

SPARC/Sec/SE/2018-19/029

4<sup>th</sup> September 2018

To

**The 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 - 400001

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

**Sub:** *Investor Presentation—Update on NCE & NDDS programs*

Dear Sir/ Madam,

Further to our letter No. SPARC/Sec/SE/2018-19/011 dated 4<sup>th</sup> July 2018 on the subject, please find enclosed a copy of the presentation by the Company providing update on NCE & NDDS programs, which is self-explanatory.

You are requested to kindly take the same on your record & disseminate the information through your website.

Yours faithfully,

For **Sun Pharma Advanced Research Company Limited**

A handwritten signature in black ink, appearing to read "Debashis Dey".

**Debashis Dey**

Company Secretary

Encls: A/a.



# Update on R&D Pipeline

4<sup>th</sup> September 2018

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# Agenda

**1** **SPARC Strategy & Key Growth Drivers**  
Anil Raghavan – CEO

**2** **Financial Highlights**  
Chetan Rajpara – CFO

**3** **Abl Kinase Inhibitor**  
SiuLong Yao – Sr. V.P. Clinical Development & Operations

**4** **S1PR1 Agonist**  
Kristine Nograles – V.P. Dermatology & Rheumatology

**5** **Extended Ocular Retention**  
Hany Michail – V.P. Ophthalmology

**6** **Nanoformulations & Long Acting Depots**  
Ajay Khopade – V.P. Formulation Development  
Yashoraj Zala – V.P. Formulation Development

**7** **Abuse & Overdose Deterrent Platform**  
Yashoraj Zala – V.P. Formulation Development

**8** **Pipeline Build-up Strategy**  
Nitin Damle – Sr. V.P. Innovation

**9** **Competitive Landscape – Key Programs**  
Jaydeep Issrani – G.M. Business Development

**10** **Q&A**

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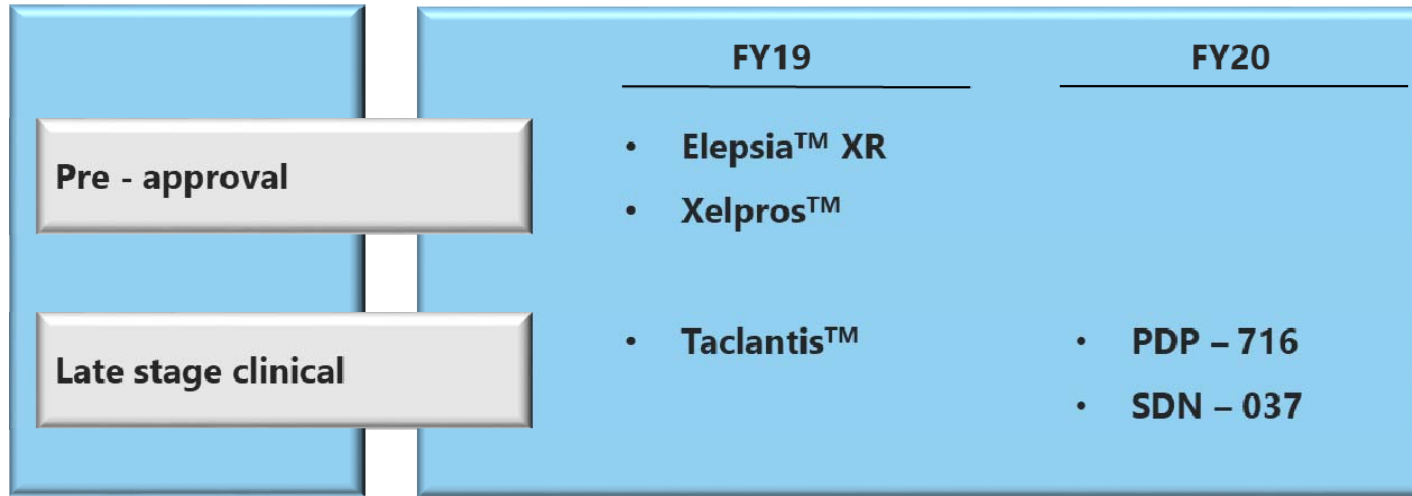
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# SPARC's Journey

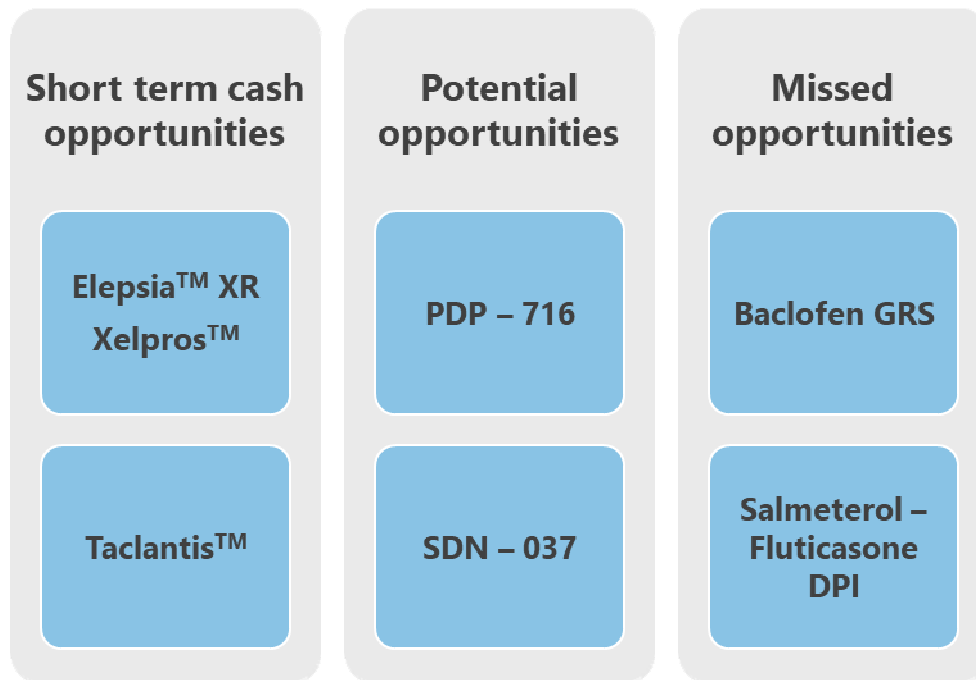
Poised to reach important milestones....



○ SPARC responded to US FDA CRLs indicating facility compliance and readiness, resetting the regulatory clock for approval

- Xelpros™ : PDUFA date – Nov'18
- Elepsia™ XR : PDUFA date – Jan'19

## ...marking the conclusion of our initial set of delivery solutions



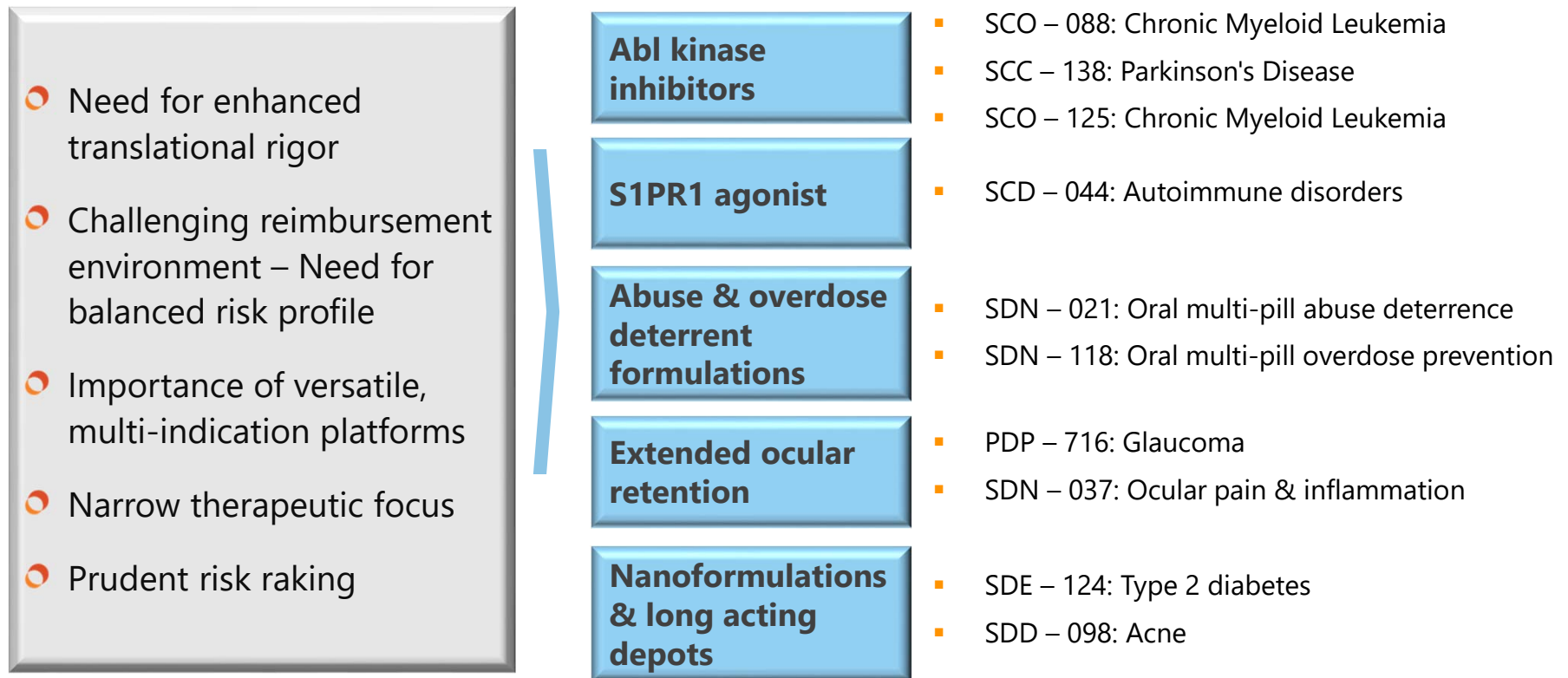
### ○ Baclofen GRS

- Pivotal studies did not meet the primary end point
- Met several clinically significant secondary end-points (E.g.: Spasm Frequency, SGIC, etc.)
- Plan to submit additional registration studies while exploring opportunities to partner

### ○ Salmeterol – Fluticasone DPI

- Completed regulatory consultations with multiple European regulatory agencies
- Registration pathway may involve additional BE and clinical endpoint studies
- Challenging commercial and reimbursement environment
- Currently exploring partnership opportunities

## Key takeaways from our initial programs

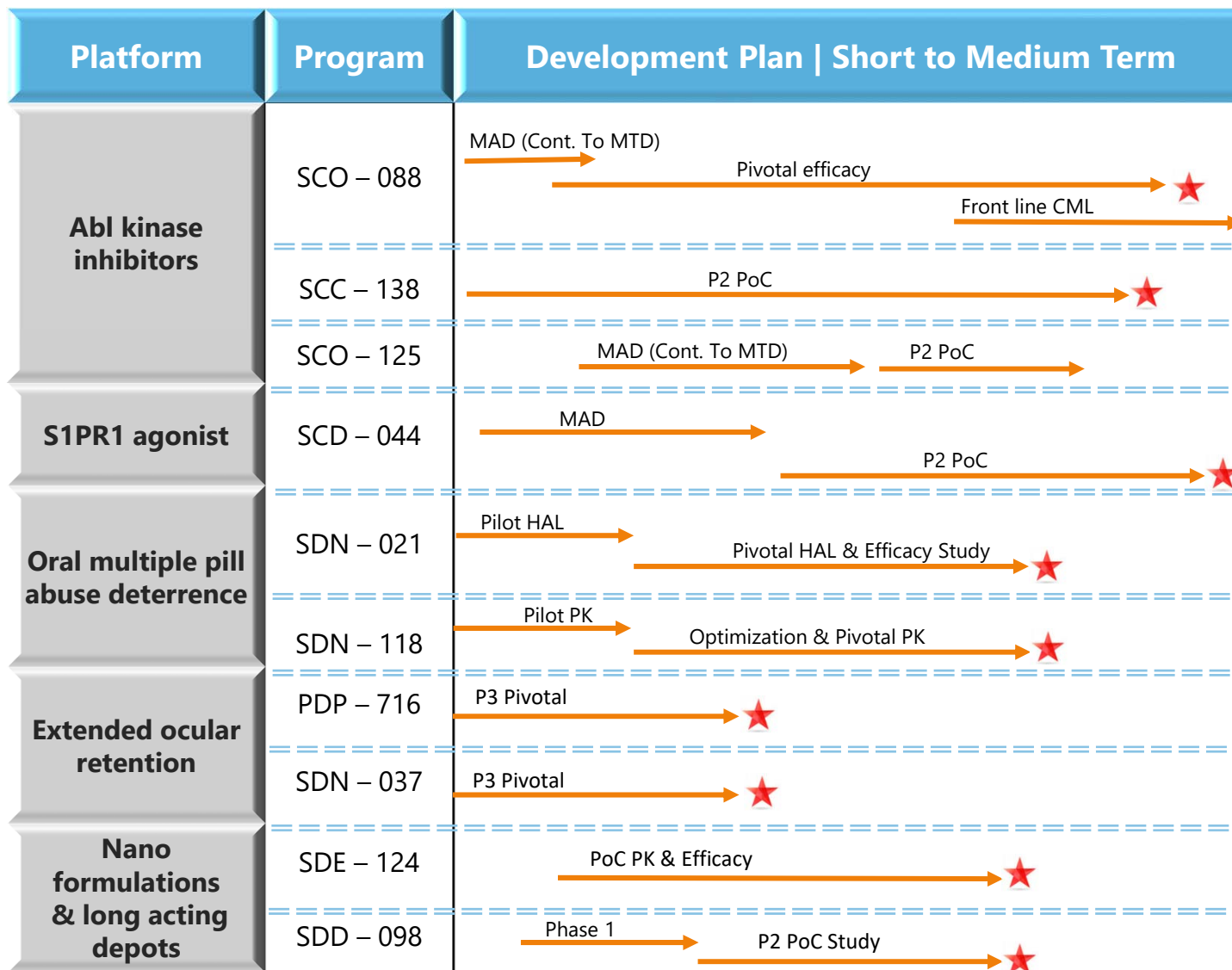


**Platforms under early clinical development will drive our portfolio value and resource allocation in the short/medium term**



# Possible value inflection points & resource allocation

A snapshot of next 24 months



Data read out, SCO – 088 = K0706 CML, SCC – 138 = K0706 Parkinson's Disease, SCO – 125 = K0954 CML, PDP – 716 = Brimonidine OD, SDD – 098 = Minocycline topical  
SDN – 037 = SDP – 037

# We will continue to be in the investment mode in the medium term

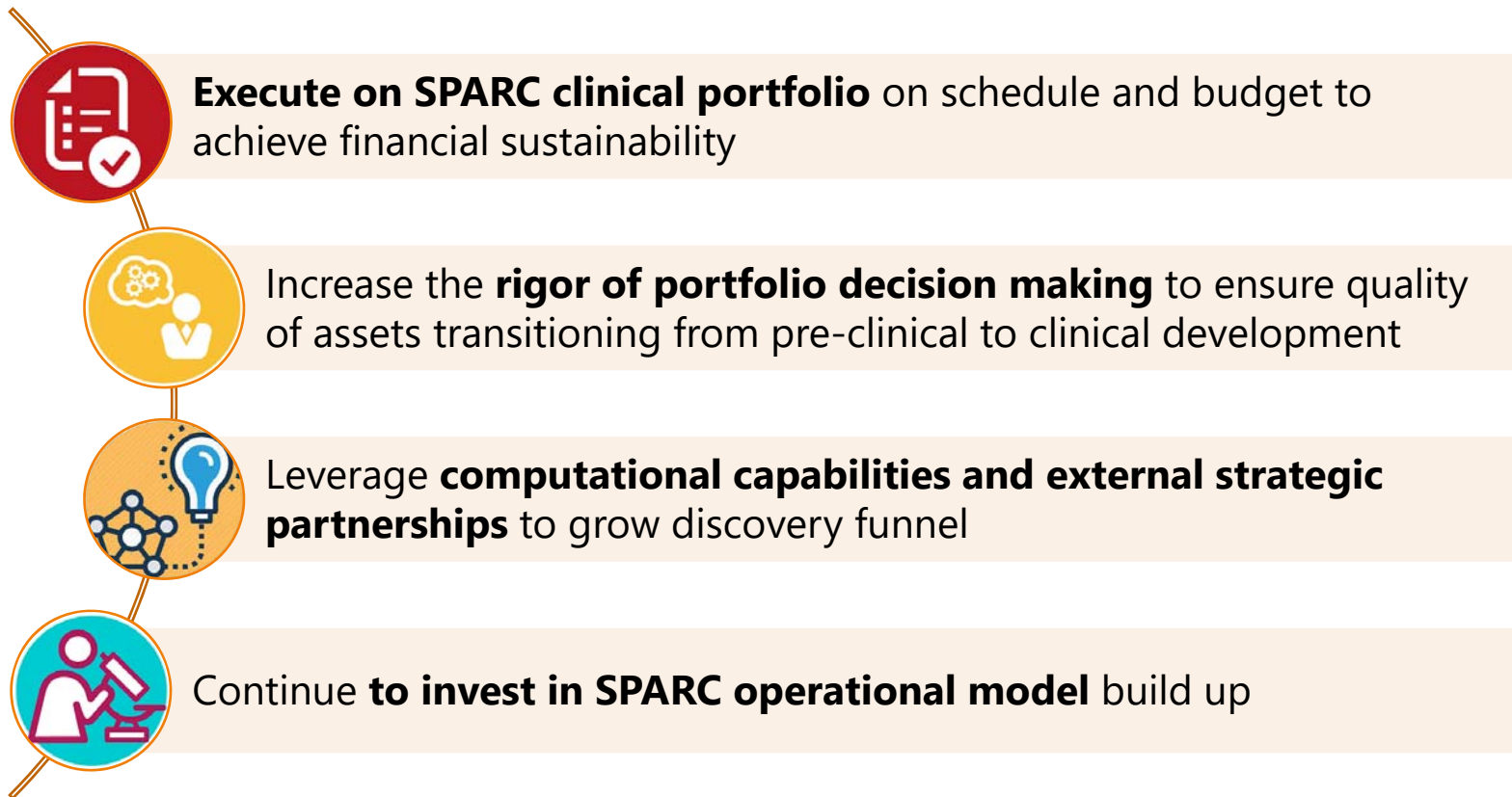


Platform	Program	Development Plan   Short to Medium Term	Cost Trend	Early Exit
Abl kinase inhibitors	SCO - 088	MAD (Cont. To MTD) → Pivotal efficacy → Front line CML → ★	+++	
	SCC - 138	P2 PoC → ★	+++	
	SCO - 125	MAD (Cont. To MTD) → P2 PoC →	+	
S1PR1 agonist	SCD - 044	MAD → P2 PoC → ★	+++	
Oral multiple pill abuse deterrence	SDN - 021	Pilot HAL → Pivotal HAL & Efficacy Study → ★	++	
	SDN - 118	Pilot PK → Optimization & Pivotal PK → ★	++	
Extended ocular retention	PDP - 716	P3 Pivotal → ★	+	✓
	SDN - 037	P3 Pivotal → ★	+	✓
Nano formulations & long acting depots	SDE - 124	PoC PK & Efficacy → ★	+	✓
	SDD - 098	Phase 1 → P2 PoC Study → ★	+	✓



Data read out, SCO - 088 = K0706 CML, SCC - 138 = K0706 Parkinson's Disease, SCO - 125 = K0954 CML, PDP - 716 = Brimonidine OD, SDD - 098 = Minocycline topical  
SDN - 037 = SDP - 037

## SPARC R&D priorities



**SPARC will continue to focus on building versatile platforms which can advance the standards of care meaningfully in chosen therapeutic segments**

## Dedicated research facility at Savli, Vadodara



- Dedicated, modern campus with world class infrastructure
- Augmenting research capabilities with state of the art technology and equipment
- Plan to shift to new facility by Q4 FY19

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## Financial summary

(INR mn)	FY18	FY17	FY16	FY15	FY14
<b>Total Income</b>	832	1,947	1,642	1,588	1,770
<b>Total Expenses</b>	3,292	3,137	2,342	1,983	1,427
<b>Exceptional Item</b>	490	-	-	-	-
<b>Profit (Loss) after Tax</b>	(1,970)	(1,190)	(700)	(395)	303
<b>Total Comprehensive Income (Net of tax)</b>	(1,984)	(1,195)	N.A.	N.A.	N.A.

### Liquidity Status

- Cash and cash equivalents INR 1,764 mn as on 31-Aug-18
- Higher working capital need due to GST

# Financial Summary

- Expected cash outflows
  - Increased number of clinical programs
  - Higher operating expenses
  - Refurbishing cost of new facility at Savli
  
- Expected cash inflows
  - Raised INR 5,000 mn through Preferential Issue of Warrants (70% received, INR 1,500 mn to be received in Jan-19)
  - Milestone payments upon approval of Xelpros™ and Elepsia™
  - Out-licensing of Taclantis™, if pivotal BE study outcome is positive

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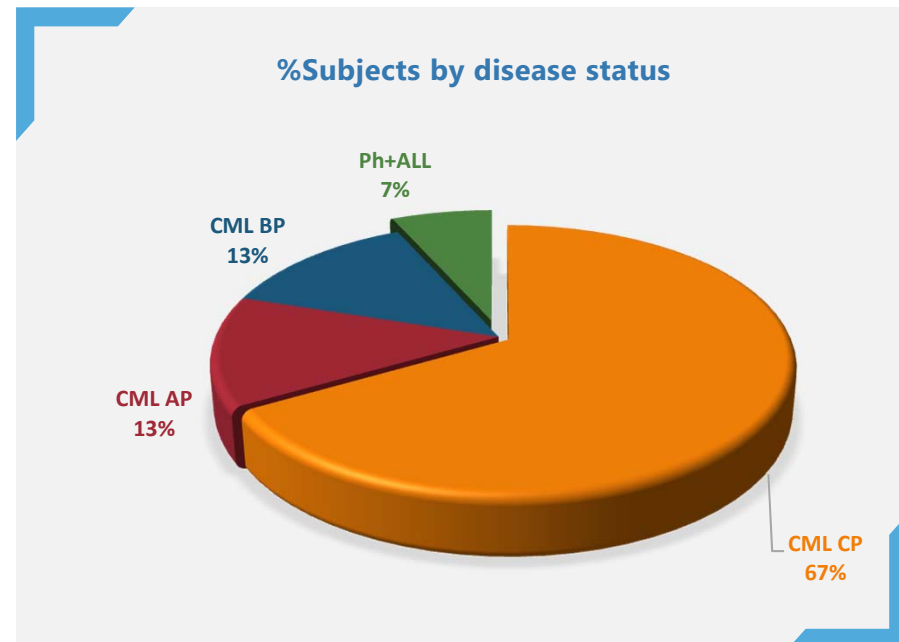


# SCO – 088



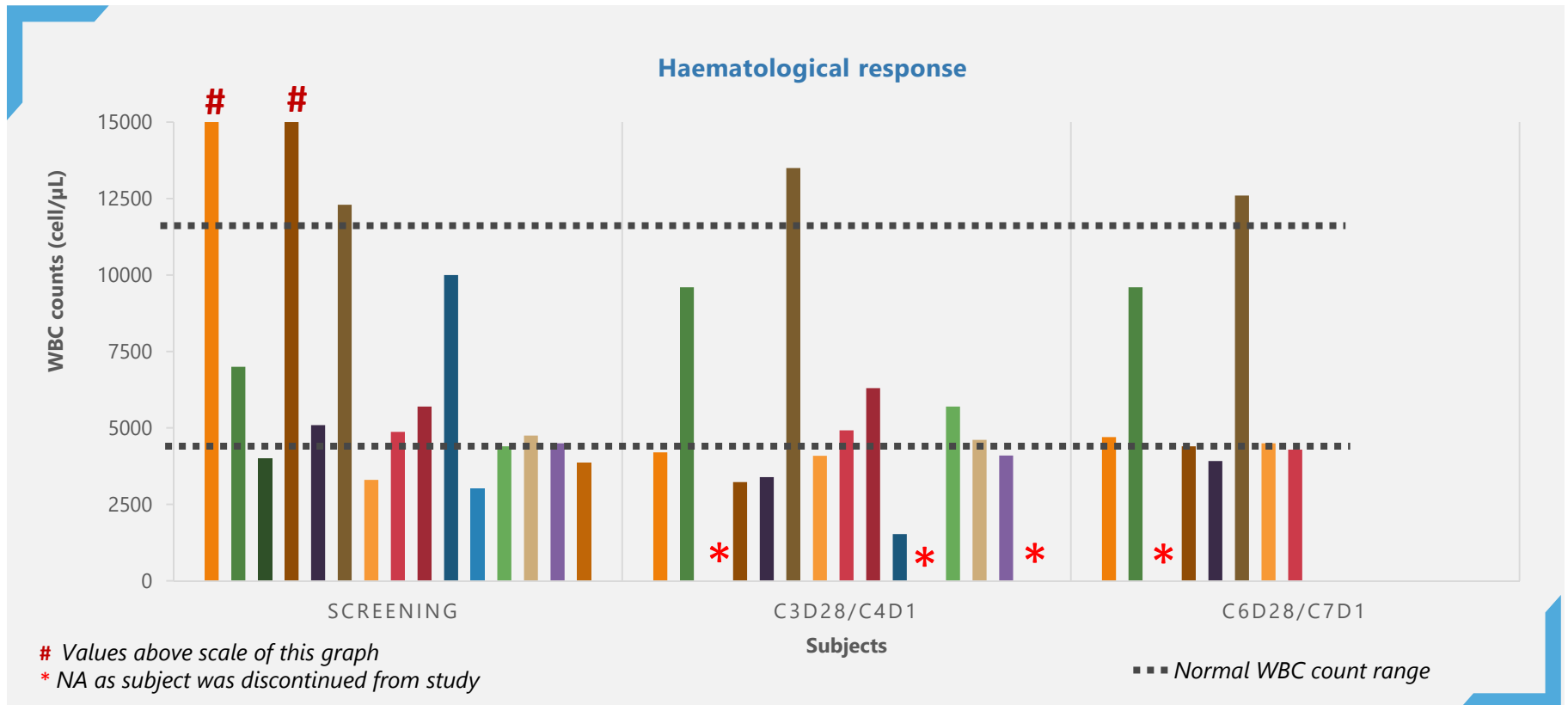
Encouraging preliminary efficacy and safety observed

- Effective against BCR-ABL and its mutants, including T315I mutation
- Multiple Ascending Dose (MAD) study ongoing in CML patients
  - Completed 5 dose escalations
  - PK supports once-a-day dosing
  - 1<sup>st</sup> subject continuing treatment, completed 17 cycles



# SCO – 088

## Haematological response in CML patients



- Haematological response rate ~80% in subjects enrolled
- No cardiovascular events reported till date
- Transient self-limiting grade 1/2 neutropenia reported in one patient only

# SCO – 088

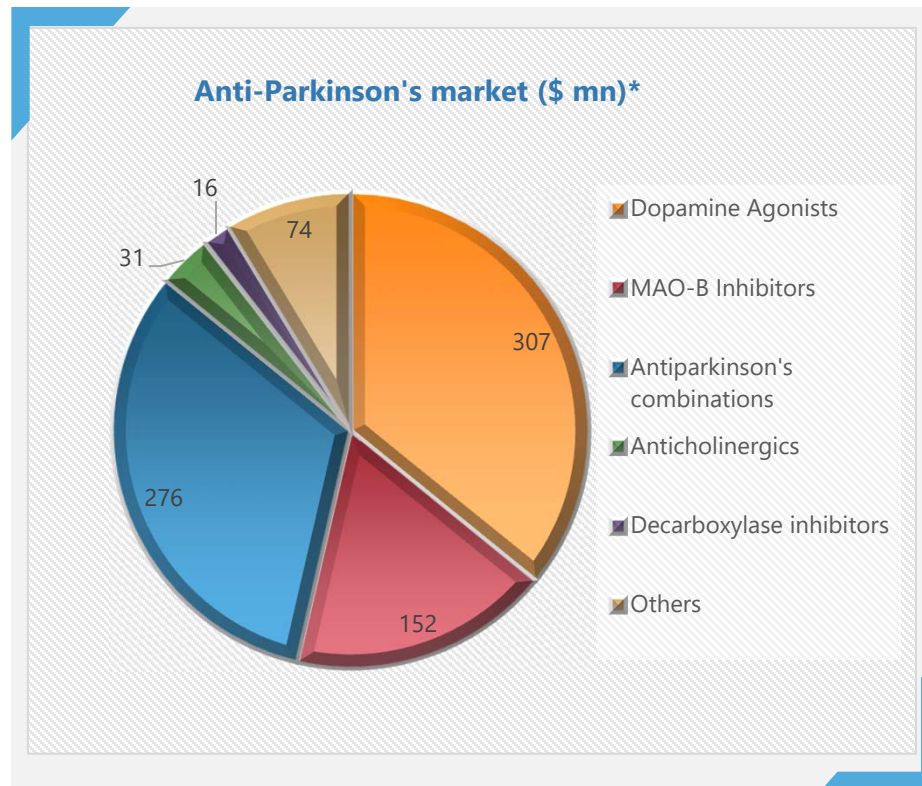
## Development status update



- Plan to complete MAD study by Q4 FY19
- Phase 2 pivotal efficacy study
  - Single arm, open label, efficacy study in 150 subjects failed on  $\geq 3$  TKIs
  - Protocol submission to US FDA by Q2 FY19
  - Study initiation by Q3 FY19

# Parkinson's Disease

Increasing incidence due to the aging population



- Over 1 mn people living with Parkinson's Disease in the US<sup>^</sup>
- Expected to grow to ~1.35 mn by 2022 with about 60,000 new patients diagnosed every year
- No disease modifying therapy available
  - Currently available therapies provide symptomatic relief only

# SCC – 138

## Supporting pre-clinical data in Parkinson's Disease



### Pre-clinical development

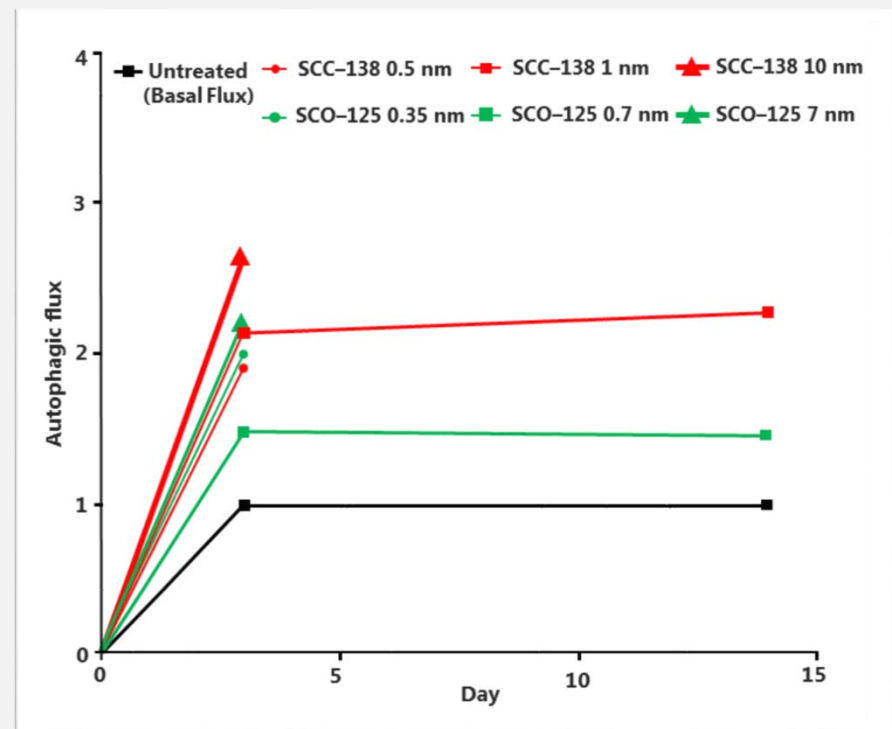
Therapeutic potential in  $\alpha$ -synuclein PFF induced model

#### Role of SCC – 138 in human IPSC-derived neurons

- 1) Augmenting Parkin activity
- 2) Modulating autophagic flux and  $\alpha$ -synuclein metabolism
- 3) Altering  $\alpha$ -synuclein inclusions

Therapeutic potential in AAV1/2  $\alpha$ -synuclein rat model

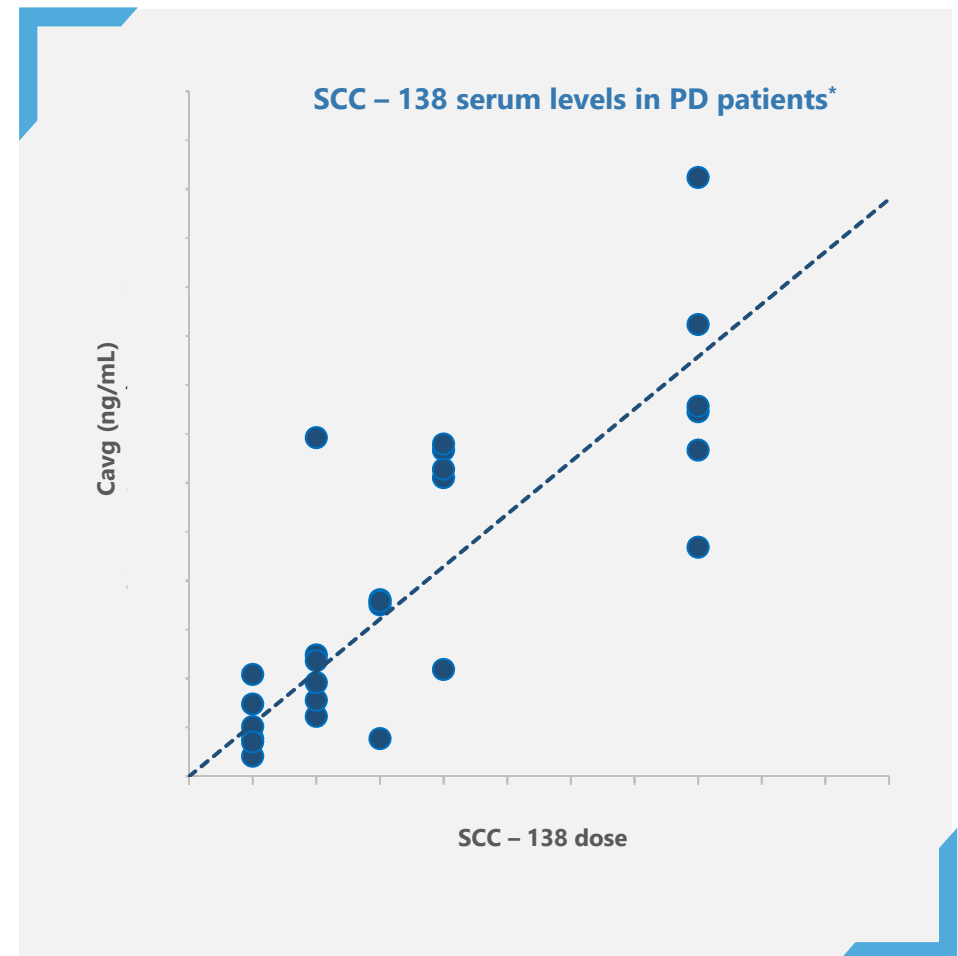
Effect of 3-day vs. 14-day treatment of the SPARC c-Abl inhibitors on the autophagic flux.



# SCC – 138

1<sup>st</sup> in class disease modifying treatment

- Orally active, disease modifying treatment with potential neuro-protective activity
- Inhibits Abl and Fyn kinase – relevant to neurodegeneration
- Completed 6 dose cohorts in Phase 1 PD patients study
- No significant adverse events observed in highest studied dose level\*
- Preliminary human PK data demonstrates drug presence in CSF



# SCC – 138

## Development status update



- MAD study on-going; plan to add higher dose levels
- Phase 2 PoC to be initiated in PD patients by Q3 FY19 at multiple centres across North America, Asia and Europe

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## SCD – 044

### Selective S1PR1 agonist for autoimmune diseases



- SPARC is developing a novel orally bioavailable, potent and selective S1PR1 agonist in collaboration with Bioprojet, France
- S1PR1 agonists cause diminished migration of lymphocytes out of lymphoid tissues leading to decrease in circulating lymphocytes thereby reducing inflammation
- Encouraging results in animal models of autoimmune diseases, including psoriasis
- First-in-human study is currently ongoing to establish safety profile in healthy volunteers

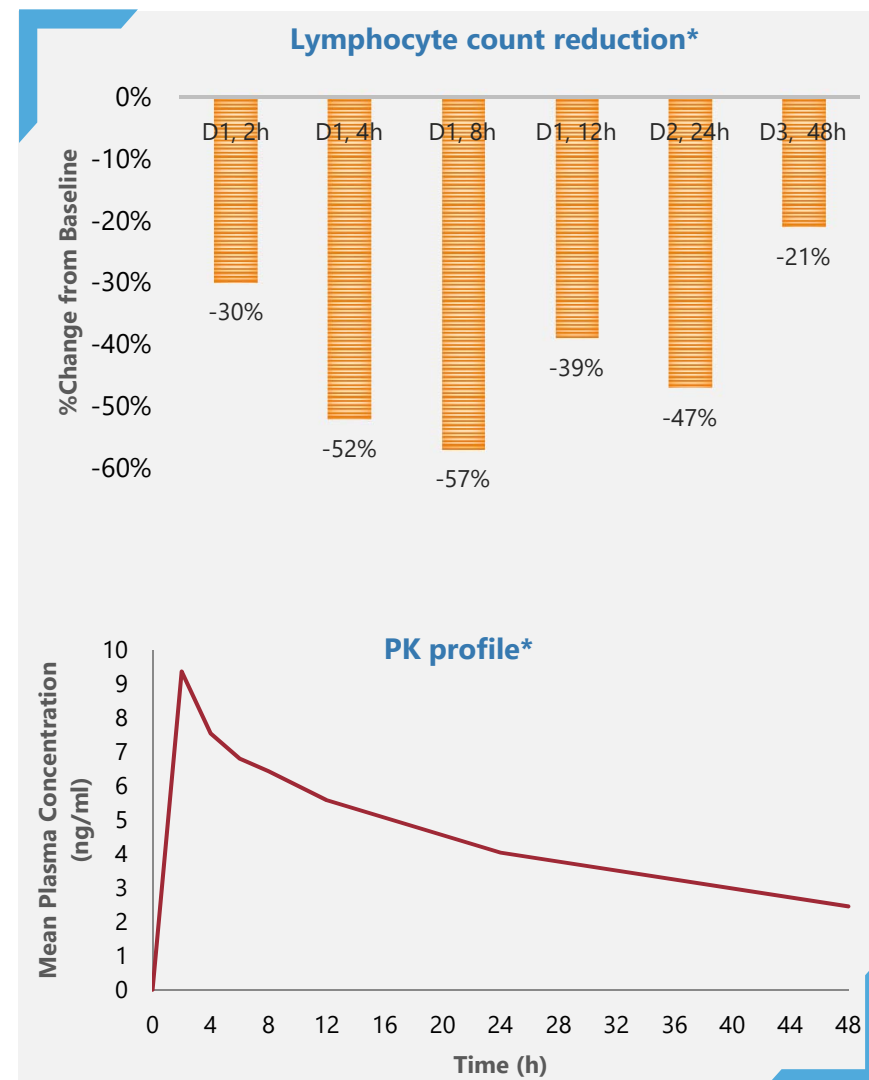
# SCD – 044

## First-in-Human Study is well underway



### Multi-part study in healthy volunteers

- **Part 1:** Single ascending dose study completed
  - 6 dose groups evaluated compared to placebo
  - Decrease in lymphocyte counts was observed at all dose levels evaluated
  - Established a maximum tolerated dose
  - Terminal elimination half-life ( $t_{1/2}$ ) of ~34 h, independent of dose
- **Part 2:** Food effect study completed
- **Part 3:** Multiple ascending dose study ongoing



\*Phase 1 part 1 SAD study, 2 mg dose.

## SCD – 044

### Development status update



- Planned completion of Phase 1 study by Q1 FY20
- Phase 2 study initiation anticipated by Q1 FY20
  - Indications under consideration include Psoriasis, Inflammatory Bowel Diseases, Atopic Dermatitis & others

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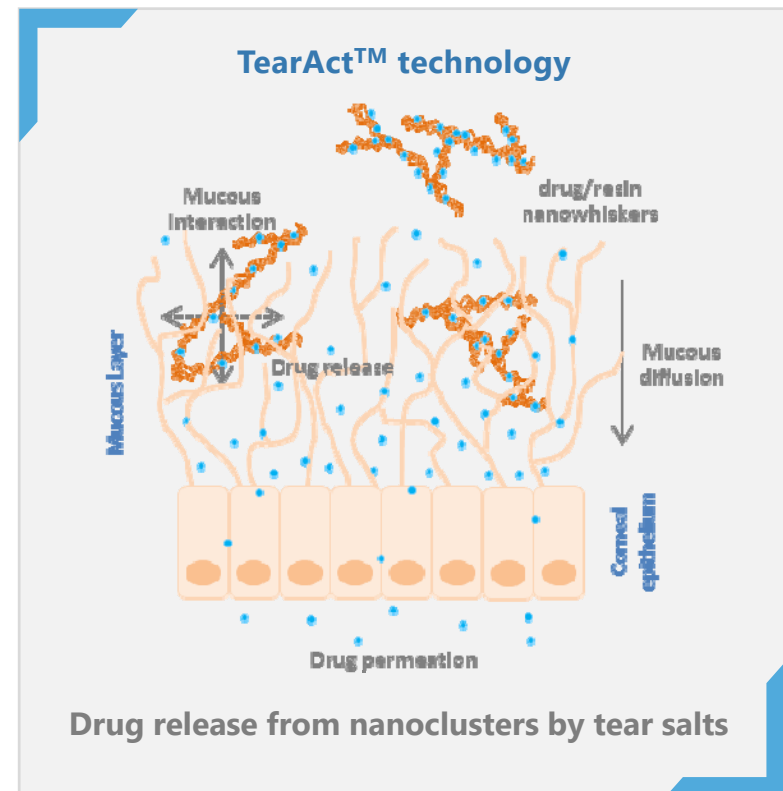
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# PDP – 716

## Novel once-a-day eye drops for Glaucoma



- Existing formulations of Brimonidine, an  $\alpha_2$  adrenergic agonist, are administered TID in the second line treatment of Glaucoma
- TID dosing often results in lower treatment adherence rates in patients\*
- SPARC is developing improved formulation of Brimonidine for once-a-day dosing utilizing its proprietary TearAct™ technology

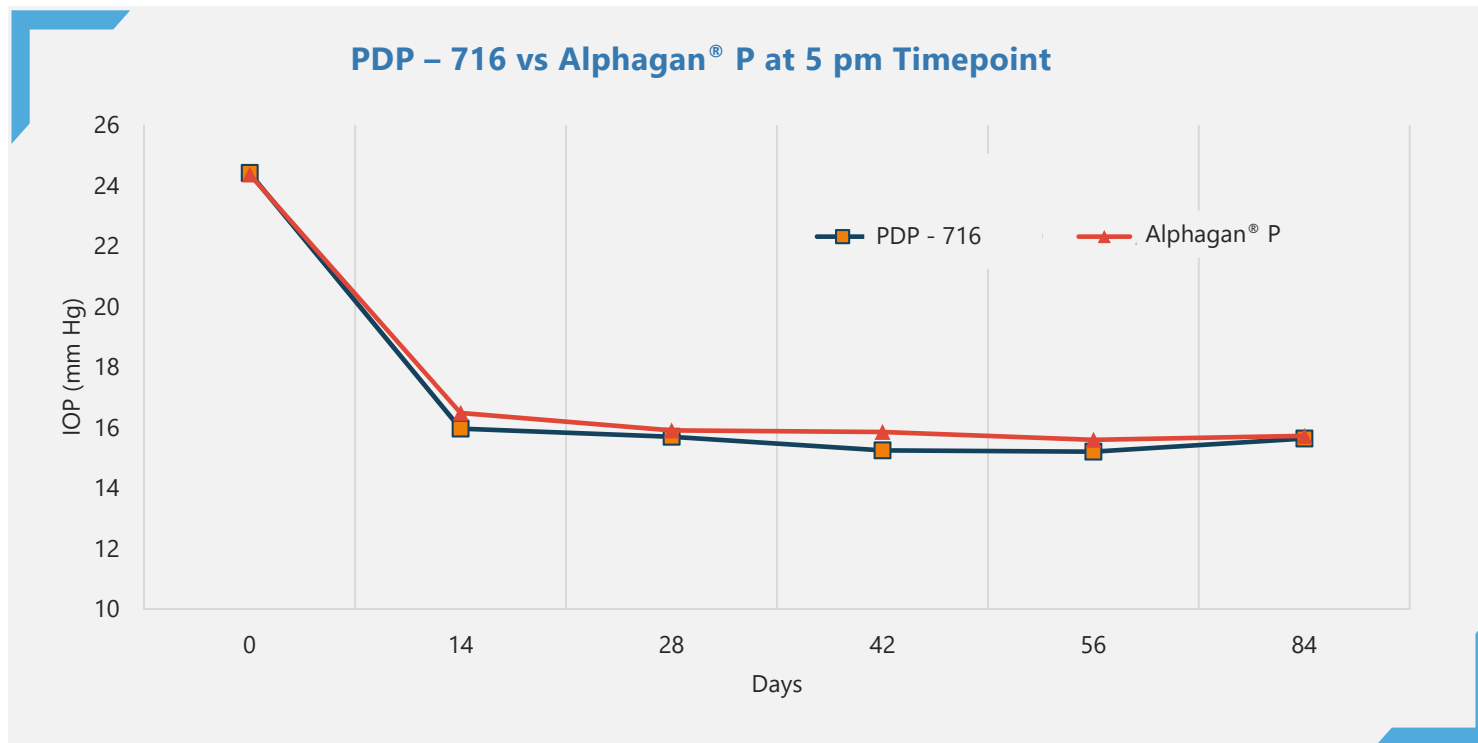


# PDP – 716



## Phase 2 data supports once-a-day dosing

- Proof of concept demonstrating equivalence to Alphagan® P dosed TID was completed in human trial
- Met pre-specified clinical equivalence efficacy criteria compared to Alphagan® P TID at all time points
- No new adverse events reported



# PDP – 716

## Development status update



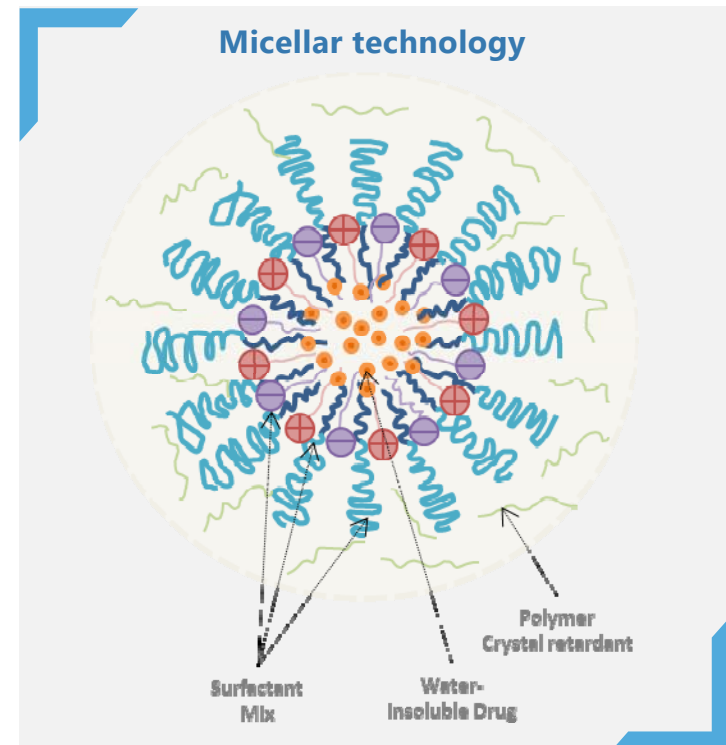
- IND submitted in Q4 FY18
- US FDA alignment on single, active controlled Phase 3 study with Alphagan® P as a comparator to support NDA submission
- Phase 3 study initiated in Q1 FY19
  - Target enrolment of 666 subjects
  - Recruitment at ~27 sites across the US
- NDA submission planned by Q4 FY20

# SDN – 037



## Improved ocular steroid with reduced dosing frequency

- Currently marketed steroid eye drops are approved for QID dosing
- Additionally, marketed products have hazy/milky appearance which may blur the vision upon administration
- SPARC is developing novel formulation of an existing steroid utilizing its Micellar technology
- Differentiated topical steroid eye drops with BID dosing & clear/transparent appearance is expected to provide meaningful benefit to the patients





# SDN – 037

## Development status update



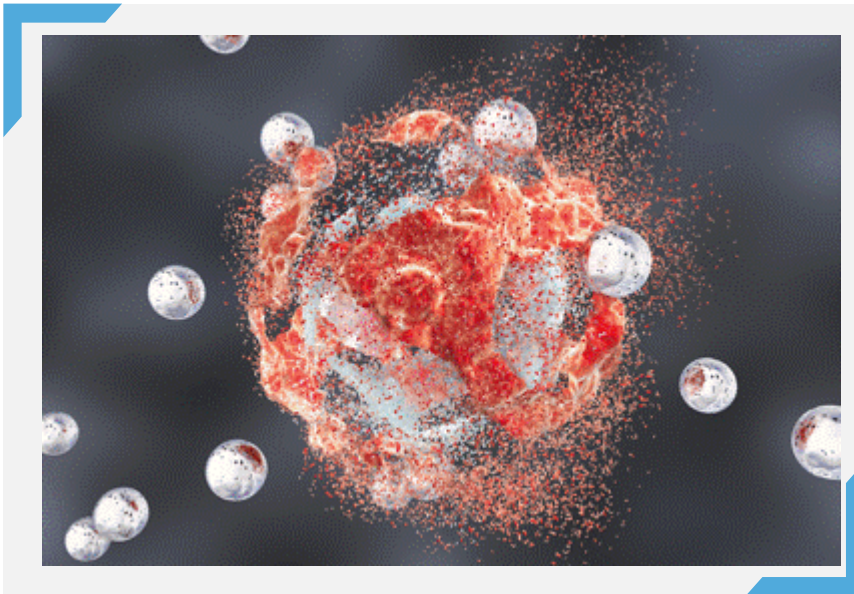
- US FDA alignment on single, vehicle controlled Phase 3 study to support NDA submission
- Phase 3 study initiated in Q1 FY19
  - Target enrolment of 386 subjects
  - Recruitment at ~15 sites across US
- NDA submission planned by Q2 FY20

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### Novel formulation of paclitaxel using SPARC's proprietary Nanotecton™ platform technology



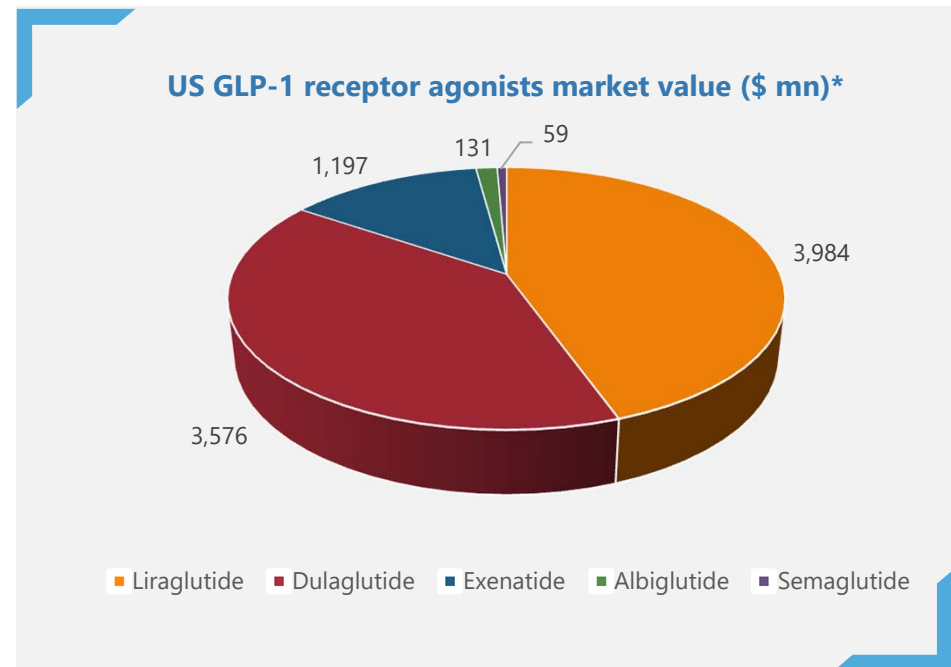
- Pivotal BE study fully enrolled
  - 142 patients randomized
  - 99 evaluable patients
  - No hypersensitivity reactions observed
- Data read out expected by Q3 FY19
- Planned NDA filing by Q4 FY19

# SDE – 124



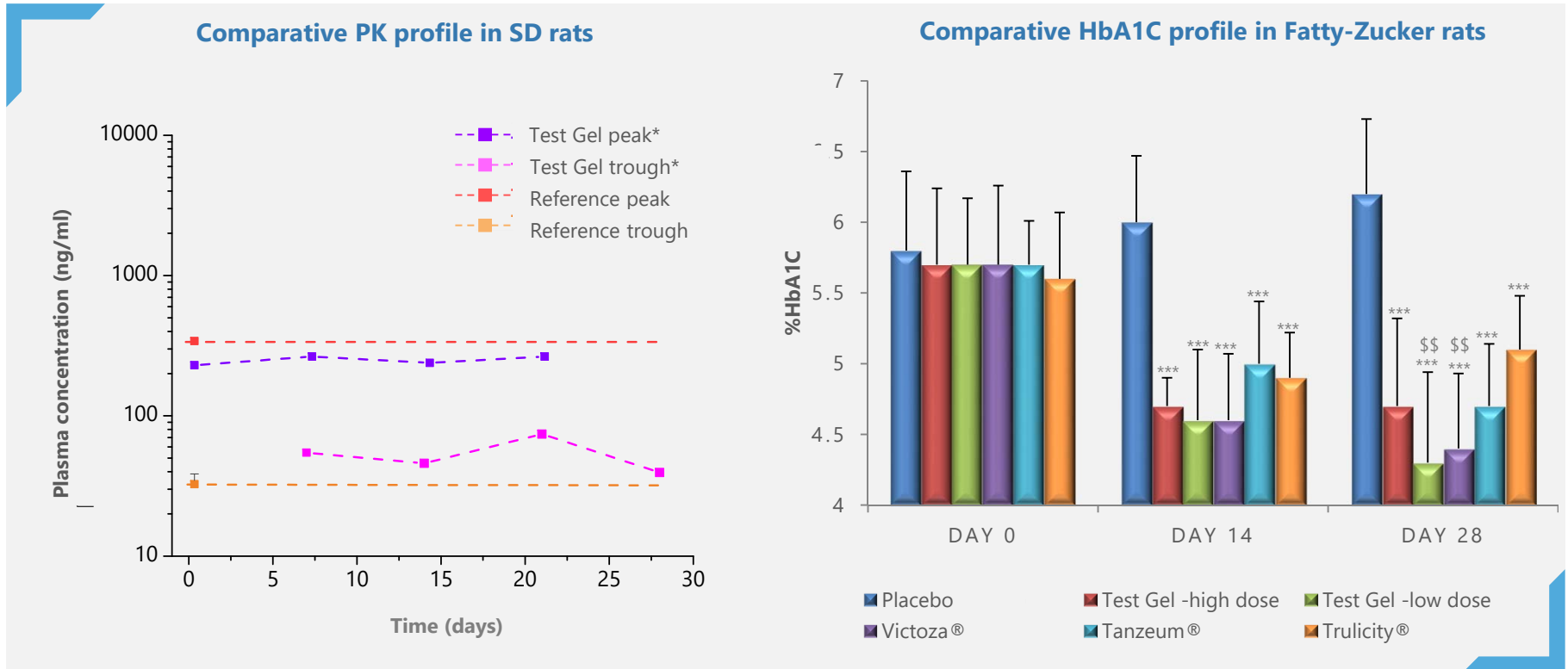
## Long acting formulation of GLP-1 receptor agonist

- 21 mn diagnosed cases of type 2 diabetes in the US<sup>#</sup>; estimated 1.5 mn new cases diagnosed annually<sup>^</sup>
- GLP-1 receptor agonists reported annual sales of ~\$9 bn with 39% YoY growth\*
- Currently marketed reference product available as a daily injection
- Developed long acting, subcutaneous injection for self administration
- Nanostructured gel; harnesses drug and excipient's self-assembling property
  - Drug release by erosion
  - Employs GRAS excipients



# SDE – 124

## Encouraging efficacy in pre-clinical setting



- Therapeutically effective levels maintained for desired duration in SD rats
- Significant reduction in %HbA1C was observed after multiple SC injections

\*Extrapolated to expected human equivalent dose, Two way ANOVA followed by Bonferroni post test, \*\*\*p<0.001 as compared to Placebo, \$\$p<0.01 as compared to Trulicity  
SD rats = Sprague Daeley rats SC = Sub-cutaneous

# SDE – 124

## Development status update



- Prototype formulation ready; short term stability study ongoing
- Pre-IND meeting with US FDA completed
- IND enabling toxicology studies planned to be initiated by Q3 FY19
- IND submission by Q3 FY20
- Phase 1 human PoC study initiation by Q4 FY20

# SDD – 098

## Development status update



- According to AAD, more than 5 mn people seek medical treatment for acne and has significant impact on productivity for affected individuals
- SPARC is developing novel topical formulation of Minocycline designed to reduce systemic side-effects associated with oral dosing
- Phase 1 enabling toxicity study ongoing
- Pre-IND meeting completed with US FDA
- IND filing expected by Q4 FY19



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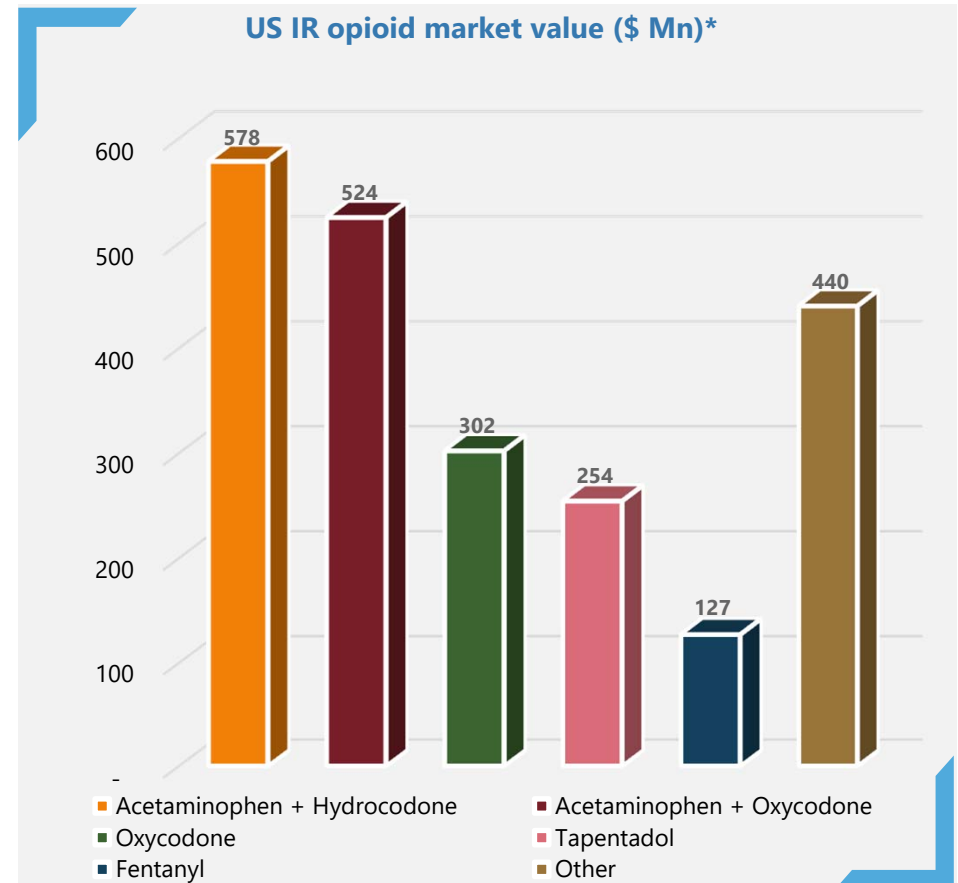


# SDN – 021



## Potential to deter oral multiple pill abuse

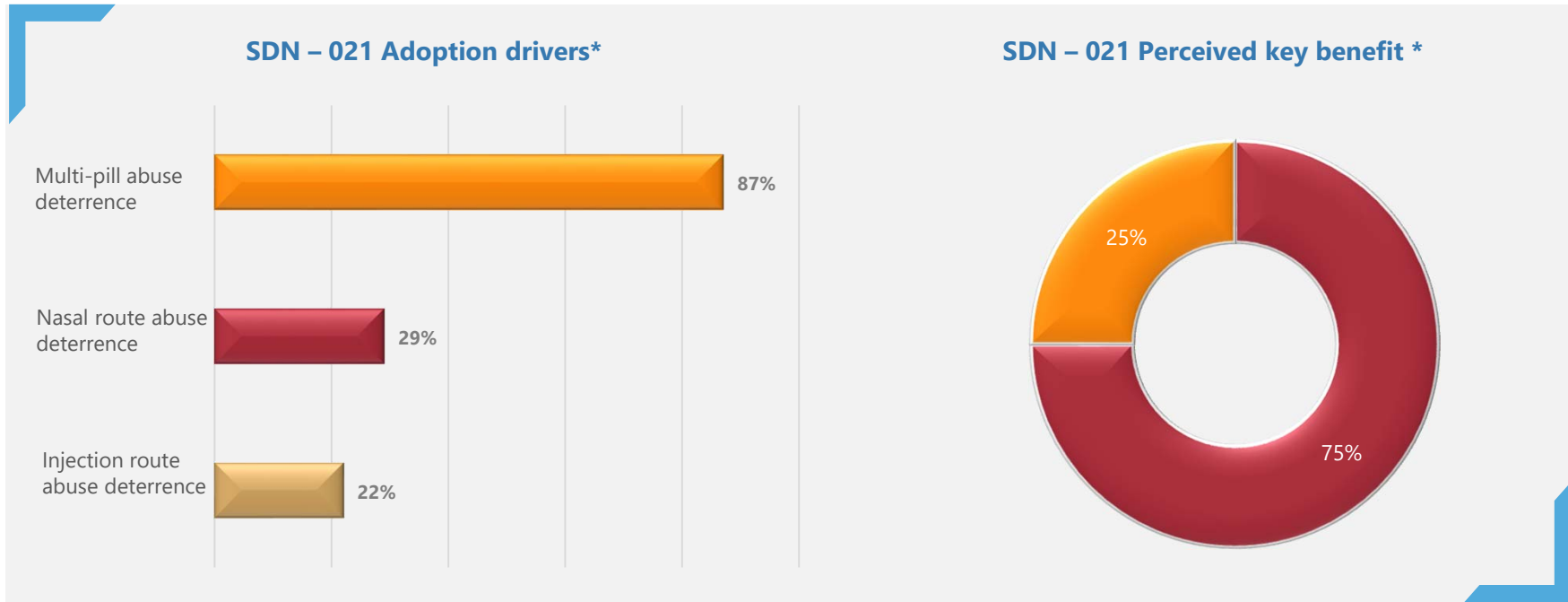
- 187 mn prescriptions generated for IR opioids with estimated value of ~\$2 bn\*
- 66% of the abusers prefer IR formulations due to ease of manipulation^
- SPARC developed IR opioid formulation with abuse deterrent properties for oral, nasal and IV abuse
- Includes presence of an aversive agent to further deter abuse if tampered
- Encouraging results in Category I *in-vitro* tamperability evaluation



\*IQVIA MAT June 2018, ^Postgraduate Medicine, 2016, 128:1, 85-96 IR = Immediate release IV = Intra venous

# SDN – 021

## Multiple pill abuse deterrence – main driver to adoption\*



87% of physicians see oral multi-pill abuse deterrence as a driver to utilize SDN-021\*

75% of payers view oral multi-pill abuse deterrence as a major benefit\*

Q: What are the main drivers of your utilization? (n=44)

Q: What are the major benefits of SDN-021? (n=12)

\*Based on primary market research conducted on behalf of SPARC by third party in the US

# SDN – 021

## Development status update



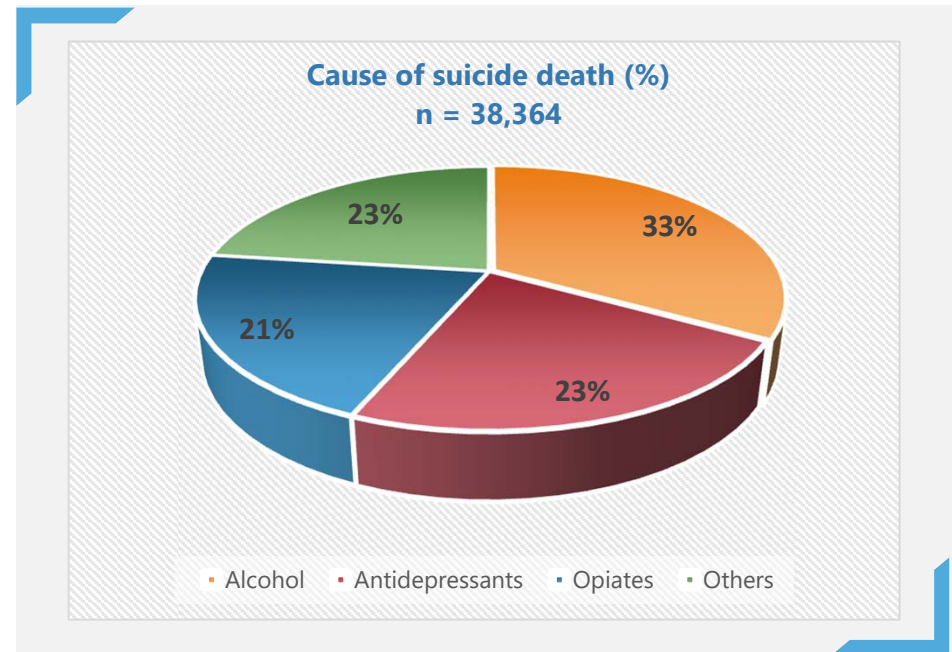
- Pilot Human Abuse Liability (HAL) study ongoing
  - Primary endpoint: Drug Liking –  $E_{\max}$
  - Cohort A recruitment completed
  - Cohort B recruitment ongoing
  - Topline data expected by Q3 FY19
- Phase 3 clinical study planned in concurrence with US FDA guidance; planned initiation by Q3 FY19
- Pivotal Category 1 studies planned in Q1 FY20

# SDN – 118

## Addressing prescription drug overdose

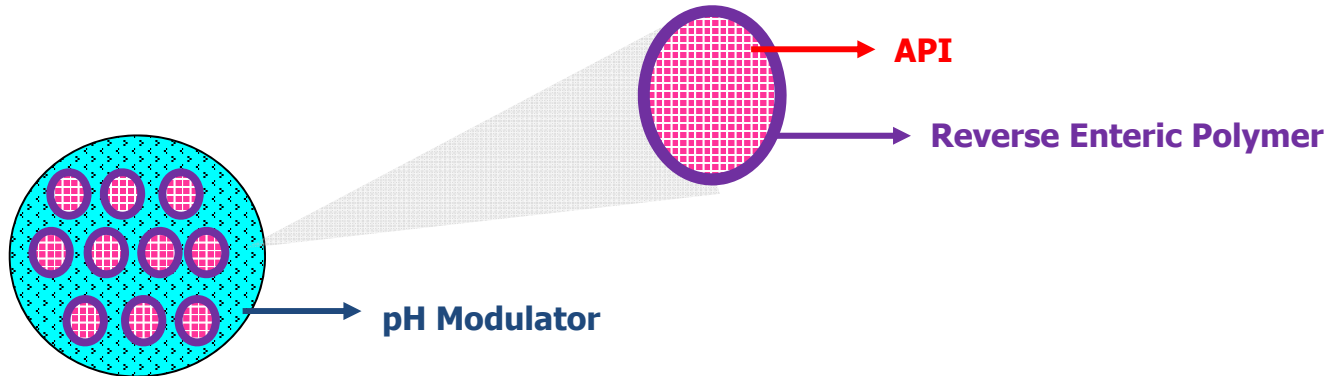


- Suicide, one of the top 10 leading causes of death in the US
- SPARC has developed an anti-depressant product based on overdose prevention technology platform
- Technology works to curb release on ingestion of multiple pills either intentionally or accidentally
- Single dose preliminary PK studies encouraging



# SDN – 118

## Overdose prevention technology



### Mechanism of release from one pill

- Quantity of pH modulator released from 1 pill does not affect the microenvironment of stomach
- Polymer solubilizes
- Therapeutic dose delivered

### Mechanism of release from multiple pills

- Quantity of pH modulator released from multiple pills changes the microenvironment of stomach
- Changed microenvironment restricts solubility of polymer and thus drug release
- Harm due to multiple pill overdose may thus be reduced

# SDN – 118

## Development status update



- Pre-IND advice received from the US FDA
- IND filing planned in Q3 FY19
- Overdose PoC PK studies planned in Q4 FY19

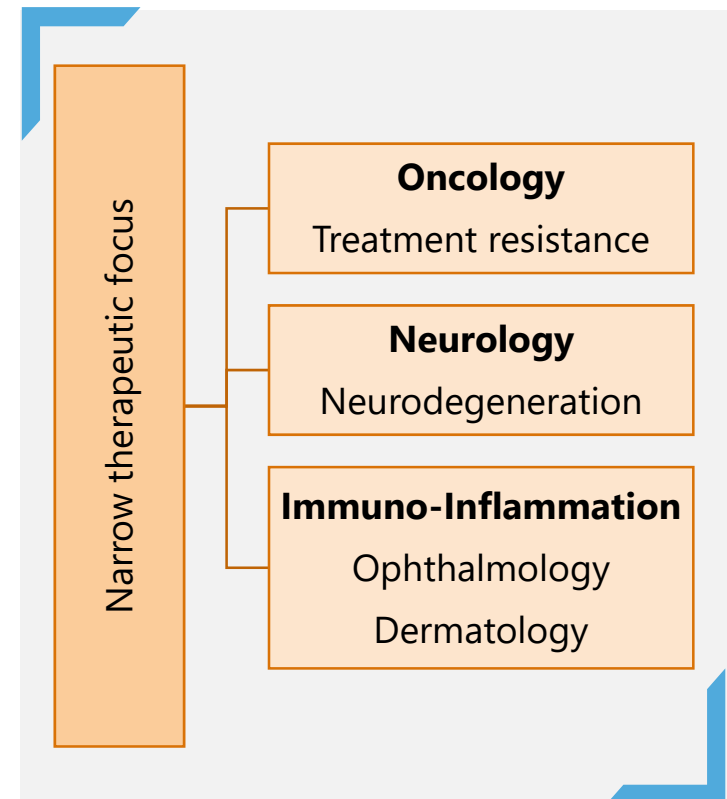
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- 1** SPARC Strategy & Key Growth Drivers  
Anil Raghavan – CEO
- 2** Financial Highlights  
Chetan Rajpara – CFO
- 3** Abl Kinase Inhibitor  
SiuLong Yao – Sr. V.P. Clinical Development & Operations
- 4** S1PR1 Agonist  
Kristine Nograles – V.P. Dermatology & Rheumatology
- 5** Extended Ocular Retention  
Hany Michail – V.P. Ophthalmology

- 6** Nanoformulations & Long Acting Depots  
Ajay Khopade – V.P. Formulation Development  
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- 7** Abuse & Overdose Deterrent Platform  
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- 9** Competitive Landscape – Key Programs  
Jaydeep Issrani – G.M. Business Development
- 10** Q&A

# Early stage pipeline building strategy

- Internal ideation
  - Chase validated drug targets in select therapeutic areas
  - Leverage capabilities in complex drug delivery systems to pursue commercially attractive 505(b)(2) opportunities
- External innovation network
  - Partnerships with leading global academic centers to source promising early stage innovative science/biology
  - Pursue novel first-in-class or best-in-class opportunities with high unmet clinical needs
- Exploratory programs
  - Augmenting capabilities to pursue new treatment modalities outside of traditional small molecule drug discovery



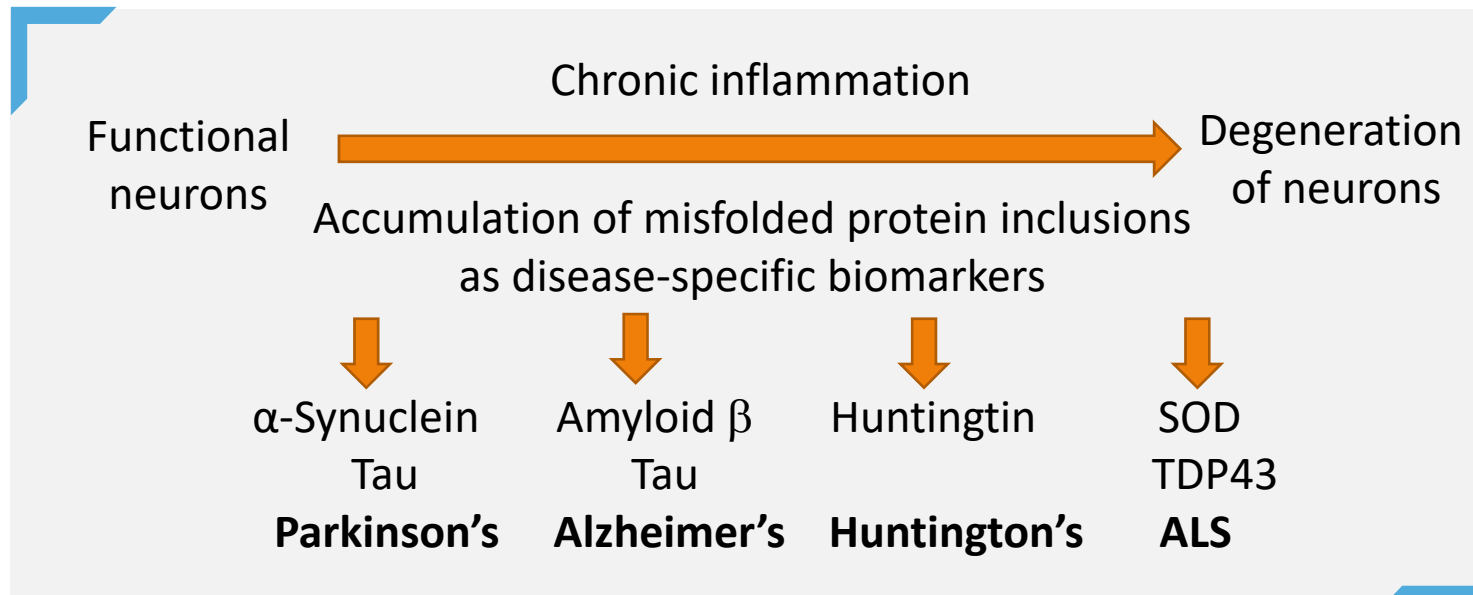


# Attacking treatment resistance in cancer

- Fast follower approach in a clinically and commercially validated space
- A number of molecularly targeted therapies against the indications of interest
- Emerging evidence of the development of resistance to targeted therapies
  - Resistance often attributed to mutations in the molecular targets rendering the targeted therapeutic being chased ineffective
  - Resistance due to adaptation to an alternative signaling pathway(s)
- Resistance to hormonal therapies against carcinomas of breast and prostate
  - ER $\alpha$  targeting by tamoxifen or fulvestrant
  - AR targeting by enzalutamide or apalutamide
- Targeted therapy for B lymphoid malignancies
  - Targeting ibrutinib/acalabrutinib resistance

# Neurodegeneration

- A common pathway of neuronal death irrespective of disease-specific misfolded protein inclusions in distinct neurodegenerative diseases



- Autophagy, a process by which cells try to eliminate nonfunctional misfolded proteins and organelles
- Inability of neurons to mediate autophagy often leads to neurodegeneration
- SPARC's emphasis is on prevention of neuronal death in these neurodegenerative diseases

## Update on collaborations

- Pursue active collaborations with global academic centres and research institutes
- Unique academic partnering proposition for significant value creation
  - Cash investment
  - In-kind contribution leveraging internal infrastructure in preclinical & clinical development
- Flexible partnering structures
  - Standard in-licensing
  - Grant funding with option to license
  - Material transfer with option to license
  - Sponsored research

## SPARC – Washington University Collaboration

- SPARC partnered with Skandalaris Center of Washington University, St. Louis, US
  - Identifying translational inventions and advancing them towards commercialisation
- SPARC supported Skandalaris Center's LEAP (Leadership in Entrepreneurial Acceleration Program) Inventor Challenge Program
  - Up to \$250,000 per program in awards every year for three (3) years
  - Additional in-kind support utilizing internal R&D capabilities at SPARC
  - Option to license IP on worldwide exclusive basis



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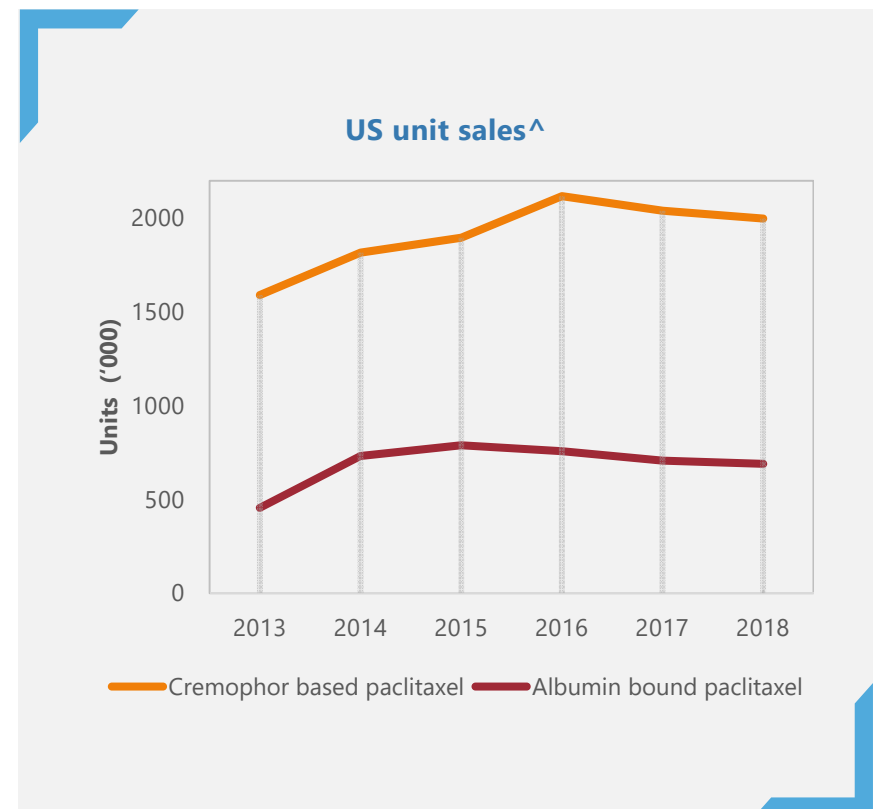
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# Taclantis™

## Albumin free nanoformulation of Paclitaxel



- Over 45% of US clinicians documented hypersensitivity reactions in more than 10% patients treated with Cremophor® based paclitaxel\*
- More than 60% of US physicians view risk of hypersensitivity and ease of administration as important factors influencing choice of therapy\*
- Cremophor® based formulations account for ~70% of total Paclitaxel units prescribed#
- Significant opportunity for conversion to novel formulations like Taclantis™

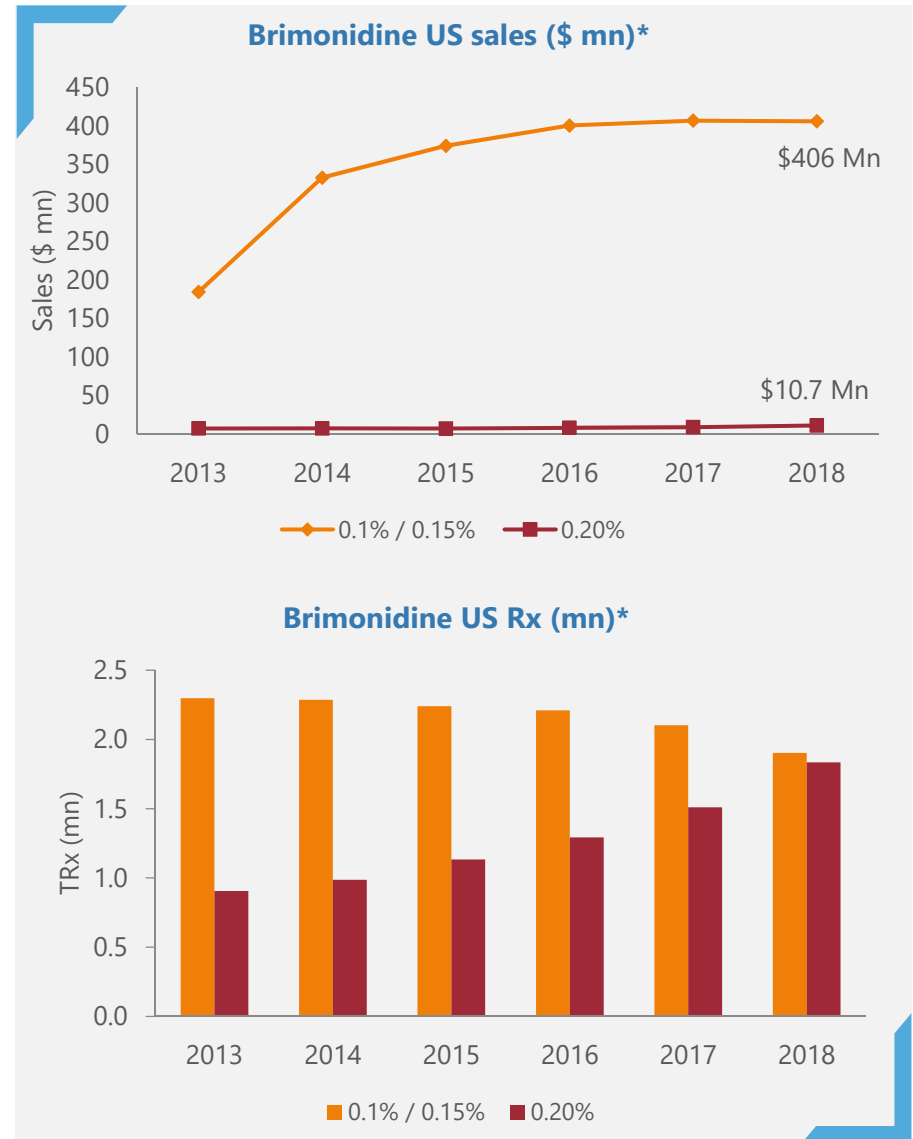


# PDP – 716

## US market opportunity



- US Glaucoma market is estimated at \$ 3.0 bn in 2017\*
- Brimonidine is one of the most widely prescribed anti-glaucoma drug with sales of \$ 417 mn and 3.7 mn prescriptions dispensed annually\*
- Brimonidine branded product commands significant market share inspite of genericization of lower strength formulation

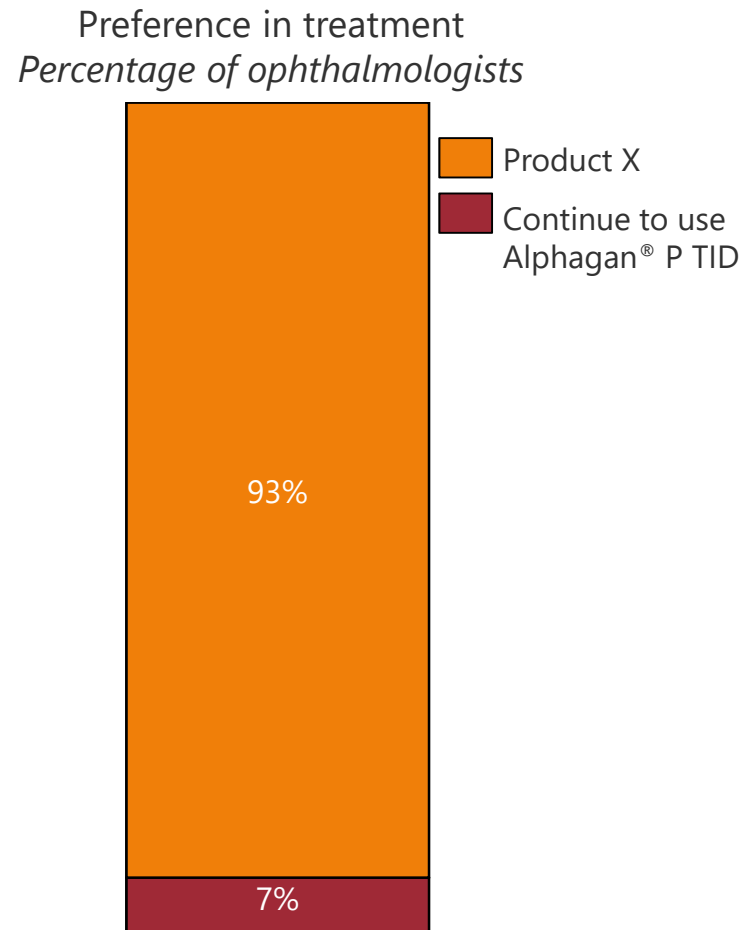


# PDP – 716



## Once-a-day eye drops perceived favourably by physicians

- Clear preference of physicians for PDP – 716\*
- 93% of physicians would prefer to prescribe once a day eye drops
- Novel once-a-day Brimonidine eye drops expected to take meaningful market share



Q. Given a choice, which of the following eye drops of Brimonidine would you prefer to prescribe? (n=30)

\* Based on primary market research conducted on behalf of SPARC by third party in the US. PDP – 716 = Brimonidine OD. TID = Three times-a-day

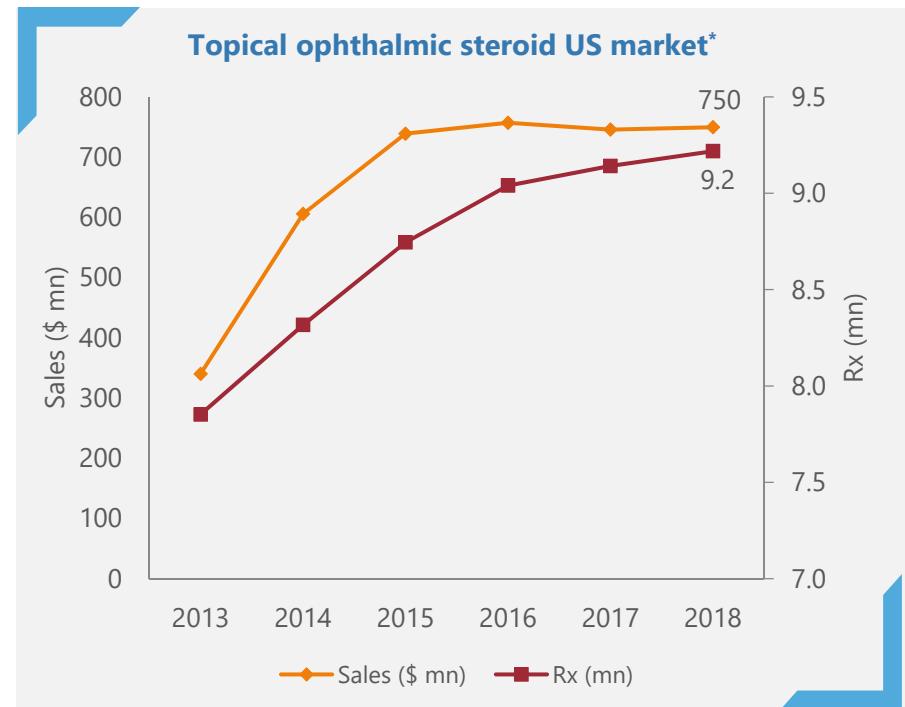


# SDN – 037

## US market opportunity



- Cataract causes half of all cases of blindness and affects more than 24 mn people in US with age 40 and older
- Topical steroids are standard of care for the treatment of pain & inflammation associated with cataract surgery
- US topical ocular steroid market valued at \$ 750 mn with ~9 mn Rx dispensed annually\*
- Currently marketed formulation cause blurring of vision and need to be dosed four times-a-day
- Novel improved steroid composition with BID dosing would provide significant compliance benefit



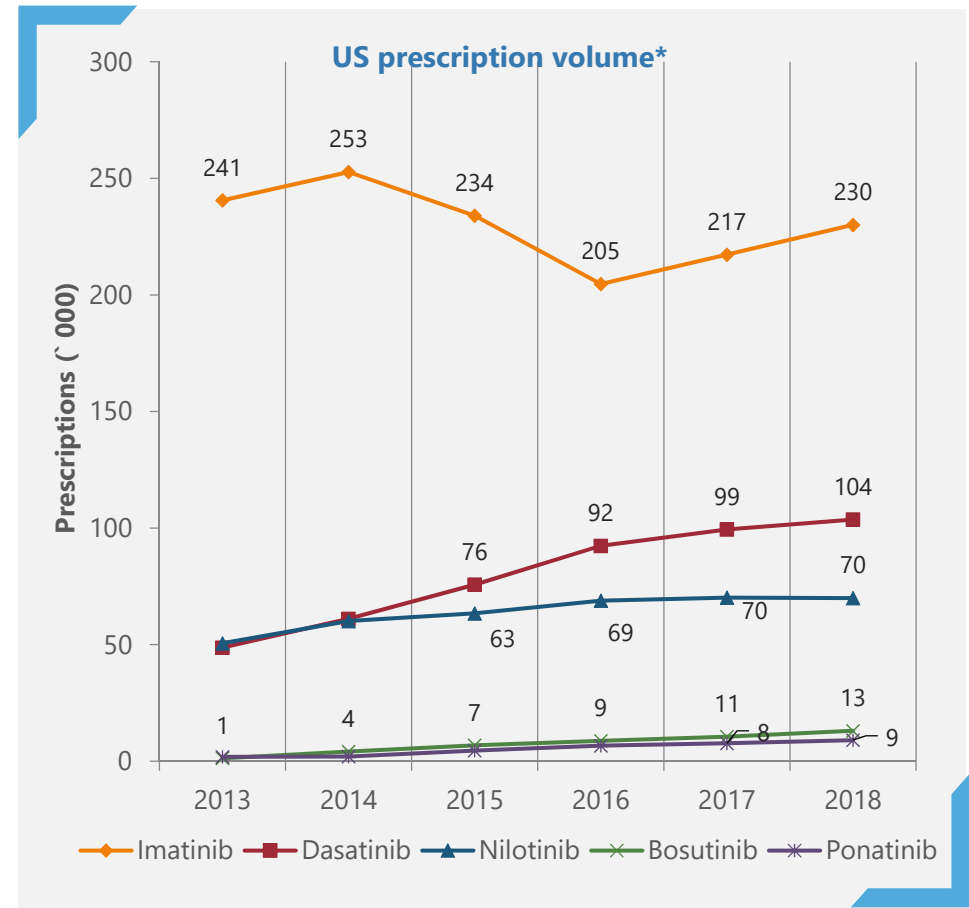
\*IQVIA MAT June 2018 SDN – 037 = SDP – 037 BID = Two times-a-day

# SCO – 088



## Targeting treatment intolerance and resistance in CML

- Increasing usage of 2<sup>nd</sup> and 3<sup>rd</sup> generation TKIs
- Limited treatment options for 3<sup>rd</sup> line and beyond
- Physicians believe, the currently available therapies are inadequate for 3<sup>rd</sup> line treatment in CML<sup>#</sup>
- KOLs acknowledged the need for an agent with a reasonable toxicity profile for T315I mutation disease<sup>#</sup>



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# R&D Pipeline





# Thank You

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