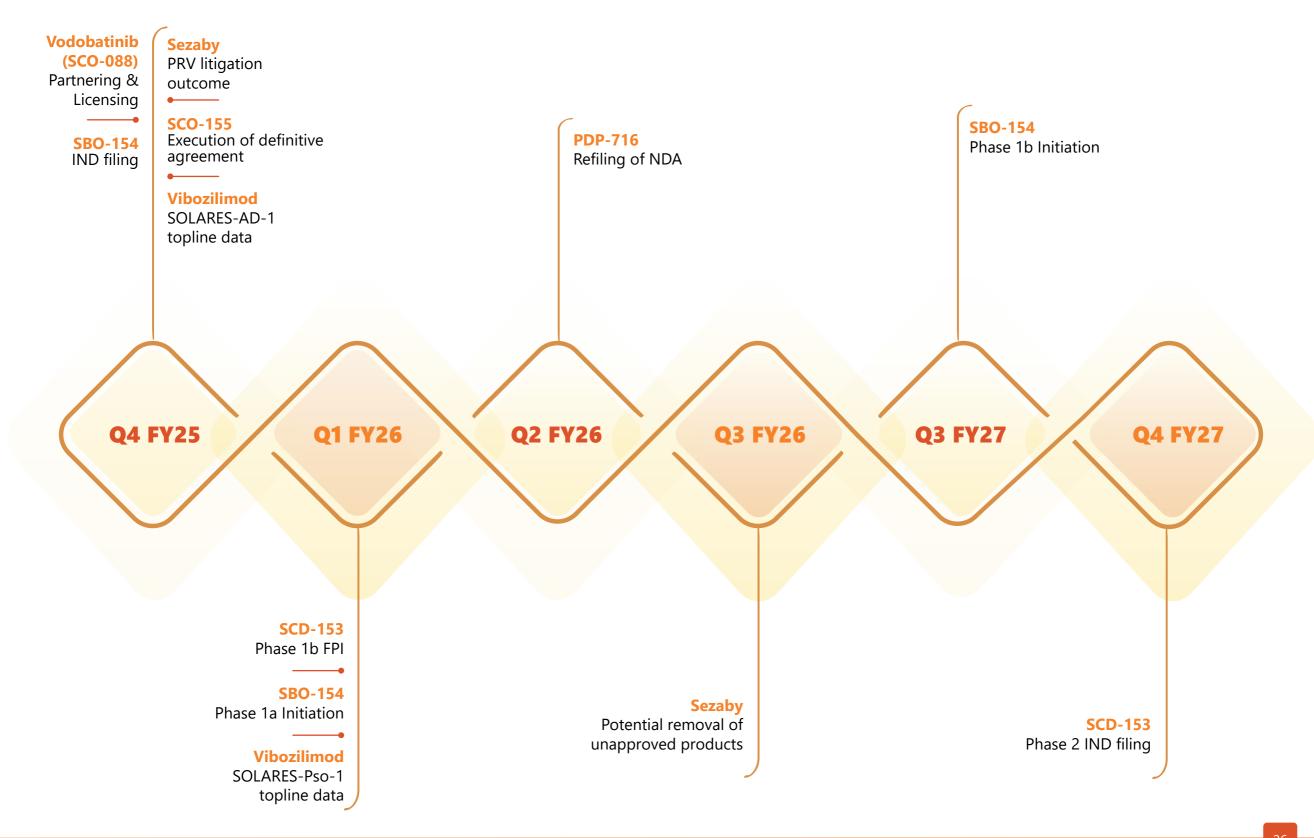


- Available debt and cost optimization measures can provide runway upto May 2025
- Expected milestones defer the imminent need of fundraise

FY25 HC as on 30th Sep 2024 | FY24 HC as on 31st Mar 2024



Key execution priorities for next 24 months



AD: Atopic Dermatitis | Pso: Plaque Psoriasis

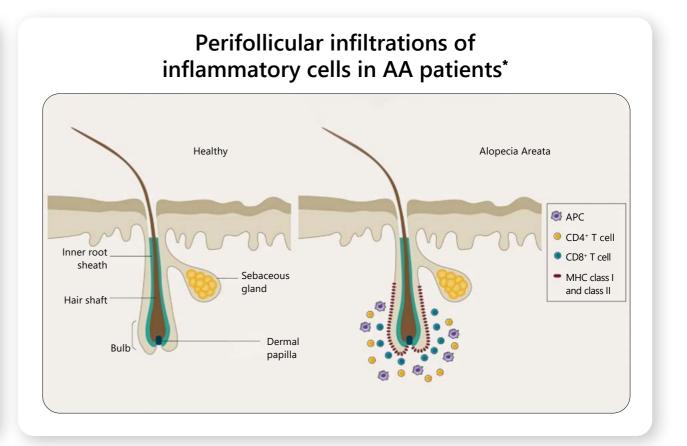






Alopecia Areata: Autoimmune disease causing spontaneous hair loss

Current approved oral drugs carry risk of long-term serious side effects



- Alopecia Areata affects 2% of global population
- After first episode ~50% patients spontaneously recover in one year. Relapse rate is up to 85%, reaching 100% in long-term
- Chronic treatments are needed; disease relapses on withdrawal of treatment
- Approved oral JAK inhibitors and off-label steroids carry significant risk on long-term use

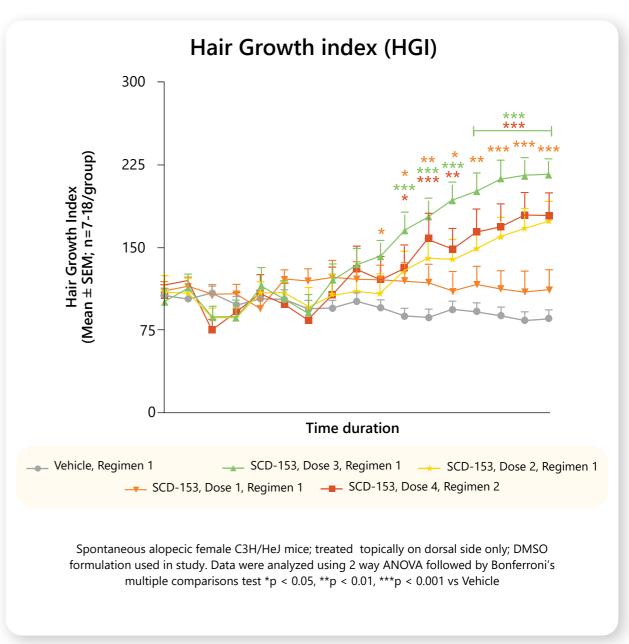
 In AA, CD8+ T cells at the base of follicle secrete inflammatory cytokines, leading to hair loss



SCD-153 induces hair growth in AA disease-relevant C3H/HeJ mouse model

Potential first-in-class agent for Alopecia Areata

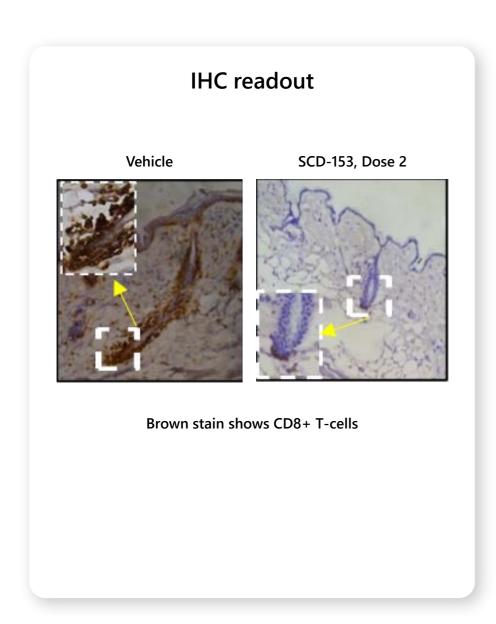


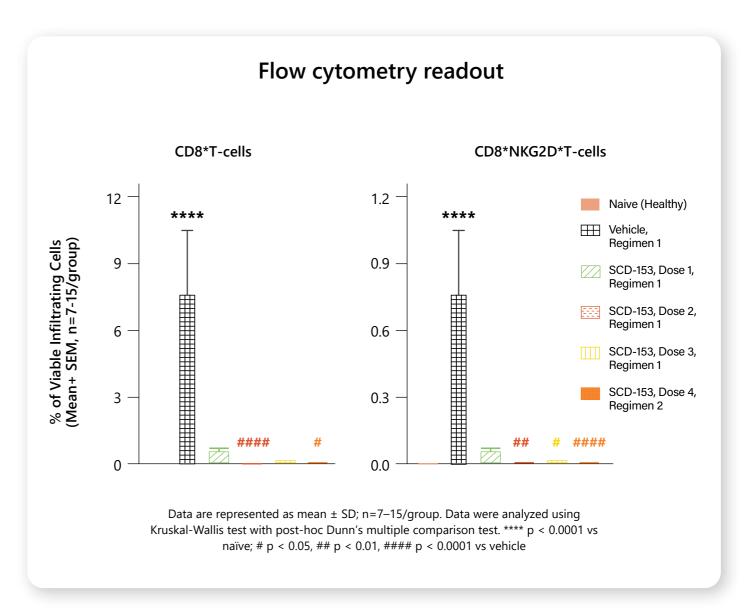


SCD-153 treatment shows robust dose-dependent increase in hair growth



SCD-153 acts by reducing number of cytotoxic CD8+ T-cells in skin of AA diseased mice



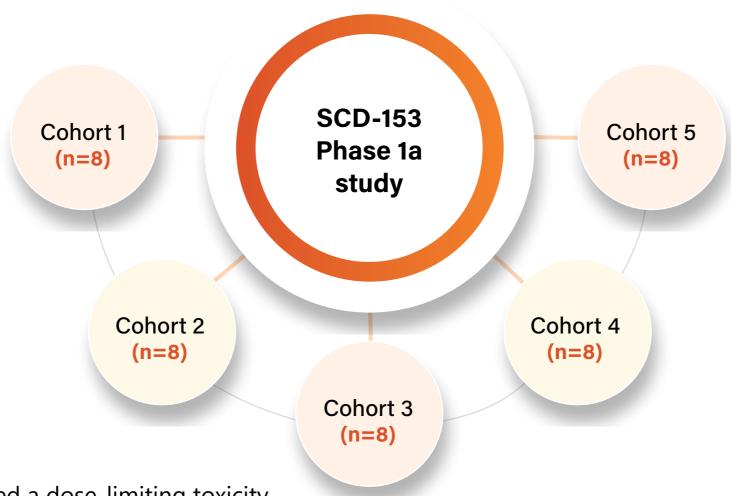


- CD8+ T-cells are the immune cell type associated with AA
- In particular, CD8+ NKG2D+ T-cell is the established disease-causative subtype in AA
- SCD-153 reduces both CD8+ T-cells and CD8+ NKG2D+ T-cells in skin and thereby improves hair growth



SCD-153 safe & well-tolerated in Phase 1a study

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



- No subject experienced a dose-limiting toxicity
- Measurable concentration detected in dermis and epidermis
- The maximum safe dose was not reached

SCD-153, at all strengths, is safe and well-tolerated



No systemic AEs related to SCD-153 observed in Phase 1a study

Summary of subjects with drug related AEs (N=40)

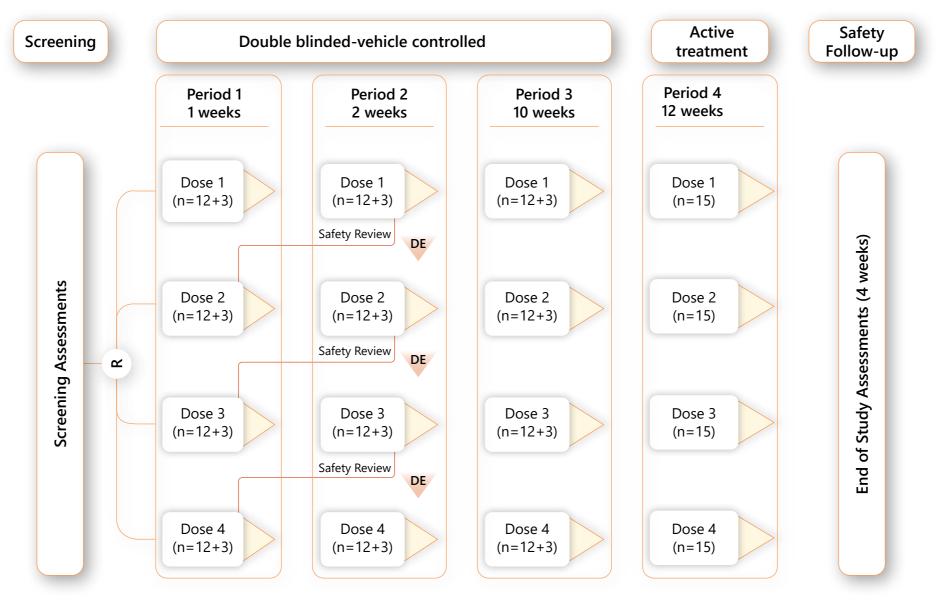
Doses	Adverse Events
Dose 1	None
Dose 2	None
Dose 3	None
Dose 4	2 (related: Erythema; score 2 and Burning sensation; n=1)
Dose 5	3 (related: Erythema; score 2; n=2, Burning sensation; n=1)

All AEs were mild in severity and were resolved without treatment



Phase 1b study in Alopecia Areata patients

- A Randomized, Double-Blind, Vehicle-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of Topically Applied SCD-153 in Patients With Alopecia Areata (AA)
- Primary Objective: To determine the maximum safe dose of topical SCD-153 in patients with AA
- Secondary Objective: To evaluate the safety and local tolerability of multiple ascending doses of topical SCD-153 in patients with AA



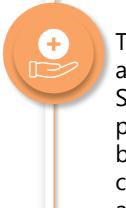
R: Randomization; DE: Dose Escalation; n=12 (active treatments) + 3 (vehicle)



SCD-153 expands pathway & modality options

Addressing the need for safer and convenient alternatives in Immunology





Topical administration of SCD-153 offers possibilities to be used either in combination or as maintenance treatment with SoC



Multiple formulation options provide opportunities to expand indications and cater to a large patient pool

Topical SCD-153 addresses the limitations of current treatments and offers a class alternative



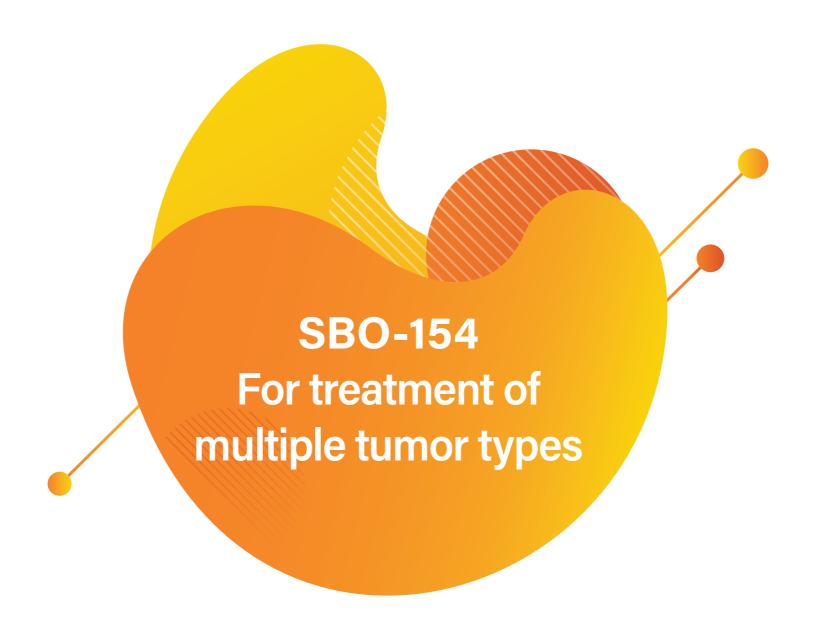
Next Steps for SCD-153





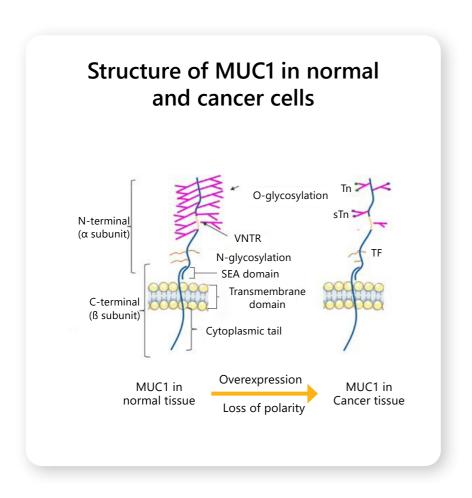


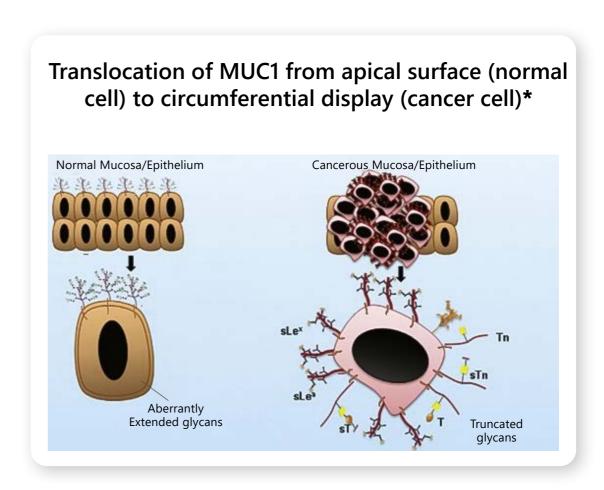






MUC1 offers an excellent opportunity to preferentially target tumor cells





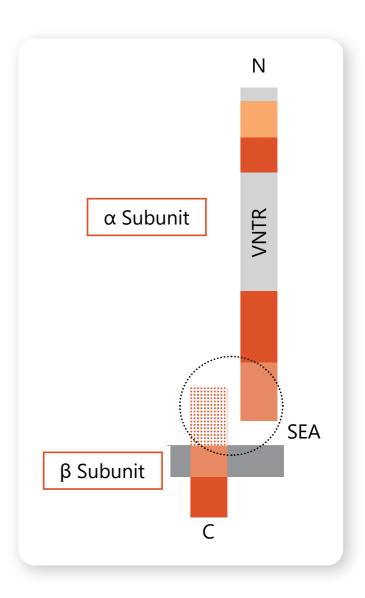
- MUC1 is normally expressed exclusively on the apical surface of glandular epithelial cells
- In cancer cells such polar expression is lost and MUC1 expression occurs across the entire membrane



SBO-154 targets the membrane proximal SEA domain of MUC1

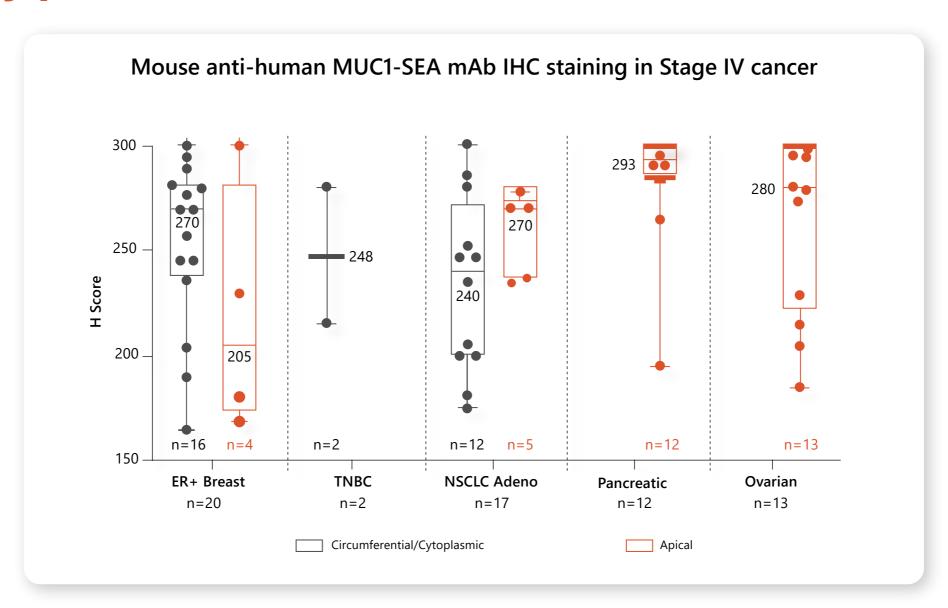
Novel targeting approach makes SBO-154 unlikely to be subject to a sink effect in plasma

- MUC1, the glycoprotein antigen on the cell surface consists of two parts the α & β subunit
- The junction of α subunit (outside the membrane) & the β subunit (partly embedded) makes the SEA domain
- Drug targeting at SEA domain has higher potential of therapeutic efficacy compared to MUC1-α subunit
- SBO-154 may represent a first-in-class MUC1-SEA-targeted therapeutic agent to be developed for use in cancer therapy





High MUC1-SEA expression level in human tumors of highly prevalent cancers

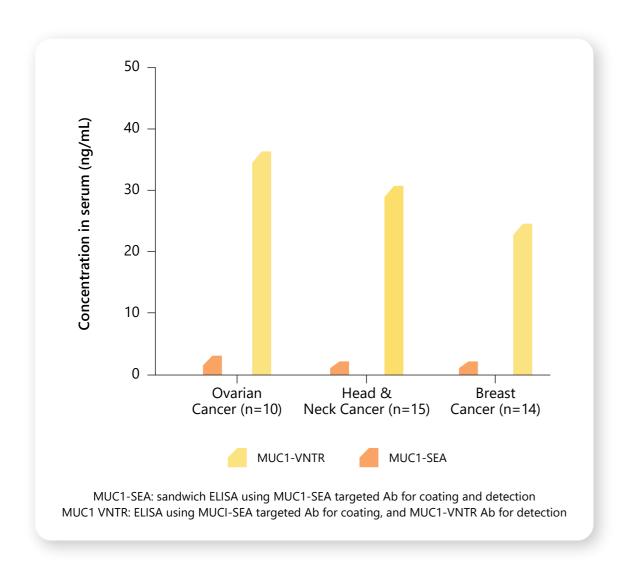


- High MUC1-SEA expression (IHC-H score > 200) in ER+ breast cancer, non-small cell lung adenocarcinomas, ovarian and pancreatic carcinomas
- Expression increases as the stage of the tumor advances
- Preclinical studies further corroborate suitability of MUC1-SEA as an ADC target and establish relevance of antigen expression level



SBO-154: Hypothesis validated

SEA targeting ADC relatively unaffected by shed antigen, retains function of tumor-targeting



- Almost all patients with MUC1+ tumors have levels of shed MUC1-VNTR antigen in the plasma
- This shed MUC1-VNTR binds to therapeutic ADCs, acting as a "sink" in the peripheral blood, and may be responsible for the lack of anti-tumor activity of the 1st generation MUC1 targeting ADCs
- Very low levels of MUC1-SEA in plasma of patients with MUC1 expressing tumors, compared to MUC1-VNTR

Finding consistent with the hypothesis that SBO-154 may not lose activity due to the "sink" effect



Preclinical efficacy of SBO-154 correlates with MUC1-SEA expression level

In vitro cytotoxicity studies

Carcinoma cell line	Expression level (by flow cytometry)	SBO-154 ADC IC ₅₀ (µg/mL)	Anti-CD20 ADC (unrelated ADC) IC ₅₀ (μg/mL)
Colo-357 (Pancreatic)	+++	0.05	3.45
MCF7 (ER+ve Breast cancer)	++	0.07	>10
HT29 (Colon)	+/-	>10	>10

SBO-154 ADC shows high potency in cells where MUC1 expression is high

In vivo mouse xenograft studies 1200 **COLO 357 Pancreatic Cancer** 2000 HT-29 Colon Cancer H Score: 130 H Score: 46 Tumor volume (mm³) (Mean ± S.E.M, n= 6-8) 900 1500 Tumor volume (mm³) (Mean ±S.E.M, n= 6-8) 600 1000 300 500 13 17 17 21 Vehicle ★ SBO-154 (3 mg/kg, IV, Q4D X 4) Vehicle ★ SBO-154 (3 mg/kg, IV, Q4D X 5)

SBO-154 ADC shows higher activity in vivo against tumors where MUC1 expression is high



Preliminary NHP Tox suggests SBO-154 is well-tolerated with toxicity profile comparable to other MMAE-based ADCs

NHP exploratory 7 week DRF study

Doses	1, 3, 6 mpk of SBO-154	
Dosing schedule	Q3W x 3; Dosing Days: 1, 22 and 43	
Results	 No mortality or clinical signs No effect on body weight and feed consumption at any dose Hematology data showed reduced RBC, WBC and neutrophil count at 3 mpk and 6 mpk. Expected based on known effects of MMAE Histopathology: Minimal to moderate, decreased hematopoietic cellularity (all lineages) in sternal bone marrow was observed in males at 3 mpk and in females at ≥ 3 mpk HNSTD: 6 mg/kg, Q3W x 3, IV; 7-week study 	
Toxicokinetics	Dose-proportional increase in exposure with no gender difference and accumulation following Q3W X 2, IV administration	

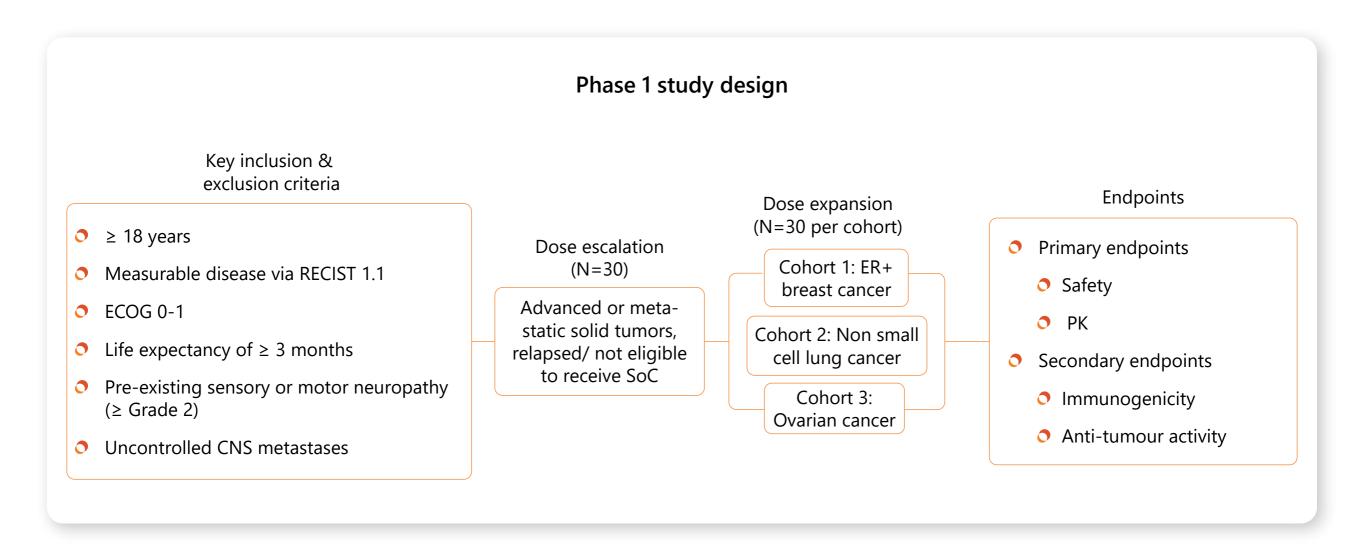
Up to 6 mg/kg IV dose was generally well-tolerated (n=1M+1F/group)



SBO-154 development update

Preparedness for Phase 1 study

- Pre-IND meeting
 - USFDA response received at the end of Nov 2024 indicates broad agreement with SPARC's proposed IND data package with no significant barriers to planned IND submission
- Phase 1 study
 - Global Phase 1 study planned to include the United States and India





Timelines & Milestones

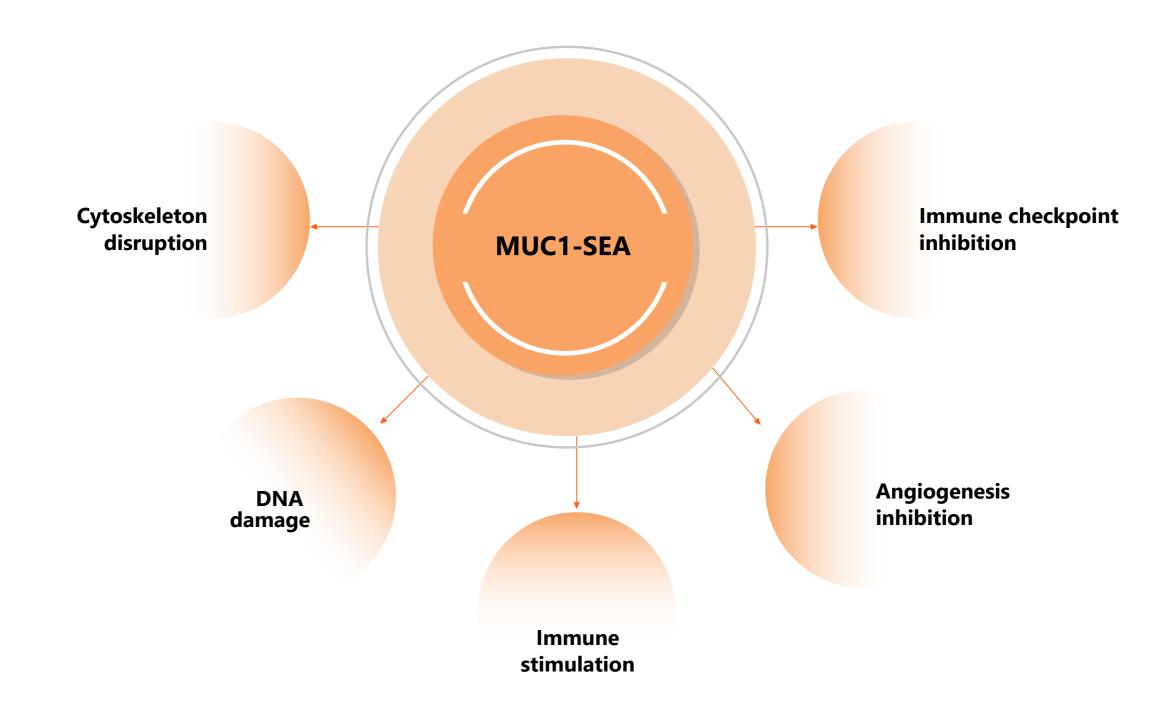




FY27
Phase 1b Initiation

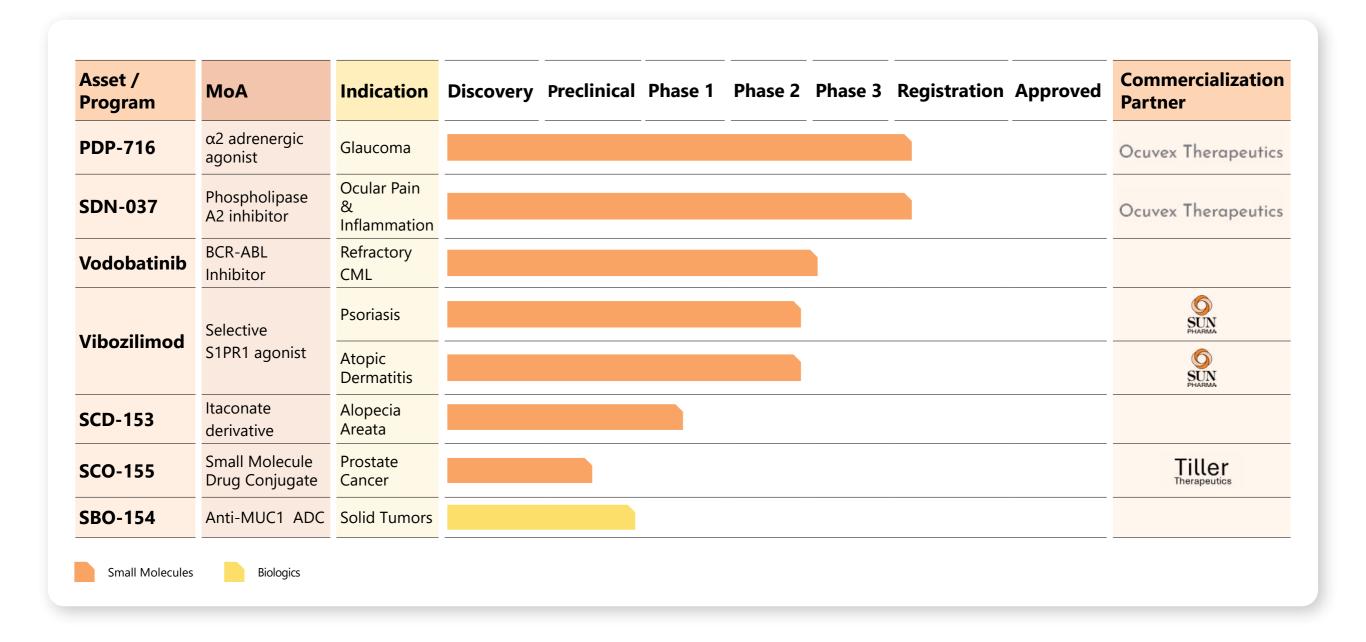


Modular platform which can deliver multiple products to the pipeline





Pipeline summary - Multiple first-in-class assets under development



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