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**SUN PHARMA
ADVANCED RESEARCH
COMPANY LTD.**



SPARC/Sec/SE/2016-17/011

4th August 2016

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 dated 25th July 2016 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**


Debashis Dey
Company Secretary

Encls: A/a.



Investor Update on R&D Pipeline

August 4, 2016

Investor Update on R&D Pipeline

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SPARC Portfolio – An Overview

○ Growing Clinical Portfolio

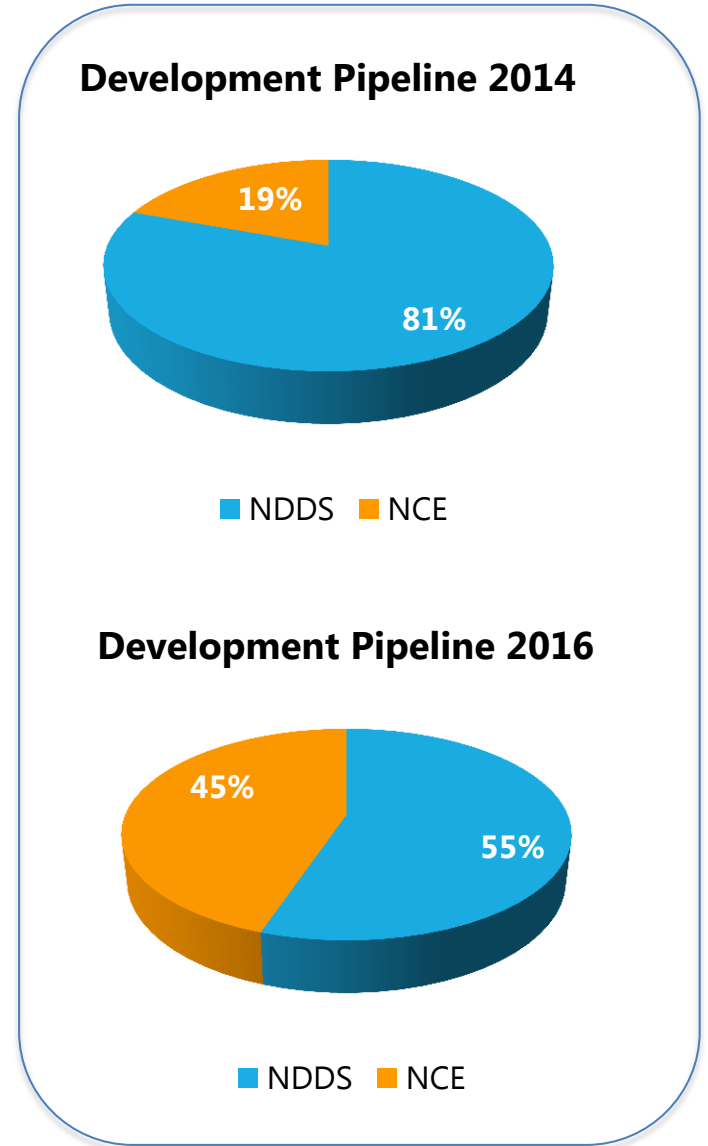
- 2 NDAs submitted
- 3 Late stage clinical programs
- 5 programs under early clinical development
- Multiple opportunities for revenue growth

○ Robust early stage discovery pipeline

- Transitioning from predominantly NDDS focus to balanced portfolio of NCE & NDDS programs
- Several new programs initiated on NCE and NDDS platforms

○ Portfolio Rationalization

- Deprioritized DICN



NDA = New Drug Application. NCE = New Chemical Entity, NDDS = Novel Drug Delivery System

Delivering on Commitments

Licensing & Commercialization of
Elepsia™ XR



Signed licensing deal with Sun Pharma

Xelpros™ approval by USFDA

Awaiting approval, pending site
clearance by USFDA

PICN launch in India



Bevetex® launched

Initiation of pivotal clinical trial for PICN

Approval strategy with BE study being
implemented

Filing of 4 INDs



Filed 4 INDs

Clinical development on track for Baclofen GRS, Sal-Flu DPI and SUN-K706

Strategic Roadmap for Sustainable Growth

Smart Portfolio Growth

- Oncology – Next generation agents targeting treatment resistance
- Ophthalmology – Solving complex delivery challenges
- CNS – New pathways in Neuro-degeneration, Abuse Deterrence
- Beyond Small Molecules – New treatment modalities

Driving Functional Excellence

- Accelerate product development
- Strategic portfolio review & optimization

Augmenting Internal Capabilities & Infrastructure

- Scaling up clinical, regulatory & program management capabilities
- Computer Aided Drug Design (CADD)
- In-vivo infrastructure improvement

External Partnerships

- Sourcing new science
- Collaborations for bridging competency & expertise
- Clinical partnerships with thought leaders

Financial Summary

	FY16	FY15	FY14	FY13
Total Income	1,613	1,557	1,670	873
Total Expenses	2,321	1,981	1,371	1,074
Net Profit / (Loss)	(700)	(395)	303	(225)

INR Mn

- **Raised INR 2500 Mn. through Rights Issue**
- **Cash and equivalents INR 2120 Mn. as on June '16**
- **Development costs expected to increase significantly in the short term**
 - Increased clinical trial spend as pipeline transitions to late stage clinical trials
 - External partnerships to access to early translational research work
 - Employee cost escalation in select, strategic areas

Upcoming Key Events



Elepsia™ XR and Xelpros™

USFDA Approval &
Commercialization



Baclofen GRS

Completion of patient
recruitment in Pivotal Phase III
study



Salmeterol – Fluticasone DPI

Completion of Pivotal studies



SUN – K706

Establish Recommended Phase 2
Dose



PICN

Completion of Pivotal BE study



Brimonidine OD

Completion of PoC efficacy study



Regulatory Filings

4 INDs in USA

Licensing and Commercialization Update

○ Elepsia™ XR

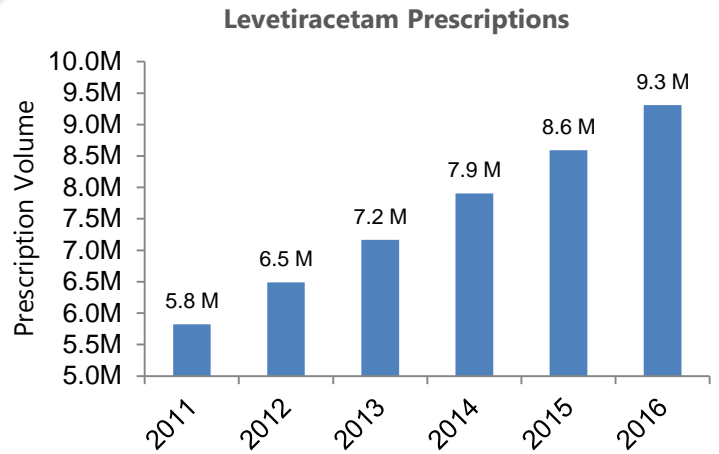
- Licensed Elepsia™ XR to a subsidiary of Sun Pharma for the US market
- Up-front payment of US\$10 million, additional milestones and sales based royalties
- Sun Pharma to create a dedicated CNS sales team to commercialize Elepsia™ XR in US

○ Xelpros™

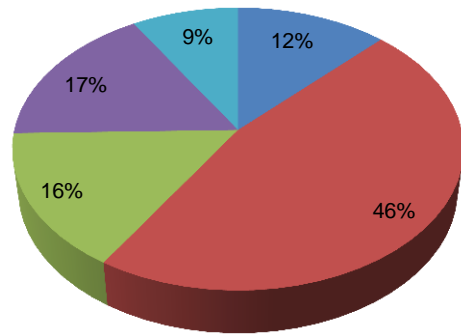
- Licensed Xelpros™ in 2015 to a subsidiary of Sun Pharma for the US market
- Sun Pharma launched a new specialty division, Sun Ophthalmics, to commercialize branded ophthalmic products in US including Xelpros™

Elepsia™ XR

US Commercial Opportunity



Patients on Levetiracetam Daily Dose*

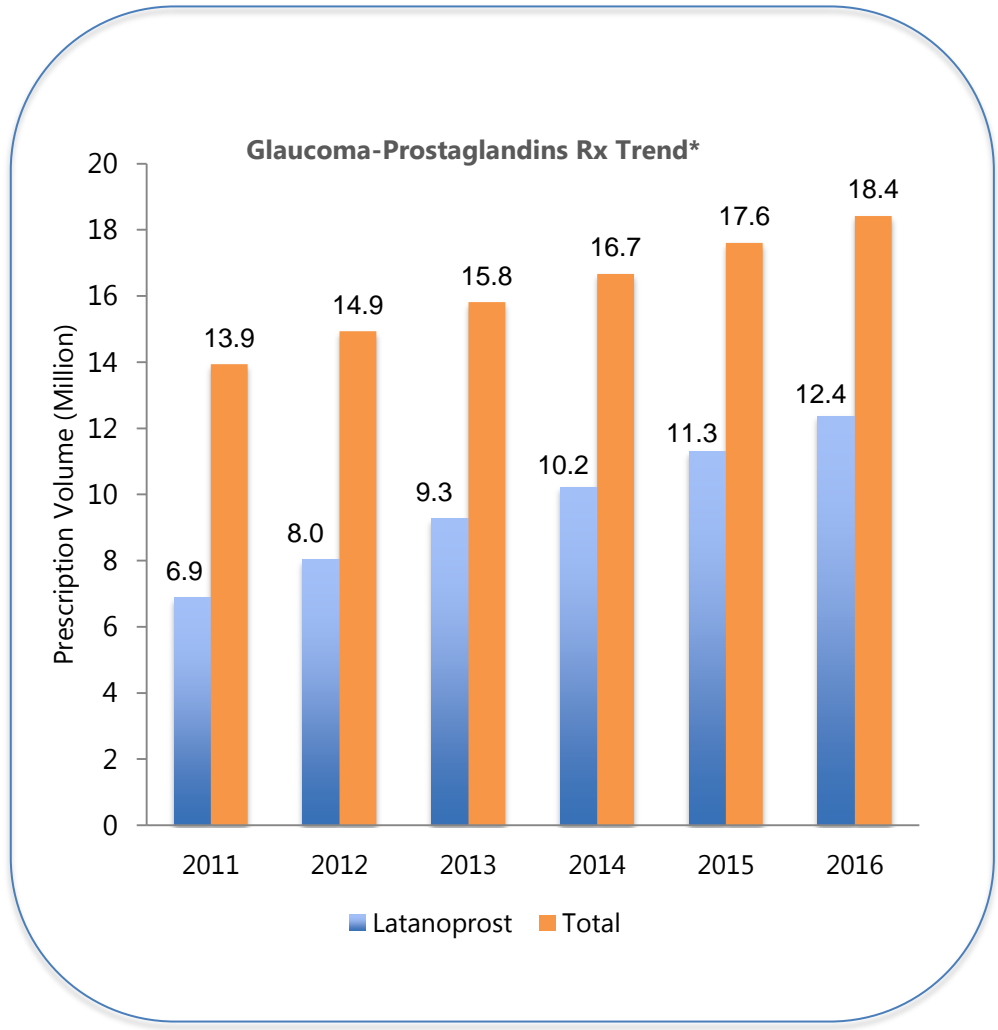


■ <1000 mg ■ 1000 mg ■ 1500 mg ■ 2000 mg ■ >2000 mg

- Healthy Rx growth despite no promotion
- For the majority of Epilepsy patients, pill burden remains high
 - Over 50% patients need >6 pills per day
- >80% patients on Levetiracetam require dose exceeding 1000 mg/day
- Extended Release, once daily dosing and reducing the pill burden seen as major advantages by neurologists[#]
- Elepsia™ XR peak sales potential US\$ 50 Mn.

Primary Market Research conducted through 3rd Party. Rx = Prescription. *IMS MAT Jun 2016

Commercial Opportunity for BAK-free Latanoprost



- Prostaglandin analogues for Glaucoma is US\$ 1.4 Bn. market in US*
- Latanoprost is the most widely prescribed Prostaglandin for Glaucoma with ~67% share of prescriptions
- 10% - 16% patients on Xalatan® and other BAK containing products develop Ocular Surface Disease (OSD) symptoms#
- Ophthalmologists showed preference for BAK-free Latanoprost formulation #
- Xelpos™ peak sales potential US\$ 50 Mn.

Primary Market Research conducted through 3rd Party. *IMS MAT Jun'16

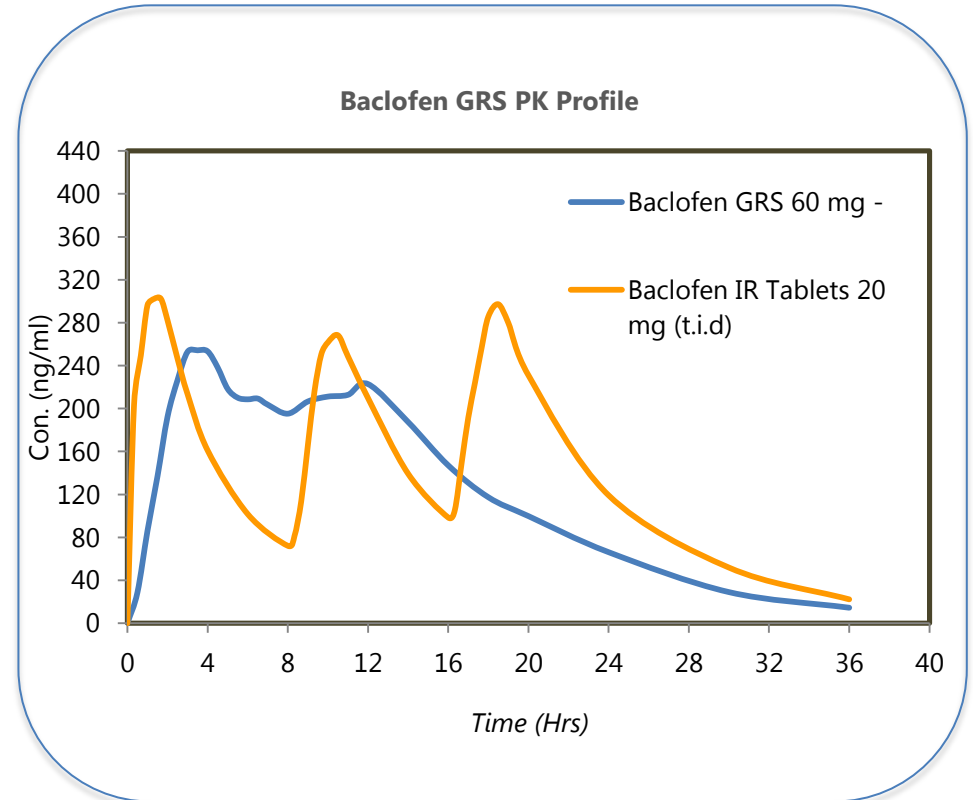


CNS
Baclofen
GRS

Baclofen GRS

Designed to improve compliance in patients with Spasticity

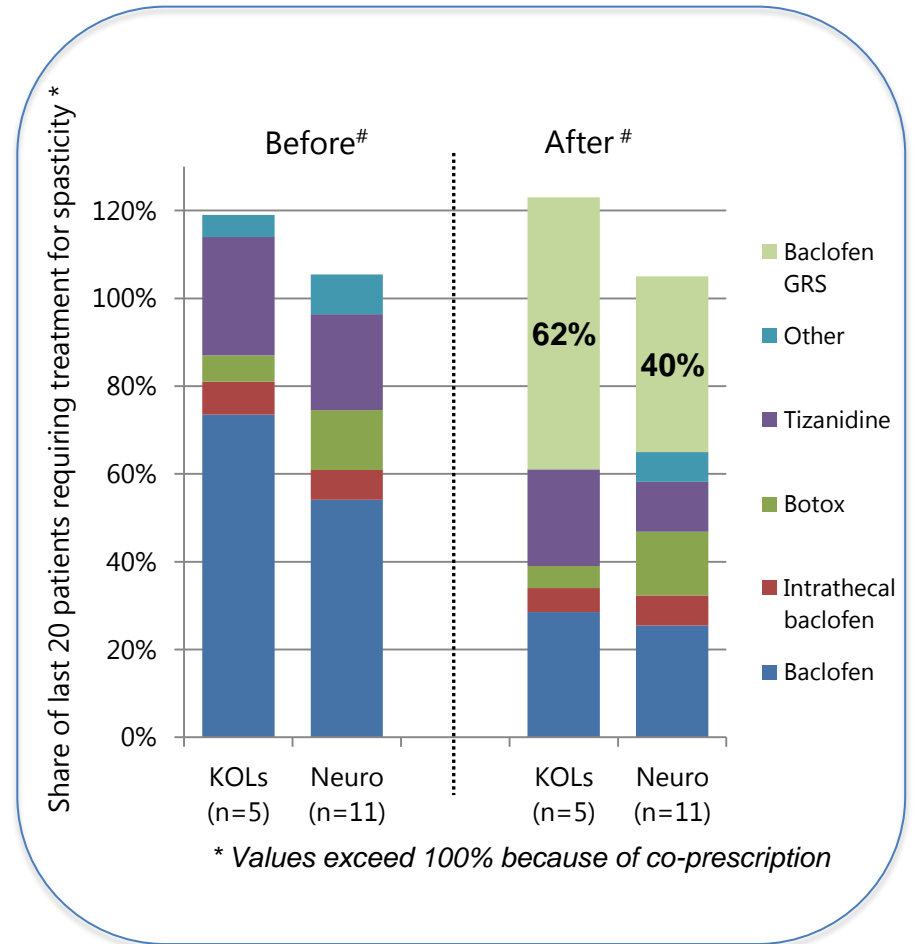
- Once-a-Day Baclofen with Proprietary Gastro Retentive Innovative Device (GRID™) technology
- Combination of mechanisms leads to successful “once -a- day” formulation
 - Flotation
 - Size expansion
 - Muco-adhesion
- Patent portfolio comprising of formulation , once a day therapy and indication patents with last patent expiring in 2027



Baclofen GRS

Physicians favorably respond to the distinct product attributes

- In primary research, the majority of physicians responded that steady blood levels and once-a-day dosing are key benefits over IR Baclofen
- Based on physicians survey Baclofen GRS would take significant share of spasticity patients[^]
 - 40% - 60% if Tier 2 formulary position
 - 20% - 30% if Tier 3 formulary position
- **Market Opportunity****
 - Baclofen volume in US (630 million units) is growing at 5%
 - 34% prescriptions for spasticity related to neurological indications



[^] Market Research conducted by 3rd party, Qualitative data, sample size not adequate for forecasting. **IMS MAT April 2016.
[#]Before and After depicted in the chart represents potential prescription share change after availability of Baclofen GRS

Baclofen GRS

Development Status Update

- **Clinical studies under SPA* with FDA**
- **Phase 3 efficacy study**
 - 45 active sites, opened new sites in Europe
 - 161/214 patients completed study
- **Open label safety study**
 - 200 subject enrolment completed
- **Duration of action study**
 - 84/93 patients completed
- **Targeted NDA filing by Q4FY18**

*SPA = Special Protocol Assessment



Oncology
PICN

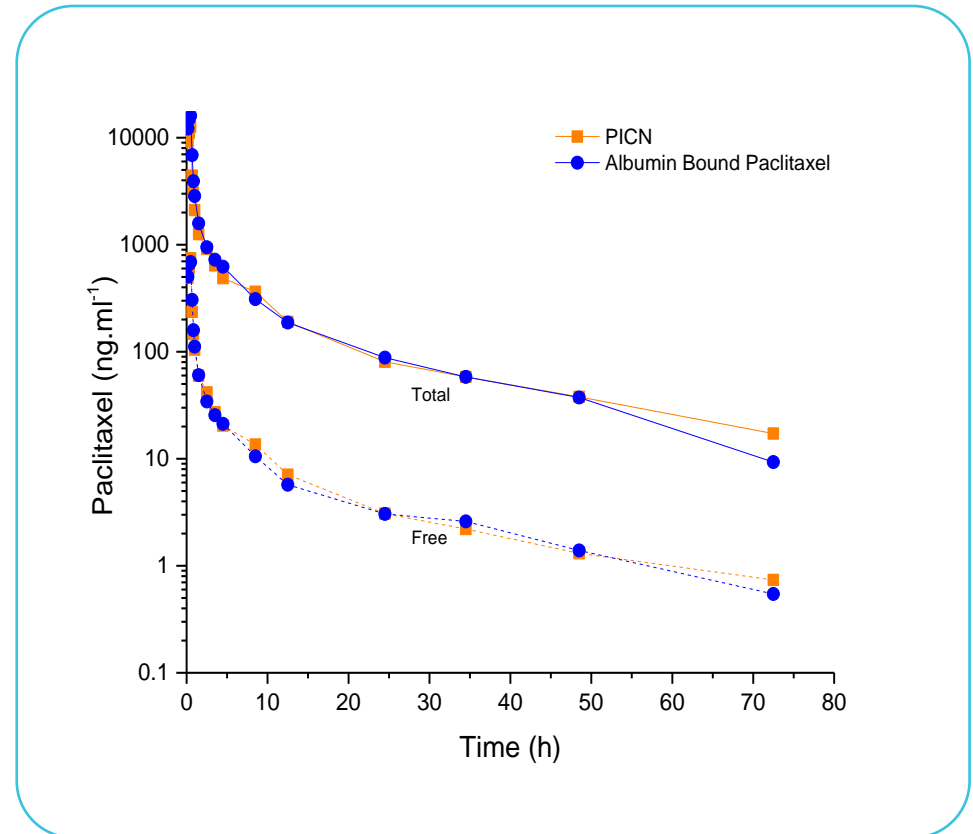
Paclitaxel Injection Concentrate for Nanodispersion (Taclantis™)

- **Novel formulation of paclitaxel using SPARC's proprietary Nanotecton™ platform technology**
 - Cremophor® and albumin free formulation
 - Short infusion time
 - No standard paclitaxel pre-medications required
 - Allows higher dose than Taxol®
 - Launched in India as Bevetex®



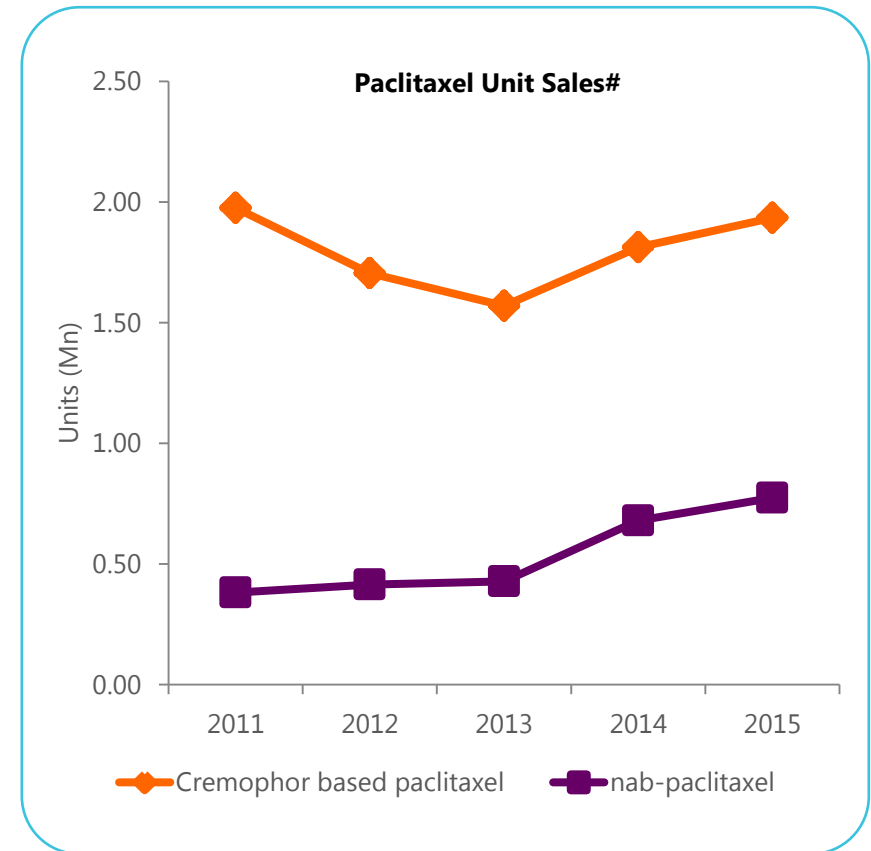
Pursuing PK strategy to compare Taclantis™ with albumin bound Paclitaxel

- Completed pilot BA/BE study with additional patients
- SPARC is evaluating PK data for optimizing study design in consultation with USFDA
- To initiate pivotal BE study by Q4FY17
- Planned NDA filing by Q4FY18



Significant opportunity for Cremophor® free paclitaxel formulations

- Albumin bound paclitaxel generated sales of ~ US\$ 668 Mn in the US^{^ ^}
- Over 70% marketed units are Cremophor® based paclitaxel formulations^{^ ^}
- ~150,000 patients being treated with Cremophor® based paclitaxel[^]
- Over 60% of Physicians view risk of hypersensitivity and ease of administration as important factors influencing choice of therapy*
- Taclantis™ has the opportunity to acquire a meaningful patient share from Cremophor® based paclitaxel formulations



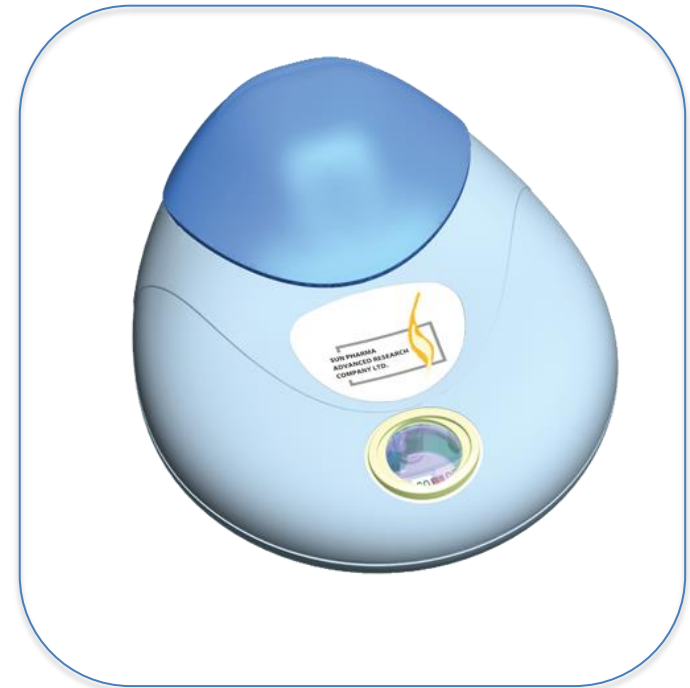


Respiratory DPI

Dry Powder Inhaler

SPARC's DPI is a pre-metered, 60 dose, breath activated device for administration of combination of inhaled steroids and bronchodilator drugs

- High efficiency device, delivers more to the lung
- Comparable PK profile to Seretide[®] Accuhaler[®] at half the dose
- Uniform dose delivery independent of inspiratory flow rate
- On most of the device characteristics physicians rated SPARC DPI better than Seretide[®] Accuhaler[®]*



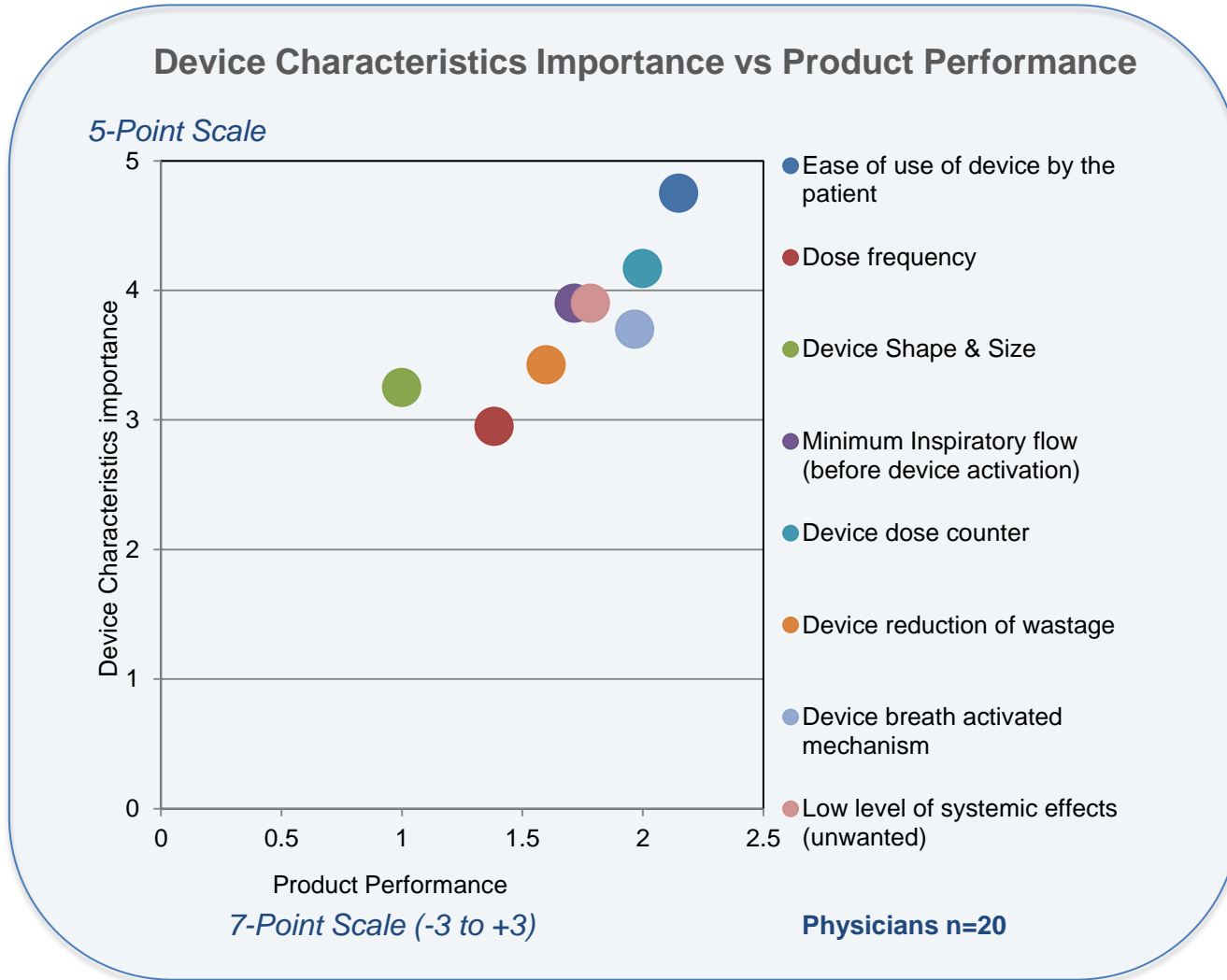
*Primary research conducted through 3rd party in EU

Salmeterol – Fluticasone DPI

Development status update – Europe

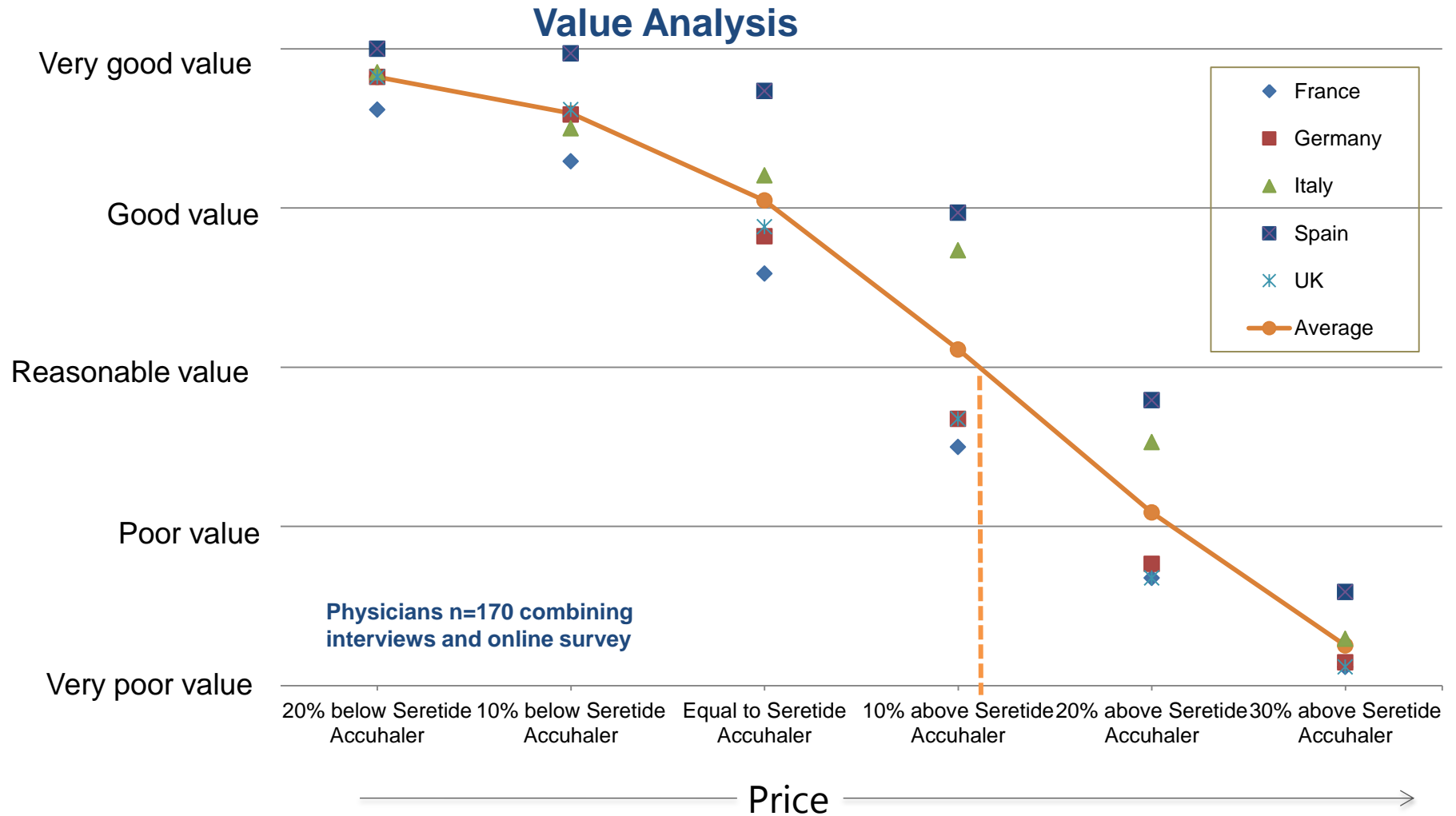
- **120 subject Peak Inspiratory Flow rate study initiated in Europe**
 - 20 subjects completed
 - Additional 20 subjects enrolled
- **Low dose PK study awaiting Regulatory Approval in Europe**
 - Plan to initiate study by Q2FY17
- **High dose PK study**
 - Plan to initiate study by Q4FY17
- **Plan to file for marketing authorization by Q4FY18**

Physicians responded favourably to SPARC DPI's device characteristics*



*Primary research conducted through 3rd party in EU

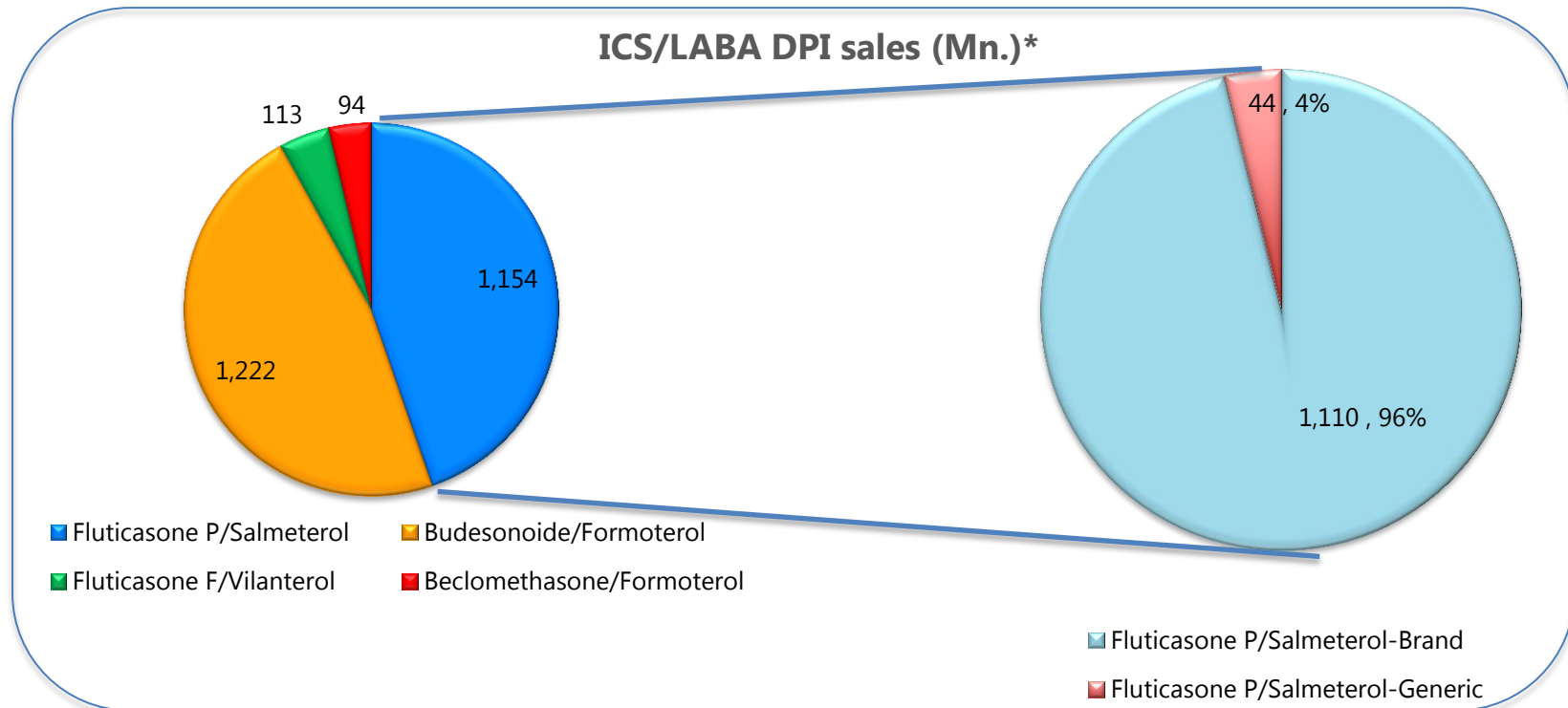
Physicians across Europe value SPARC device better than Seretide® Accuhaler®*



*Primary research conducted through 3rd party in EU

Salmeterol – Fluticasone DPI

ICS/LABA DPI market dynamics in Europe

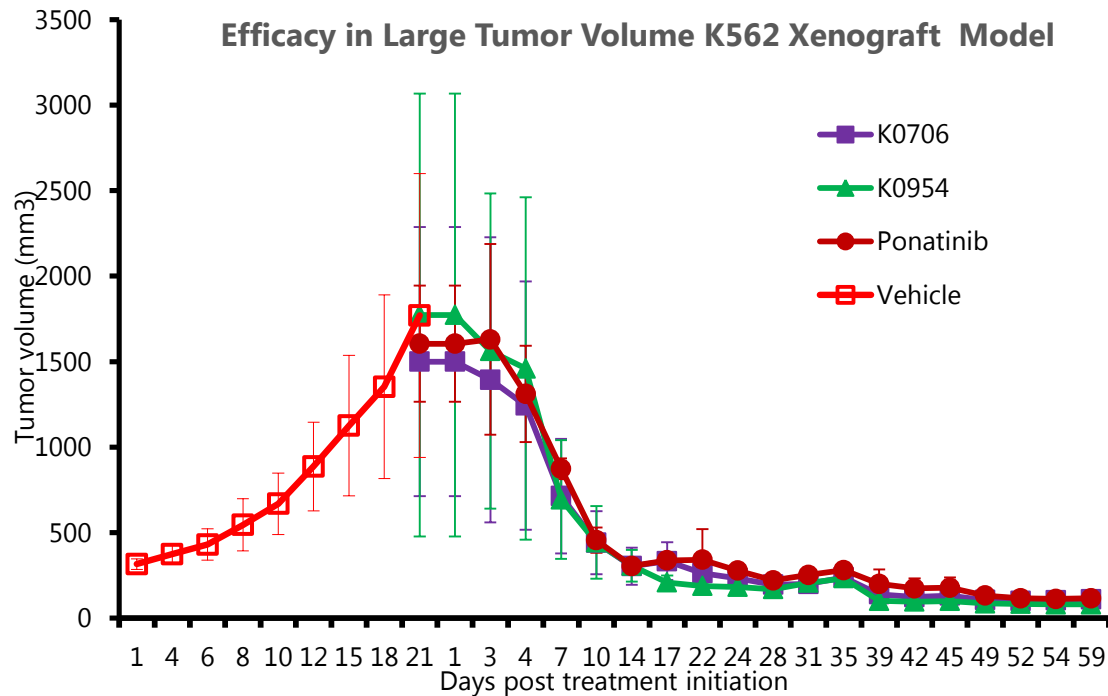


- Total ICS/LABA Dry Powder Inhaler market in Europe is estimated to be ~ 2.6 Bn.*
- Seretide® Accuhaler® has market share of 45% in ICS/LABA market with sales of ~1 Bn.*
- Seretide® Accuhaler® generics have so far achieved limited penetration*
- Market may see additional generics, however, the market would still offer opportunities for differentiated products like SPARC DPI

A background image showing a microscopic view of cells, likely cancer cells, with various colors (blue, yellow, purple) and sizes, suggesting a diverse population or different stages of cell growth. The cells are arranged in a somewhat circular pattern on the left side of the slide.

Oncology CML Program

SUN-K706 and SUN-K954 demonstrated efficacy in Imatinib resistant CML



○ **In pre-clinical studies both SUN-K706 and SUN-K954**

- Cause tumor regressions in an imatinib resistant xenograft model
- Better therapeutic index compared to Ponatinib

CML Program

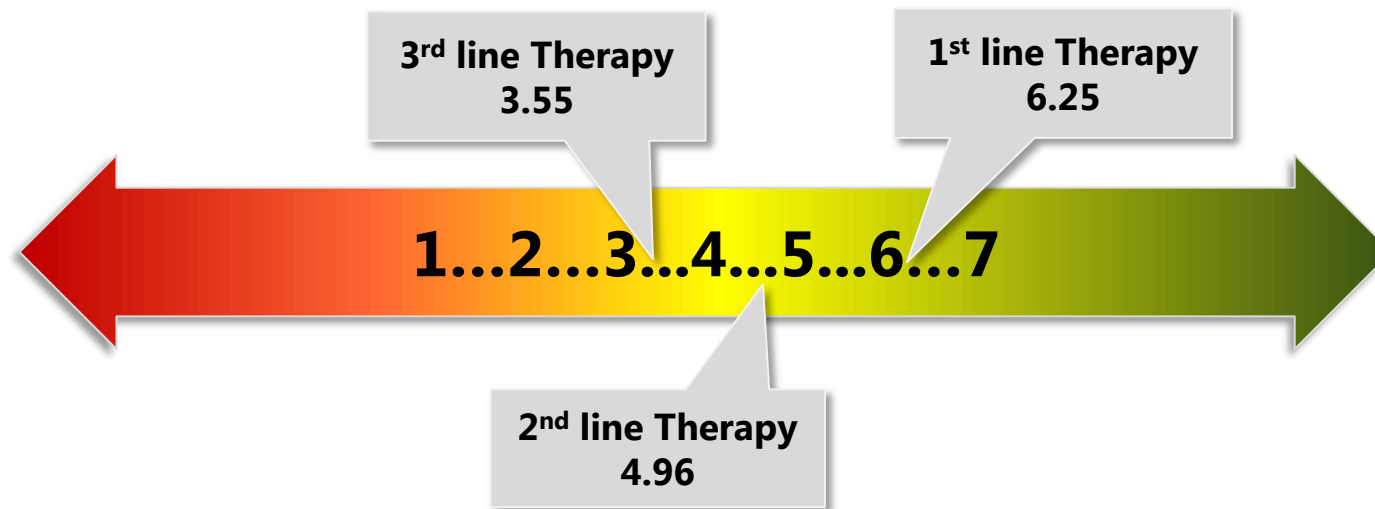
Development Status Update

- **SUN-K706**
 - US IND opened
 - Phase I dose escalation study ongoing in USA
 - Expecting indicative efficacy data by Q4FY17
- **SUN-K954**
 - IND enabling toxicology studies ongoing
 - Plan to file IND by Q4FY17

CML Treatment

Physicians believe available treatments are inadequate for 3rd line of CML treatment*

- Physician satisfaction score decreases for treatment choices when proceeding from 1st to 3rd line treatment options*
- KOLs acknowledged the need for an agent with a reasonable toxicity profile for T315I mutation disease*

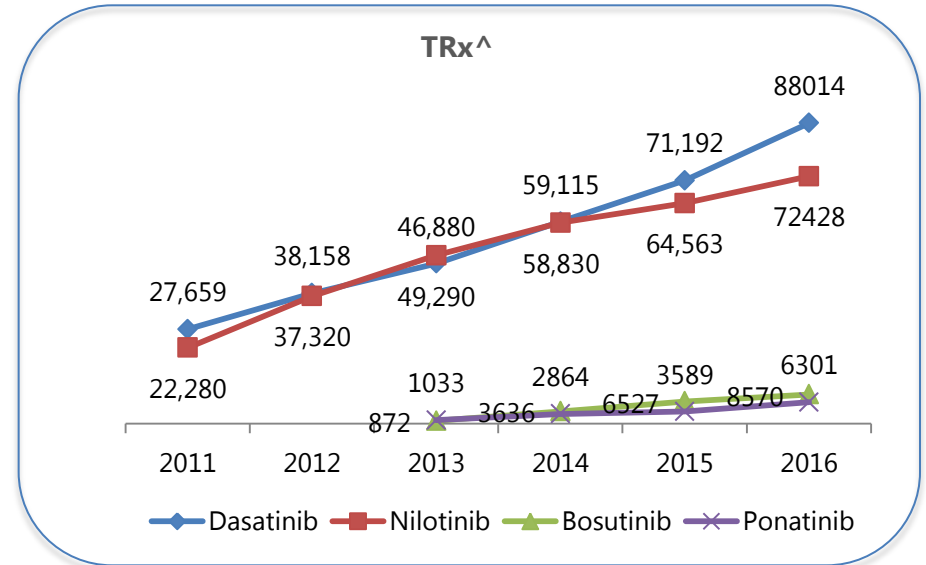
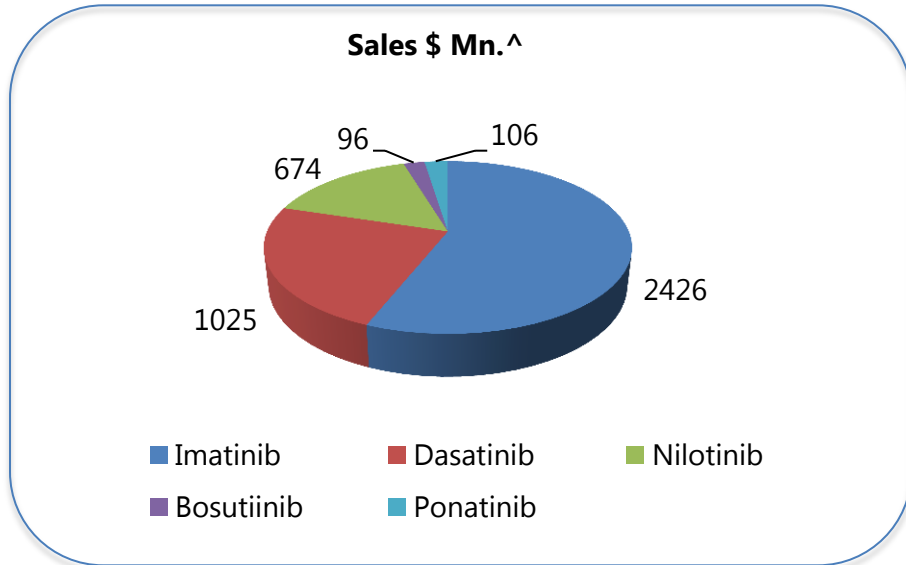


How satisfied are you with the current treatment options and outcomes in 1st, 2nd- and 3rd-line CML patients? Please rate on a scale of 1 to 7 (1 = extremely unsatisfied, 7 = extremely satisfied)

*Primary research conducted through 3rd party

SPARC CML Program

Treatment resistant CML – Niche market, yet commercially attractive



- ~50,000 CML patients are currently treated with TKIs in USA*
- Continued uptake of second and third-generation TKIs, particularly in later lines of therapy^
- Estimated target patient population for SPARC CML program ~6,000

^ IMS MAT Apr 2016, *GlobalData Chronic Myeloid Leukemia-Global Forecast 2012-2022



Dermatology
SUN-597
Topical

SUN-597 Topical

A novel topically active steroid with low systemic bio-availability

- Prolonged continuous use of topical steroids often results in systemic side-effects as well as cutaneous adverse effects like skin atrophy#
- SUN-597 is a novel steroid designed for topical use with an improved safety profile
 - Low systemic bioavailability
 - Low HPA axis suppression
 - Low potential for induction of skin atrophy
- Demonstrated better efficacy compared to mid potency steroids such as Triamcinolone in pre-clinical models



SUN-597 Topical Development Status Update



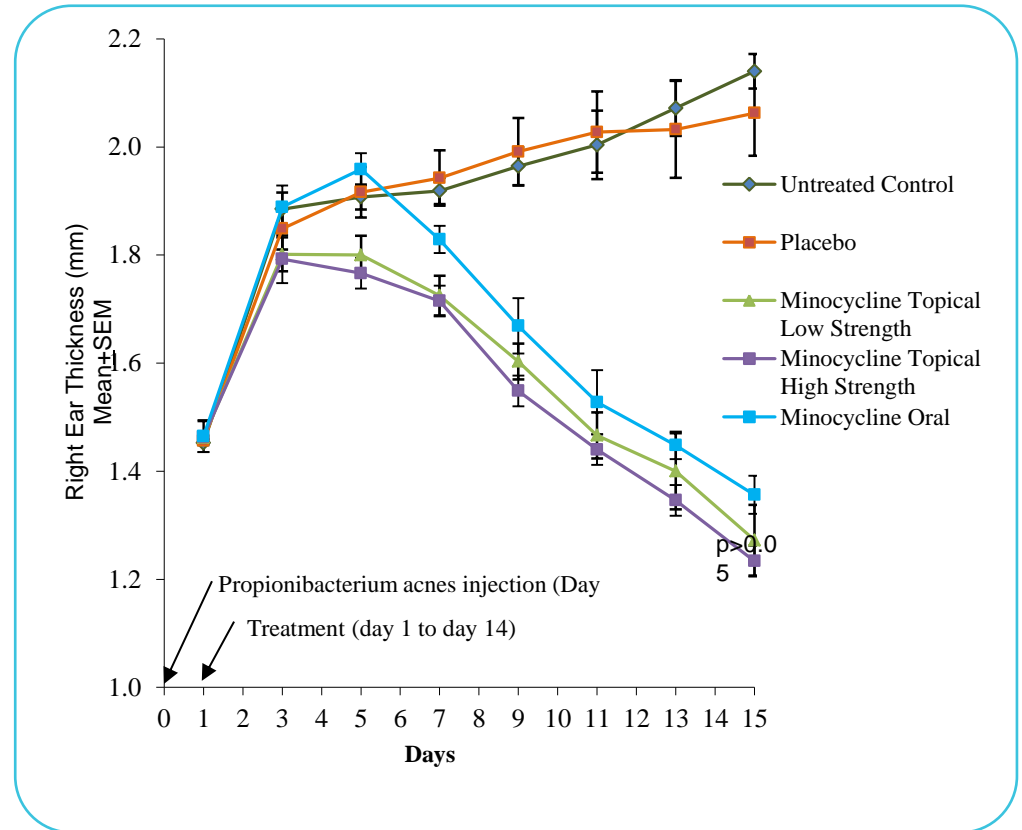
- IND opened in US
- Phase 1 vasoconstrictor assay study completed
- Phase 1 healthy volunteer safety/tolerability study is planned in Q4FY17
- Phase 1 study to evaluate SUN-597 potency in Psoriasis patients is planned in Q1FY18
- Outcome from the above studies will guide further clinical development

Dermatology
Minocycline
Topical

Minocycline Topical

Pre-clinical PoC established in Acne model

- Minocycline is a commonly prescribed antibiotic for inflammatory lesions of moderate to severe Acne
- Currently, minocycline has to be administered orally potentially resulting in undesirable systemic side-effects
- SPARC's novel formulation delivers minocycline topically to skin
 - Avoids systemic exposure
 - Potentially active in both inflammatory and non-inflammatory Acne lesions
- Product is undergoing formulation optimization based on pre-clinical study results





Ophthalmology
Brimonidine
OD

Brimonidine OD

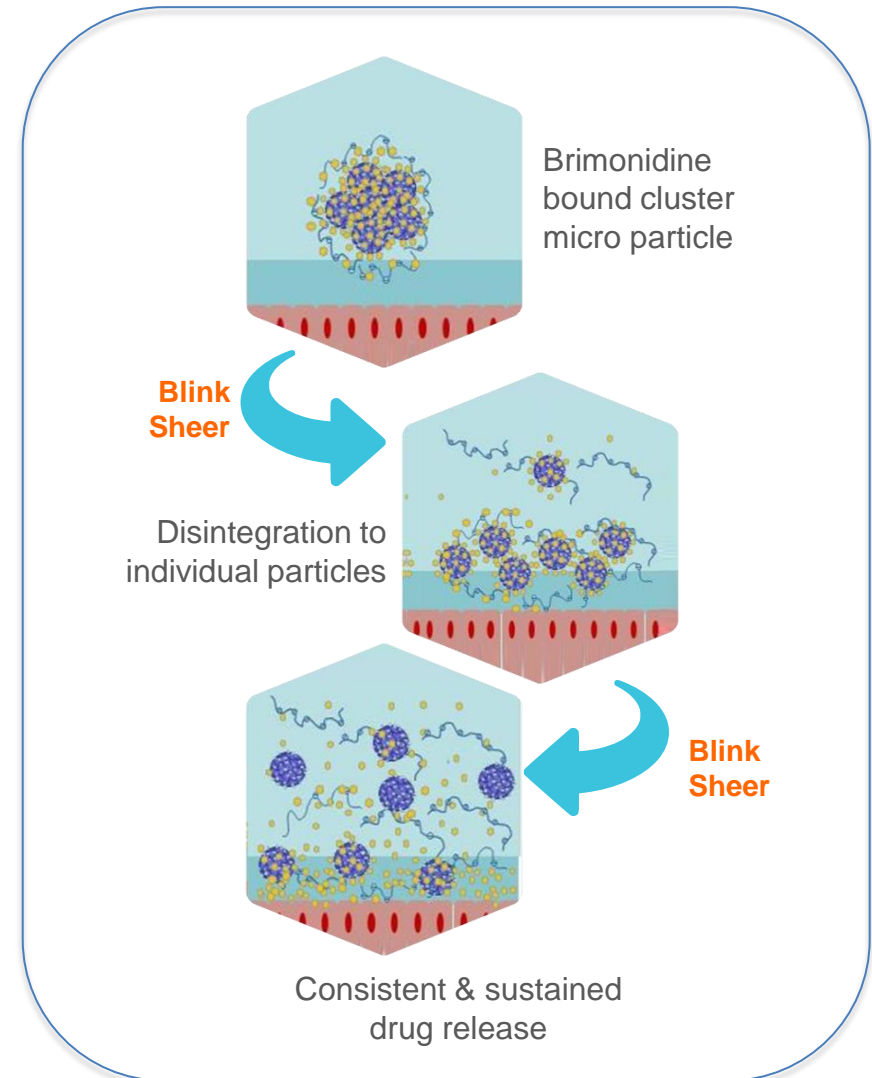
Novel Once daily formulation with TearAct™ Technology

○ Key Features

- Fine resin particles act as a template on which the drug particle is adsorbed
- Drug-resin clusters disintegrate into individual drug bound resin particles due to eye blink shear
- Drug-resin complex suspension provides a slow, consistent, and sustained exposure

○ Key Benefits

- Controlled and maximal availability of drug to ocular surface
- Reduces immediate exposure of drug
- Free of gel forming polymers



Brimonidine OD

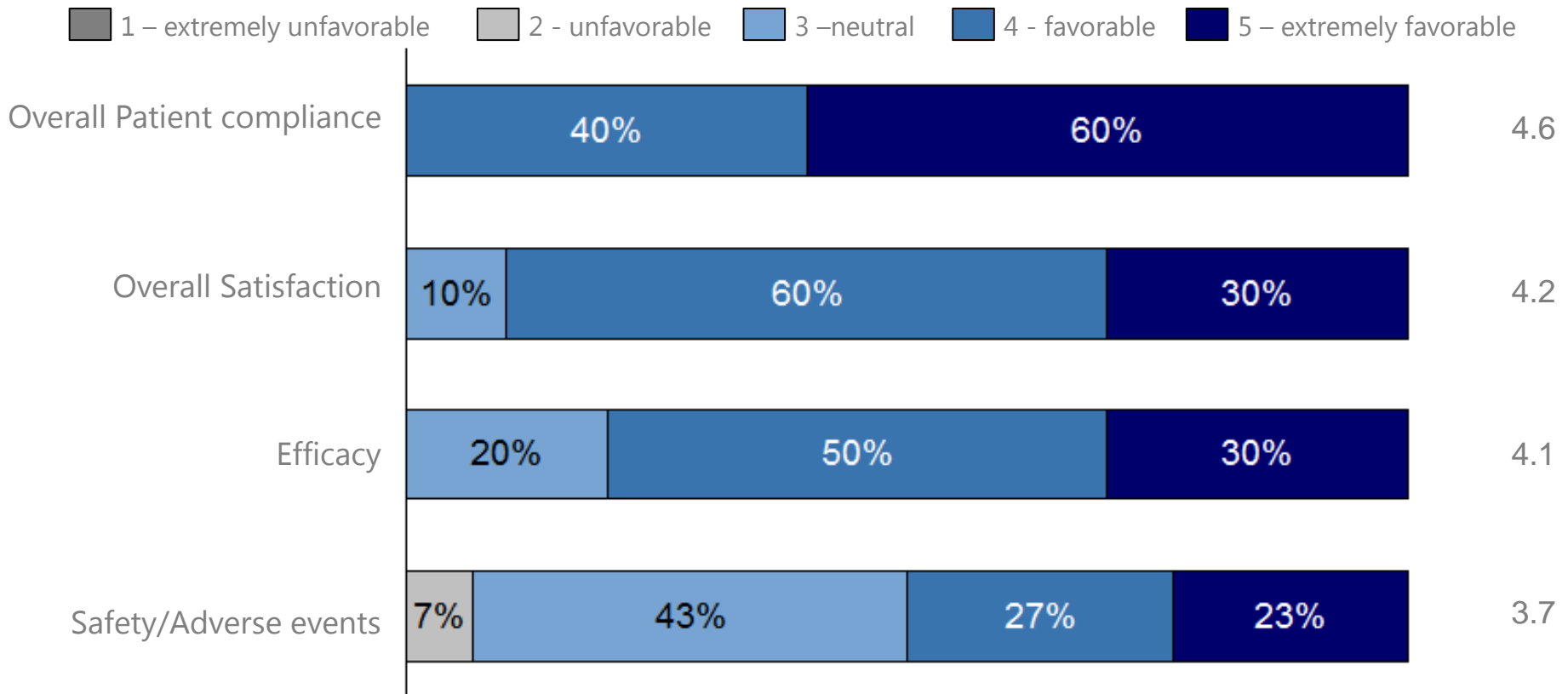
Once daily dosing to significantly help improve overall patient compliance



Initial reaction to Brimonidine OD versus Alphagan P#

% Ophthalmologists

Mean Rank




n = 30

#Primary market research conducted in US through 3rd party

Brimonidine OD

Regulatory Update

- IND enabling toxicology studies completed
- CTA approved
- Phase 2 Proof-of-Concept study initiated



Abuse Deterrent
Formulations
SDN-021

Prescription opioid drug abuse

A growing epidemic in USA

19,000 deaths occurred in 2014 due to prescription opioid overdose¹

46/day people die due to prescription opioid overdose²

~1.9 million people abused prescription opioid in 2013³

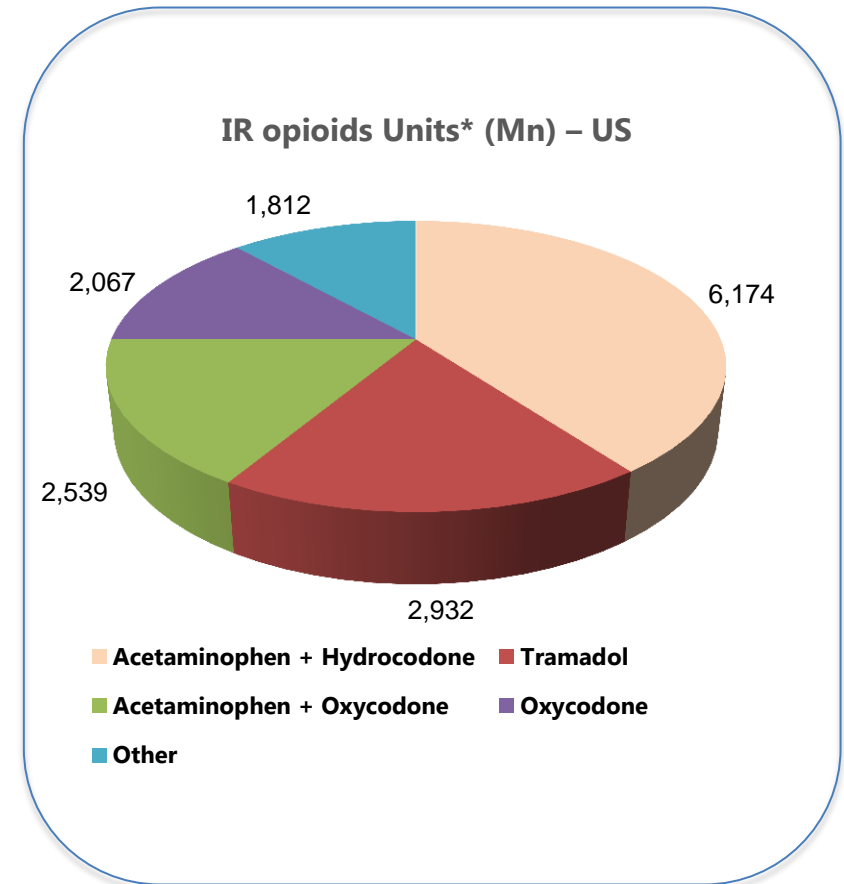
>420,000 ED visits involved abuse or misuse of prescription opioids in 2011⁴

1. CDC/NCHS, National Vital Statistics System, Mortality File 2015. 2 www.CDC.gov/vital_signs_July_2014. 3. Results from the 2013 National Survey on Drug Use and Health: US Department of Health and Human Services, Substance Abuse and Mental Health Services Administration. 4. Highlights of the 2011 Drug Abuse Warning Network (DAWN) findings on drug-related emergency department visits

Prescription opioid drug abuse

IR formulations are most vulnerable

- 221 million prescriptions were written for IR opioid analgesics in 2015-16*
- 66% of abusers prefer IR opioid formulations[^]
- Currently no approved IR opioid with abuse-deterrent labelling
- Oral ingestion of multiple pills is the most common form of abuse
- No FDA approved opioid which can deter oral multi-pill abuse



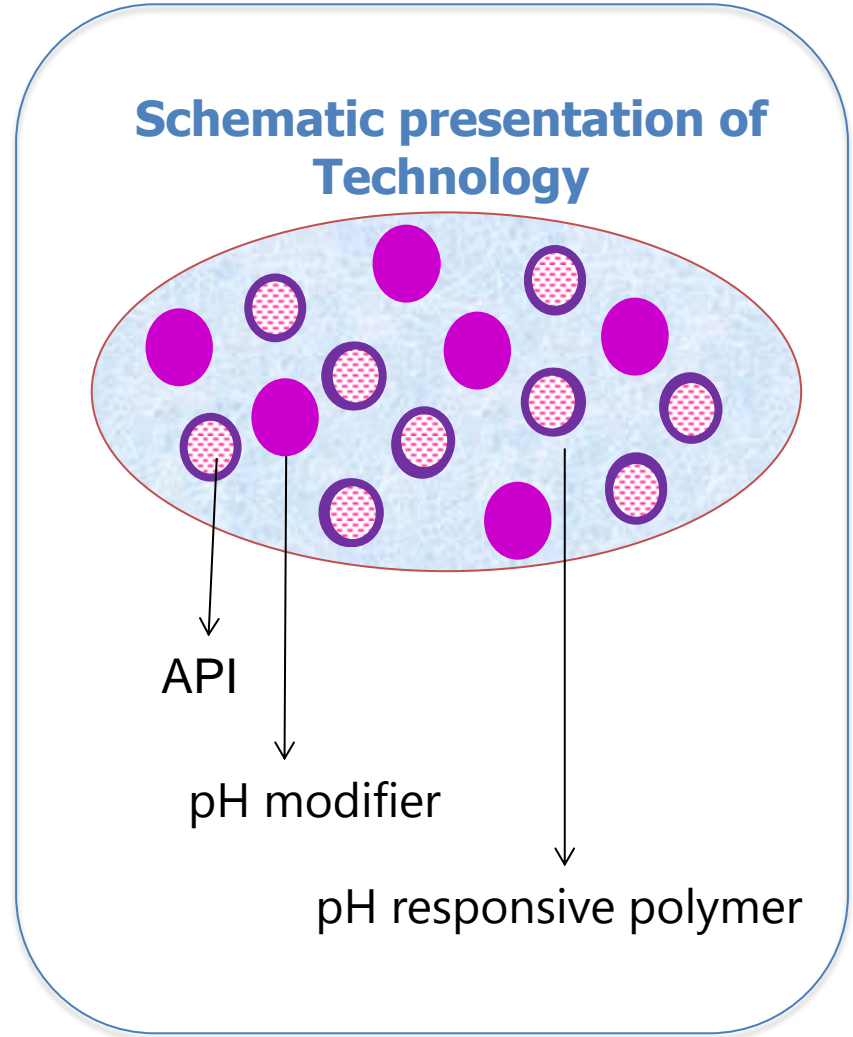
* IMS MAT APRIL 2016

[^] Researched Abuse, Diversion and Addiction-Related Surveillance System technical report Q3 2015

Abuse deterrent technology platform

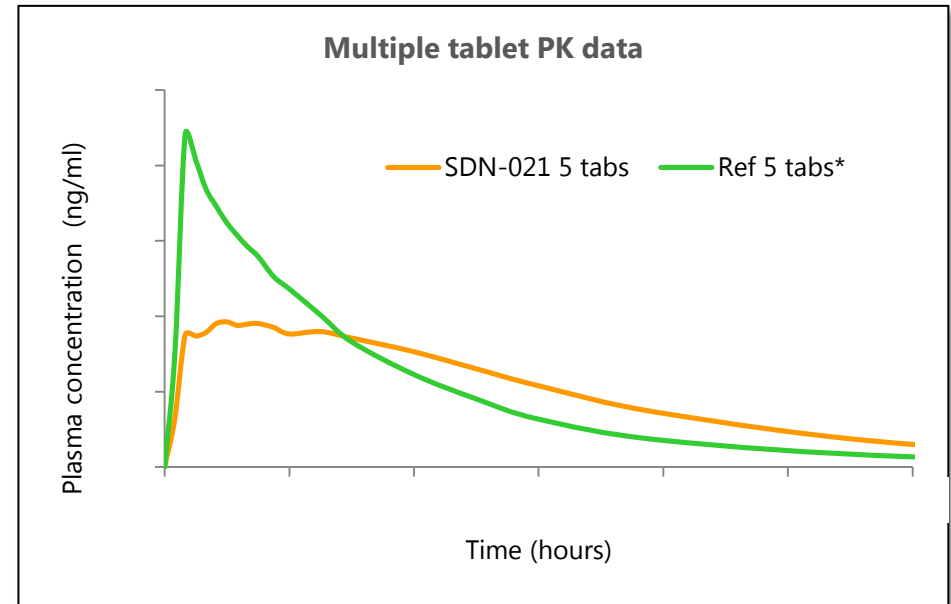
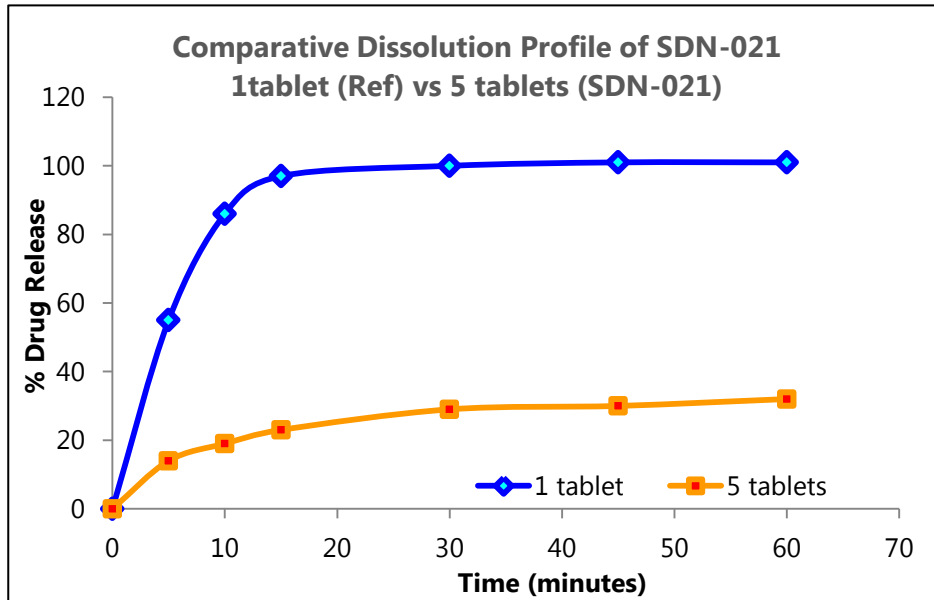
Designed to deter multi-pill abuse

- Designed to deliver clinically effective dose at prescribed dose
- Upon ingestion of multiple pills the technology reduces and delays the release of drug
- Formulation could be modified to modulate the rate and / or extent of release
- Number of pills beyond which release inhibition is desired, can be tailored
- Can also deter drug abuse by snorting or injecting
- Can prevent the drug extraction by common solvents



SDN-021

Proof of concept established for oral multi-pill abuse



- Escalating doses result in less than proportional escalations in plasma exposures
- Delayed Tmax may prevent the abuser from getting the desired “high”

*Dose corrected from one tablet

SDN-021

Development Status Update

- IND filed in Q3FY16, PoC completed
- Product optimization underway
- Additional PK studies planned in FY17



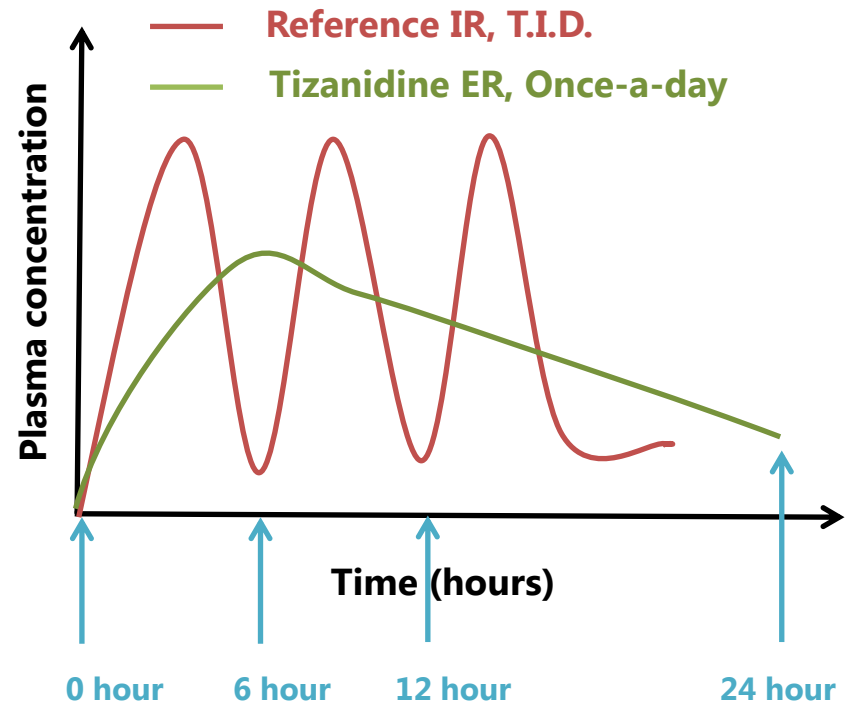
CNS
Tizanidine

Tizanidine ER for Musculoskeletal Pain

Optimizing PK to improve safety profile

- Tizanidine market in USA is estimated at 725 million tablets growing at 11%*
- About 60% Tizanidine usage is in musculoskeletal pain*
- Tizanidine use is limited due to side effects like orthostatic hypotension, somnolence, cognitive function impairment
- Currently, no “once a day” Tizanidine formulation in market
- SPARC is developing a novel extended release formulation to target
 - Patient convenience and better compliance
 - An improved side effect profile

Schematic Representation of Comparative mean Plasma Tizanidine Concentration - Time Profiles



Tizanidine ER

Development Status Update

- Simulated driving study initiated in Q1FY17
- Topline results expected in Q2FY17
- IND filing planned in Q2FY17

SPARC R&D Pipeline



For updates and specific queries,
please visit www.sunpharma.in or
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