



# Investor Update on R&D Pipeline

August 4, 2016



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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

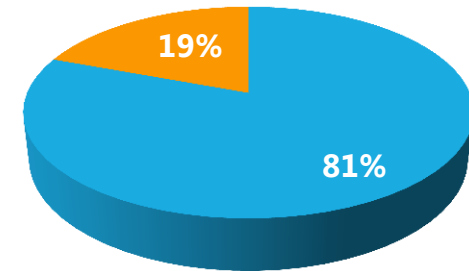
## ○ Robust early stage discovery pipeline

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

## ○ Portfolio Rationalization

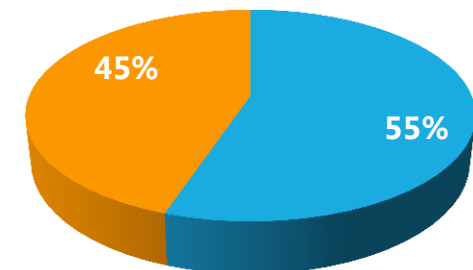
- Deprioritized DICN

**Development Pipeline 2014**



■ NDDS ■ NCE

**Development Pipeline 2016**



■ NDDS ■ NCE

# 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
<b>Total Income</b>	<b>1,613</b>	<b>1,557</b>	<b>1,670</b>	<b>873</b>
<b>Total Expenses</b>	<b>2,321</b>	<b>1,981</b>	<b>1,371</b>	<b>1,074</b>
<b>Net Profit / (Loss)</b>	<b>(700)</b>	<b>(395)</b>	<b>303</b>	<b>(225)</b>

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

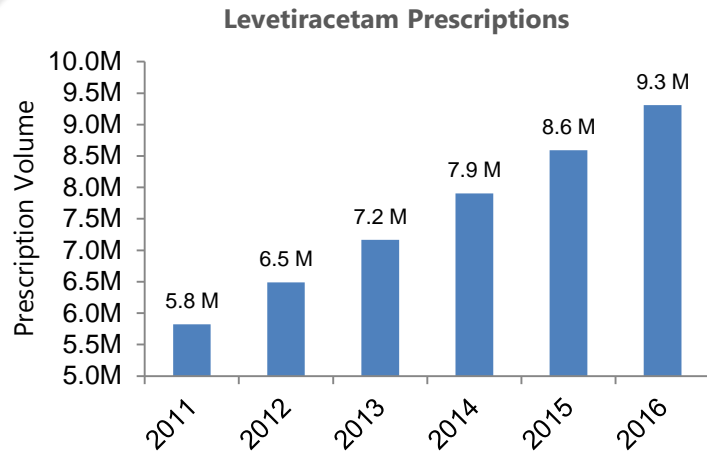
- Licensed Elepsia™ XR to a subsidiary of Sun Pharma for the US market
- Up-front payment of US\$10 million, additional milestones and sales based royalties
- Sun Pharma to create a dedicated CNS sales team to commercialize Elepsia™ XR in US

## ○ Xelpros™

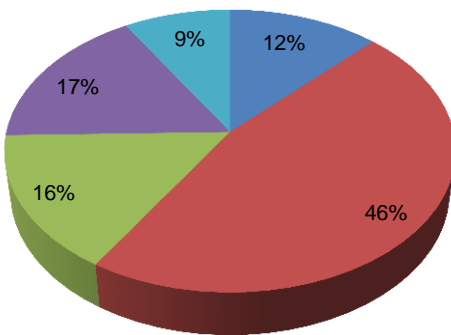
- Licensed Xelpros™ in 2015 to a subsidiary of Sun Pharma for the US market
- Sun Pharma launched a new specialty division, Sun Ophthalmics, to commercialize branded ophthalmic products in US including Xelpros™

# Elepsia™ XR

## US Commercial Opportunity



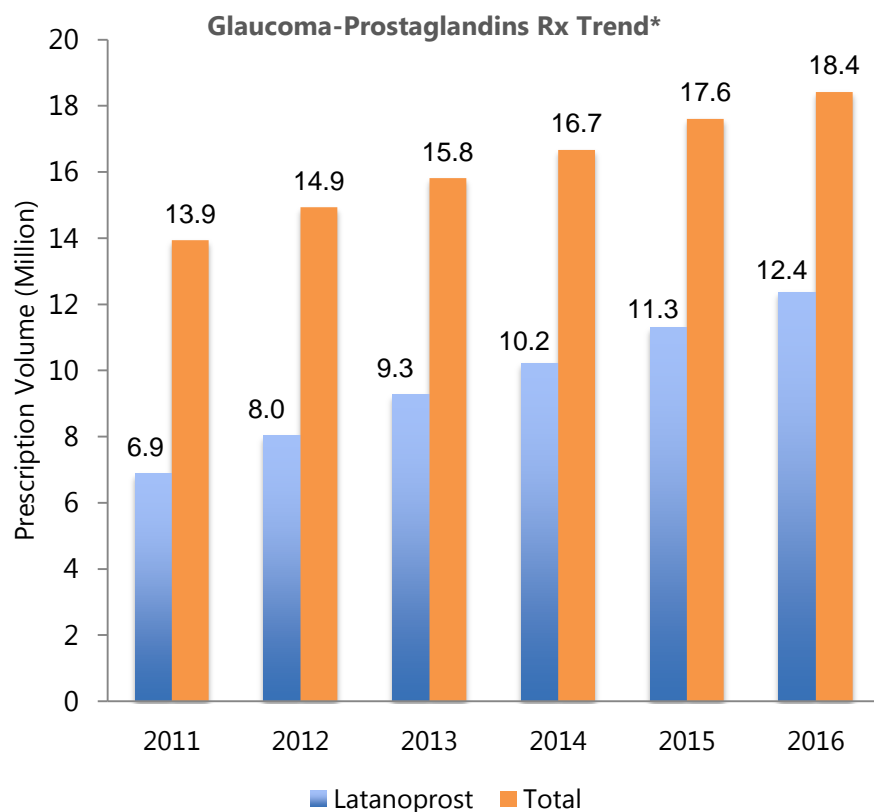
**Patients on Levetiracetam Daily Dose\***



■ <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<sup>#</sup>
- Elepsia™ XR peak sales potential US\$ 50 Mn.

## 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<sup>#</sup>
- Ophthalmologists showed preference for BAK-free Latanoprost formulation <sup>#</sup>
- Xelpros™ peak sales potential US\$ 50 Mn.



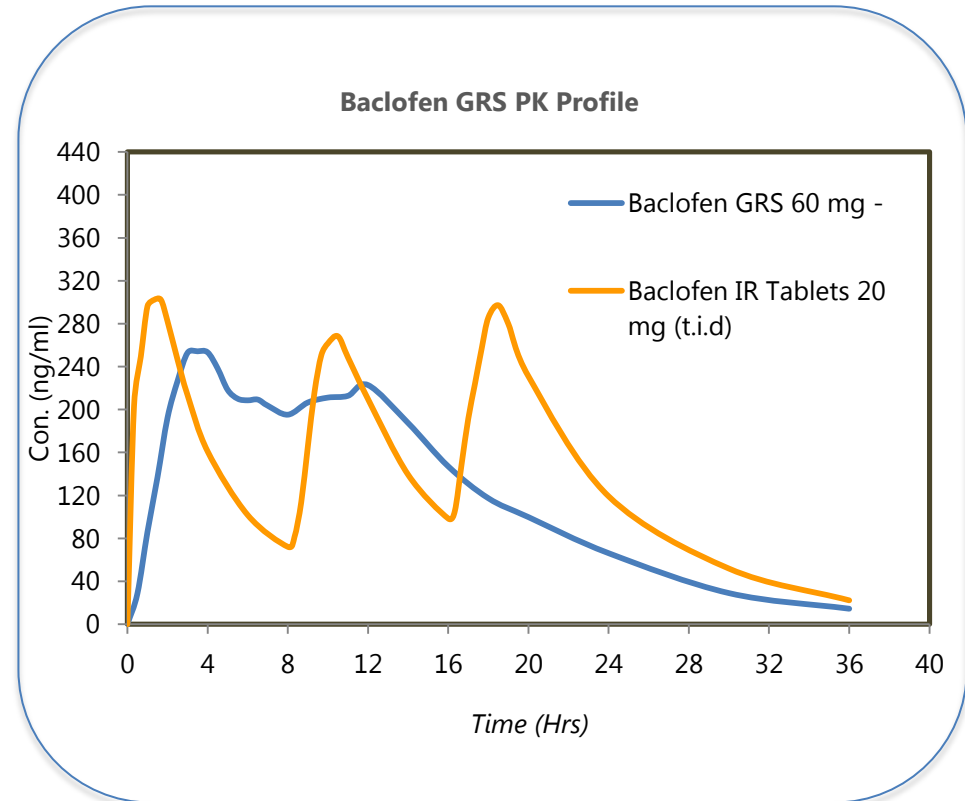
CNS  
**Baclofen**  
**GRS**

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# Baclofen GRS

Designed to improve compliance in patients with Spasticity

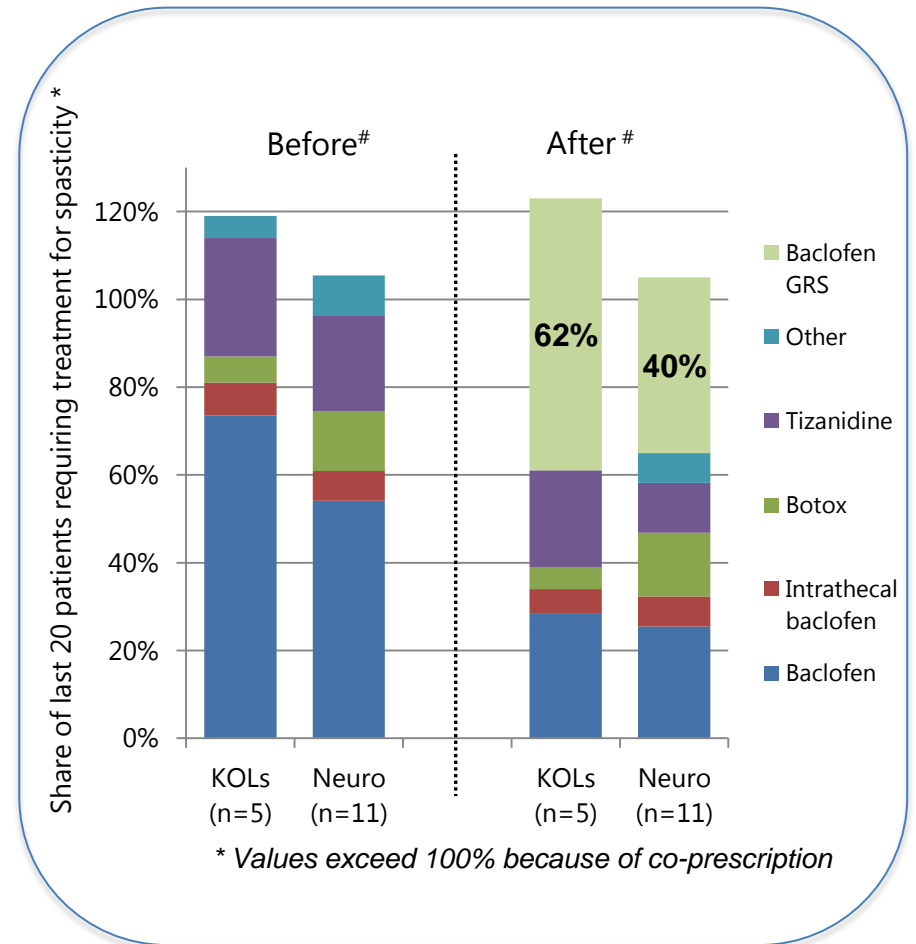
- Once-a-Day Baclofen with Proprietary Gastro Retentive Innovative Device (GRID™) technology
- Combination of mechanisms leads to successful “once -a- day” formulation
  - Flotation
  - Size expansion
  - Muco-adhesion
- Patent portfolio comprising of formulation , once a day therapy and indication patents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

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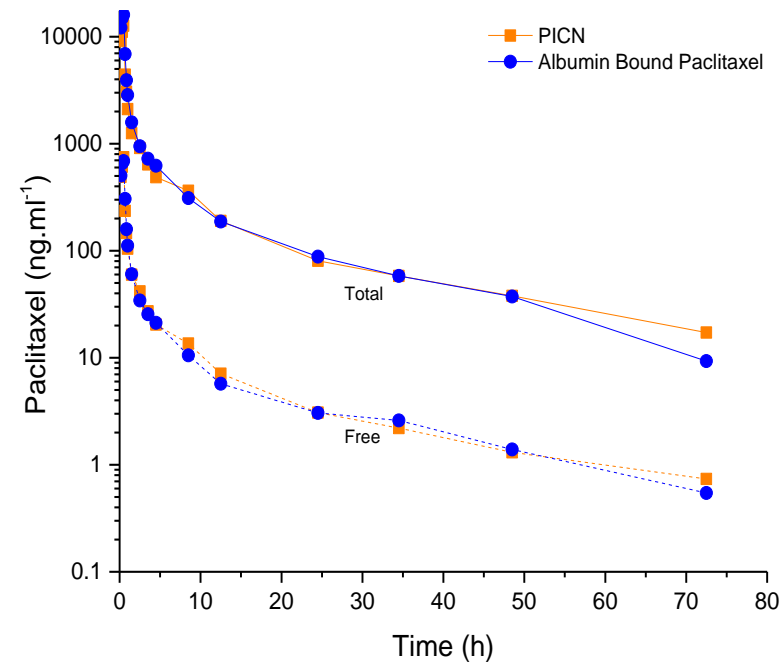
# Paclitaxel Injection Concentrate for Nanodispersion (Taclantis™)

- **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®



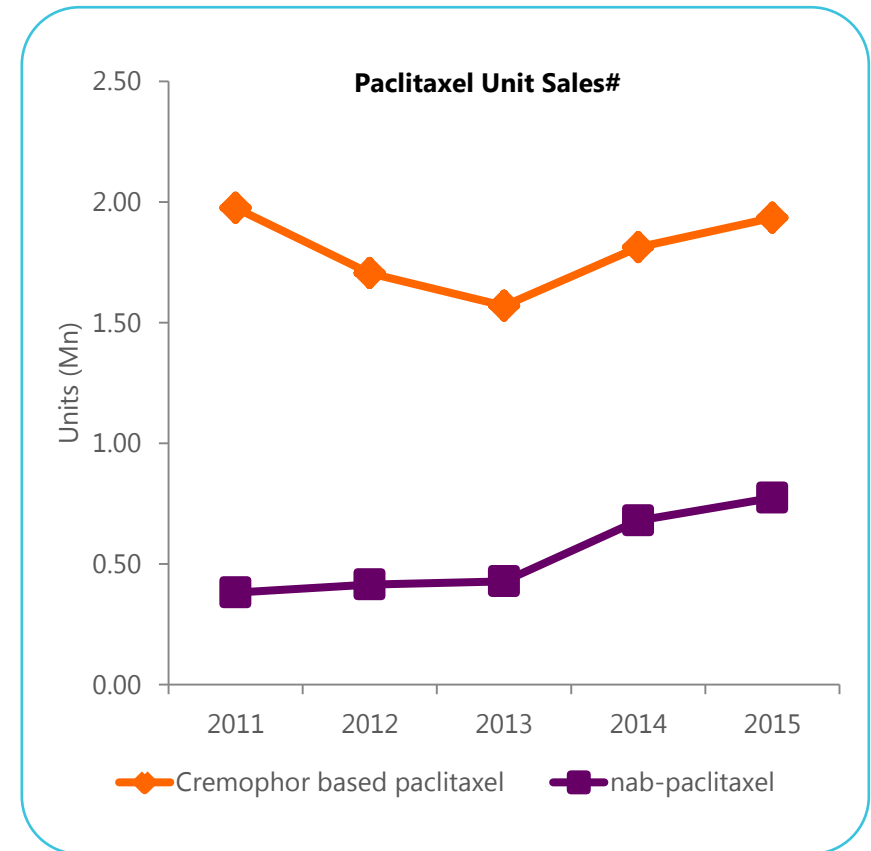
# Pursuing PK strategy to compare Taclantis™ with albumin bound Paclitaxel

- 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<sup>^</sup><sup>^^</sup>
- Over 70% marketed units are Cremophor® based paclitaxel formulations<sup>^</sup><sup>^^</sup>
- ~150,000 patients being treated with Cremophor® based paclitaxel<sup>^</sup>
- 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



# Units Equivalent to 100mg paclitaxel based on IMS MAT Apr 2016. ^Patient nos. estimated based on IMS unit sales\* Primary research conducted through 3rd party

^^ IMS MAT June 2016



# Respiratory DPI

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# 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®\*



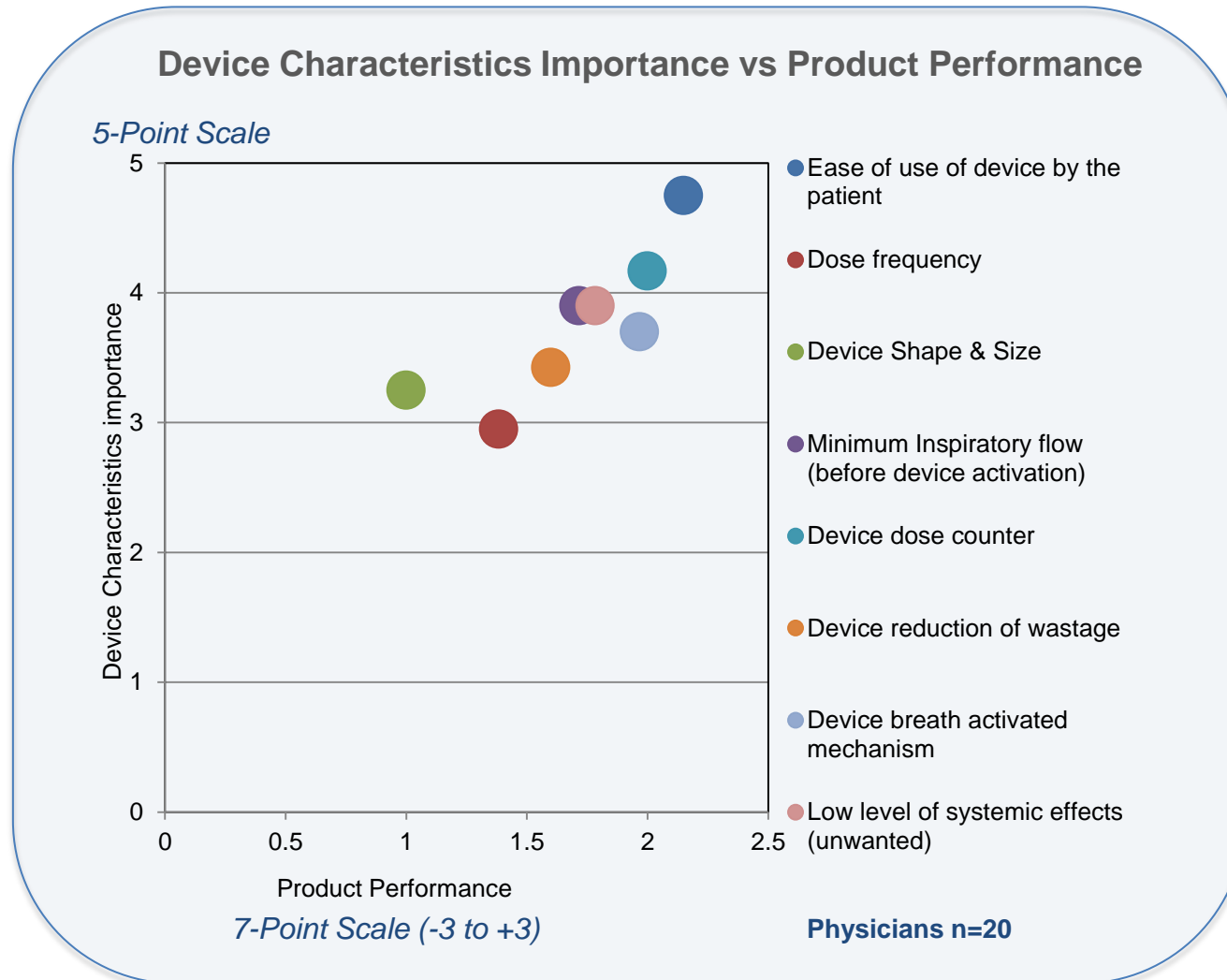
\*Primary research conducted through 3rd party in EU

# Salmeterol – Fluticasone DPI

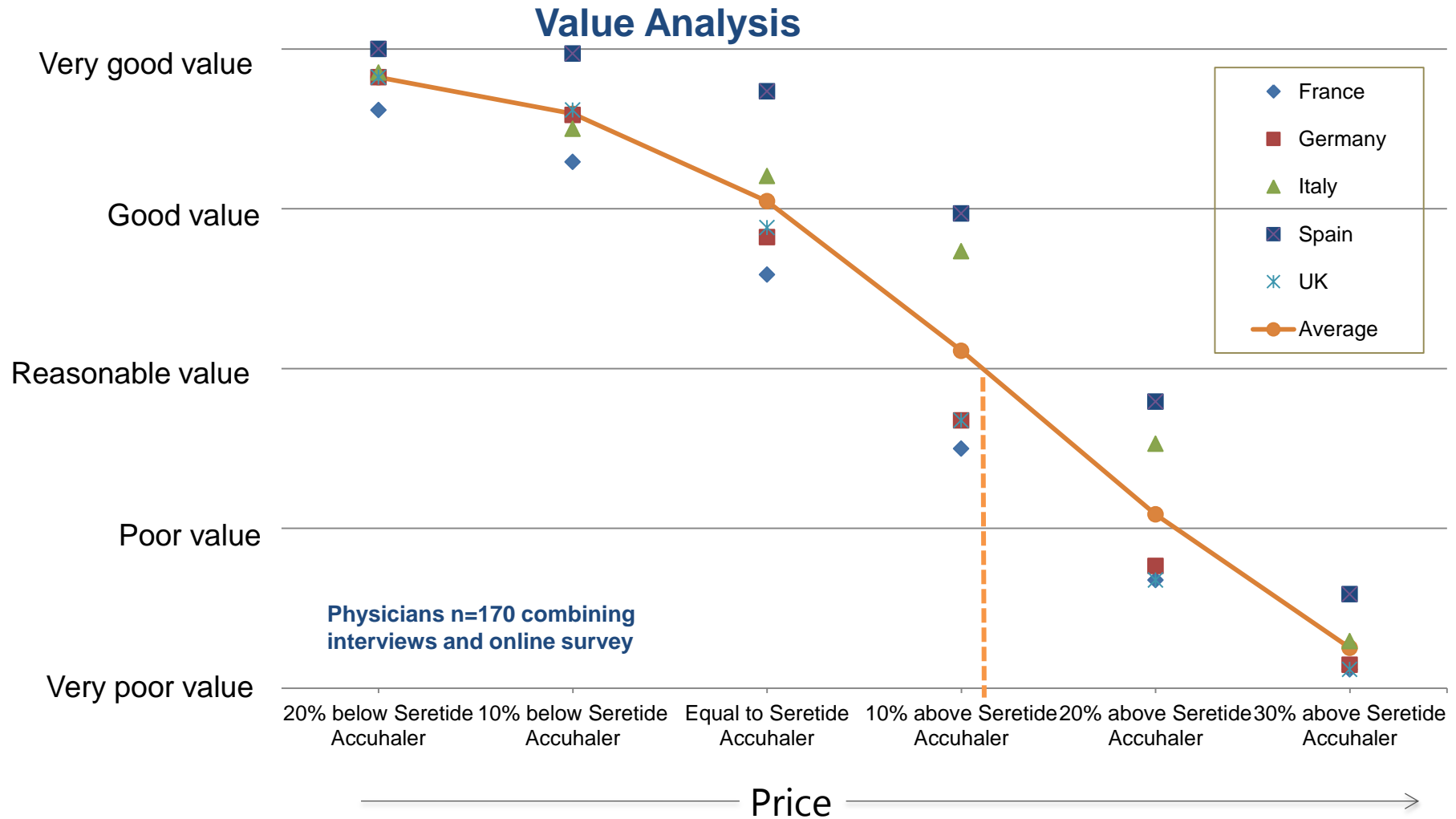
## Development status update – Europe

- **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\*



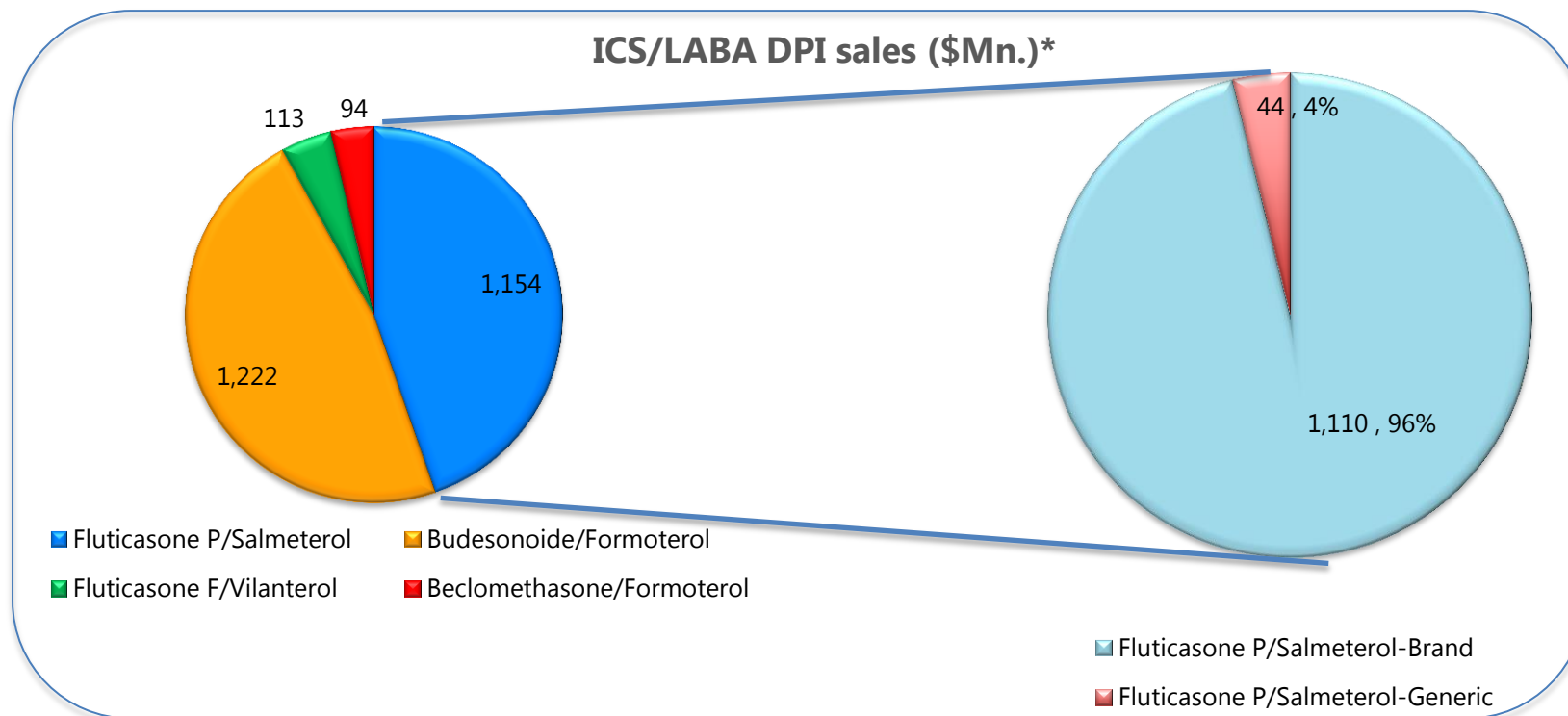
# Physicians across Europe value SPARC device better than Seretide® Accuhaler®\*



\*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 ~ US\$ 2.6 Bn.\*
- Seretide® Accuhaler® has market share of 45% in ICS/LABA market with sales of ~US\$ 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

\* IMS MAT Dec 2015. ICS = Inhaled Corticosteroids. LABA = Long- Acting Beta2-Agonists



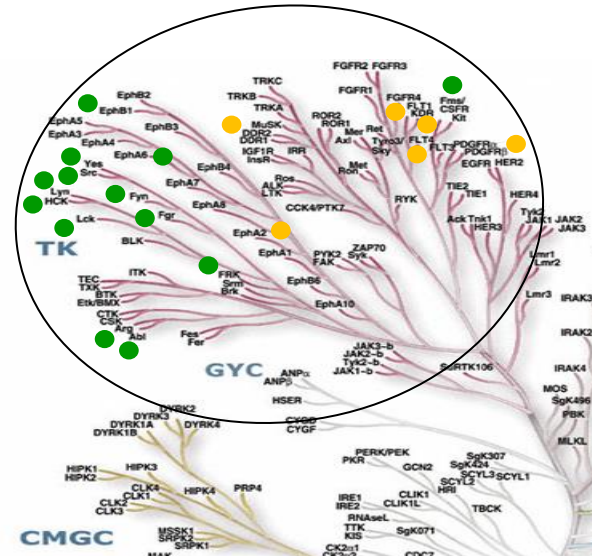
Oncology  
**CML**  
Program

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**SUN PHARMA**  
**ADVANCED RESEARCH**  
**COMPANY LTD.**

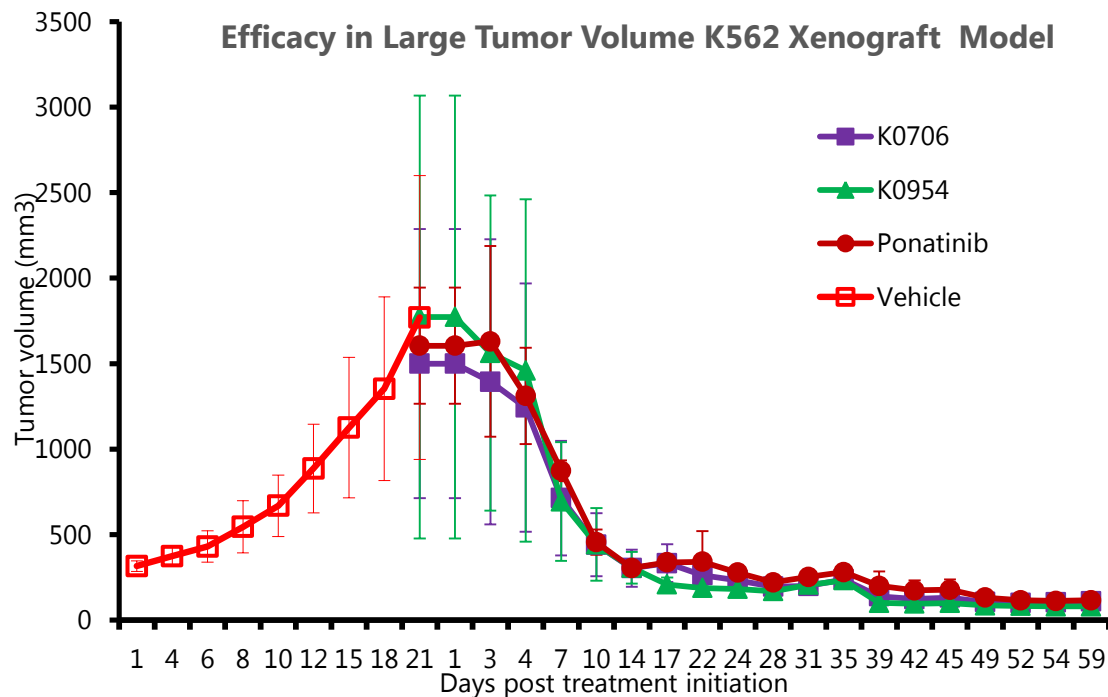
## SUN-K954 Kinome Analysis



- $IC_{50} < 10 \text{ nM}$
- $IC_{50} 10\text{-}50 \text{ nM}$

- Potent, orally available and BCR-ABL Tyrosine Kinase Inhibitors (TKIs)
- Effective against BCR-ABL and most of its mutants including the difficult to treat T315I mutation

# 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

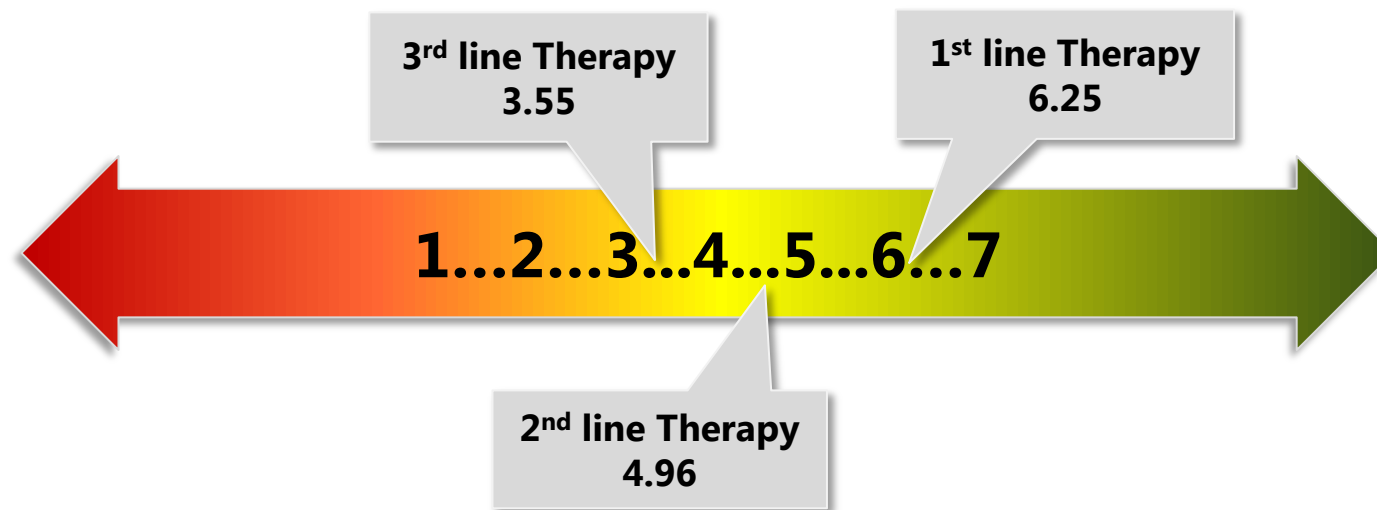
## Development Status Update

- **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\*



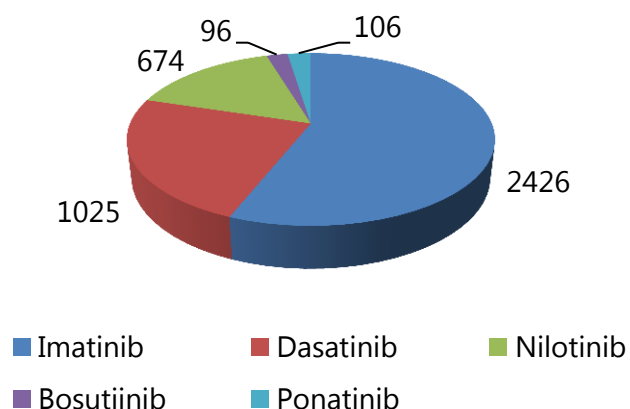
How satisfied are you with the current treatment options and outcomes in 1st, 2nd- and 3rd-line CML patients? Please rate on a scale of 1 to 7 (1 = extremely unsatisfied, 7 = extremely satisfied)

\*Primary research conducted through 3rd party

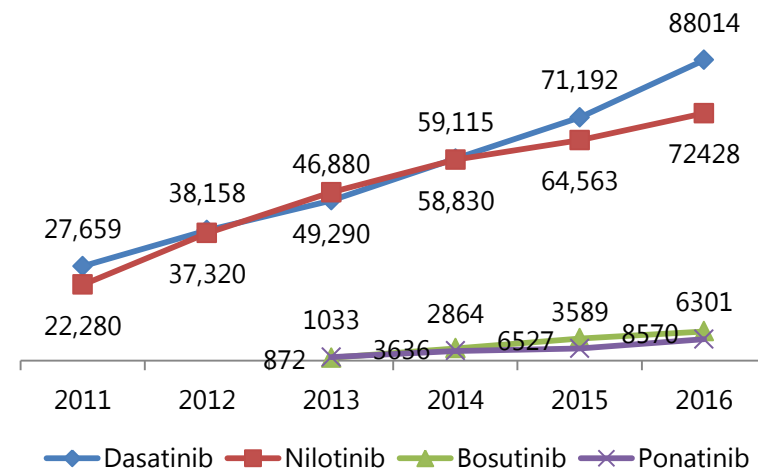
# SPARC CML Program

Treatment resistant CML – Niche market, yet commercially attractive

Sales \$ Mn.^



TRx^



- ~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



Dermatology  
**SUN-597**  
**Topical**

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# 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



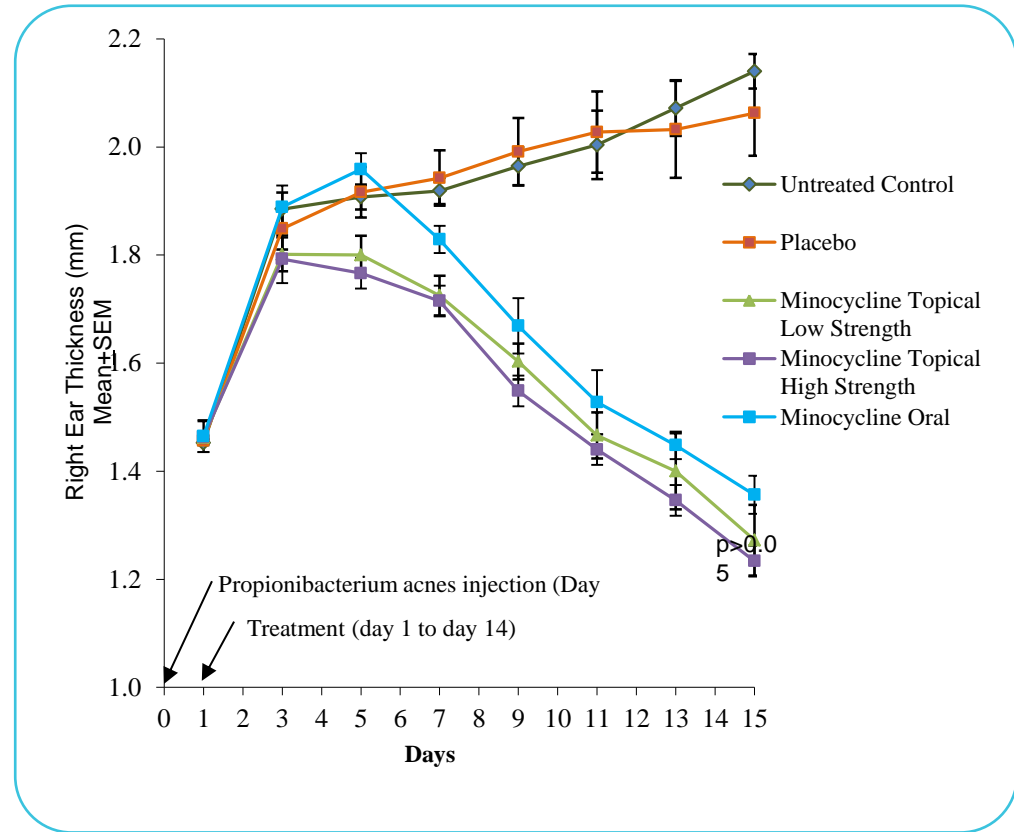
# Dermatology Minocycline Topical

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# 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**

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# Brimonidine OD

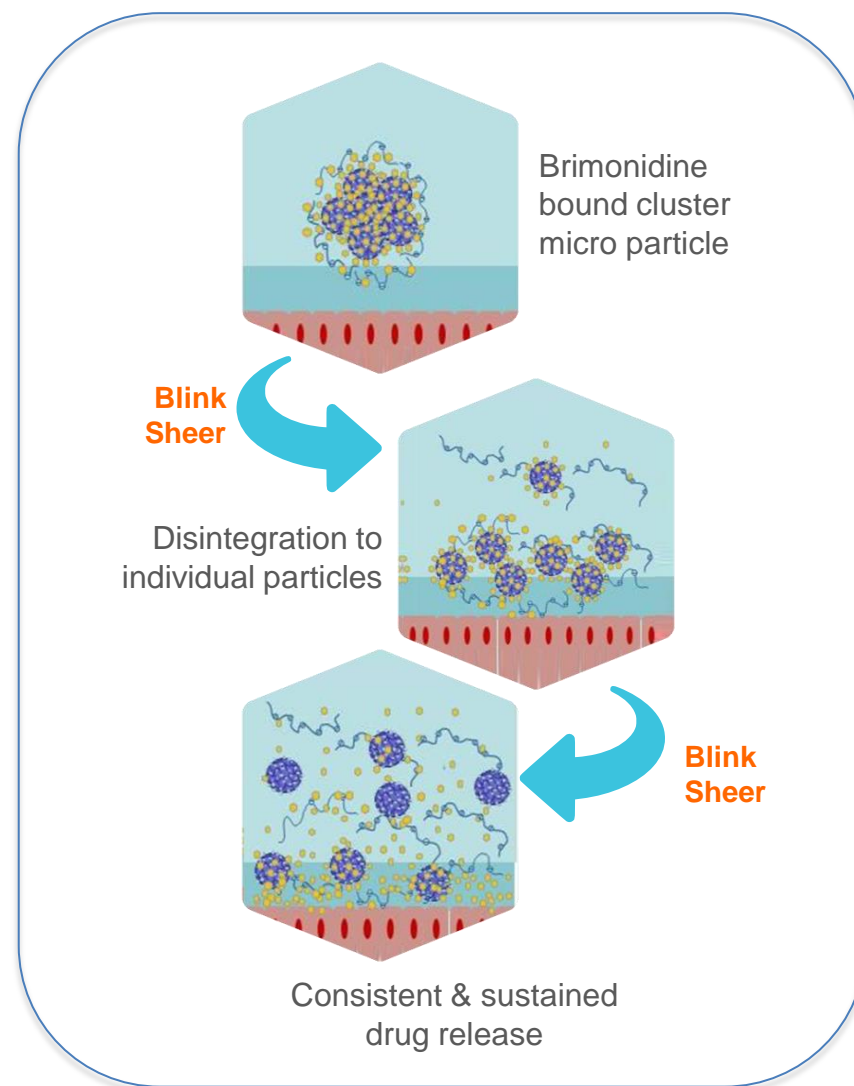
## Novel Once daily formulation with TearAct™ Technology

### ○ 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

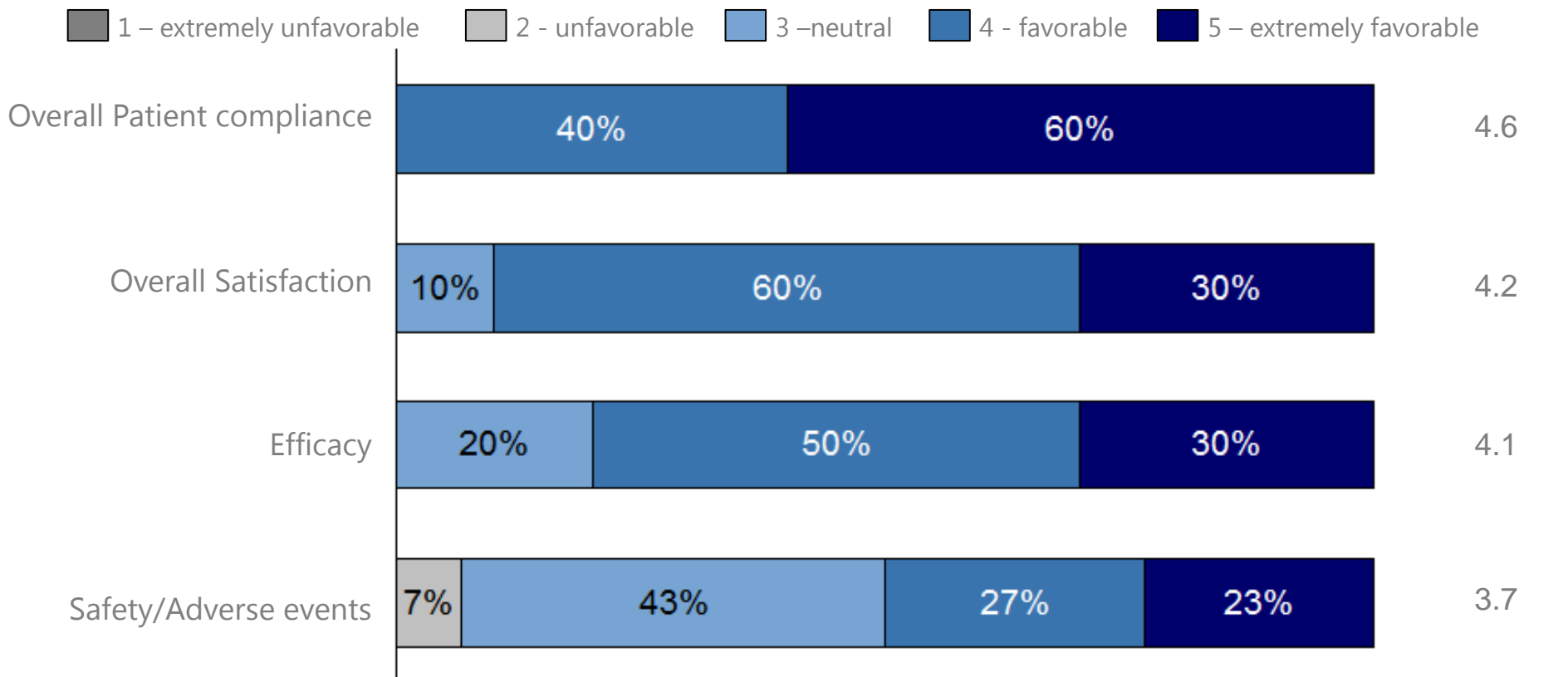
Once daily dosing to significantly help improve overall patient compliance



## 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**

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# Prescription opioid drug abuse

A growing epidemic in USA



**19,000** deaths occurred in 2014 due to prescription opioid overdose<sup>1</sup>

**46/day** people die due to prescription opioid overdose<sup>2</sup>

**~1.9 million** people abused prescription opioid in 2013<sup>3</sup>

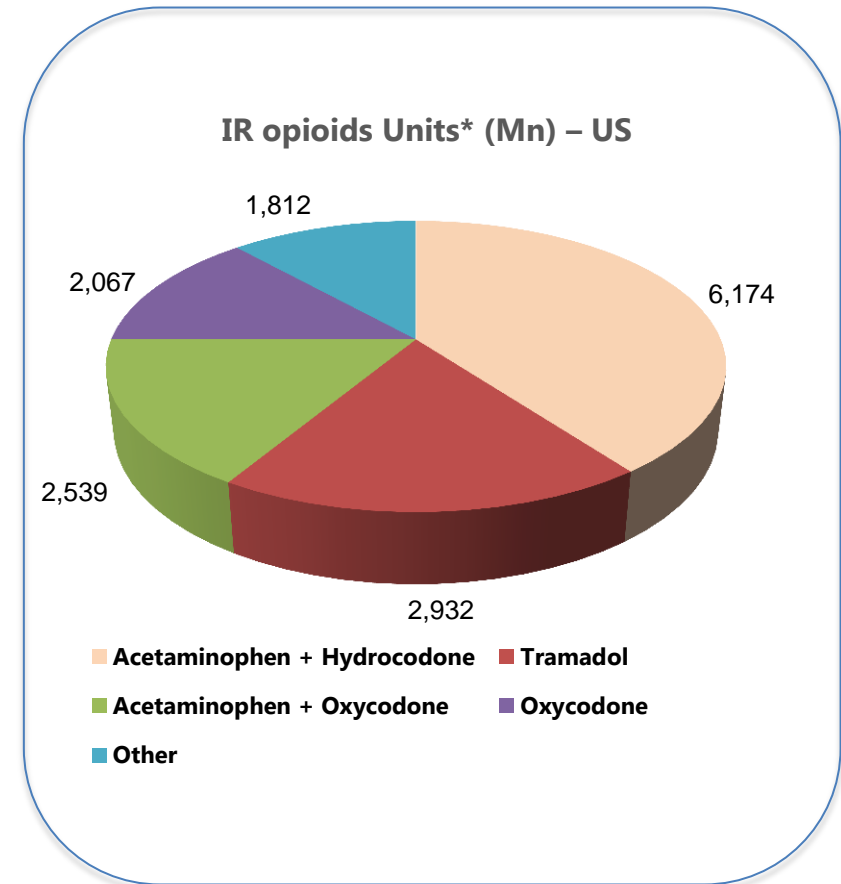
**>420,000** ED visits involved abuse or misuse of prescription opioids in 2011<sup>4</sup>

1. CDC/NCHS, National Vital Statistics System, Mortality File 2015. 2 [www.CDC.gov/vital/signs/July2014](http://www.CDC.gov/vital/signs/July2014). 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



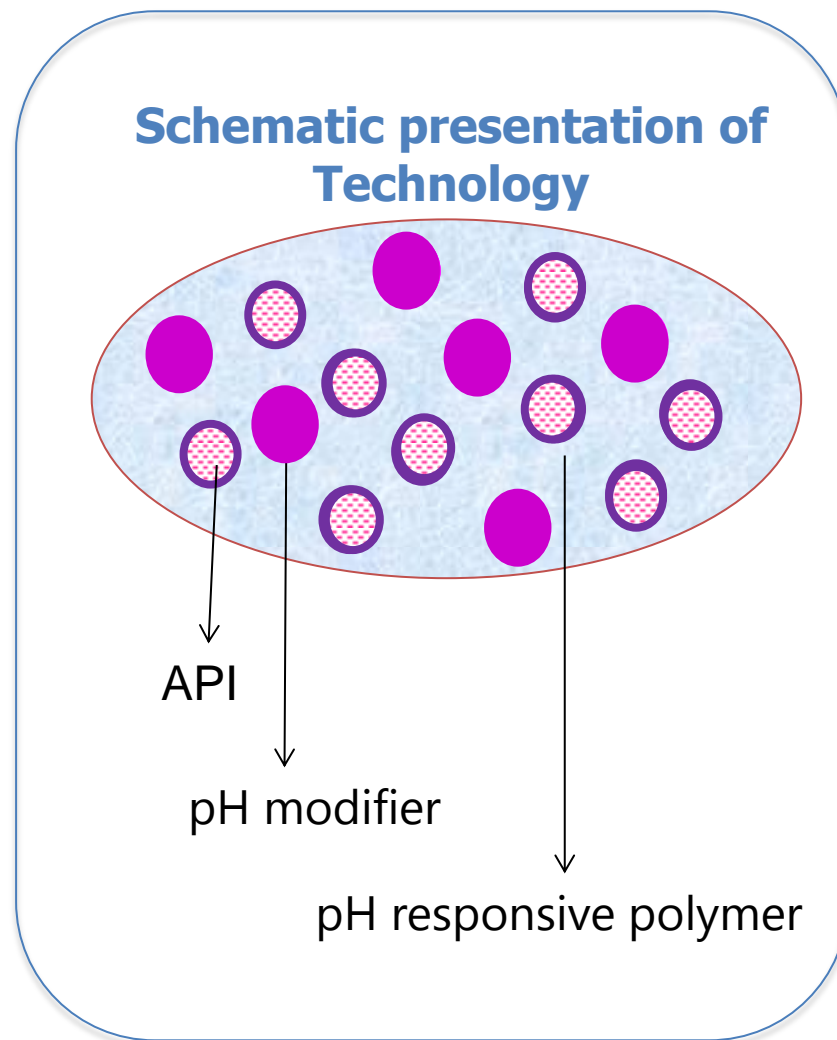
\* IMS MAT APRIL 2016

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

# Abuse deterrent technology platform

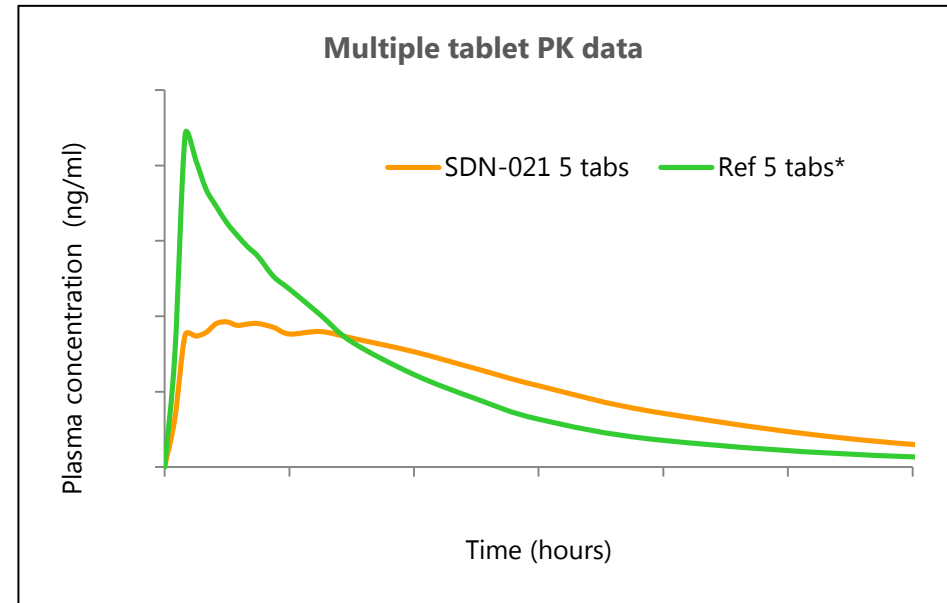
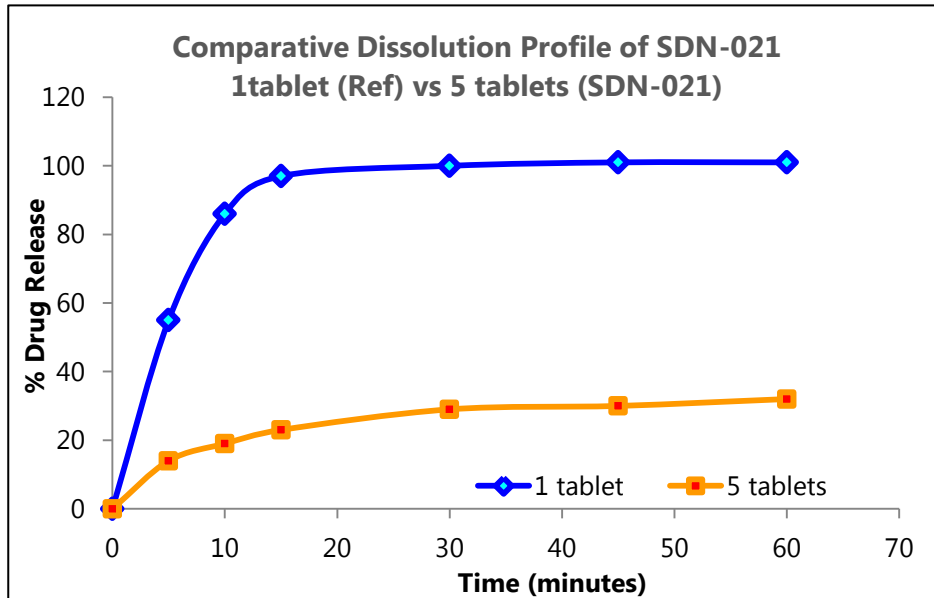
## Designed to deter multi-pill abuse

- 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

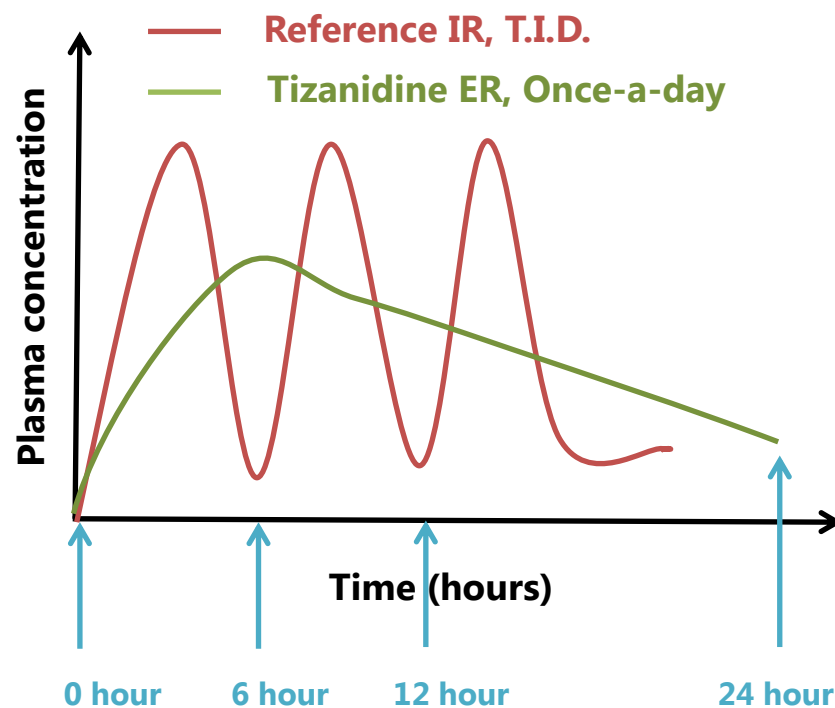
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# Tizanidine ER for Musculoskeletal Pain

## 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](http://www.sunpharma.in) or  
contact

**Narendra Lakkad**

Tel : +91 22 6645 5645, Ext 5607

Tel Direct : +91 22 66455607

Mobile : +91 9821510498

[narendra.lakkad@sparcmail.com](mailto:narendra.lakkad@sparcmail.com)

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