Update on R&D Pipeline

19 Sep, 2019

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Agenda

1. **Strategy & Growth Drivers**
   Anil Raghavan – CEO
2. **Update on Clinical Programs**
   SiuLong Yao – Sr. V.P. Clinical Development & Operations
3. **Early Stage Program Update**
   Vikram Ramanathan – V.P. Translational Development
4. **Collaborations & Partnerships**
   Nitin Damle – Sr. V.P. Innovation
5. **Financial Summary**
   Chetan Rajpara – CFO
6. **Q&A**

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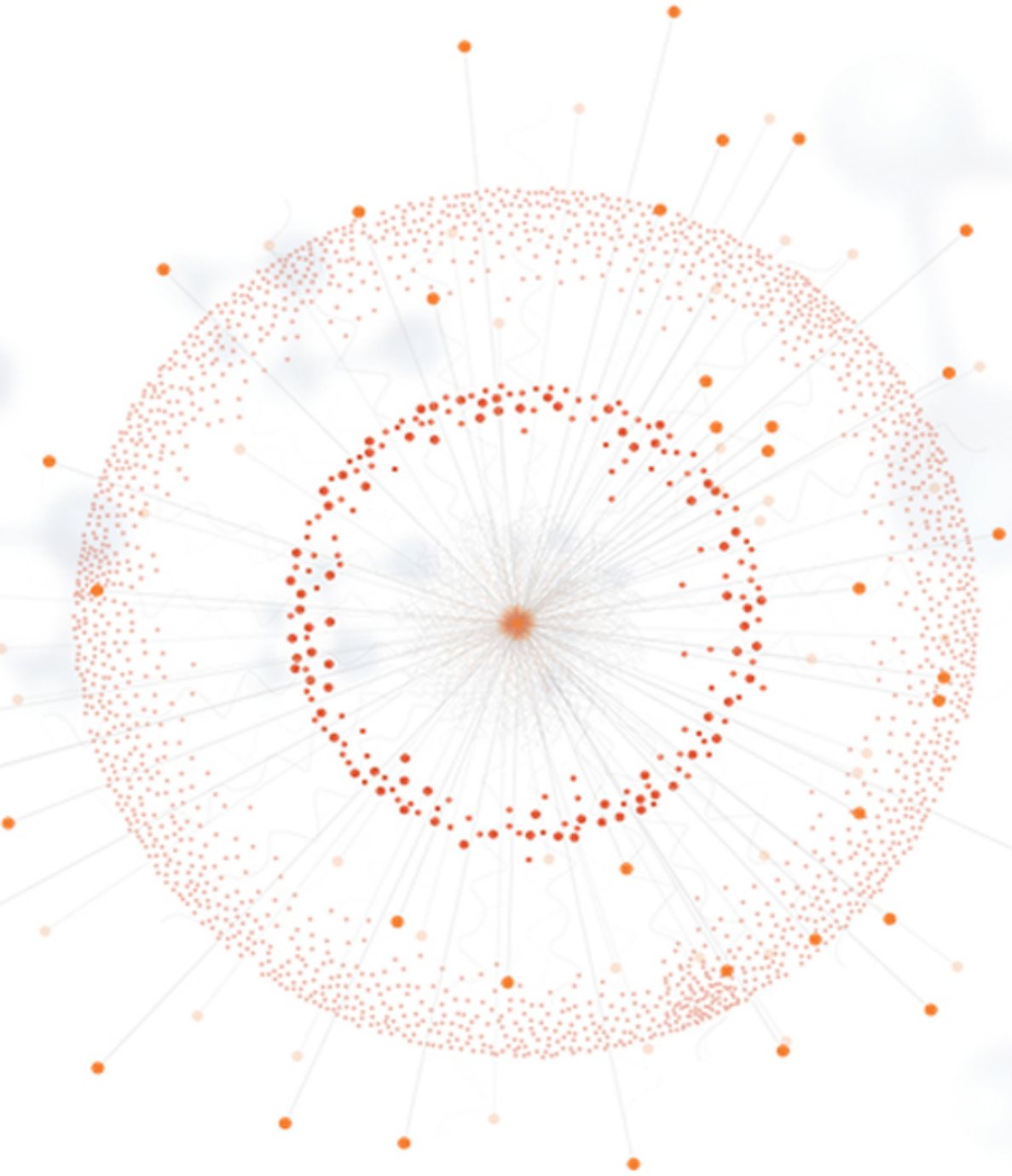

Strategy & Growth Drivers

Early programs reach the finish line

...offering validation and key lessons for the future

- SPARC received USFDA approvals for Xelpros® and Elepsia® XR
- USFDA accepted SPARC's NDA for Taclantis® (PICS)

Xelpros® BAK Free

- Xelpros® was launched in the US by Sun Pharma in Q4 FY19
- Early days yet, product gaining prescription share

Elepsia® XR 1/1.5g

- USFDA approved 1000 mg and 1500 mg strengths of Elepsia® XR
- Expect to finalize commercial partner for US in H2 FY20

Taclantis®

- NDA accepted in Q1 FY20. PDUFA date set for Feb. 2020
- SPARC is reviewing Celgene infringement challenge

USFDA = United States Food and Drug Administration; NDA = New Drug Application; PDUFA = Prescription Drug User Fee Act

Our external environment is reshaping our strategy

- Forces redefining the reimbursement environment are real and here to stay
- Society and regulatory agencies continue to encourage breakthrough innovation
- Artificial Intelligence and Digitalization are finally adding real value
- Innovation is moving beyond the traditional realms of Big Pharma, Small Molecule & Biologics Domain
- Virtualization and strategic partnering are rewriting the value propositions and operating models
- Companies need to adapt smartly to survive

First in class, Multiple modalities, Complex delivery solutions

Focus away from incremental innovation and follow-on products

Key strategic priorities

Accelerate prioritized clinical programs

- SCO-088 registration study and SCC-138 PoCs
- SCD-044 Phase 2 study for Psoriasis
- SCO-120 in ER+, HER2- metastatic Breast Cancer

Build depth and diversity of pipeline

- Obtain PoC for novel targets & complex platforms
- Grow novel Biologics pipeline
- Continue to scale up external collaborations

Streamline operating model

- Exit programs early–clinical PoC vs Market Authorization
- Increase externalization of non-core activities
- Continue to invest in Digital and AI

PoC = Proof of Concept; AI = Artificial Intelligence; ER = Estrogen Receptor; HER 2 = Human Epidermal Growth Factor Receptor 2

Key portfolio reprioritizations

- SPARC is committed to rigorous gating for resource allocations
- We have reprioritized the following programs after successful completion of early proof of concept studies

ADF Platform

- Pilot HAL trial completed successfully
- Fast evolving market environment requires a committed development partner
- PoC study for an overdose prevention variant of the platform ongoing

SDE-124

- Preclinical proof-of-concept and manufacturing viability established
- Oral GLP-1 analogues resets the standard of care
- Need to streamline therapeutic area focus

SDD-098

- Preclinical proof-of-concept established
- Commercial potential does not fit into current portfolio expectations
- Reimbursement challenges add additional layer of risk to the program

ADF = Abuse Deterrent Formulation; HAL = Human Abuse Liability; PoC = Proof of Concept; GLP-1 = Glucagon-Like Peptide 1

Setting expectations for 2020-21

- Ensure US commercial launch of Elepsia® XR and Taclantis®
- Stay on track for FY23 NDA submission for SCO-088 and FY22 Clinical PoCs for SCC-138 and SCD-044
- Complete the Phase 1 trials of SCO-120, initiate patient trial
- Complete NDA submissions for PDP-716 and SDN-037 on positive data readouts
- Transition of one more NCE to IND
- Continue to tighten the portfolio while staying open to opportunistic exits from clinical assets; and
- Continue SPARC's transition to an increasingly first-in-class, multi-modal portfolio, enabled by a digital and data driven execution engine

PoC = Proof of Concept; NDA = New Drug Application; NCE = New Chemical Entity; IND = Investigational New Drug

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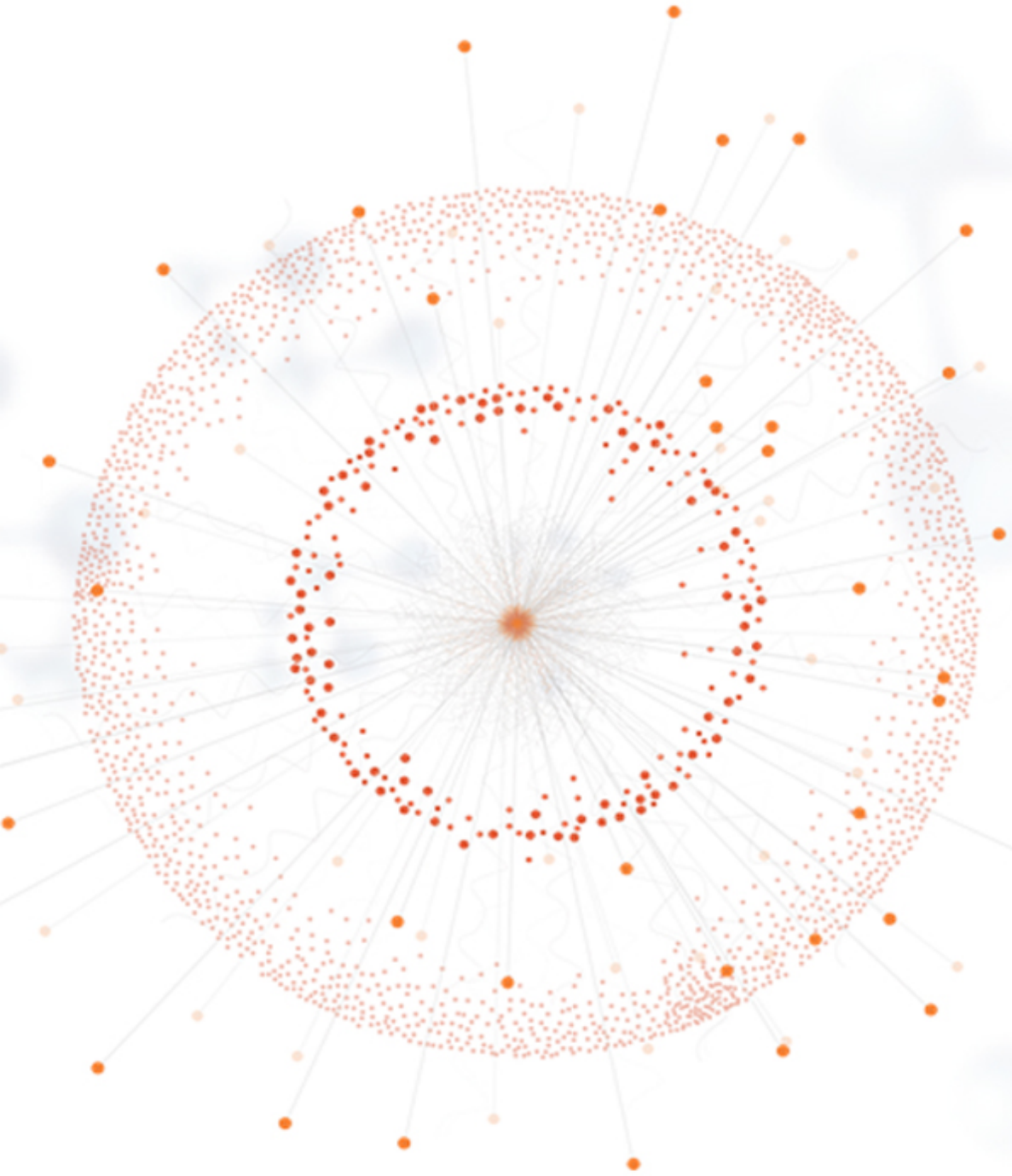
PDP-716

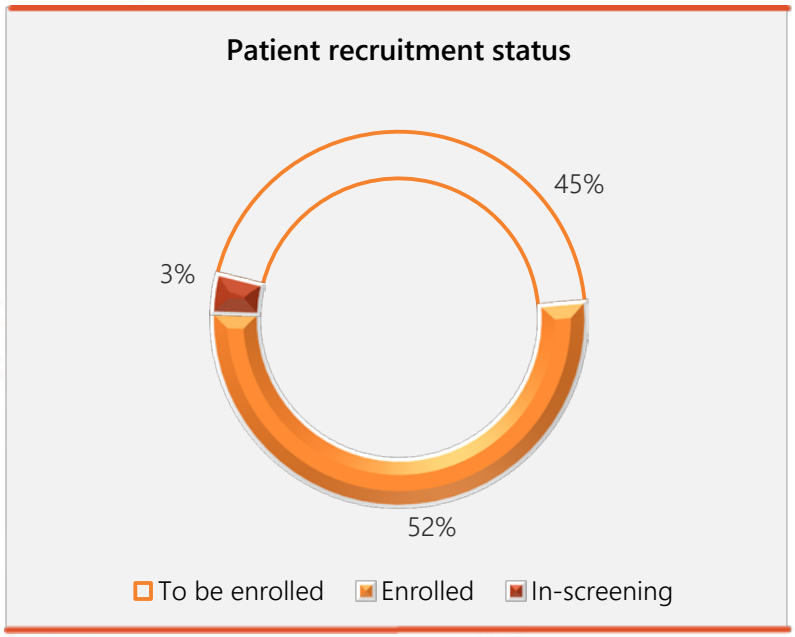
Once-a-day formulation of Brimonidine for treatment of Glaucoma



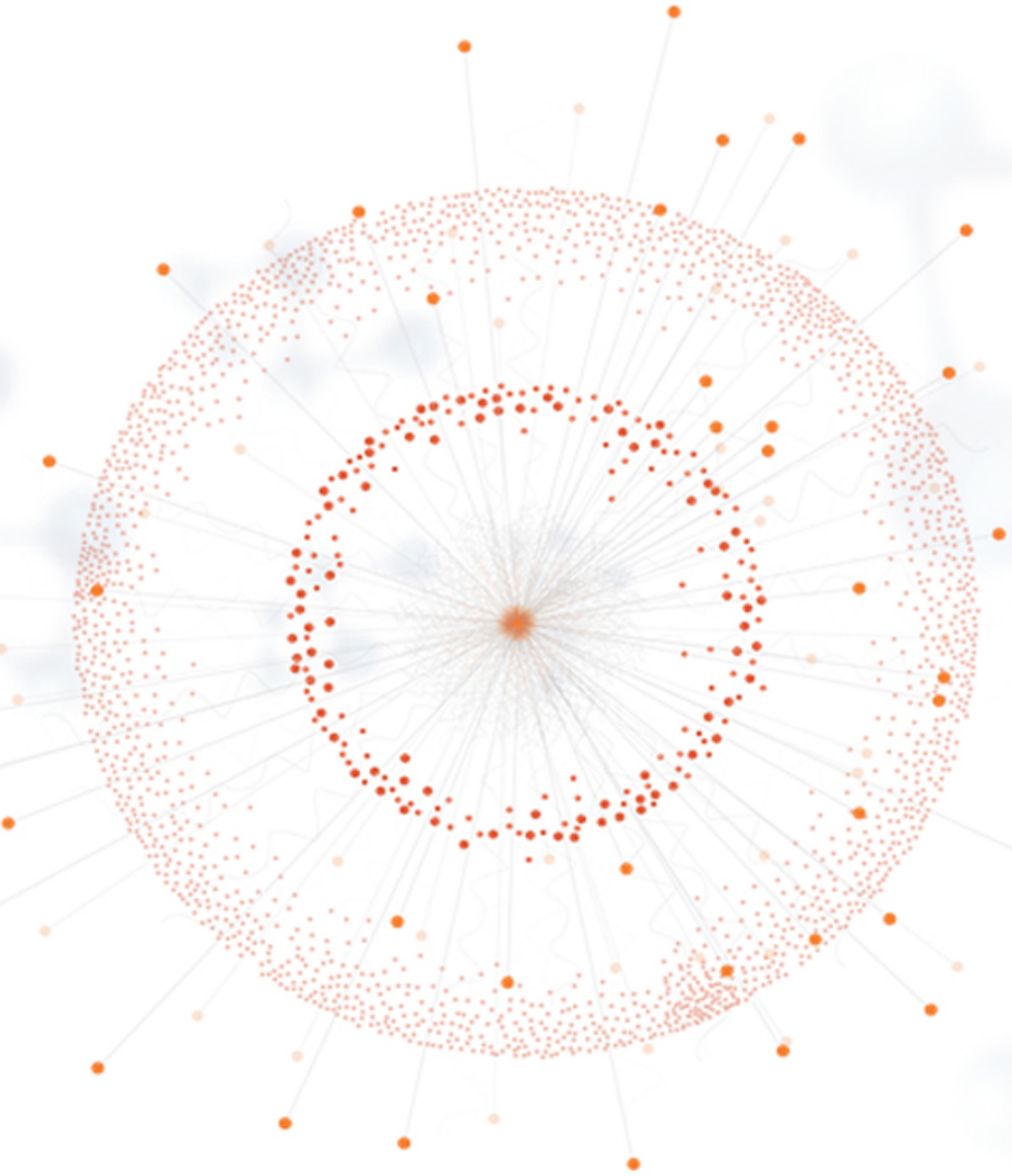
PDP-716

Development status update

- Phase 2 completed with IOP reduction equivalent to Alphagan® P
- Phase 3 study initiated in Q1 FY19
  - PDP-716 OD vs Alphagan® P TID
  - Primary endpoint of mean IOP at 8 a.m., 10 a.m., 4 p.m.
  - Number of sites recruiting ~20
  - Last subject out Q1 FY21
  - Futility analysis Q3 FY20
- Pediatric waiver granted
- NDA filing Q4 FY21



NDA = New Drug Application; IOP = Intra-ocular Pressure; OD = Once–a–day



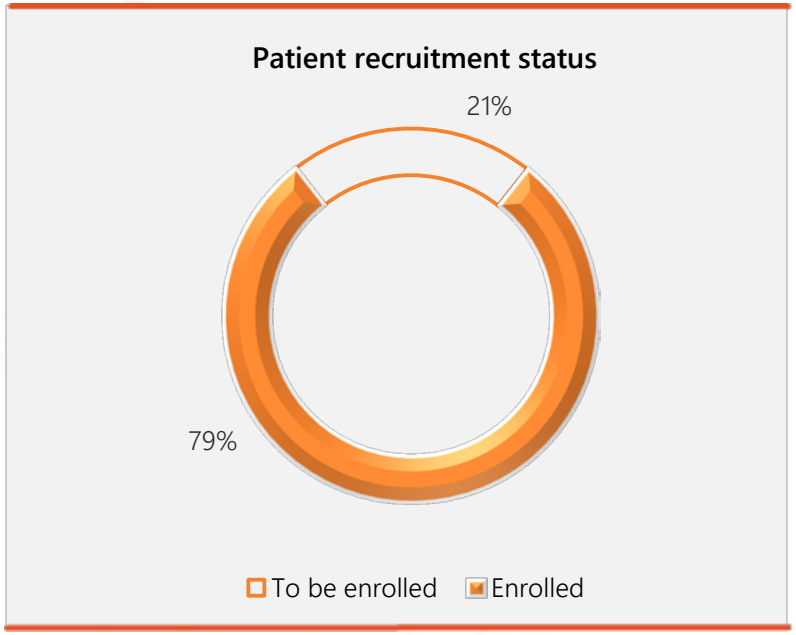
SDN-037

Novel formulation for Ocular Pain and Inflammation

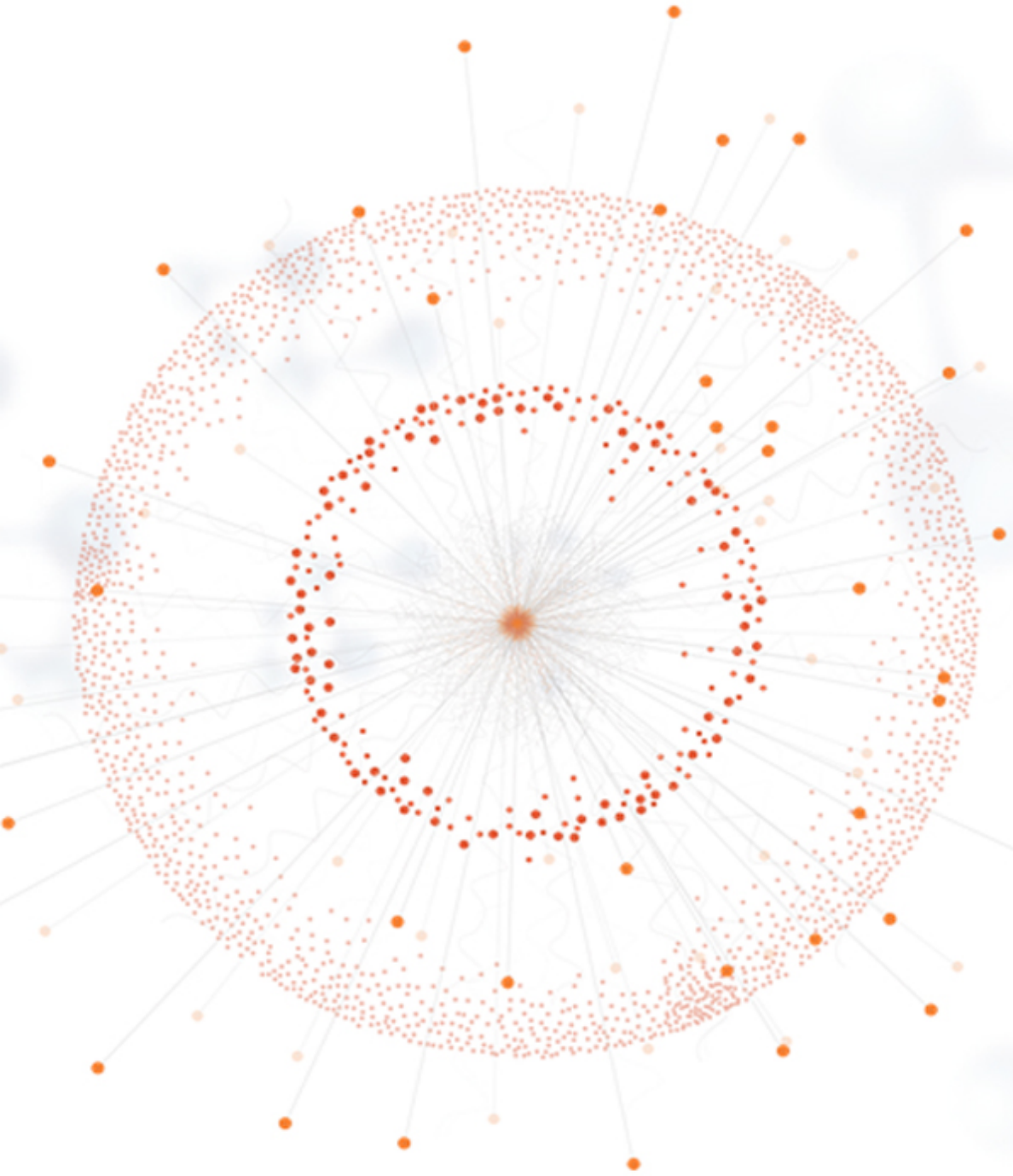
SDN-037

Development status update

- Vehicle controlled single Phase 3 study to support NDA submission initiated in Q1 FY19
  - Number of sites recruiting ~15
  - Last subject out planned by Q4 FY21
- Futility analysis outcome expected in Q3 FY20
- NDA filing planned by Q2 FY22



NDA = New Drug Application



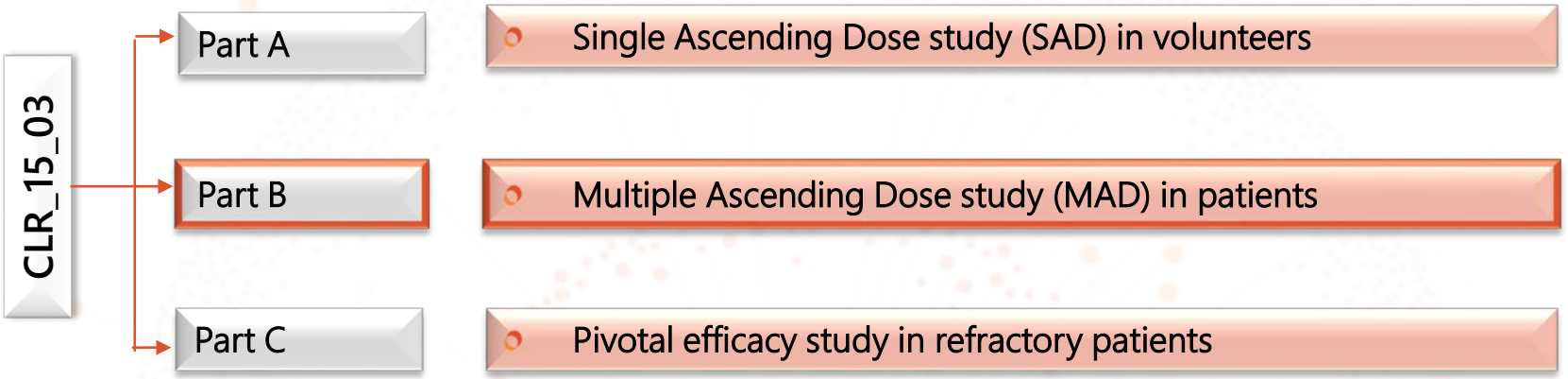
SCO-088

Highly selective BCR-ABL inhibitor for treatment resistant Chronic Myeloid Leukemia

SCO-088

Clinical development plan: Umbrella protocol

- Orphan Drug Designation approved
  - 7 years US market exclusivity
  - USFDA user fee waiver
- Completing Part B, starting Part C

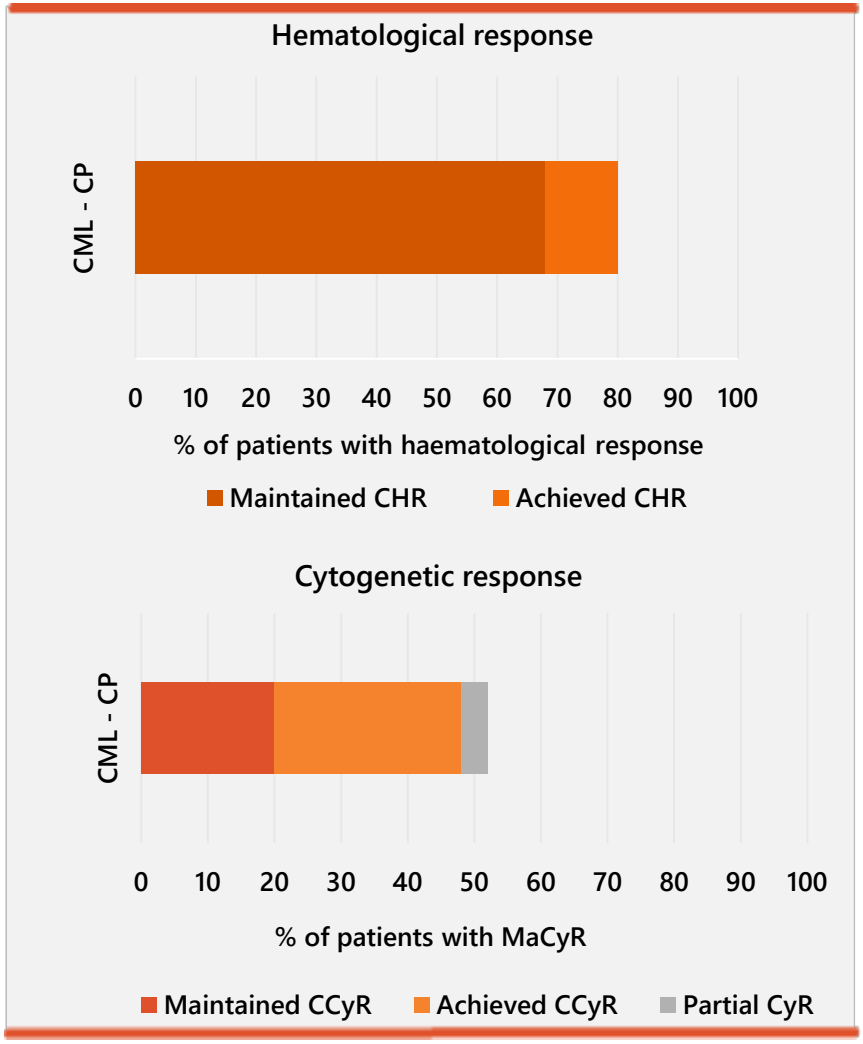


USFDA = United States Food and Drug Administration

SCO-088

Promising clinical activity - Phase 1b study

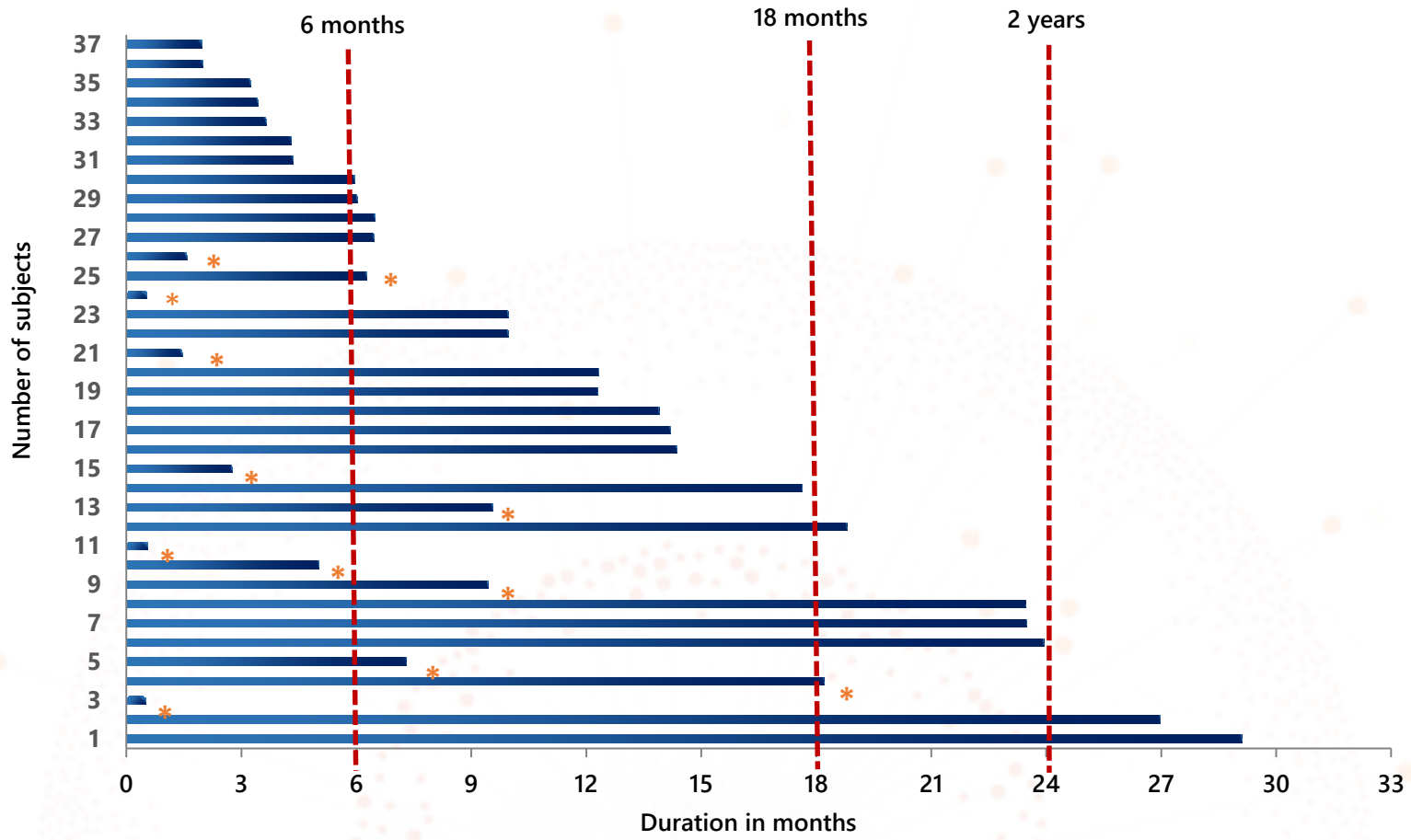
- Heterogeneous population
  - 80% failed ≥ 3 TKI therapies
  - 32% had at least 1 baseline mutation
  - 56% had refractory disease
- Early anti-leukemic efficacy
  - 81% hematological response rate
  - 52% major cytogenetic response rate
  - 13/37 subjects on treatment for >12 months



CML = Chronic Myeloid Leukemia; CCyR = Complete Cytogenetic Response; CyR= Cytogenetic Response; TKI = Tyrosine Kinase Inhibitor; MaCyR = Major Cytogenetic Response; CP = Chronic Phase; Unpublished data – Not to be replicated

SCO-088

Durable responses with about 70% patients continuing on treatment



* Discontinued study drug; Unpublished data – Not to be replicated

SCO-088

Promising activity in accelerated approval population

Dosing Cohort (mg)	12	24	48	66	90	126	174	204	240	Total
	N	N	N	N	N	N	N	N	N	N
Subjects refractory to ≥3 TKIs including Ponatinib	0	0	2	1	3	2	2	2	0	12
Responders on SCO-088	0	0	2	0	1	0	1	2	0	6

- 50% response rate following last line of therapy
- Consistent with USFDA expectations for accelerated approval

SCO-088

Well tolerated in heavily pre-treated population with refractory disease

- 2 serious adverse events related to use of SCO-088
- Mild to moderate GI disturbances and complaints of the musculoskeletal system were most commonly observed

SAE = Serious Adverse Event GI = Gastro-intestinal; Unpublished data – Not to be replicated

SCO-088

Development status update

- End of Phase 1 meeting with USFDA completed
- Agreement on study design and approval requirements
  - Single arm study in refractory subjects
- Site startup in progress
- FPI Q4 FY20

USFDA = United States Food and Drug Administration; FPI = First Patient In

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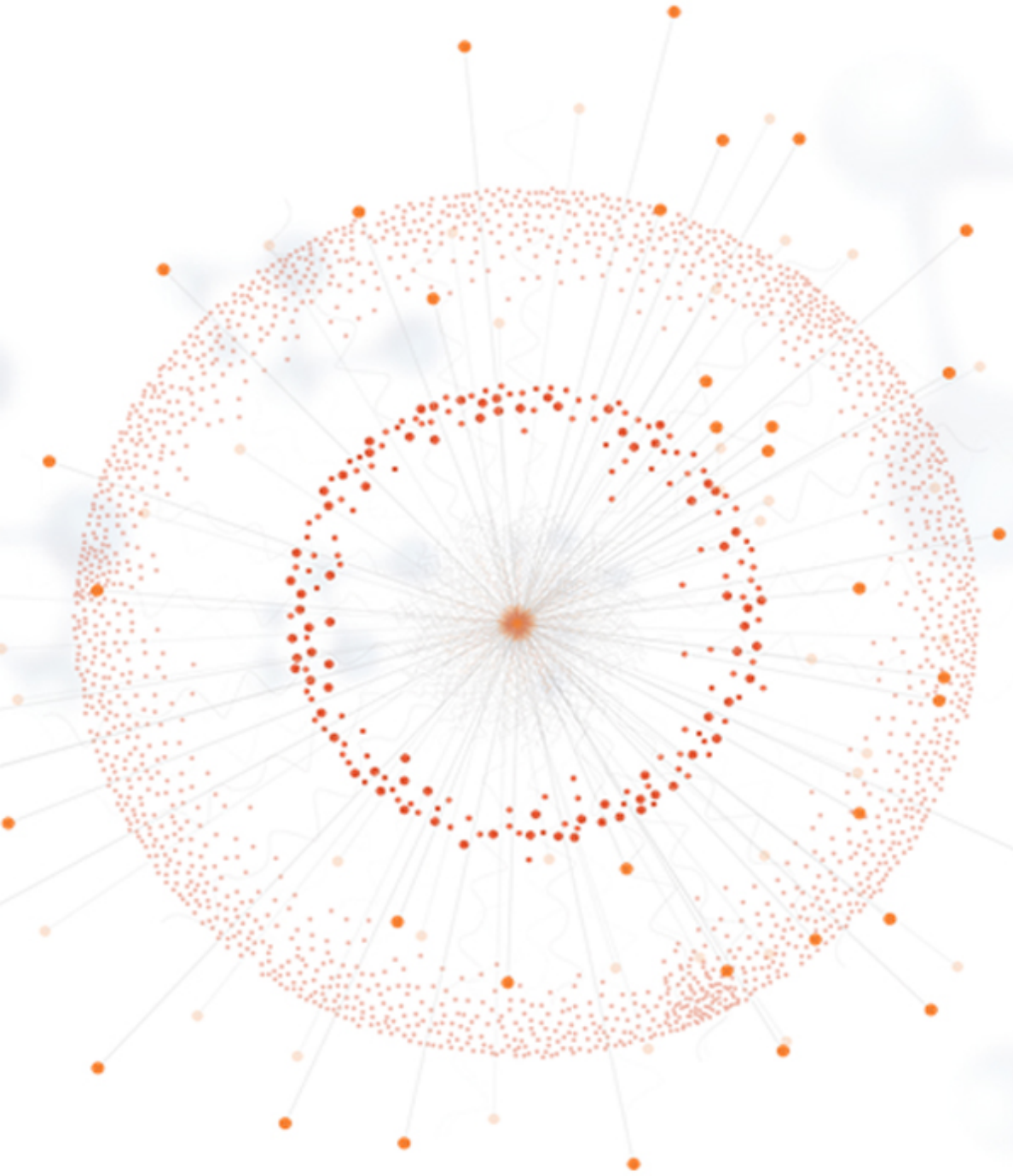


SCC-138

For treatment of Parkinson's disease

SCC-138

1st in class disease modifying treatment

Potent, orally active, brain-penetrating, small molecule inhibitor of c-Abl with potential for neuroprotection

Pre-clinical development

Role of SCC-138 in in human iPSC-derived neurons

1) Preserves Parkin activity
2) Modulating autophagic flux
3) Altering α-synuclein inclusions

PoC demonstrated in α-synuclein PFF induced mice model

PoC demonstrated in AAV1/2 α-synuclein rat model

Clinical development

Phase 1

1) Human PK established
2) Food effect study completed
3) Single Ascending Dose study completed
4) Multiple Ascending Dose study completed

Phase 2

Proof of Concept study initiated

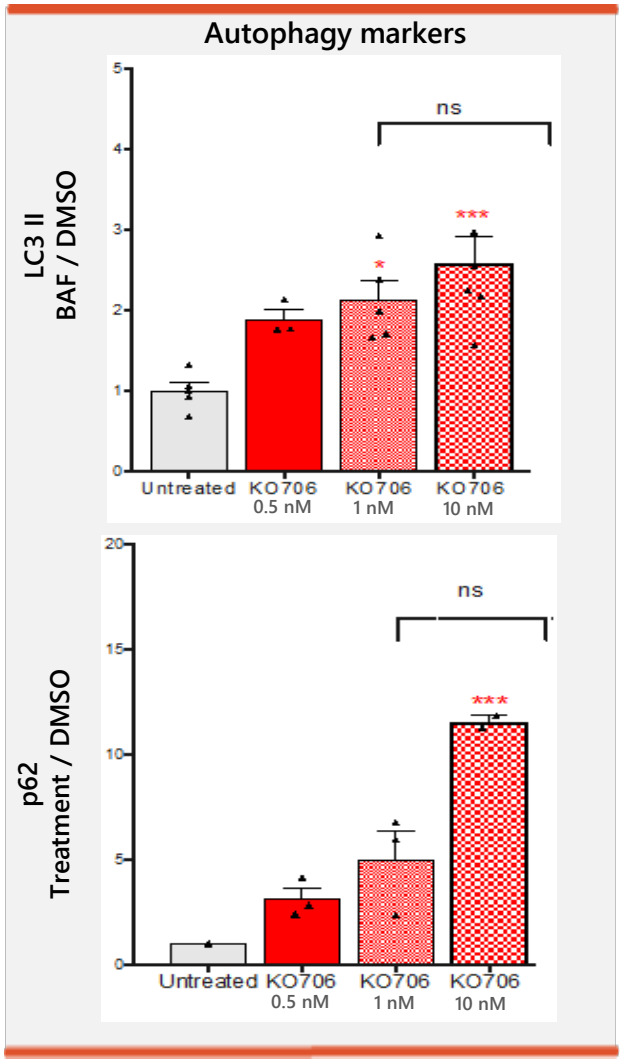
- Favorable safety profile
  - No treatment related serious adverse events reported
  - No QT interval prolongation or other cardiovascular liability reported in Phase 1 study

PFF = Pre-formed Fibrils; AAV = Adreno Adenosine Vector; iPSC = Induced Pluripotent Stem cell; PK = Pharmacokinetic; PoC = Proof of Concept; Unpublished data – Not to be replicated

SCC-138

Augmented autophagic flux in human iPSC-derived neurons*

- Augments autophagic flux
  - Can remove endogenous cABL-mediated interference in autophagy and augment autophagic flux in a sustained manner
  - Sustained autophagy is therapeutically meaningful and beneficial
- Reduces α-synuclein inclusions
  - Inhibits cABL and prevents accumulation of potentially toxic proteins such as α-synuclein, Tau, Aβ42 in the microenvironment
  - An important observation in support of a broader application of SCC-138 in various neurodegenerative diseases such as AD, ALD, DLB, HD, and PD

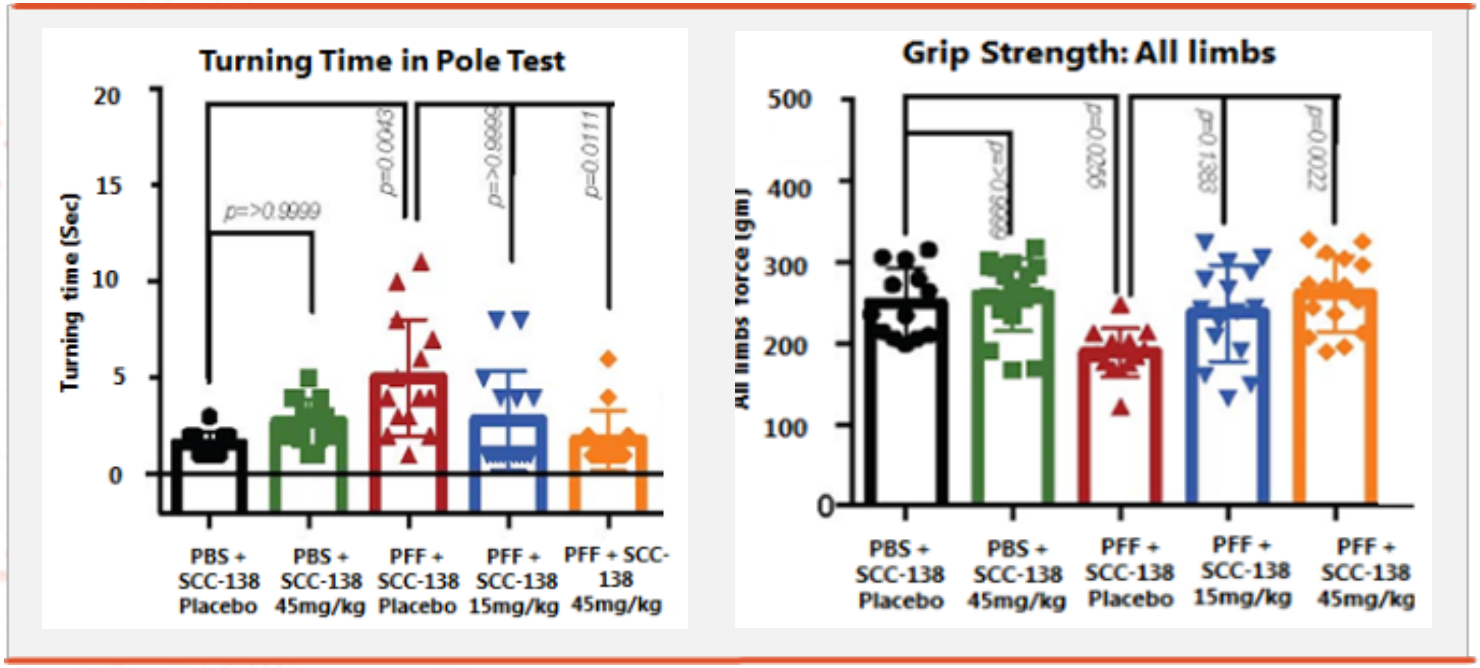


* Study conducted at Brigham and Women's Hospital Inc Boston MA

K0706 = SCC-138; AD = Alzheimer's Disease; ALD = Adrenoleukodystrophy; DLB = Dementia with Lewy Bodies; HD = Huntington's Disease; PD = Parkinson's Disease; iPSC = Induced Pluripotent Stem cell;

SCC-138

Dose dependent improvement in behavioral assessment in the PFF-induced mouse model*



- Improves PFF-induced deficits in behavioral parameters; maximum improvement at 45 mg/kg dose
  - Turning time and Descending time in pole test and grip strength evaluated

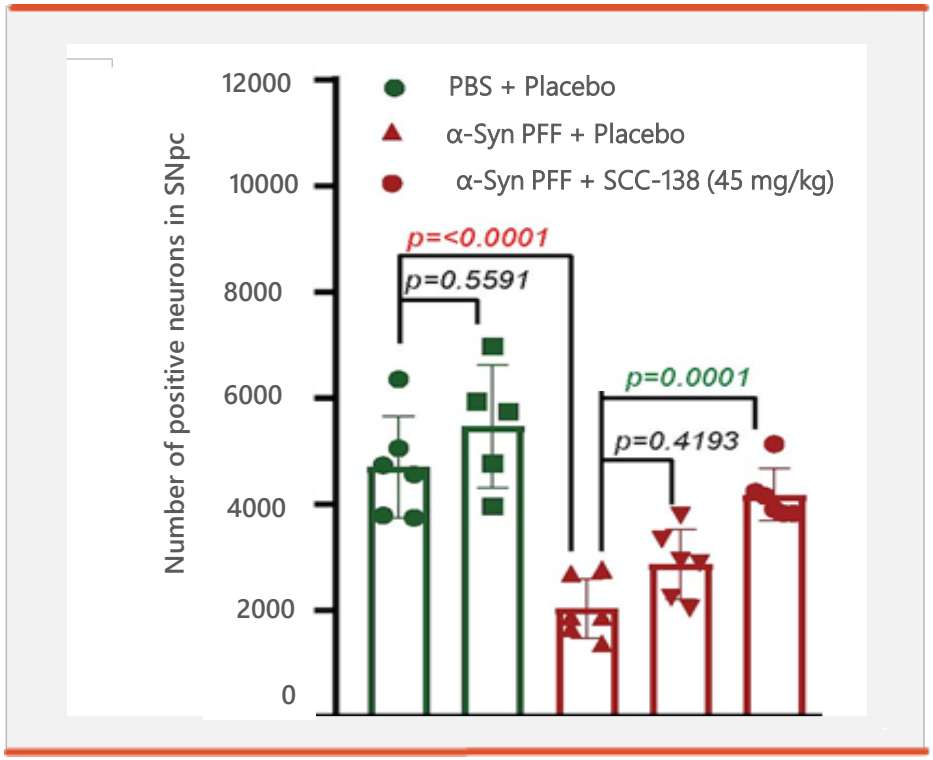
* Study conducted at Johns Hopkins University Baltimore MD

PFF = Pre-formed Fibrils; PBS = Phosphate-buffered Saline; Unpublished Data - Not to be replicated

SCC-138

Neuroprotective effect in the PFF-induced mouse model*

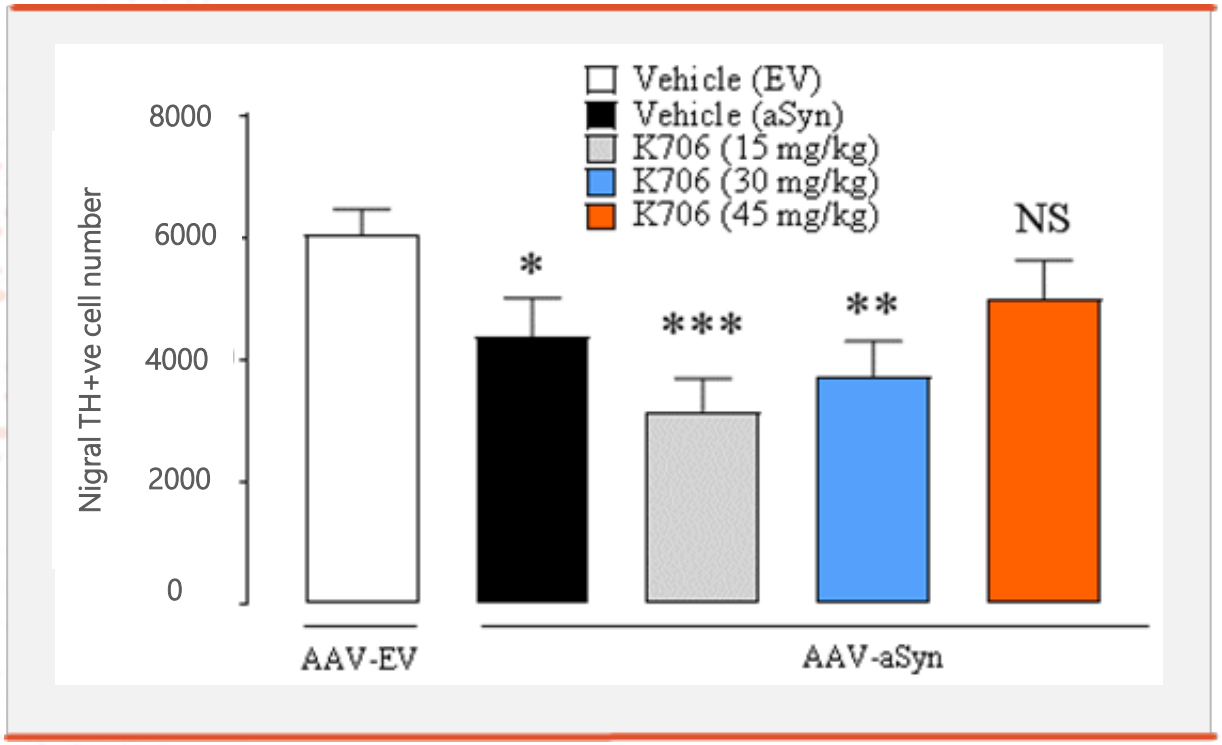
- PFF synuclein model experiment completed.
- Result confirms that SCC-138 shows a dose-dependent reduction in synuclein-mediated death of dopaminergic neurons



* Study conducted at Johns Hopkins University, Baltimore MD

SCC-138

Neuroprotective effect in the AAV driven rat A53T α-synuclein model*



1-way-RM-ANOVA with Fisher's LSD test
NS / * / ** / *** represents P>0.05, P<0.05 P<0.01 or P<0.001 cf. EV

* Study conducted by an external CRO

Unpublished Data - Not to be replicated; AAV = Adreno Adenosine Vector; α-Syn = α-Synuclein; K0706 = SCC-138
EV = Empty Vector TH= Thyrosine Hydroxylase

SCC-138

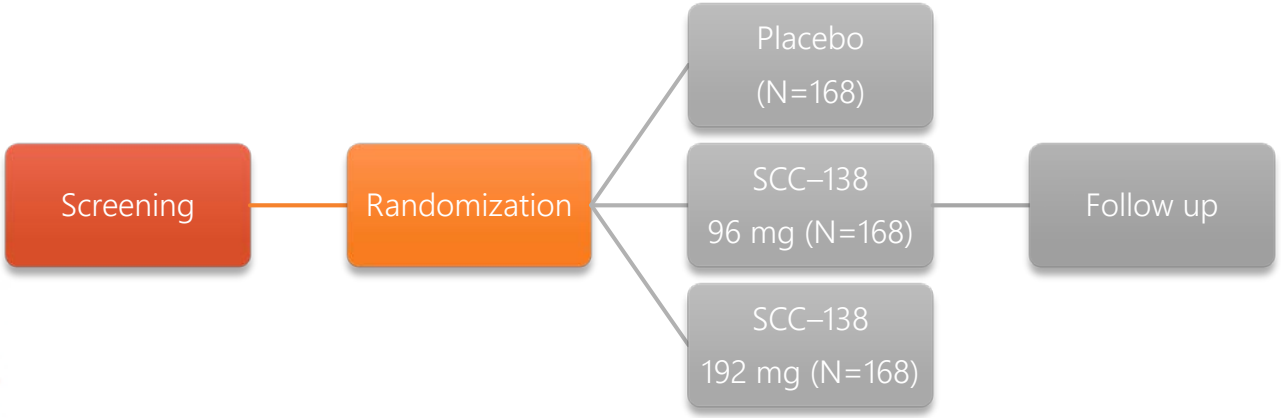
Phase 1 study update

- Phase 1 trial (14 Day study) in Parkinson's subjects completed
  - Doses up to 384 mg studied
  - Well tolerated-no severe adverse events.
- Phase 1 trial in healthy controls completed up to 384 mg x 7 days.
  - CSF collected for 24 hours in each subject.
  - Confirmed adequate levels in CSF

CSF = Cerebrospinal Fluid; MAD = Multiple Ascending Dose; Unpublished data – Not to be replicated

Phase 2 study of Abl tyrosine kinase inhibition with K0706 (SCC-138)

PROSEEK



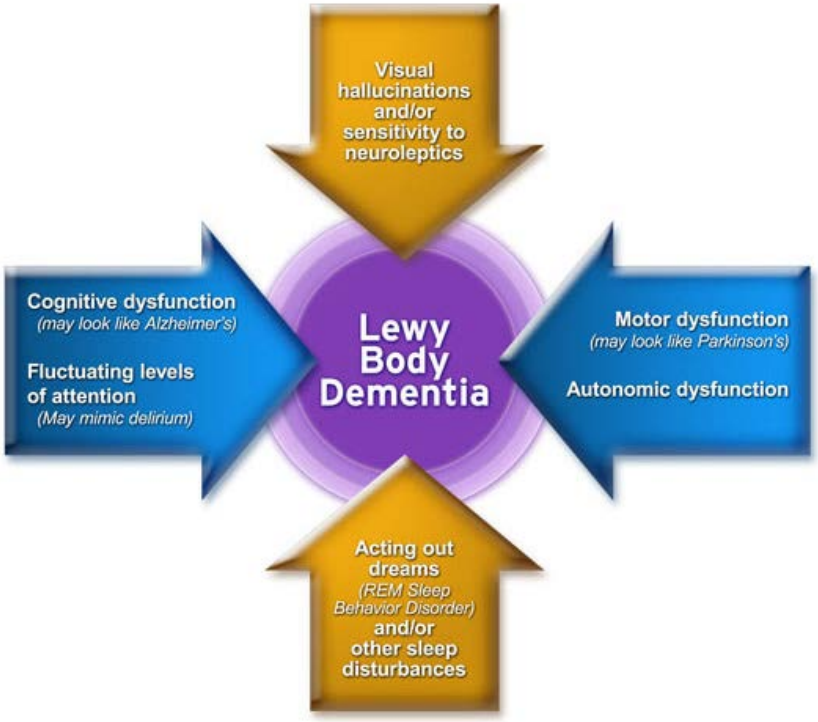
- 504 subjects randomized to placebo, 96 mg or 192 mg
- Early stage subjects not on dopaminergic medication other than MAO-B inhibitors
- Primary endpoint is change in MDS-UPDRS Part 2 & 3
- Study initiated in Feb 2019. Last subject out expected Q4 FY22

MDS-UPDRS = Movement Disorder Society – Unified Parkinson's Disease Rating Scale; MAO-B = Monoamine oxidase B

SCC-138

Broader application in other synucleinopathies – Dementia with Lewy Bodies (DLB)

- DLB, a neurodegenerative condition with progressive cognitive impairment, hallucinations and Parkinsonism
  - Estimated to affect about 1.4 million people in the USA*
  - 2nd most common cause of dementia in the elderly
- Strong overlap with Parkinson's Disease
  - Synucleinopathies with Lewy Bodies seen on autopsy, and similar genetic risks suggesting potential efficacy in DLB
- Investigator-initiated trial in collaboration with Georgetown University, Washington on-going in subjects with DLB
  - Expected completion of study by early 2021



* https://ghr.nlm.nih.gov/condition/dementia-with-lewy-bodies; Image courtesy: Lewy Body Dementia Association. Org

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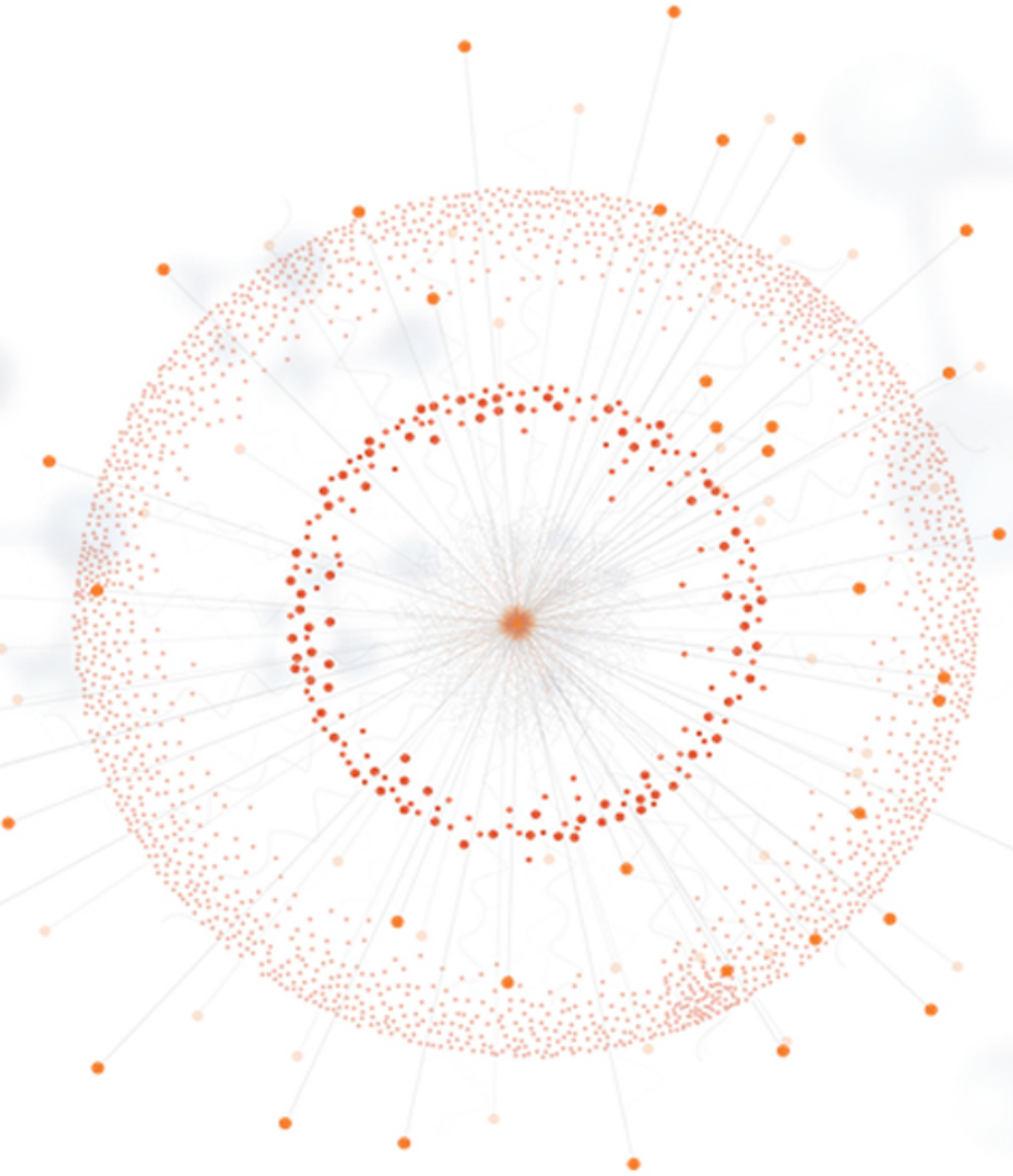


SCD-044

For treatment of
Autoimmune disorders

SCD-044

Selective S1PR1 modulator for autoimmune diseases

- SPARC is developing a novel orally bioavailable, potent and selective S1PR1 modulator in collaboration with Bioprojet, France
- Preclinical studies completed with promising results in various animal models of autoimmune diseases, including psoriasis
- Phase 1 study completed in healthy volunteers

S1PR1 = Sphingosine-1–Phosphate Receptor 1

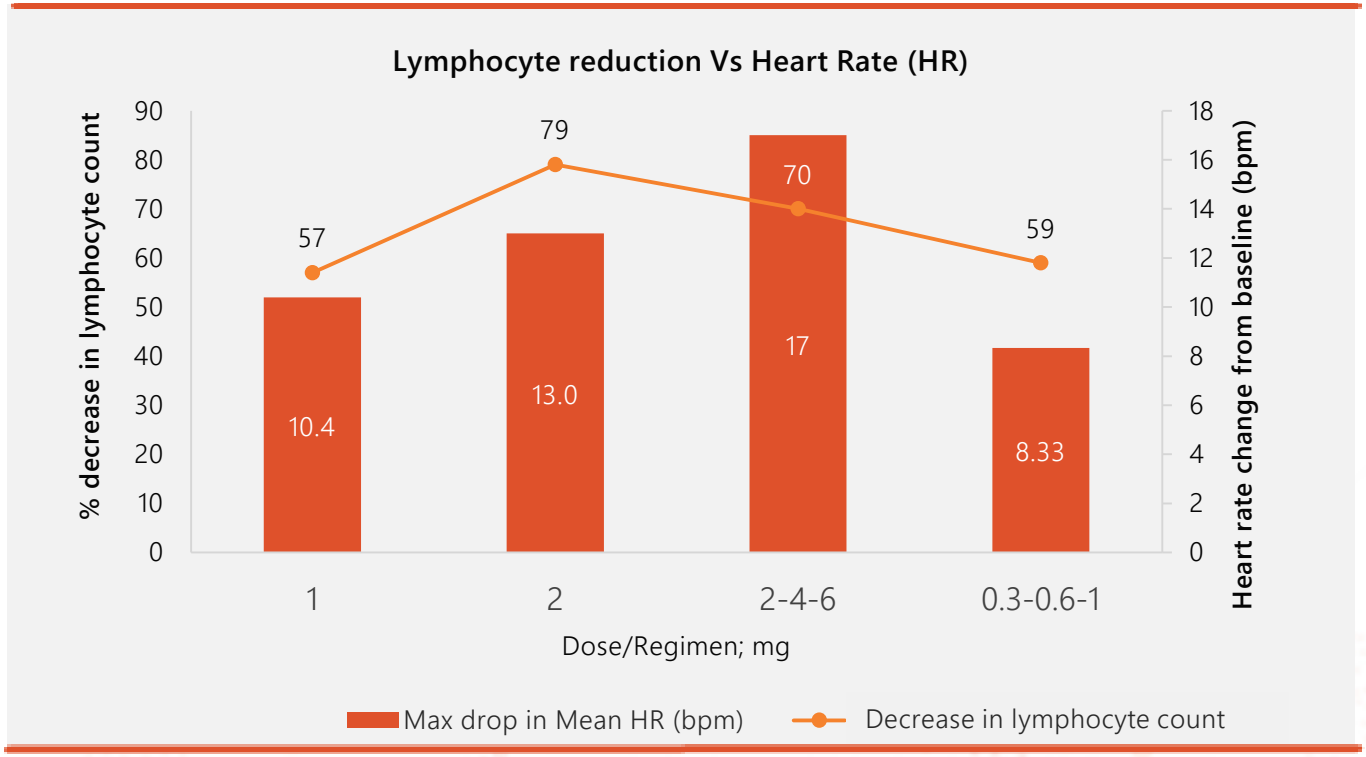
SCD-044

Safety established in Phase 1 study

- Multi-part Phase 1 study completed in healthy volunteers
- Part 1: Single ascending dose
  - Six dose levels in males and one dose level in females
  - ~55% lymphocyte count decrease following 1 mg dose
- Part 2: Food effect
  - No significant food effect
- Part 3: Multiple Ascending Dose
  - Four dose levels including two up-titration scheme in males and one up-titration scheme dose level in females
  - ~60% lymphocyte count reduction observed at 1 mg dose with asymptomatic bradycardia

SCD-044

Heart rate and lymphocyte count relationship



- Escalation scheme of 0.3-0.6-1 results in target decrease in lymphocyte count with less effect on heart rate

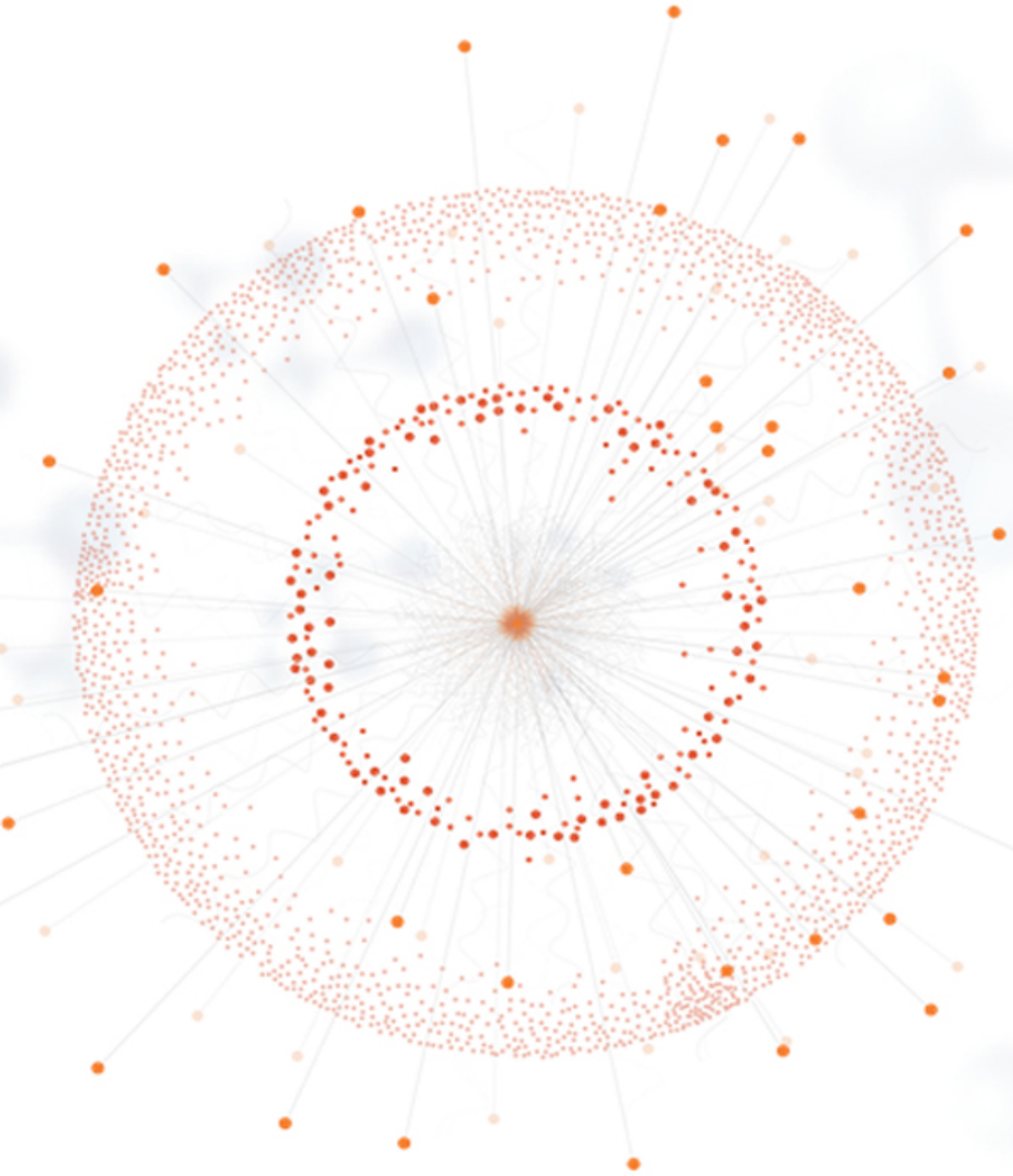
Data readout based on top line data; Unpublished Data – Not be replicated; bpm = Beats per minute

SCD-044

Development status update

- IND filing by Q3 FY20
- Phase 2 study initiation by H2 FY20

IND = Investigational New Drug



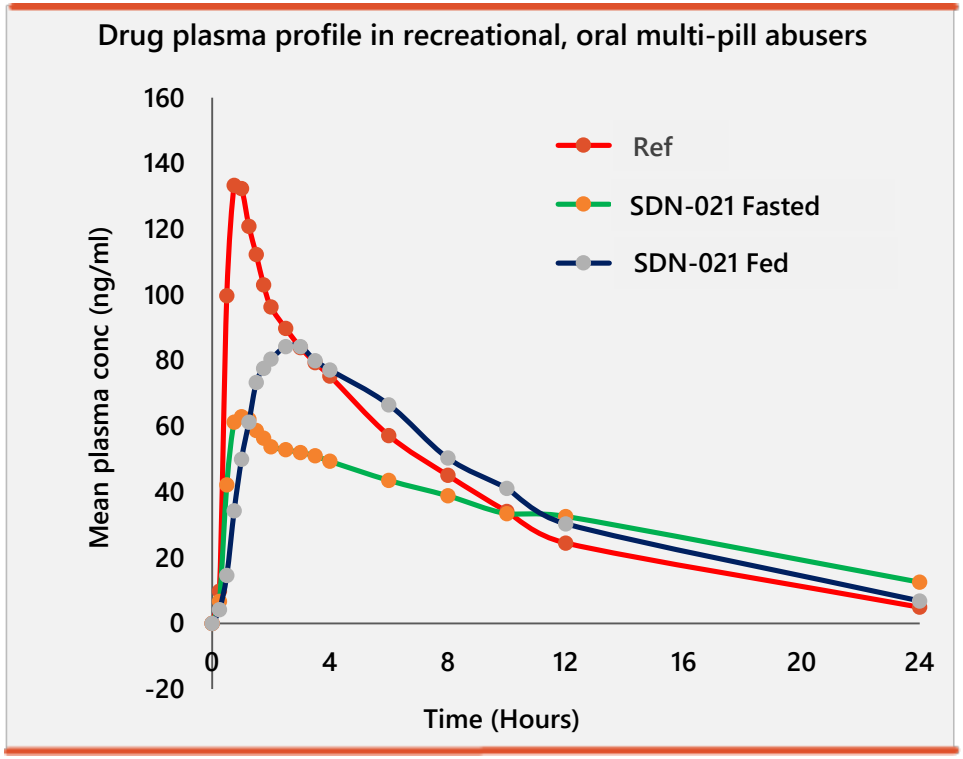
SDN-021

For prevention of multi pill oral abuse

SDN-021

Abuse deterrent opioid

- Designed to deliver clinically effective dose at prescribed dose
  - Upon ingestion of multiple pills the technology reduces peak drug levels and slows down the release
  - Ability to deter abuse by other prevalent routes – injection and snorting
  - Includes presence of an aversive agent to further deter abuse if tampered
- Significant reduction in C_{max} and partial AUC for initial 2 hours compared to Reference in both fasted and fed conditions; prolonged T_{max} in fed condition

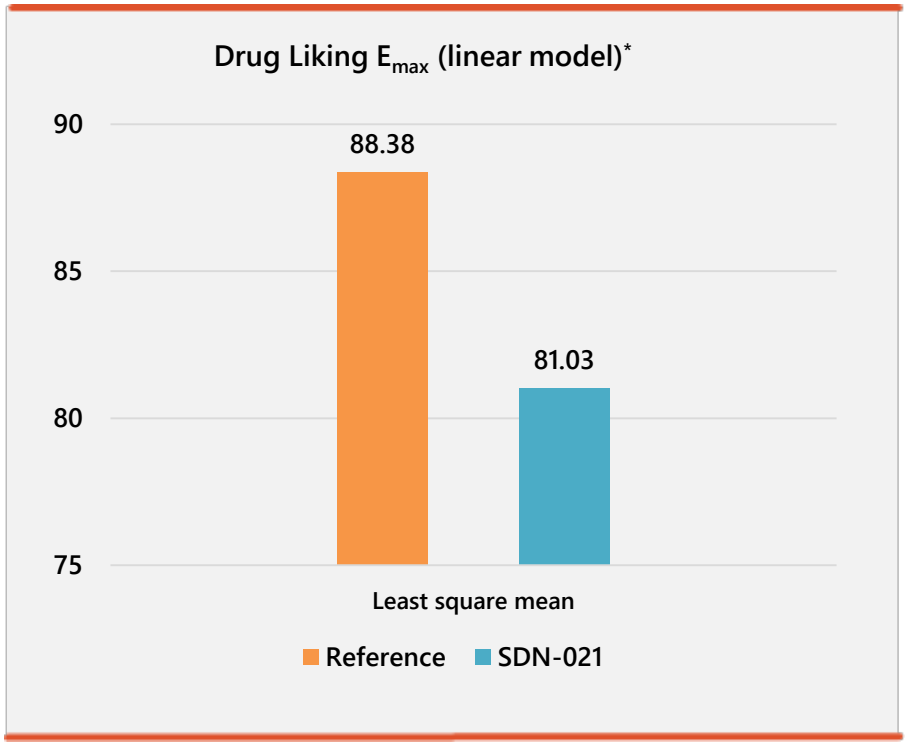


AUC = Area Under the Curve; C_{max} = Maximum Concentration; T_{max} = Time required to reach C_{max} ;
Unpublished data – Not to be replicated

SDN-021

Trend indicating potential to deter oral multi-pill abuse

- Encouraging results in Category 1 *in vitro* tamperability evaluation
- Reduction in drug liking was observed in favour of SDN-021 implied by lower E_{max} compared to Reference
- Recreational, oral multi-pill abusers experienced significantly less "Drug High" measured on visual analogue scale



* Pilot HAL study Cohort A: Participants able to differentiate between two doses of Reference and Placebo

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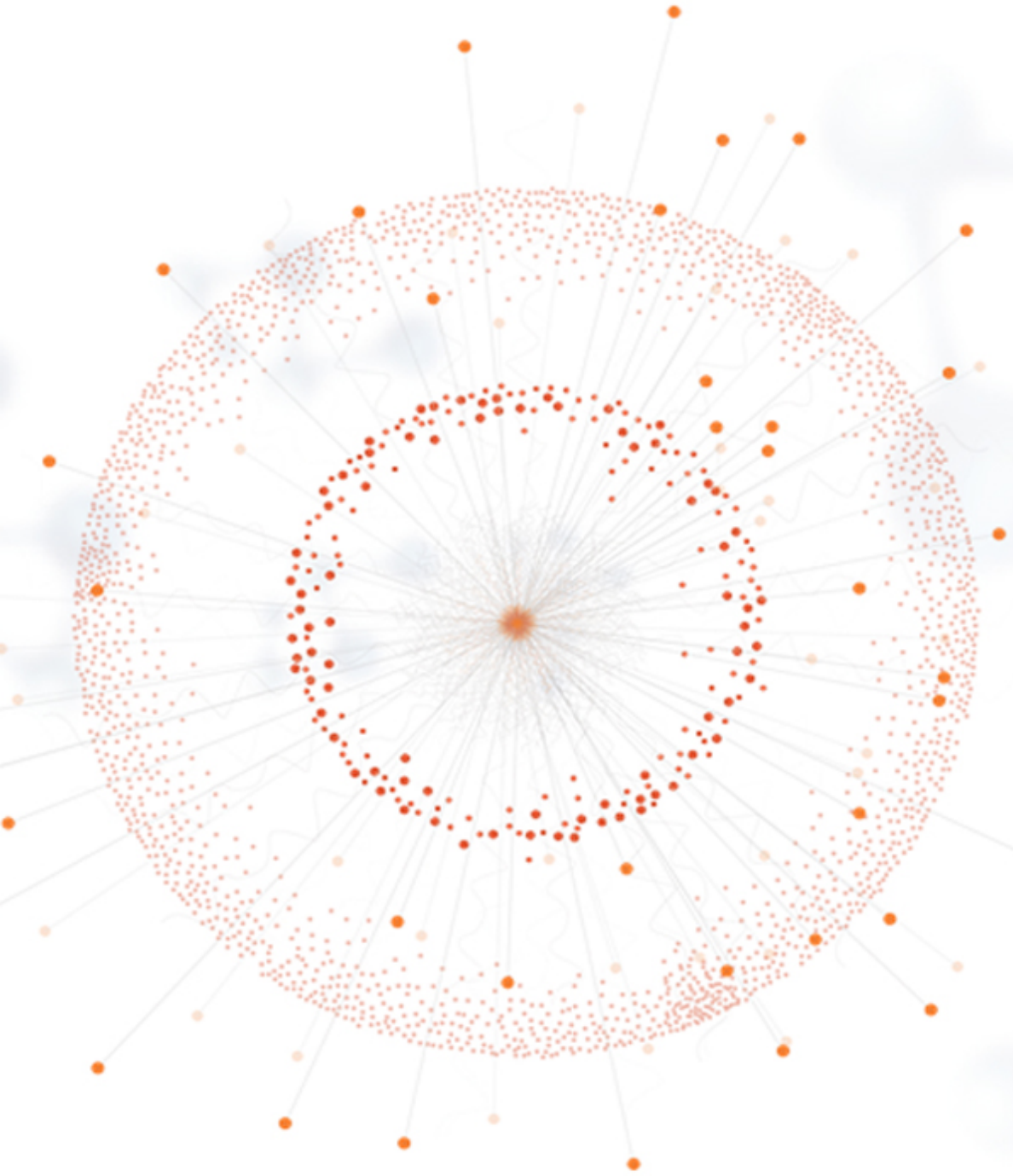


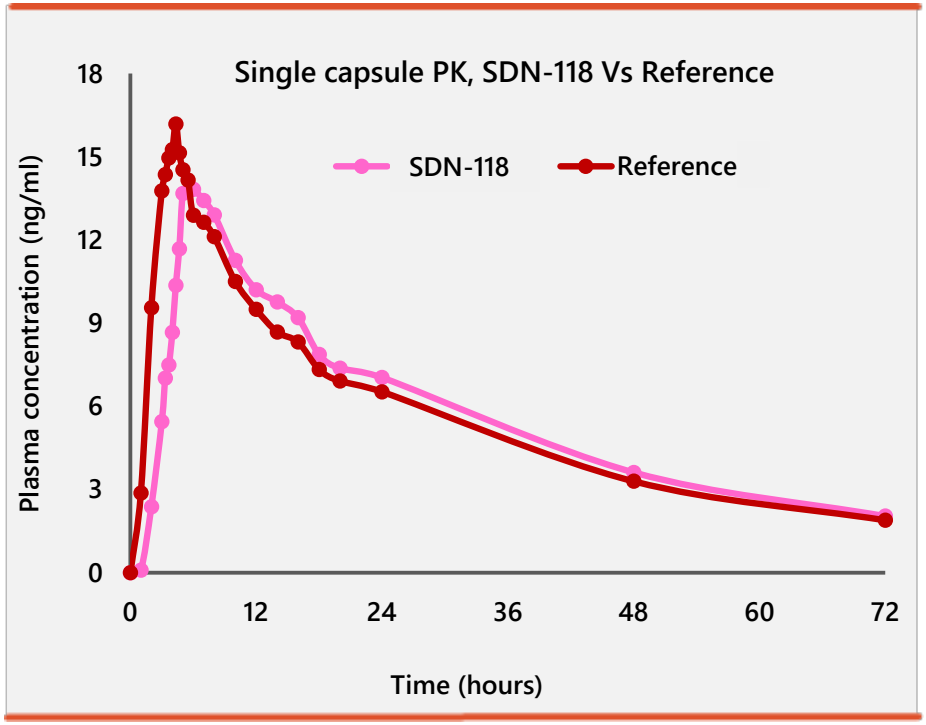
SDN-118

Overdose prevention

SDN-118

Addressing intentional / accidental drug overdose

- Targets the population at risk of suicidal ideation
- Multi-component system employs pH dependent solubility of existing anti-depressant
  - Changes the pH of stomach micro environment upon ingestion of multiple pills
  - Restricts the rate and extent of drug release, thereby reducing the potential harm due to overdose
- Encouraging results in single unit PK study; multiple unit PoC PK study underway



PK = Pharmacokinetic; PoC = Proof of Concept; Unpublished data – Not to be replicated

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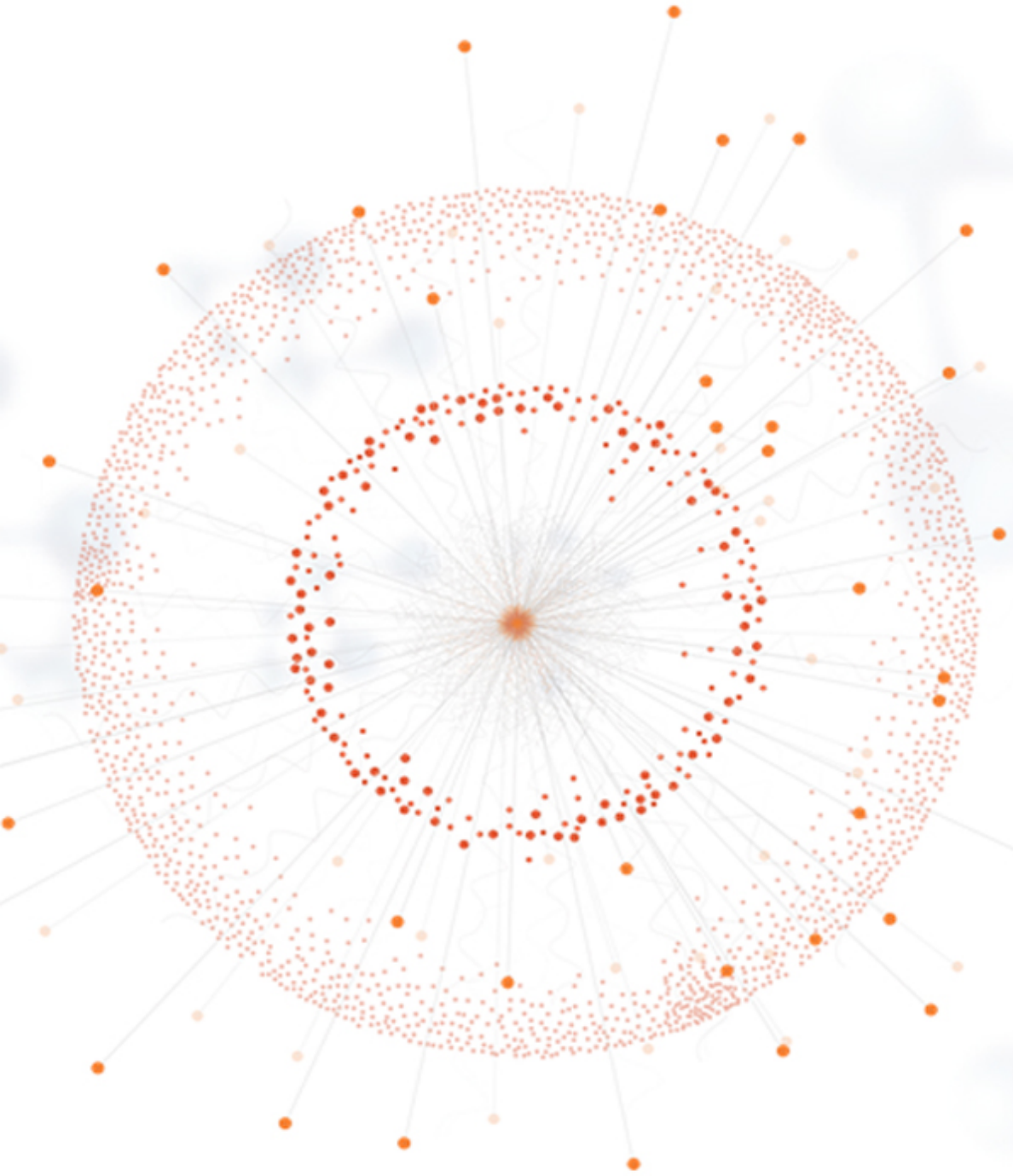
   Chetan Rajpara- CFO
6. **Q&A**



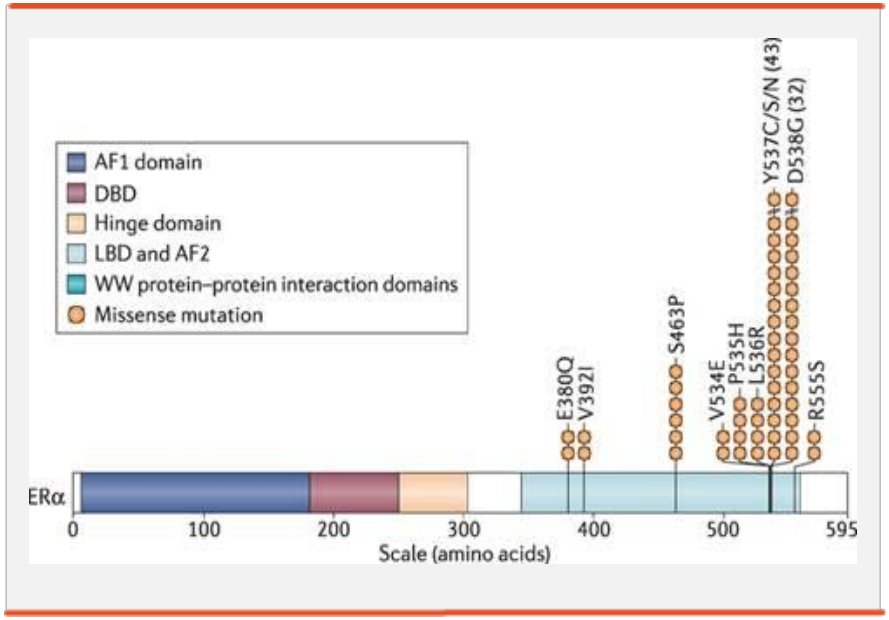
SCO-120

Targeting ESR1 mutations

SCO-120

Orally bioavailable SERD

- Anti-estrogen therapy is mainstay of treatment for women with breast cancer whose tumors express ERα
- Degradation of ERα is deemed a superior therapeutic approach in the treatment of ER +ve breast cancer
- 20-50% of patients with metastatic breast cancer develop resistance to anti-estrogen therapies due to emergence of mutations in the ERα
- Currently, fulvestrant is the only approved SERD. However, it is an intramuscular injection and low levels are achievable *in vivo*
- SCO-120 is a novel, orally-active, selective ER degrader targeting both wild type and mutant forms of ER



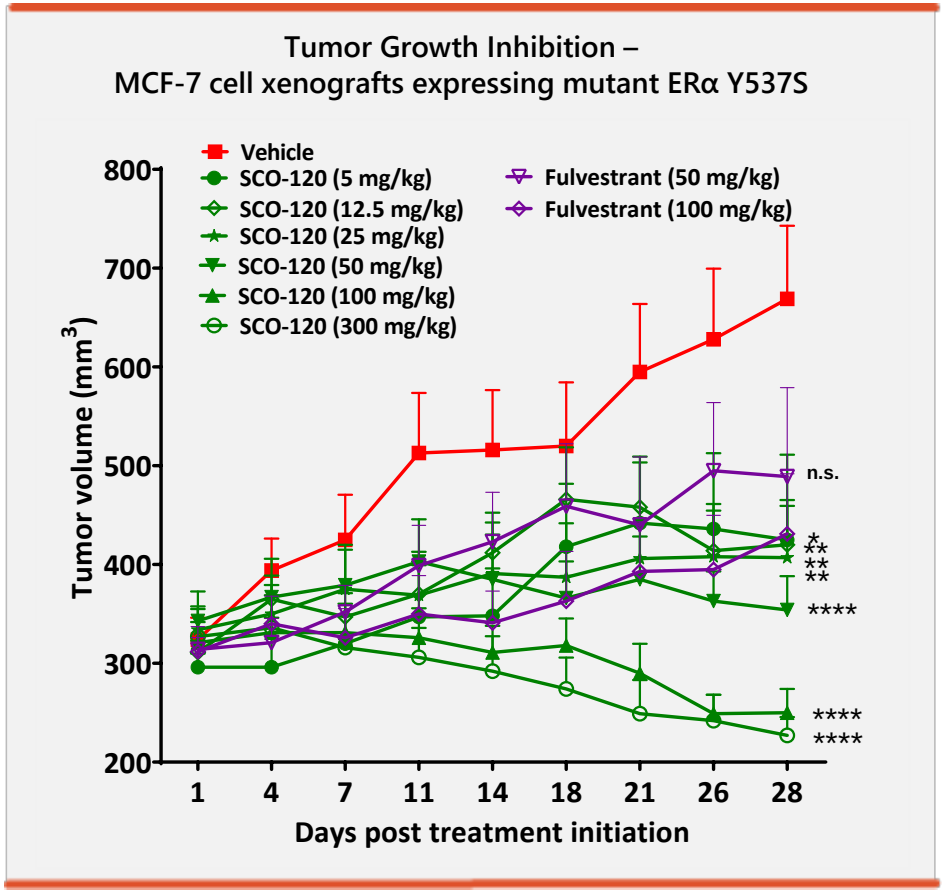
SERD = Selective Estrogen Receptor Degrader; ERα = Estrogen Receptor Alpha

Image courtesy: Ma C, et.al., Mechanisms of aromatase inhibitors resistance. *Nat Rev Cancer* (2015) 15:261–75.

SCO-120

Efficacy established in preclinical assessments*

- Potent *in vitro* SERD activity in breast cancer MCF-7 cells expressing ERα wild type (WT) and its mutants, including Y537S and D538G mutations
- SCO-120 shows robust tumor growth inhibition of WT as well as Y537S and D538G xenografts
- Superior efficacy in comparison to fulvestrant against Y537S and D538G mutant xenografts

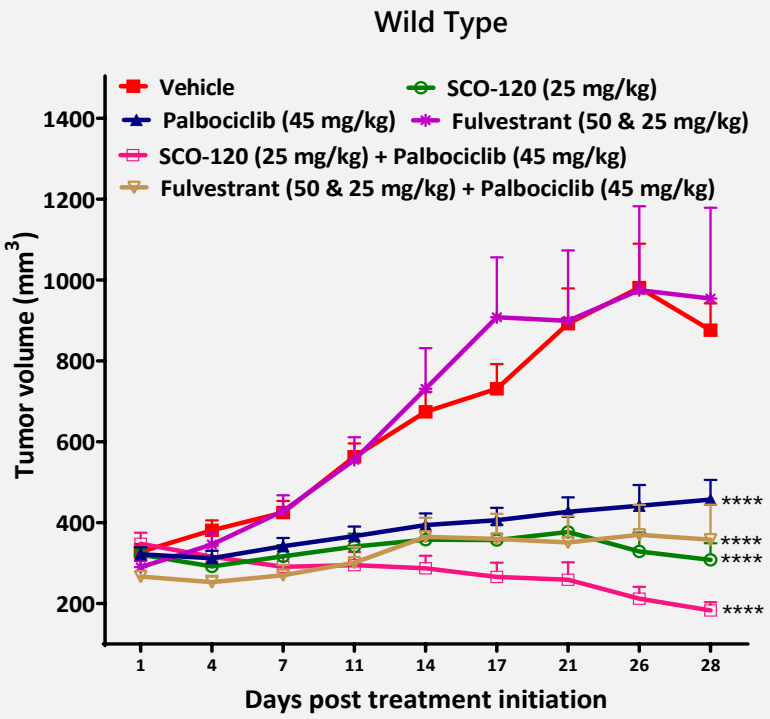


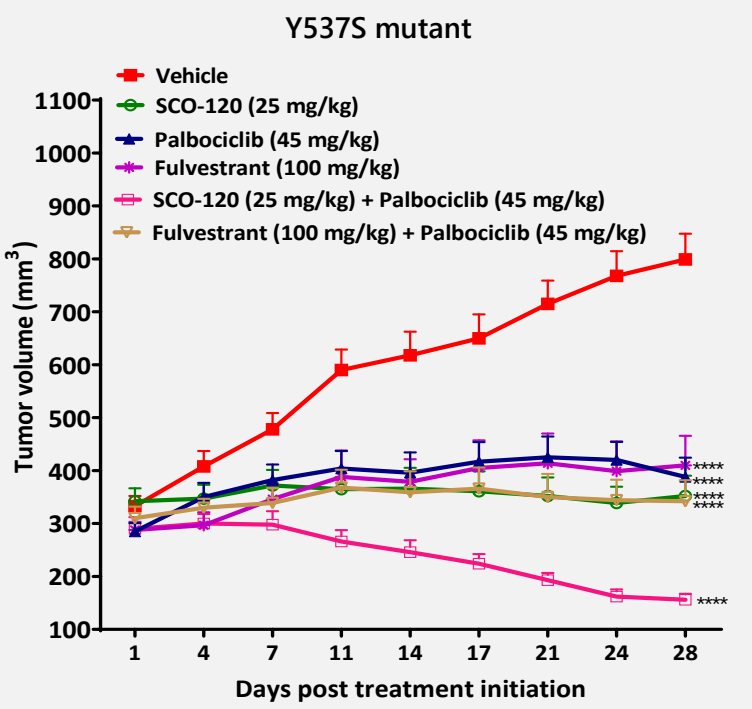
* Study conducted using cells developed at The Institute of Cancer Research, London

SERD = Selective Estrogen Receptor Degrader; ERα = Estrogen Receptor Alpha; Unpublished data, not to be replicated

SCO-120

Combination with CDK 4/6 inhibitor: xenograft studies*





- SCO-120 shows promising activity against resistant mutants alone, and the effect is further enhanced in combination with Palbociclib

* Study conducted using cells developed at The Institute of Cancer Research, London

Fulvestrant group received 50 mg/kg as loading dose thrice- weekly for first week, followed by 25 mg/kg twice-weekly for remaining 3 weeks; Unpublished data – Not to be replicated

SCO-120

Encouraging preclinical toxicity results

- IND enabling toxicity studies have been completed
  - Acute and sub-chronic toxicity evaluated in mice, rats, dogs and monkeys. No Observed Adverse Effect Levels (NOAEL) established
  - Non-mutagenic and non-genotoxic
- Battery of *in vivo* safety pharmacology studies completed - No adverse effects on CNS, respiratory and CVS parameters
- Generally clean *in vitro* off-target profile vs 87 targets. Low liability for uterotrophic effect

IND = Investigational New Drug; CNS = Central Nervous System; CVS = Cardio Vascular System;
Unpublished data – Not to be replicated

SCO-120

Development status update

- Completed pre-IND meeting with USFDA
- Phase 1 study will be initiated in Q4 FY20

USFDA = United States Food and Drug Administration; IND = Investigational New Drug

Agenda

1. **SPARC Strategy & Growth Drivers**
   Anil Raghavan – CEO
2. **Update on Clinical Programs**
   SiuLong Yao– Sr. V.P. Clinical Development & Operations
3. **Early Stage Program Update**
   Vikram Ramanathan – V.P. Translational Development
4. **Collaborations & Partnerships**
   Nitin Damle– Sr. V.P. Innovation
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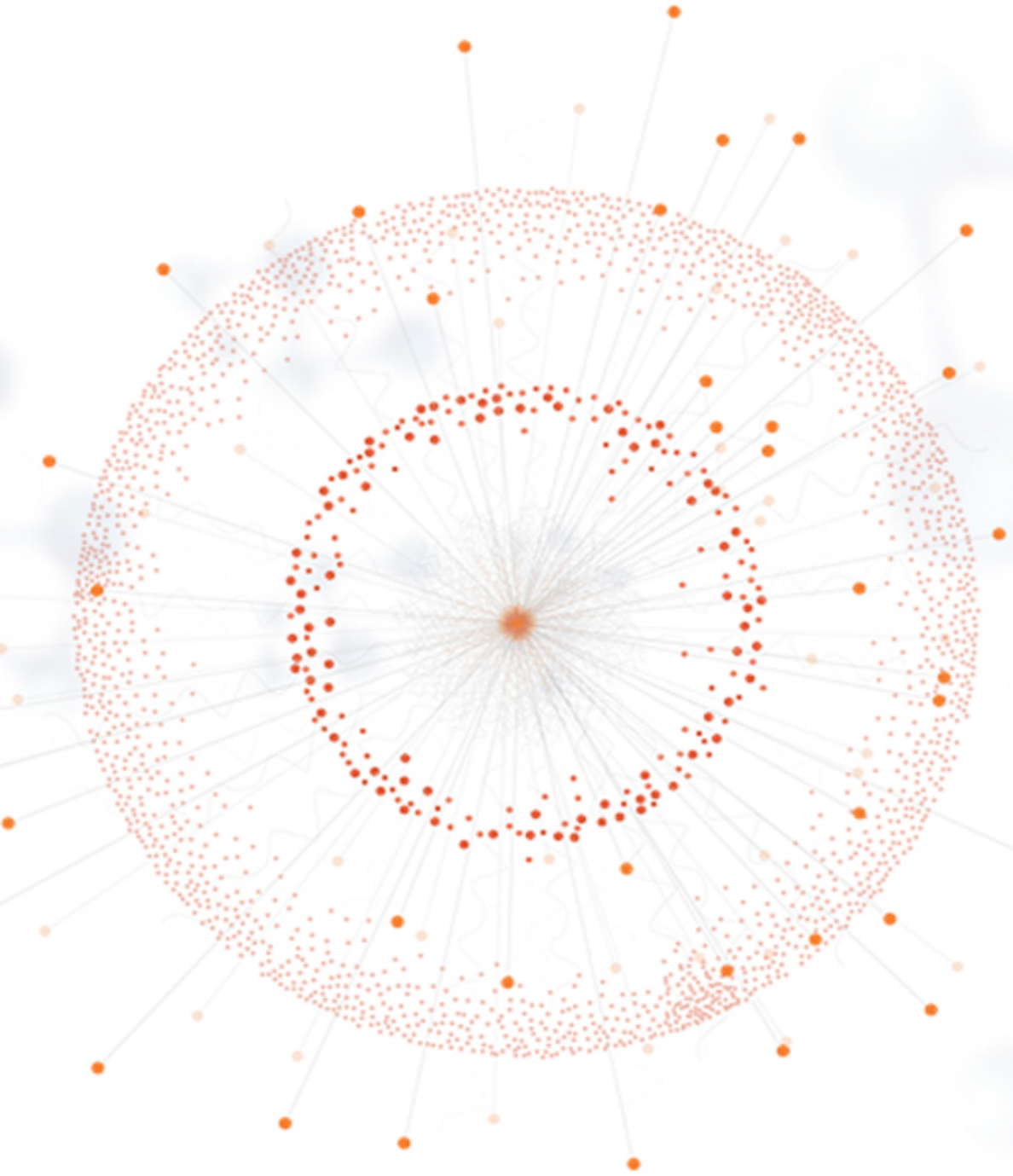

Collaborations & Partnerships

Build diversified drug pipeline

...by complementing in-house expertise with strategic external partnerships

Oncology

Immuno-inflammation

Neuro-degeneration

Ophthalmology

Complex drug delivery systems

- Collaborations with external innovators
  - Partnerships with leading global researchers to source promising early stage innovative science/biology
  - Focus continues to be on novel first-in-class or best-in-class opportunities as well as complex drug delivery platforms to address high unmet clinical needs
- Internal ideation
  - Chase validated as wells as first-in-class drug targets in select therapeutic areas
  - SPARC continues to pursue novel 505(b)(2) opportunities with high commercial potential
- Exploratory programs
  - Augment capabilities to pursue new treatment modalities like novel biologics that may offer significant value proposition versus existing therapies

Developing external innovation network

...to tap novel science early on

- Scale-up strategic partnerships with global academic centres as well as leading research service providers
- SPARC – Washington University collaboration
  - SPARC is evaluating and considering few unique research opportunities for providing grant funding
- Additionally, SPARC has been expanding tie-ups with other leading academic institutes in the US
  - University of Arizona, Tucson

Update on external innovation

SPARC–HitGen collaboration

- SPARC and HitGen have entered in to a research collaboration to identify novel small molecule leads for targets of interest to SPARC
- Under this collaboration, HitGen will apply its proprietary technology platform, based on DNA-encoded library design, synthesis and screening; to discover novel leads for SPARC
- HitGen shall be eligible to receive upfront payment and certain success based milestone payments
- HitGen has initiated screening of its DNA-encoded compound library against a drug target of interest to SPARC in Q2 FY20

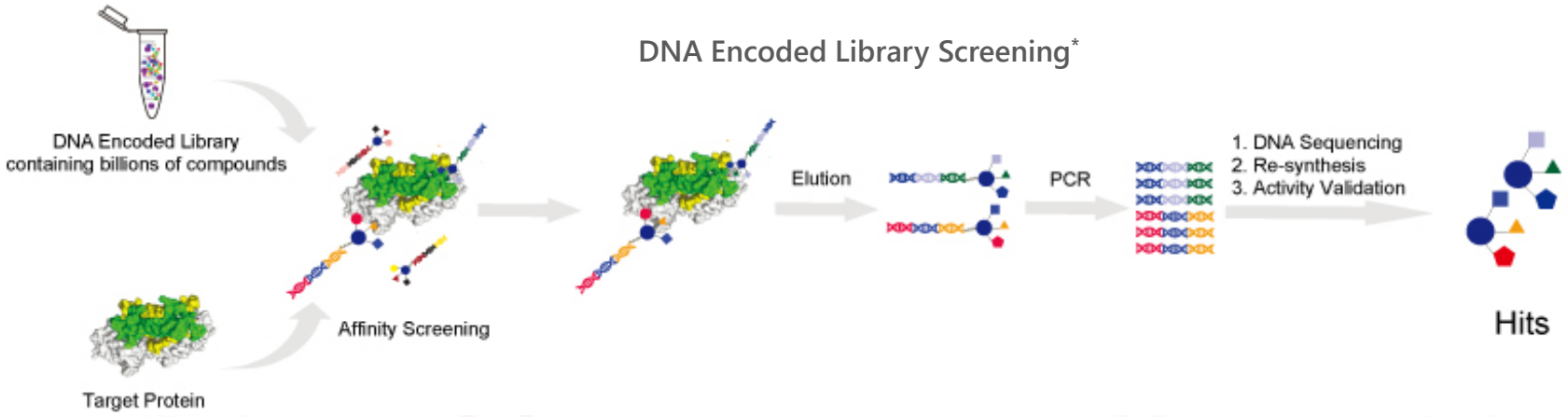

*Image courtesy: HitGen

Update on external innovation

SPARC–University of Arizona collaboration

- SPARC has collaborated with University of Arizona, Tucson to develop novel molecule(s) derived from natural sources for treatment resistant cancer
- SPARC is currently conducting *in vitro* and *in vivo* studies to establish proof-of-concept
- SPARC has the option to exclusively license the molecule(s) on worldwide basis
- SPARC shall be responsible for further development & commercialization of the drug

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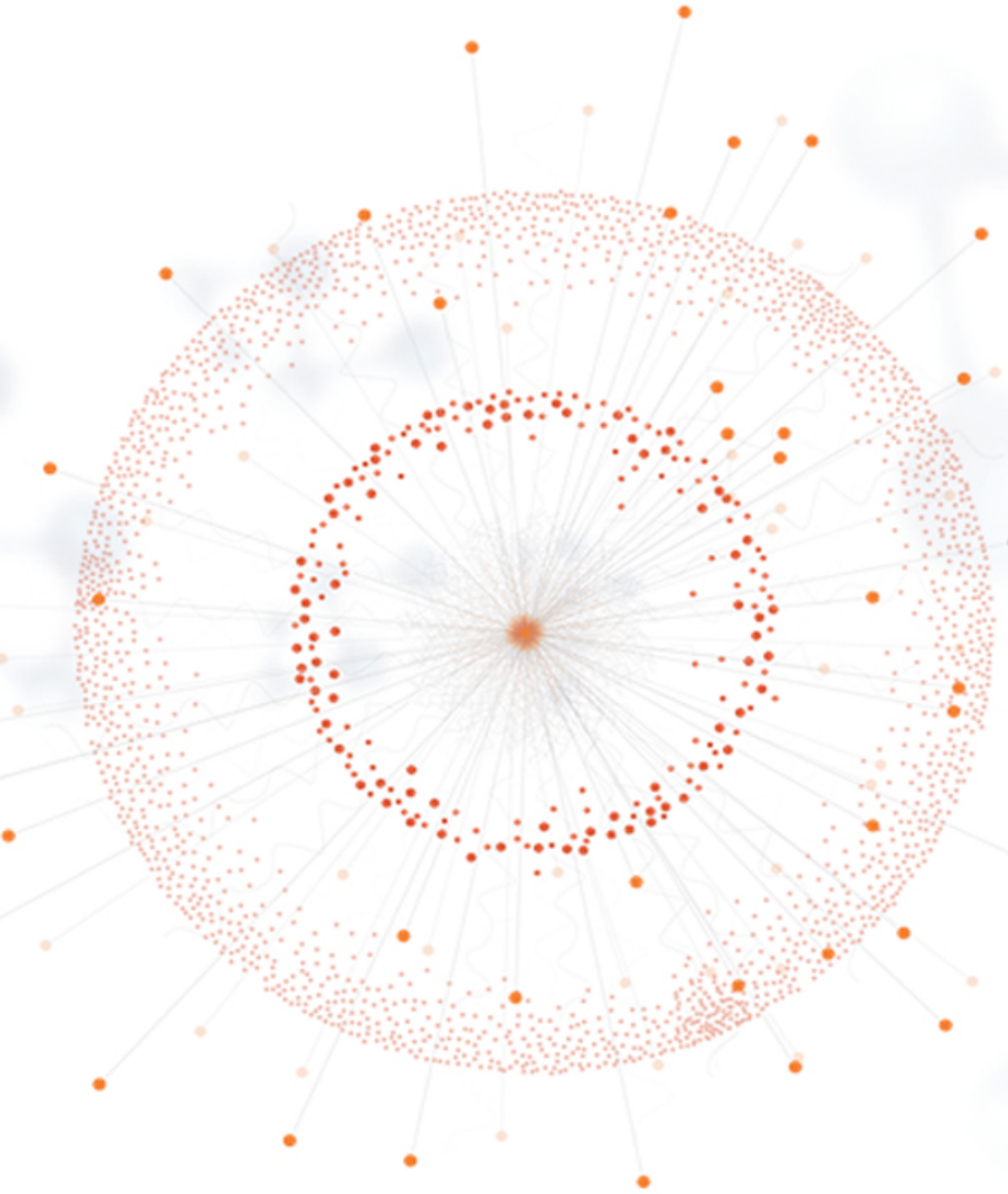


Financial Summary

Financial Summary

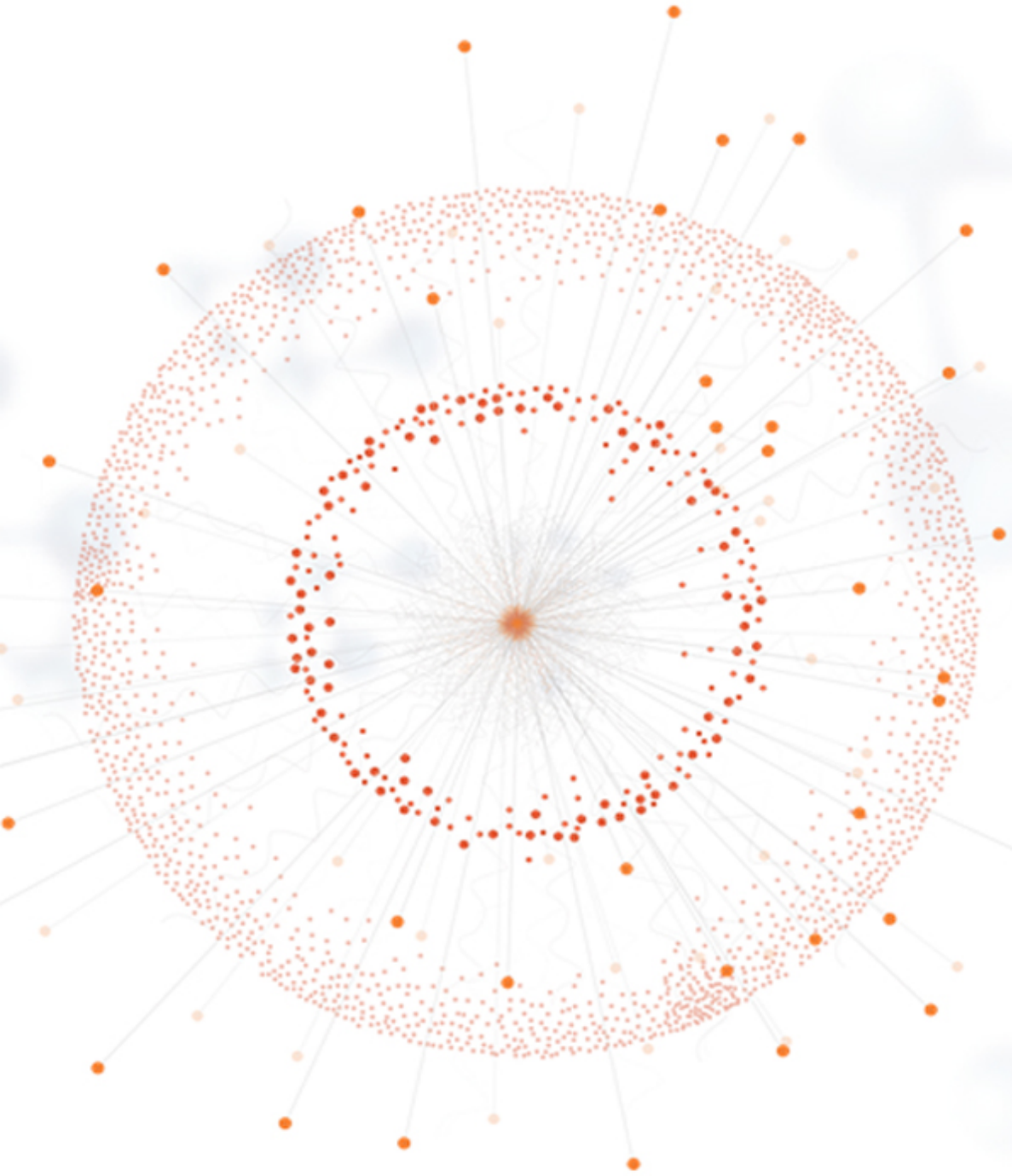
(INR mn)	FY19	FY18	FY17	FY16	FY15
Total Income	1,964	832	1,947	1,642	1,588
Total Expenses	3,418	3,292	3,137	2,342	1,983
Exceptional Item	-	490	-	-	-
Profit / (Loss) after Tax	(1,454)	(1,970)	(1,190)	(700)	(395)
Total Comprehensive Income (Net of tax)	(1,447)	(1,984)	(1,195)	N.A.	N.A.

Liquidity Status

- Cash and cash equivalents INR 788 Mn as on 31-Aug-19

INR = Indian Rupees

sparc



Pipeline

R&D Pipeline

CML = Chronic Myeloid Leukemia

THANK YOU

For updates and specific queries,
please visit www.sparc.life or write to us at bus.dev@sparcmail.com