

SUN PHARMA  
ADVANCED RESEARCH  
COMPANY LTD.



# Investor Update on R&D Pipeline

June 10, 2015

BSE:532872 • NSE: SPARC • BLOOMBERG: SPADV@IN • REUTERS: SPRC.BO

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# Major Milestones

## ELEPSIA™ XR

- USFDA approval in March 2015

## XELPROS™

- Signed licensing & commercialization agreement with Sun Pharma
- Approval in 3 Emerging Markets
- Responded to the USFDA complete response letter

## Salmeterol & Fluticasone Dry Powder Inhaler

- PK study in Germany indicates comparable PK parameters to Seretide® Accuhaler®
- Received guidance from 3 regulatory agencies in EU for registrational studies

## PICN

- Completed EOP2<sup>#</sup> CMC<sup>^</sup> meeting with USFDA
- USFDA concurrence on Phase 3 Metastatic Breast Cancer protocol
- Promising data in Cholangiocarcinoma
- In a Pilot PK study, PICN demonstrated encouraging results, compared to albumin bound Paclitaxel

## Abuse Deterrent Formulations

- SPARC has developed a platform technology for Abuse Deterrent Formulations (ADF)
- Completed pre-IND meeting to discuss the product concept

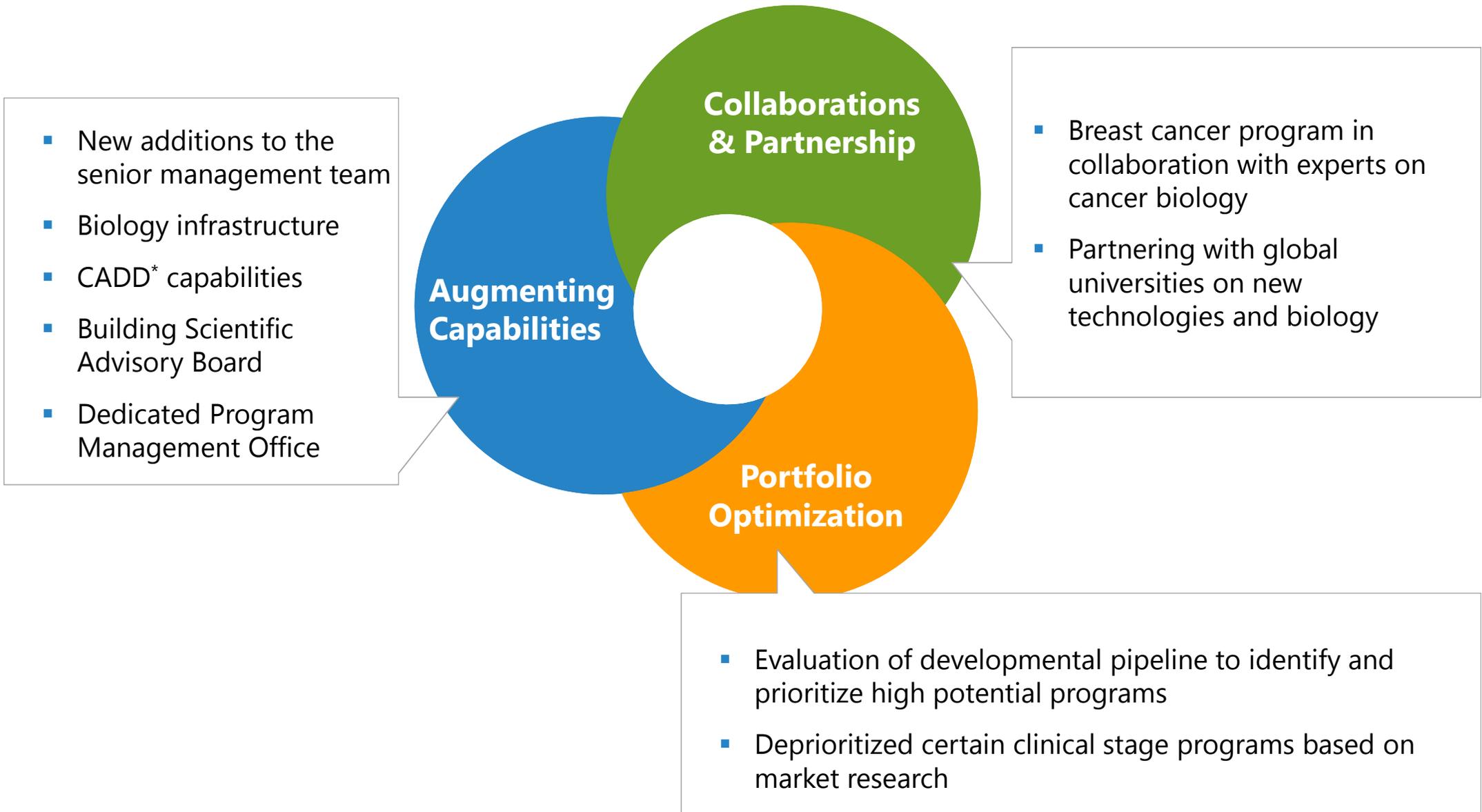
## Accelerated Program Development

- Completed 9 meetings with regulatory agencies in US and EU to discuss development plans of key programs

## Patent Estate

- 27 patents granted since last update; 19 more filed.
- 121 patents granted worldwide till date

# Strategic Initiatives



# Augmenting Senior Management Team

## **Anil Raghavan** *B.Tech*

Anil Raghavan, is CEO of SPARC. Prior to joining SPARC, he served as the Managing Director of the India and Sri Lanka business of Quintiles. He was part of the Quintiles global leadership team and an active member of the AsiaPac management board.

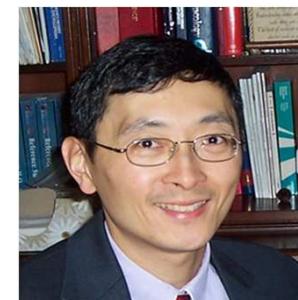
In past, he spent a decade consulting with leading firms such as Arthur Andersen, KPMG and Cambridge Technology Partners.



## **Dr. Siu-Long Yao**, *MD*

Dr. Siu-Long Yao, Sr. VP for Clinical Development & Operations, oversees design & execution of clinical research globally.

Siu brings in 20 years of experience in clinical research. Prior to joining SPARC, he held positions of increasing responsibility in Clinical Pharmacology & Oncology at Merck, Sanofi-Aventis and Schering-Plough. He completed sub-specialty training in hematology & oncology at Johns Hopkins and is a Board certified Internist, Hematologist and Oncologist.



## **Dr. Nitin K. Damle**, *PhD*

Dr. Nitin Damle, Sr. VP for Discovery Biology and Preclinical R&D, oversees design and execution of preclinical research and development.

Nitin brings in 30 years of experience in drug discovery and preclinical development in Oncology and Immuno-Inflammatory therapeutic areas with focus on both small molecules and biologics. He was Director of Oncology and Immuno-Inflammatory diseases at Wyeth, and Sr. Director of Preclinical Research at Endo Pharmaceuticals before joining SPARC.



# Deprioritized Programs

Upon commercial assessment and portfolio reorganization, following programs were deprioritized

- SUN-L731
- Venlafaxine ER 300mg
- SUN-597 Nasal/Inhalation
- Latanoprost + Timolol in EU
- Baclofen GRS for Alcohol dependence in EU
- SPARC is evaluating development of SUN-L731 and SUN-597 Nasal/ Inhalation for India and other emerging markets
- Timolol OD and Latanoprost + Timolol are being evaluated for select emerging markets

# Upcoming Key Events



**Licensing & Commercialization of Elepsia™ XR**



**Xelpros™ Approval by USFDA**



**PICN Launch in India**



**Initiation of Pivotal Clinical Trial for PICN**



**Filing of 4 INDs**

Indicative timeline based on the current estimates of the management and are subject to change. The Company cannot assure that this indicative date will be achieved. The actual results, performance or achievements, could thus differ materially from those projected herein.

# Strategic Therapy Areas and Research Programs

## Ophthalmology

- Xelpros™
- Brimonidine OD

## Oncology

- PICN
- SUN-K706

## CNS

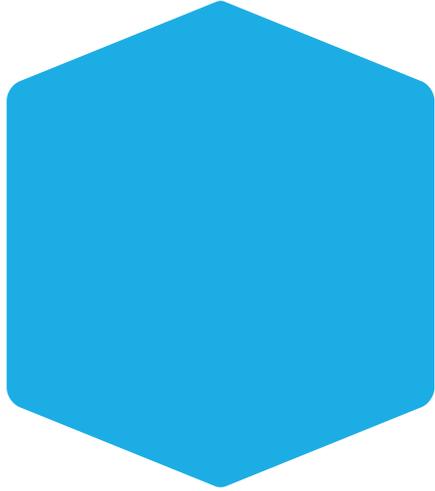
- Elepsia™ XR
- Baclofen GRS
- Tizanidine ER

## Dermatology

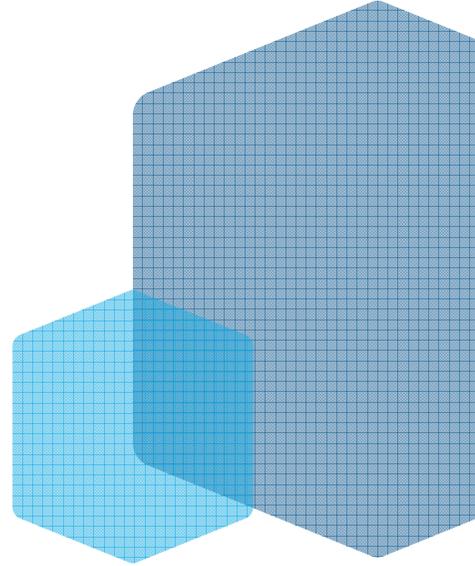
- SUN-597 Topical
- Minocycline Topical

## Respiratory

- Salmeterol + Fluticasone DPI



Ophthalmology  
**Xelpros™**



# Xelpros™ Ophthalmic Emulsion

## Regulatory Update

- Received Complete Response Letter (CRL) from USFDA in Nov'14
  - Change in nomenclature of dosage form
  - No additional pre-clinical or clinical data requirement
- Submitted the response to CRL



# Xelpros™ Ophthalmic Emulsion

## Licensing & Commercialization

- SPARC signed licensing deal with a Sun Pharma subsidiary for US market
  - \$3 million as upfront and certain other milestone payments both totaling to \$16 million
  - Additionally, SPARC is eligible for certain defined royalties and milestone payments linked to actual sales performance



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CNS

Elepsia™ XR

# Elepsia™ XR

- USFDA approval in March 2015
  - 1<sup>st</sup> NDA approval for SPARC
- Composition and dose specific patents granted in US with last patent expiry in 2027
- Elepsia™ XR 1000mg & 1500mg patents are listed in the Orange Book

Application No	Patent No	Patent Expiration
N204417	8163306	3-Sep-27
N204417	8425938	22-Feb-26
N204417	8431156	31-Oct-27
N204417	8470367	30-Jun-24
N204417	8535717	22-Feb-26



## Wrap Matrix™

Use of Laser drill to achieve a controlled release with minimal excipients

# Elepsia™ XR

## US Commercial Opportunity

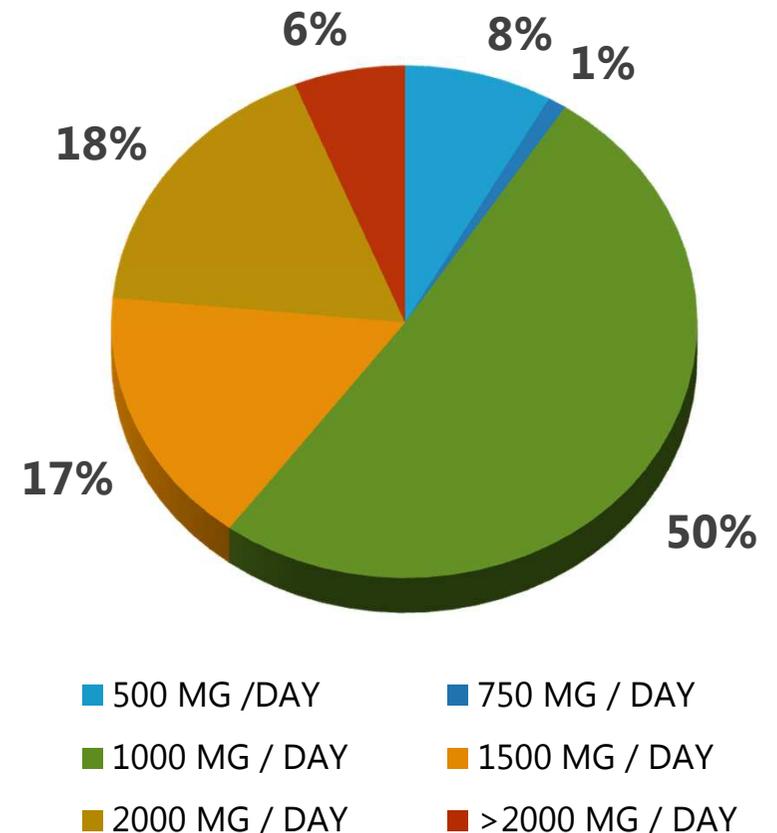
### Market access studies in US<sup>#</sup>

- Pill burden in epilepsy patients remains high
  - >55% patients at >6 pills per day
  - >80% patients need daily dosage of 1000mg-3000mg
- Elepsia™ XR represents a new therapeutic option to reduce pill burden in epilepsy patients

### Elepsia™ XR market potential

- Levetiracetam market in US is currently at 720 million units and is growing at 5 year CAGR of 9%\*
- Opportunity to market Elepsia™ XR at significant premium to generics<sup>#</sup>

### Levetiracetam Use by Daily Dosage\*

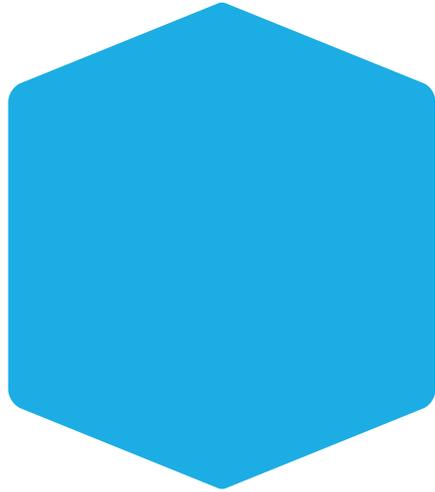


# Elepsia™ XR

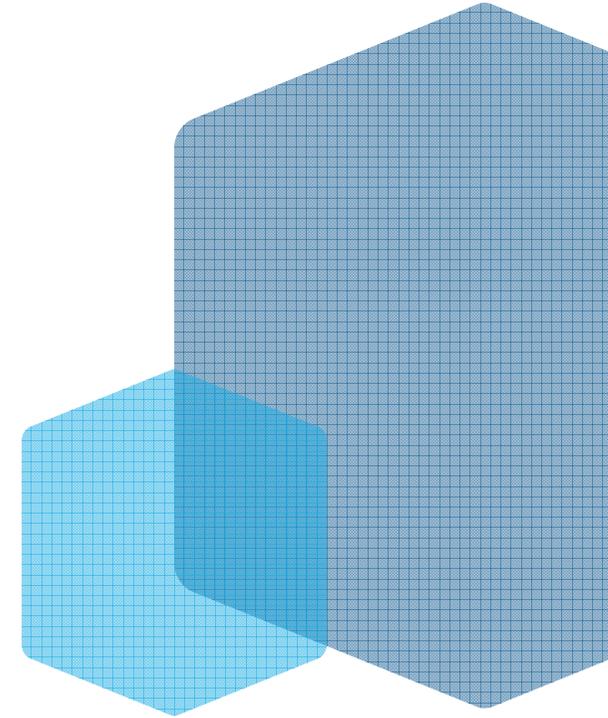
## Licensing & Commercialization

- SPARC is at advanced stage of licensing discussions with potential partners
- Elepsia™ XR commercialization in US market by 2<sup>nd</sup> half of 2015 – 2016\*

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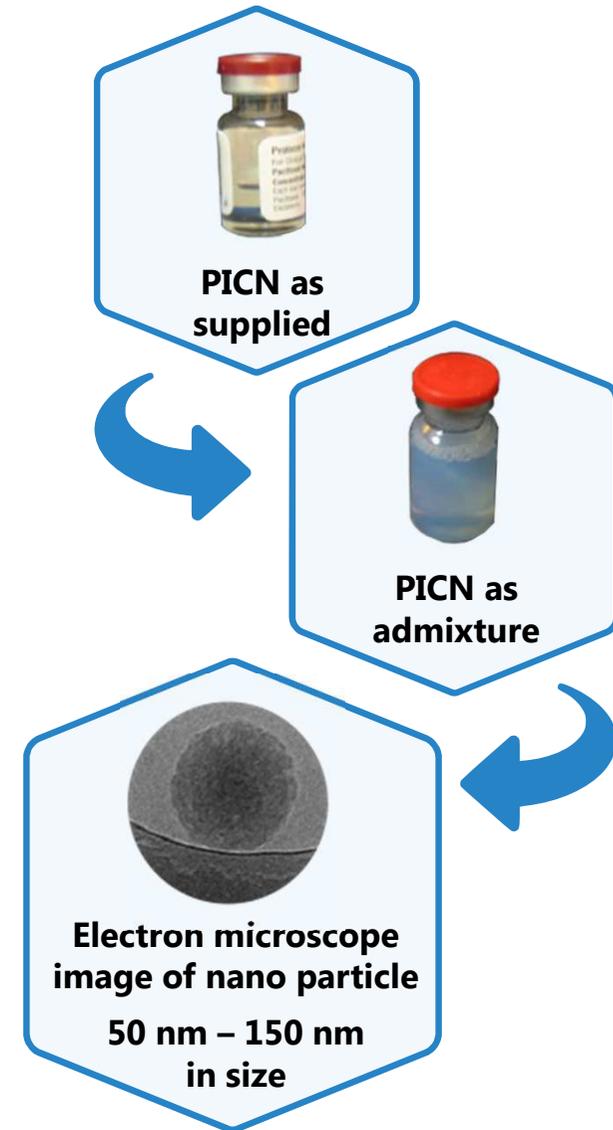
Oncology  
**PICN**



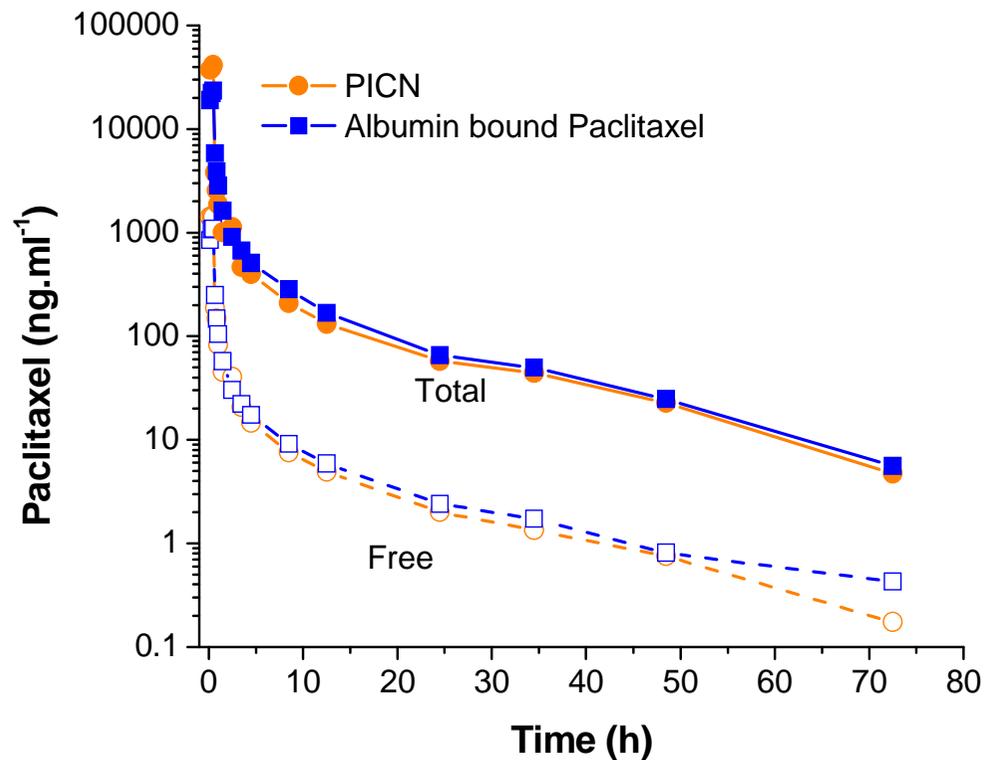
# Paclitaxel Injection Concentrate for Nanodispersion (PICN)

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

- Cremophor® and Albumin free formulation
- 30 minute infusion
- No standard Paclitaxel pre-medications required
- Allows higher dose than Taxol®



# Encouraging results in a PK study comparing PICN with albumin bound Paclitaxel



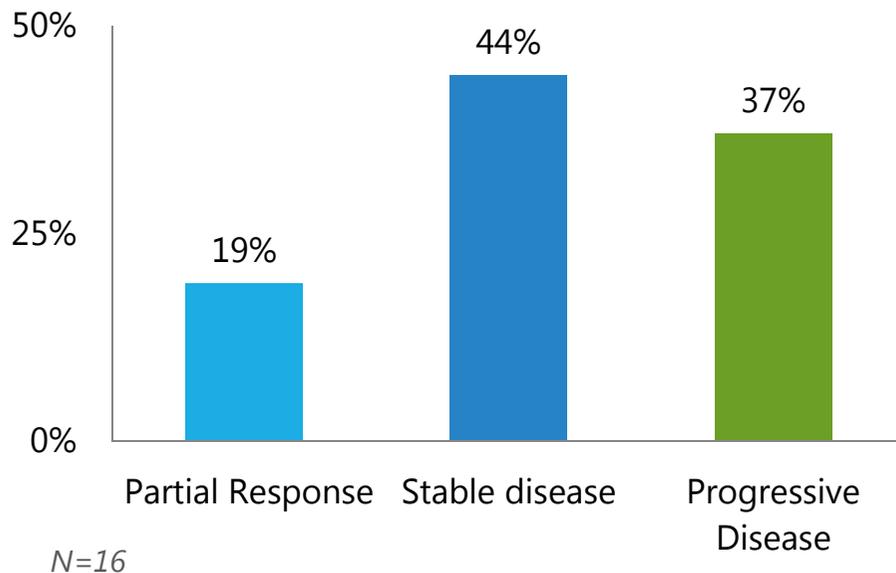
- SPARC conducted Pilot BA/BE study in India
- Data supports probability of BE with albumin bound Paclitaxel
- Additional patients are being enrolled to gain further confirmation
- Pivotal BE study planned in Q4, 2015-2016\* based on the outcomes of the ongoing Pilot study

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# Encouraging PICN data in Cholangiocarcinoma

**SPARC evaluated PICN in  $\geq 2^{\text{nd}}$  line treatment of Cholangiocarcinoma in an expanded cohort of ongoing program in US**

## Outcomes from Cholangiocarcinoma Cohort



- PICN has demonstrated 19 % response rate in subjects with metastatic Cholangiocarcinoma who have failed at least 1 line of chemotherapy
- SPARC plans to discuss with USFDA for approval pathway

## Breast Cancer Program Update

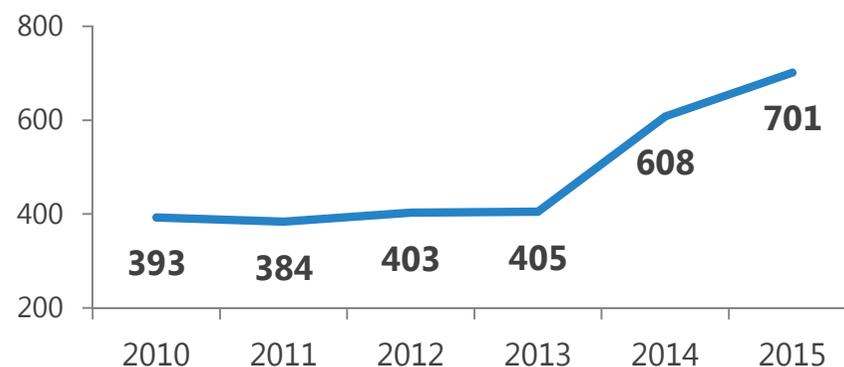
- Completed End of Phase 2 CMC meeting with USFDA
- Received USFDA concurrence on Phase 3 MBC protocol
- Plan to initiate study by Q4, 2015-16\*

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# PICN US Opportunity

- Paclitaxel is still a standard of care in MBC and other solid tumors and its use is growing
- Estimated 165,000 patients receive Paclitaxel therapy every year<sup>#</sup>
  - About 25,000 metastatic breast cancer patients are treated with Paclitaxel<sup>#</sup>
- With efficacy and safety similar to Abraxane<sup>®</sup>, PICN could address this patient population

### Paclitaxel Sales (Mn.\$)



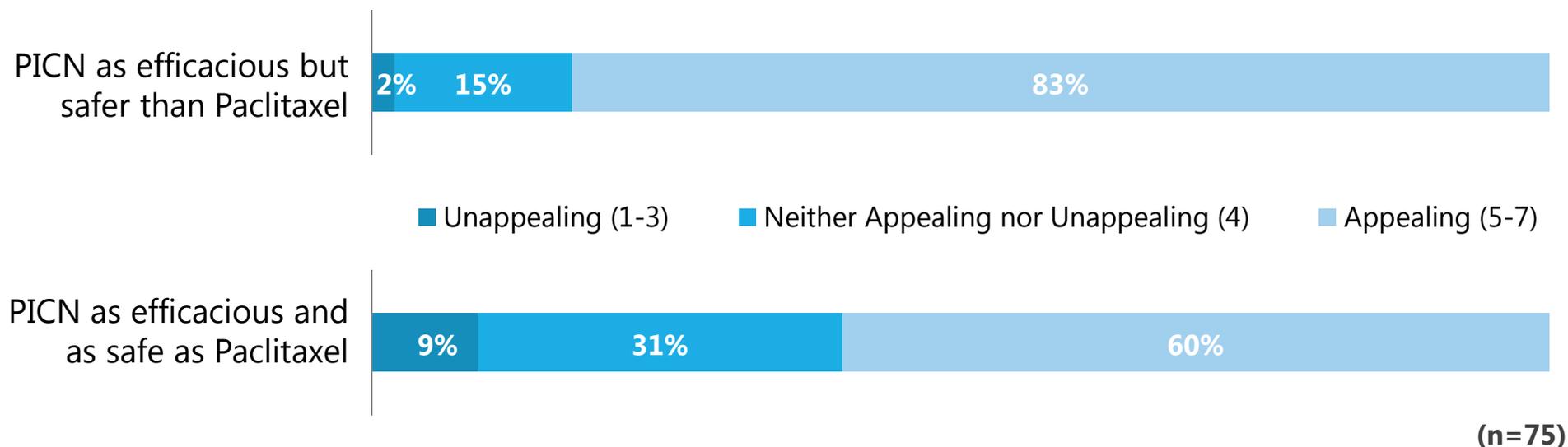
### Paclitaxel Sales (Est. Mn. Units\*)



# Overall PICN appeal as second line MBC treatment

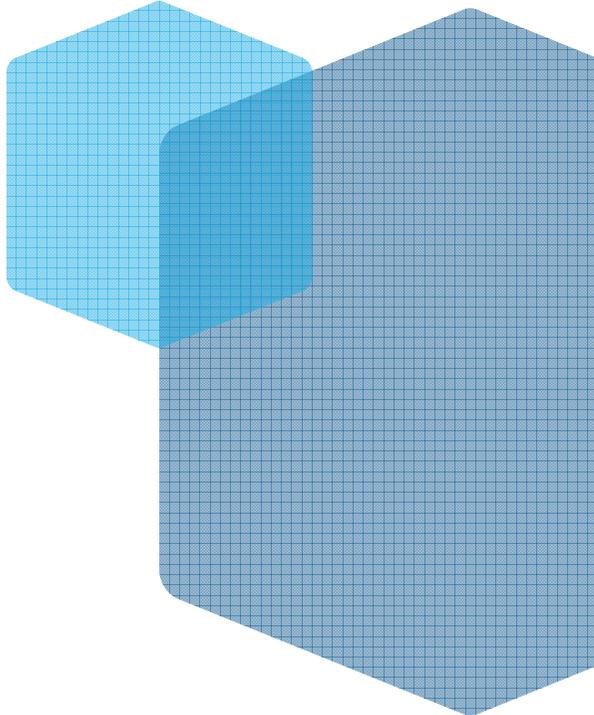
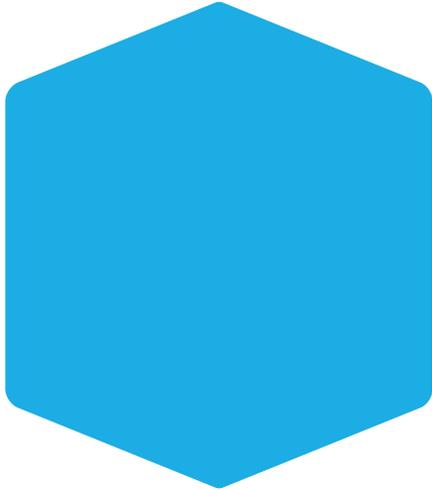
Prior to any mention of pricing, appeal of "Most Likely" PICN was quite strong; even with "Base Case" data 60% of oncologists found it appealing<sup>#</sup>

## Overall Impression of PICN – All Physicians –





Respiratory  
DPI



# Dry Powder Inhaler

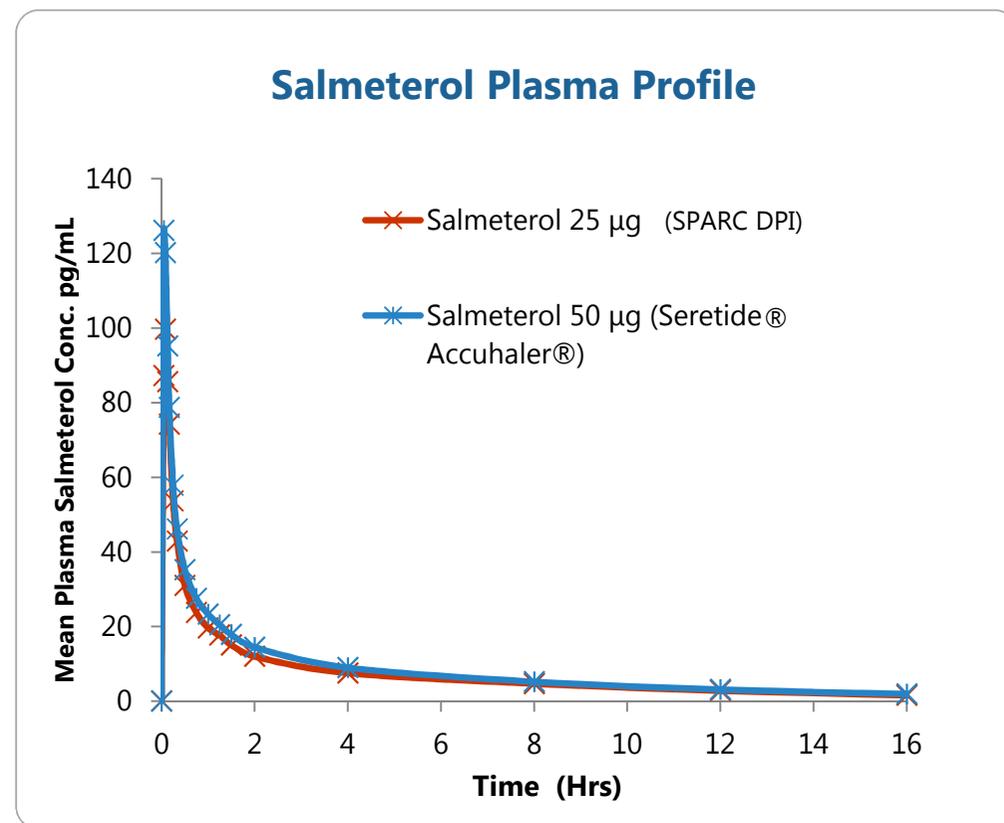
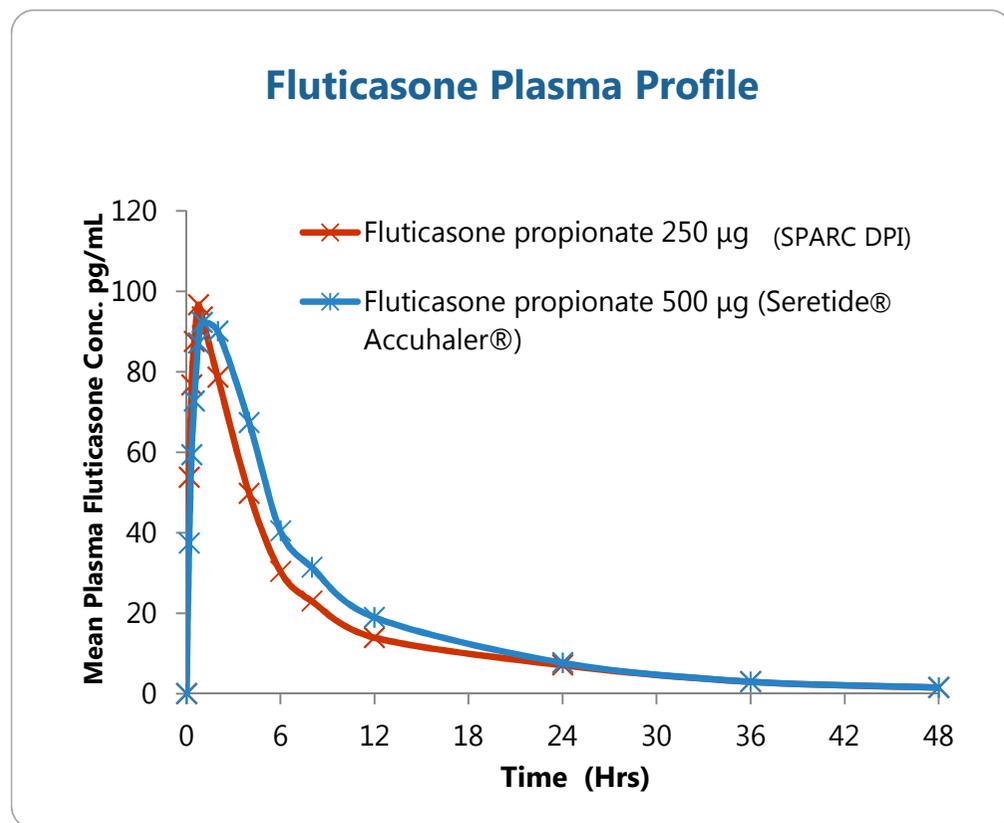
**SPARC's DPI is a pre-metered, 60 dose, breath activated device for administration of combination of inhaled steroids and bronchodilator drugs**

- Uniform dose delivery independent of inspiratory flow rate
- Consistently delivers higher amount of drug to lungs
- Eliminates double dosing and dose wastage
- Provides visual, audible and tactile feedback upon dose administration
- Glow-in-the-dark feature for easy night-time use
- Feature for assisting visually impaired, as reminder to refill device, when 8 doses remain
- Small and convenient, easy to carry
- Compliant to the stringent USFDA and European requirements



# Salmeterol & Fluticasone DPI

## Comparable PK at half the dose of Seretide® Accuhaler®



The pulmonary deposition and systemic fluticasone and salmeterol exposure outcomes were comparable to Seretide® Accuhaler®

# Salmeterol & Fluticasone DPI

## Development Status Update

### EU

- Discussed the PK study outcome and clinical development program with 3 EU regulatory agencies
- Achieved concurrence with regulatory agencies on the SPARC proposed clinical program
- SPARC to accelerate recommended clinical studies
- Targeting EU Regulatory filing by Q4, 2017-18\*

### US

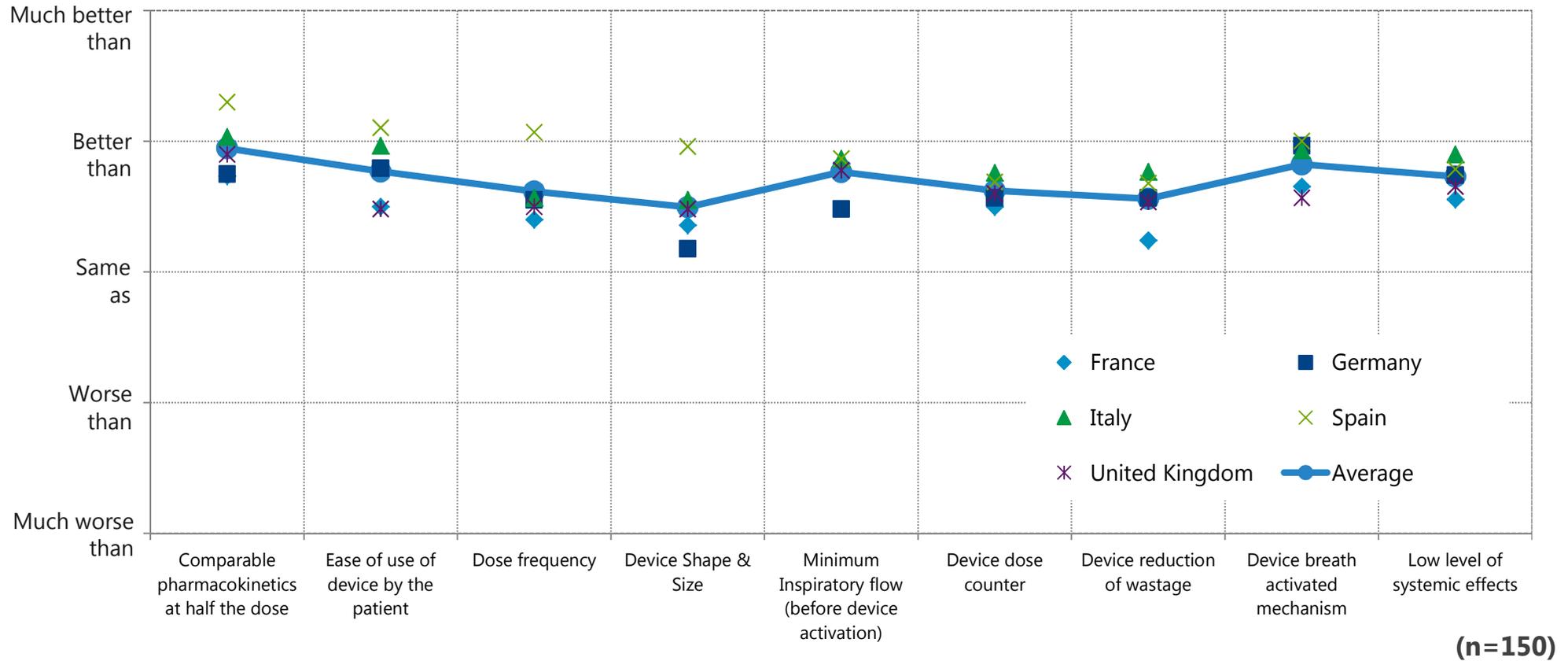
- To obtain regulatory advice and develop clinical strategy

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# Salmeterol & Fluticasone DPI

## EU Market Opportunity

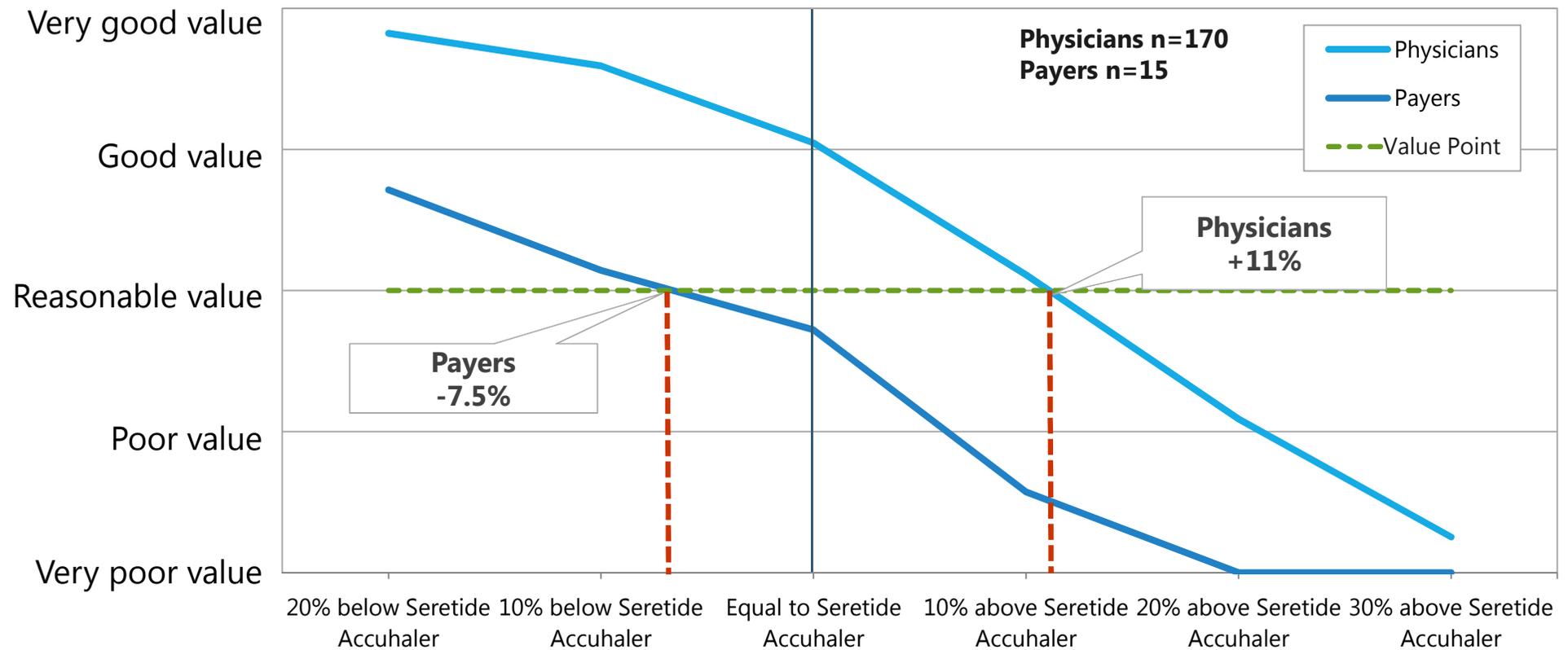
### Comparison to Seretide® Accuhaler® on Device Characteristics



On all characteristics SPARC DPI is viewed as better than Seretide® Accuhaler®#

# SPARC DPI Value Analysis

## EU Market Opportunity



Both physicians and payers suggest price parity to Seretide<sup>®</sup> Accuhaler<sup>®</sup>#



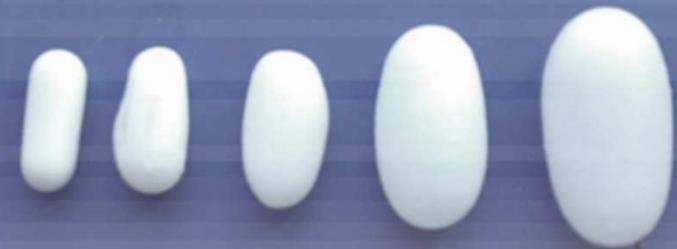
CNS

Baclofen GRS

# Baclofen GRS

- Extended release formulation of Baclofen with Proprietary Gastro Retentive Innovative Device (GRID™) technology
- Once daily, recommended fed state dosing for optimal bioavailability and minimal sedation
- Baclofen GRS will be available in 6 strengths i.e., 10 / 20 / 30 / 40 / 50 / 60 mg
- Patent portfolio comprising of formulation, once-a-day therapy and indication patents with last patent expiring in 2027

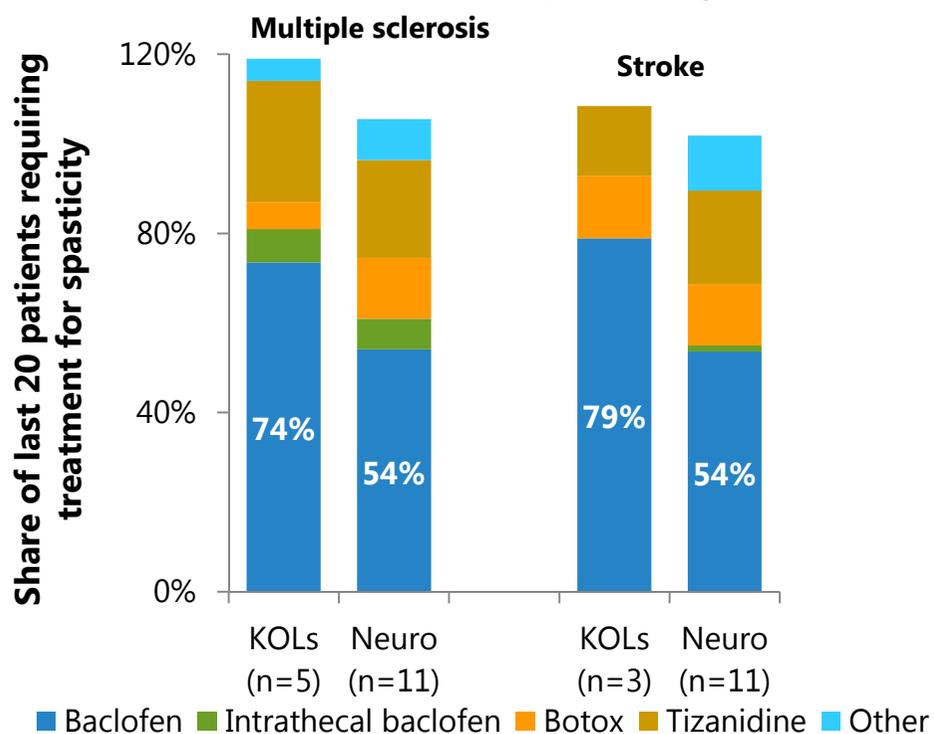
## GRID™ Technology



**Baclofen GRS swells 8 – 10 times upon ingestion**

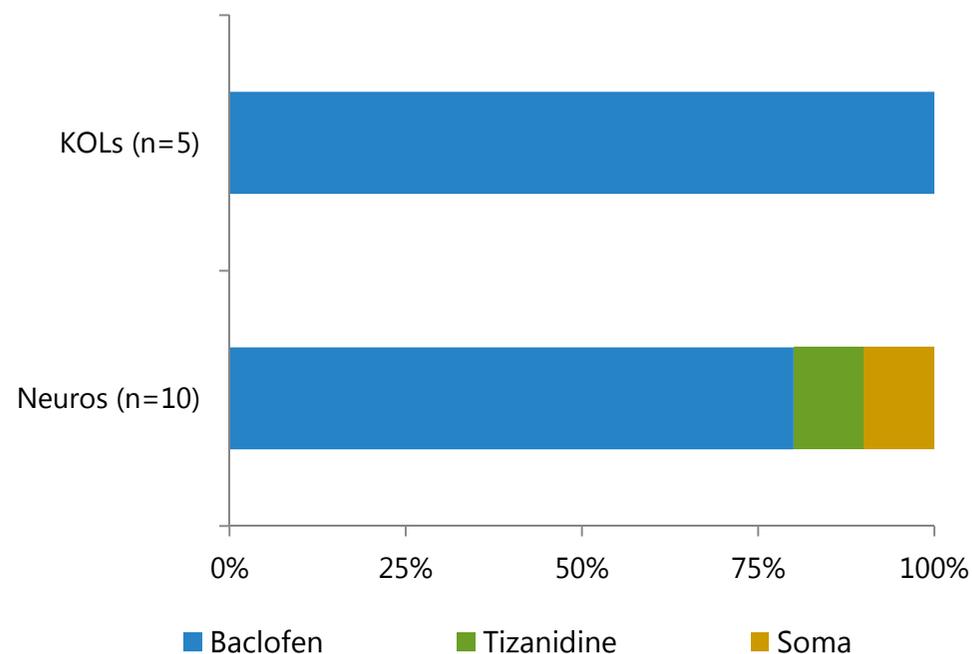
# Baclofen is the standard of care in spasticity

## Distribution of patients prescribed treatment for spasticity\*



> 50% of multiple sclerosis and stroke patients are prescribed Baclofen as anti-spasticity treatment<sup>#</sup>

## Proportion of respondents' who agree that Baclofen is the standard of care in spasticity

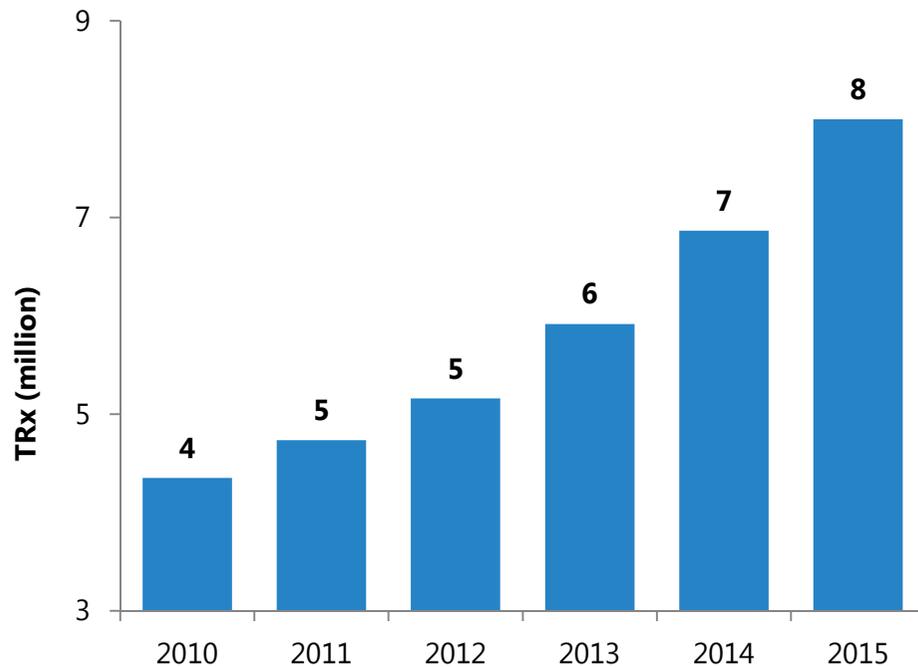


80% of KOLs and Neurologists agree that Baclofen is the standard of care for spasticity treatment<sup>#</sup>

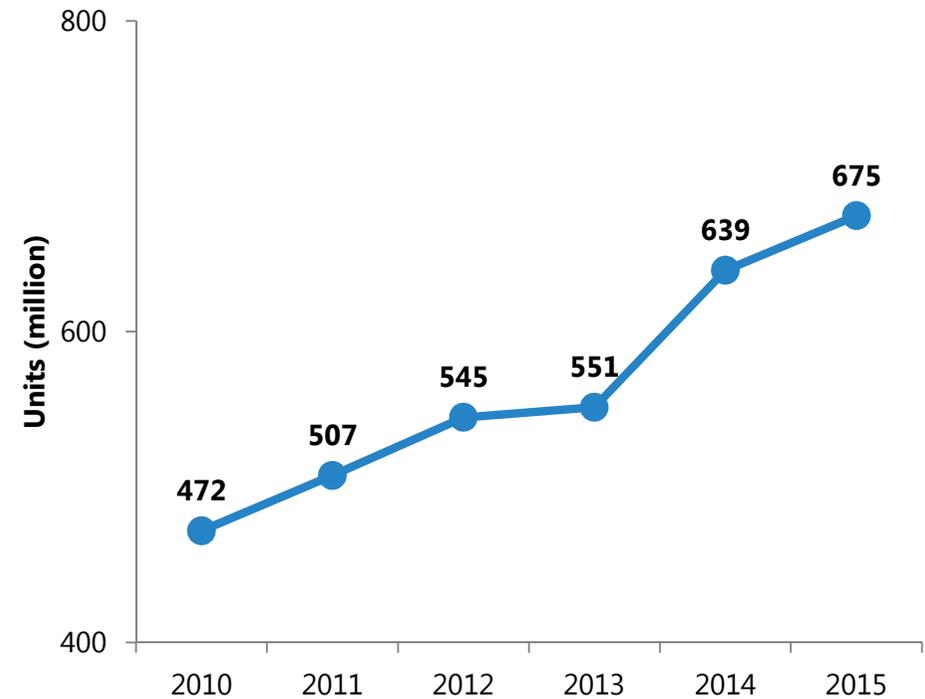
\* Values exceed 100% because of co-prescription

# Baclofen prescriptions doubled over last 5 years in US

## Baclofen Solid Oral Market (TRx)\*



## Baclofen Solid Oral Market (Units)\*



- 34% prescriptions from spasticity related neurological indications\*
- Baclofen GRS may be priced at significant premium over generics #

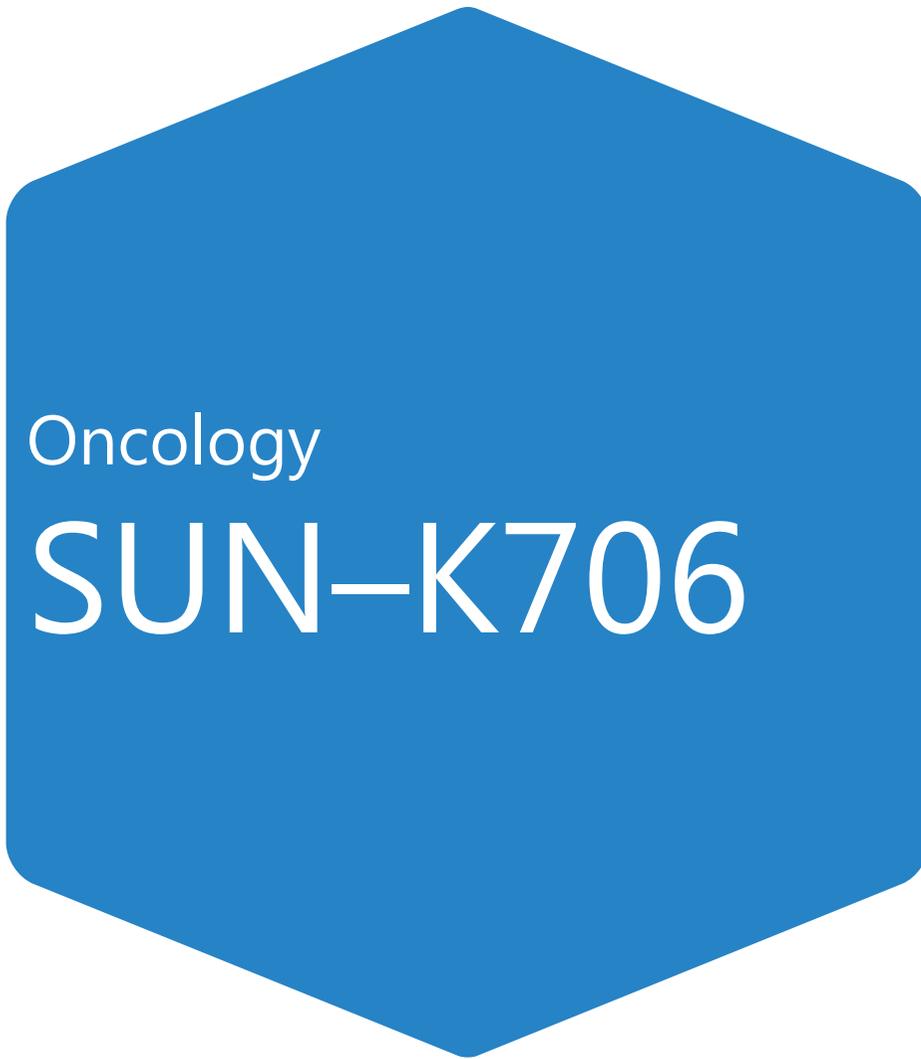
# Baclofen

## Development Status Update

- Accelerated execution of clinical studies under SPA<sup>#</sup> with FDA
  - Phase 3 efficacy study:
    - 49 sites recruiting patients; To add 25 more sites
    - 128 patients enrolled as of May'15
  - Open label safety study:
    - 193/200 patients enrolled
  - Duration of action study:
    - 59/135 patients randomized
- Targeted NDA filing by Q4, 2017 – 18\*

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# SPA=Special Protocol Assessment

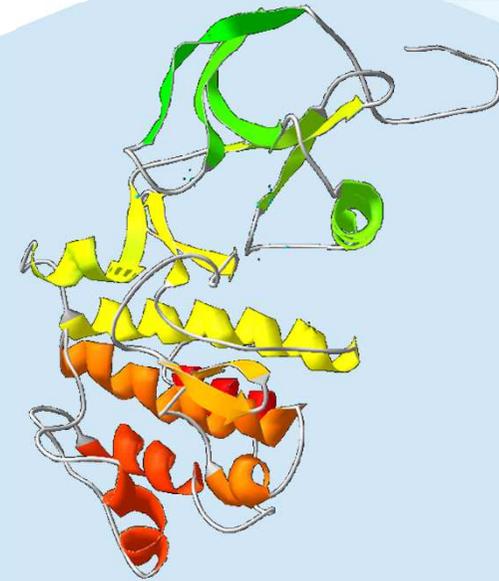


Oncology  
**SUN-K706**



# SUN-K706 targets treatment resistant CML

- SUN-K706 is a potent, orally active and highly selective Bcr-Abl Tyrosine Kinase Inhibitor (TKI)
- Significantly inhibits key Imatinib resistant mutants, including the T315I mutation
- Unlike Ponatinib, which is a multikinase inhibitor, SUN-K706 is selective for Bcr-Abl kinase and its mutants
- Being selective, SUN-K706 is less likely to have off-target side effects



**Bcr-Abl Kinase**

# SUN-K706 demonstrated favorable *in-vitro* profile

Kinases	IC <sub>50</sub> (nM)			
	SUN-K706	Ponatinib	Dasatinib	Imatinib
Abl	0.9	0.9	3.0	790
Abl(T315I)	3	0.9	NE	NE
VEGFR2	>300	13	>2000	NE

Cell Lines	IC <sub>50</sub> (nM)			
	SUN-K706	Ponatinib	Dasatinib	Imatinib
K562	0.5	0.3	0.1	150
K562-IR	2.6	0.4	0.8	9866
U937	NE	NE	NE	NE

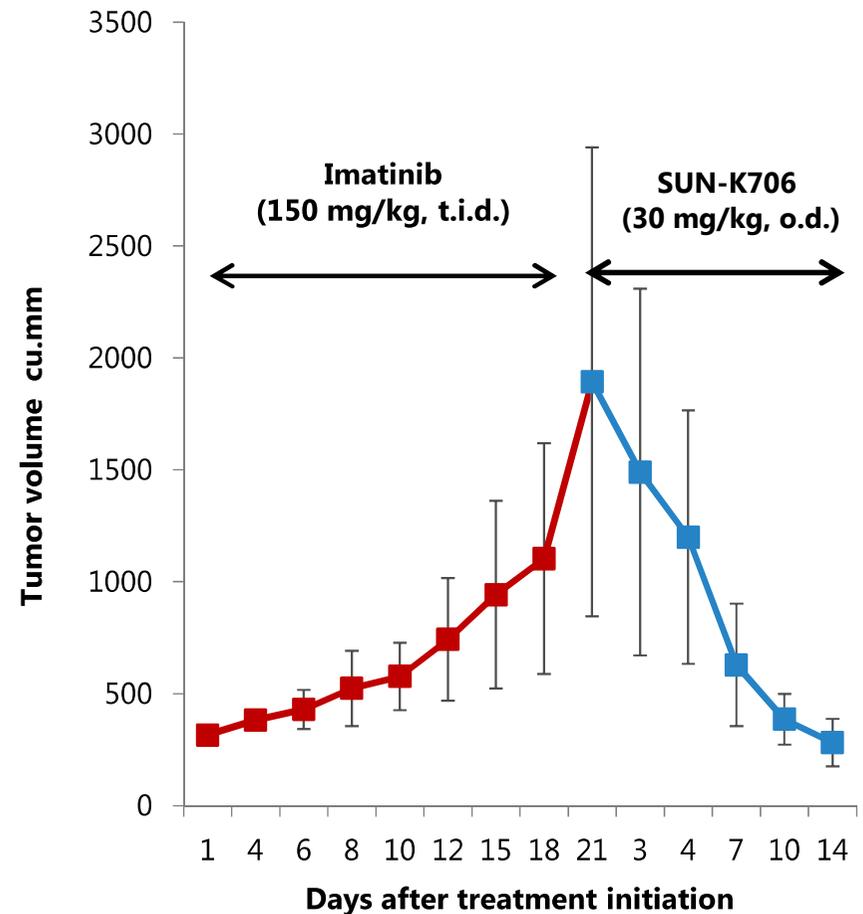
NE= Not effective (IC<sub>50</sub> = >10μM)

- SUN-K706 has potent activity against wild type BCr-Abl and the difficult to treat mutation viz. T315I
- Arterial thrombosis, a serious safety concern for Ponatinib, is attributed to VEGFR2 inhibition
- SUN-K706 may not exhibit similar safety concern

# SUN-K706 - significant efficacy in Imatinib resistant leukemia models

- Significantly prolonged survival of mice bearing patient-derived leukemia cell lines carrying either the wild type or T315I mutation-bearing Bcr-Abl
- Causes regression of large established xenografts of Imatinib resistant CML cells
- On oral administration shows consistent systemic exposure in different animal species
- Safety pharmacology data indicates that SUN-K706 has no adverse effect liability at multiples of efficacy doses on hepatic, neurologic, pulmonary and cardiac functions

## Antitumor activity against Imatinib Resistant K562 Xenograft



# SUN-K706

## Development Status Update

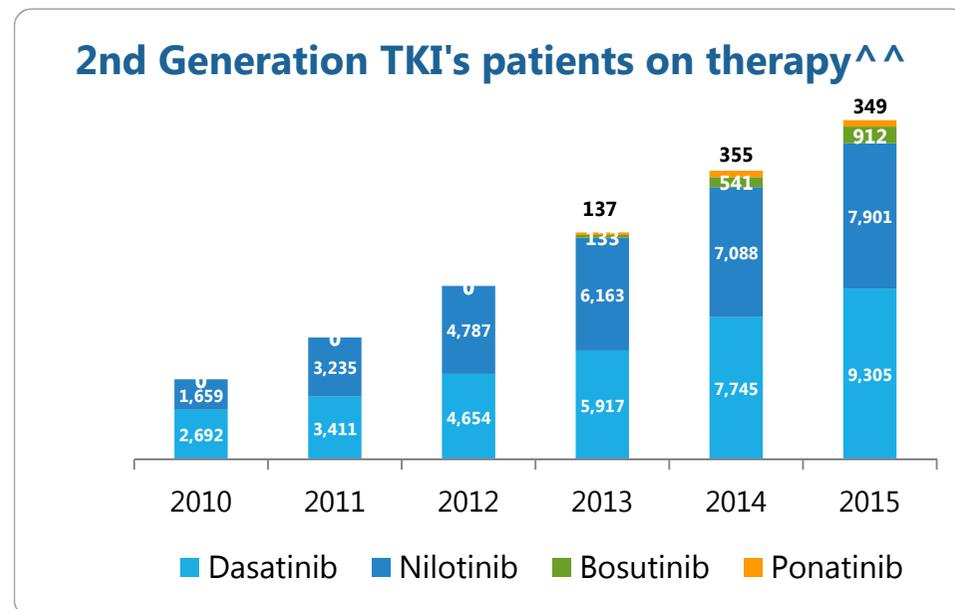
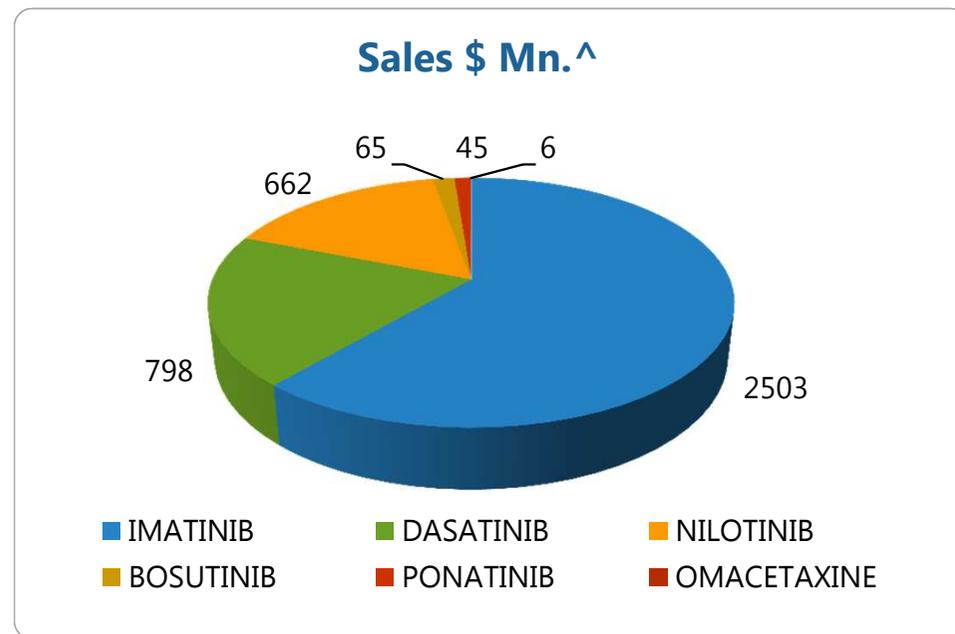
- Suitable formulation for clinical studies is optimized
- IND-enabling efficacy, safety, and toxicology studies completed
- IND filing by Q3, 2015-16\*

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# SUN-K706

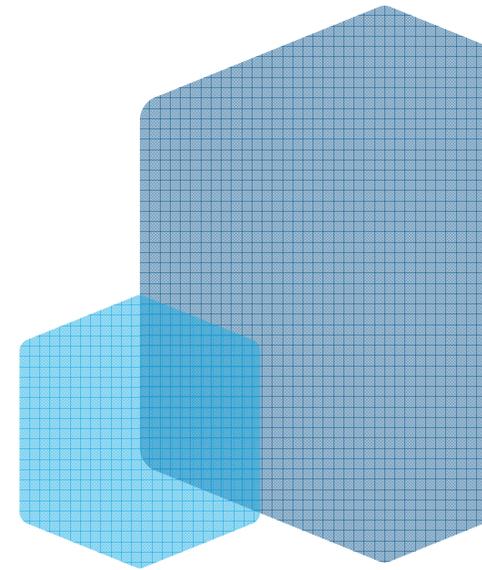
## US Opportunity

- Estimated 6500 new cases of CML are diagnosed every year\*
- The prescription trend suggests increase in use of 2nd line TKI inhibitors<sup>^</sup>
- T315I mutations incidence is as high as 40% in patients who failed second-line TKI therapy<sup>#</sup>
- Treatment gaps include better drugs to treat T315I mutation and drugs that treat advanced disease (accelerated phase or blast crisis) \$



Ophthalmology

# Brimonidine OD



# Brimonidine OD Ophthalmic Suspension

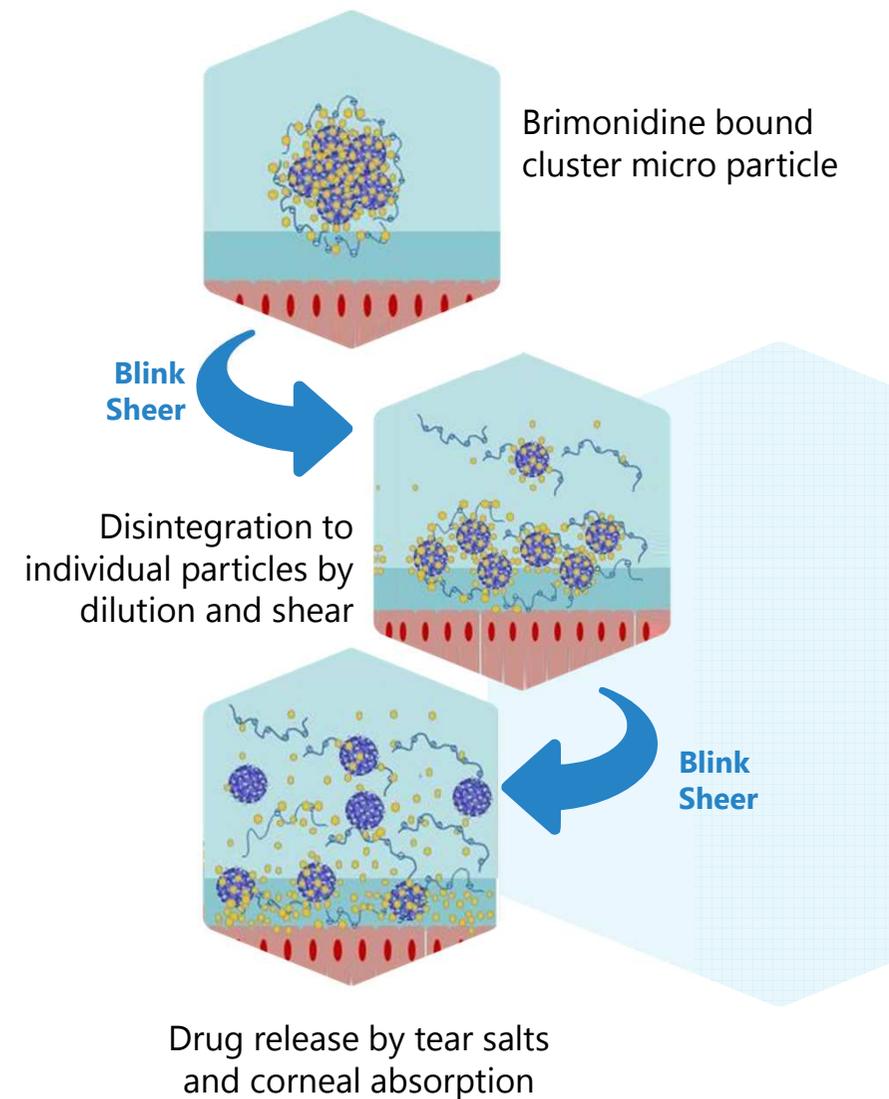
## Improving Patient Compliance

- Brimonidine is one of the most commonly used second-line treatment in Glaucoma
- Individual adherence to Brimonidine TID is highly variable and pharmacologically insufficient in more than 2/3rd patients\*
- SPARC is developing a novel once-a-day Brimonidine using proprietary NTC Ocular Technology
  - Controlled and maximal availability of drug to ocular surface
  - Reduces immediate exposure of drug
  - Free of gel forming polymers



# NanoTemplate Clusters (NTC) Ocular Technology

- NTC technology involves adsorption of water soluble drugs onto the nano templates
- NanoTemplate drug is formulated as microclusters
- Microclusters smear on ocular surface due to blink shear and embed in mucous layer
- Tear stimulus release permeable form of drug from template in the corneal vicinity
- The delivery and duration of drug is controlled and prolonged
- Coating-retention-penetration provides optimal ocular drug delivery and benefit



# Brimonidine OD Ophthalmic Suspension

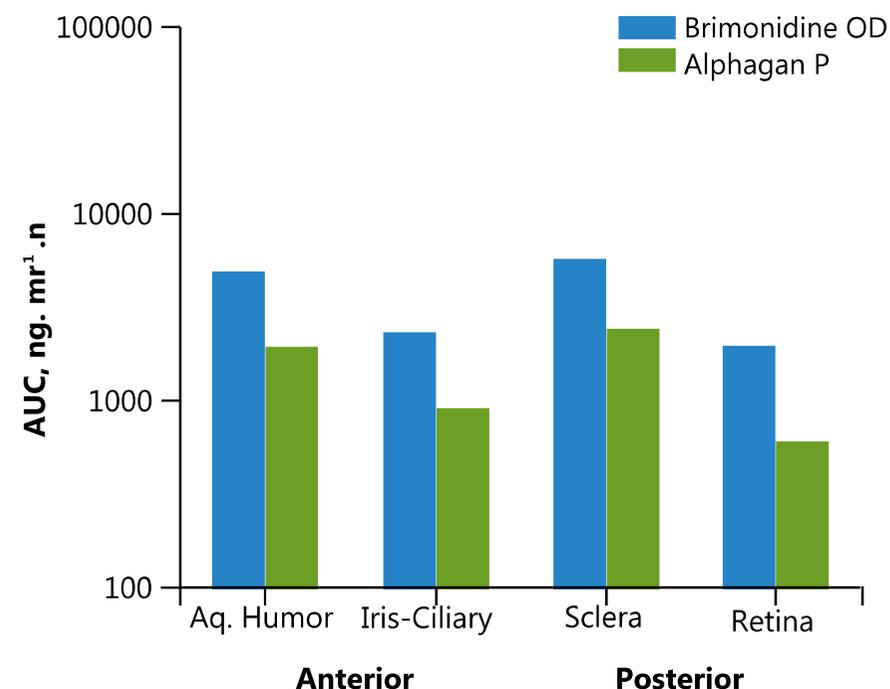
## Sustained IOP reductions achieved over 24 hours

Effect of Brimonidine OD on IOP of Ocular Hypertensive Rabbits

Peak* IOP reduction		Trough* IOP reduction	
SPARC OD	Alphagan® P TID	SPARC OD	Alphagan® P TID
8.0	6.6	4.6	2.8

\*Peak and trough IOP reduction are measured at 2-3 h and 23-24 h post 1<sup>st</sup> dose of the day

Comparable peak and trough IOP reduction (mm Hg) with Alphagan® P TID achieved



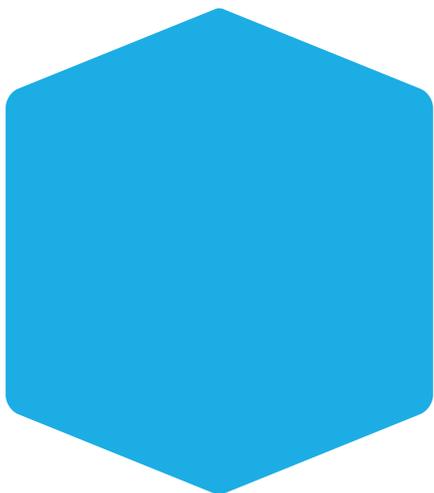
Higher exposure in posterior segment

# Brimonidine OD

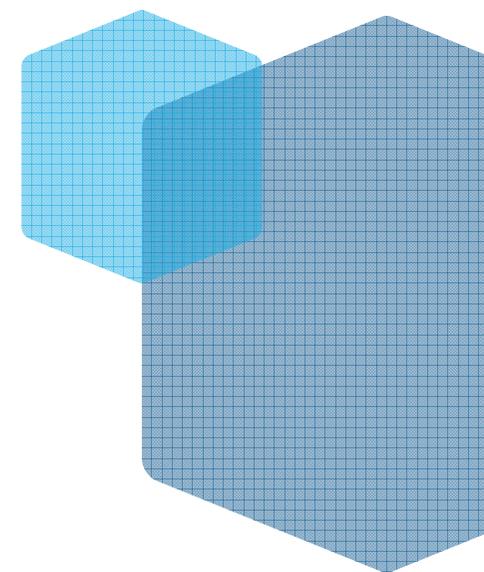
## Development Status Update

- Patent filed
- Pre-IND meeting completed
- IND filing by Q4 2015-16\*

\*Indicative timeline based on the current estimates of the management and are subject to change. The Company cannot assure that this indicative date will be achieved. The actual results, performance or achievements, could thus differ materially from those projected herein.

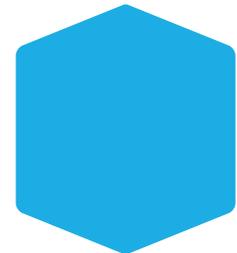


Dermatology  
**SUN-597**  
Topical



# SUN-597 Topical

- Topical steroids are the mainstay in the treatment of steroid-responsive dermatoses
  - 41 million prescriptions generated in US during 2014
- Long term use of topical steroids often results in severe & partially irreversible cutaneous adverse effects like skin atrophy<sup>#</sup>
- SUN-597 topical is a novel corticosteroid with improved safety profile
  - In preclinical models, demonstrated low potential for induction of skin atrophy
  - Showed better efficacy compared to low to mid potency steroids such as Triamcinolone
  - Efficacy was comparable with potent steroids such as Fluticasone and Clobetasol



# SUN-597 Topical

## Superior Efficacy in Psoriasis Animal Model

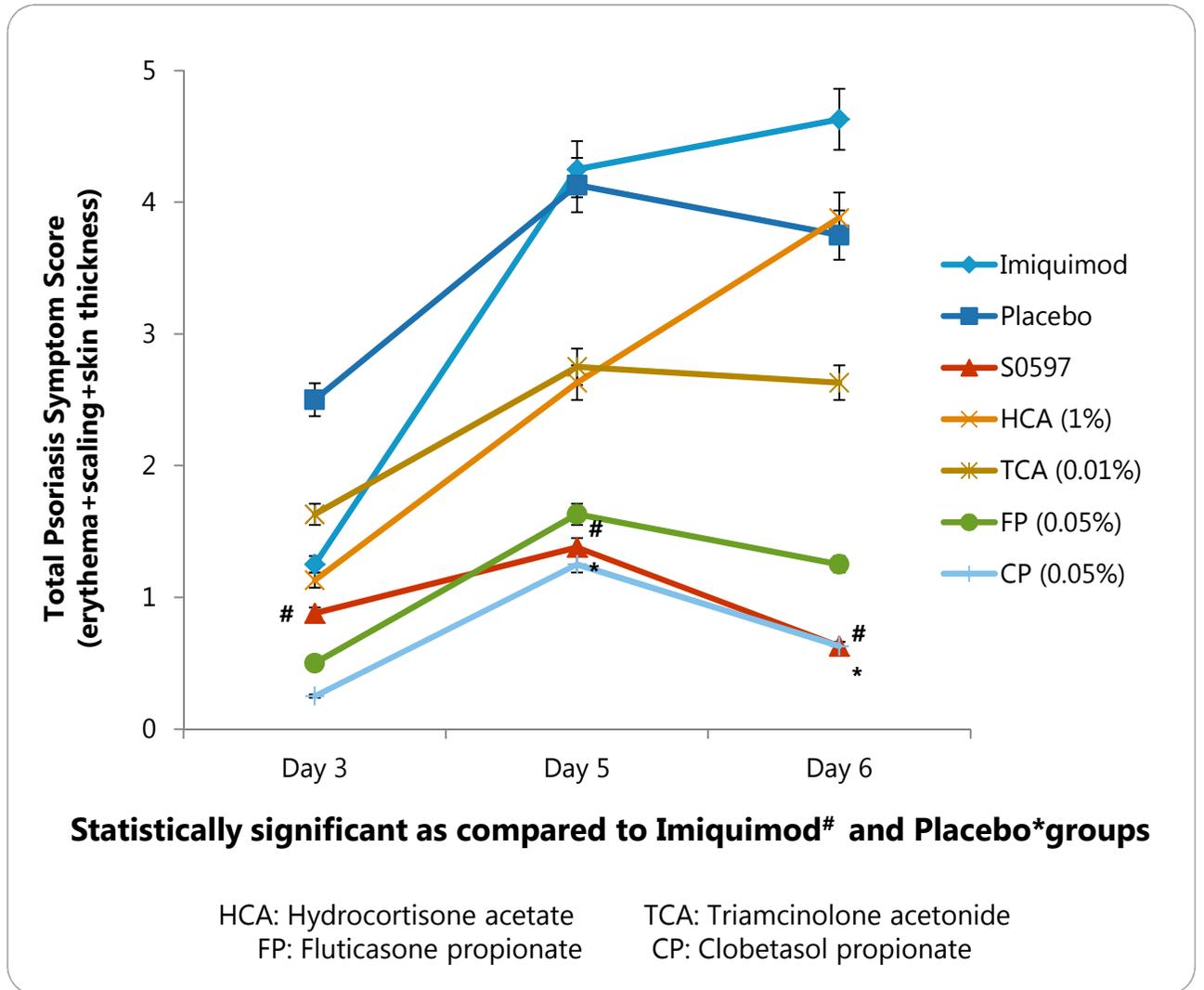
### Reduction of psoriasis symptom score

Superior to

- Hydrocortisone acetate
- Triamcinolone acetonide

Comparable to

- Fluticasone propionate
- Clobetasol propionate



# SUN-597 Topical

## Significant Reduction of Inflammatory Mediators

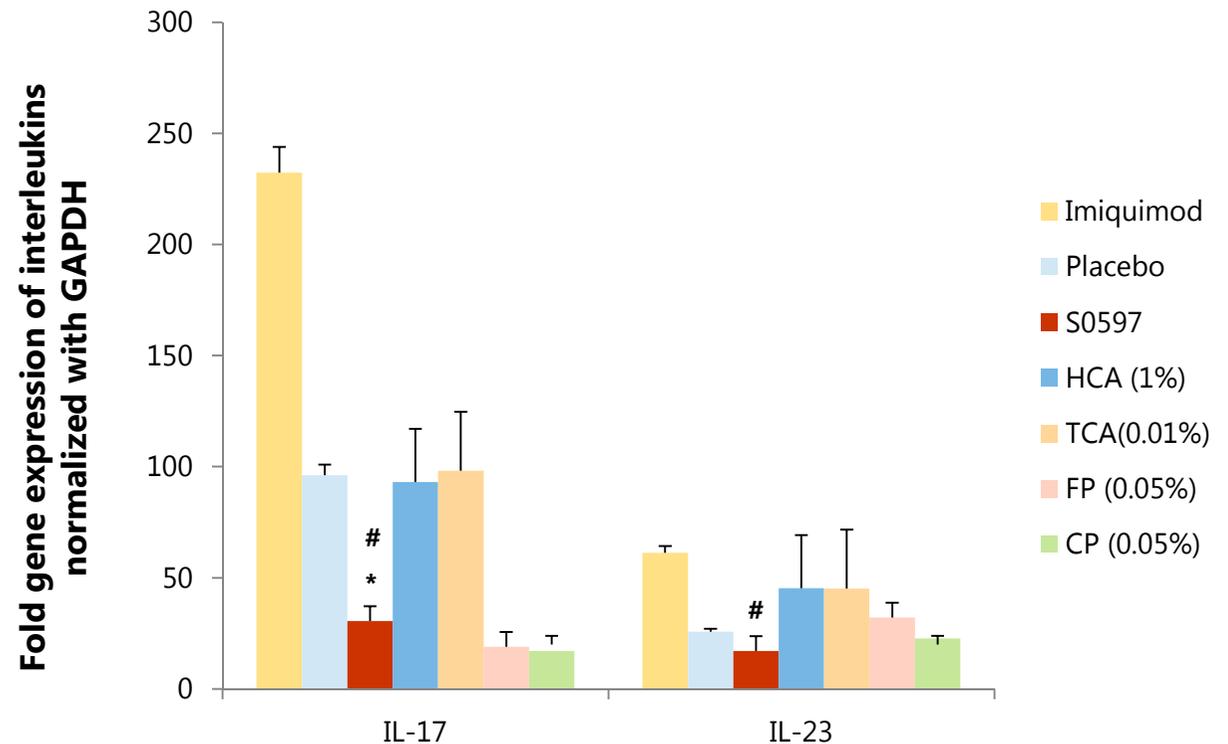
### Inhibition of inflammatory interleukins

Superior to

- Hydrocortisone acetate
- Triamcinolone acetonide

Comparable to

- Fluticasone propionate
- Clobetasol propionate



**Statistically significant as compared to Imiquimod\* and Placebo# groups**

HCA: Hydrocortisone acetate

FP: Fluticasone propionate

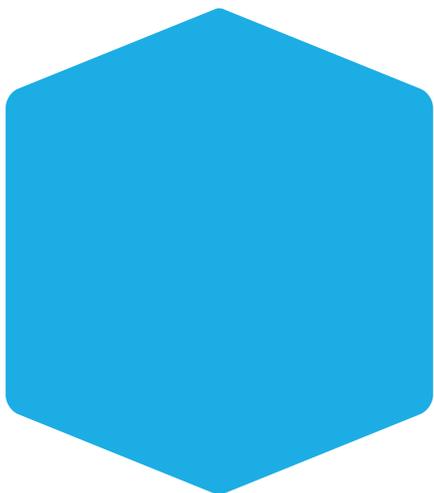
TCA: Triamcinolone acetonide

CP: Clobetasol propionate

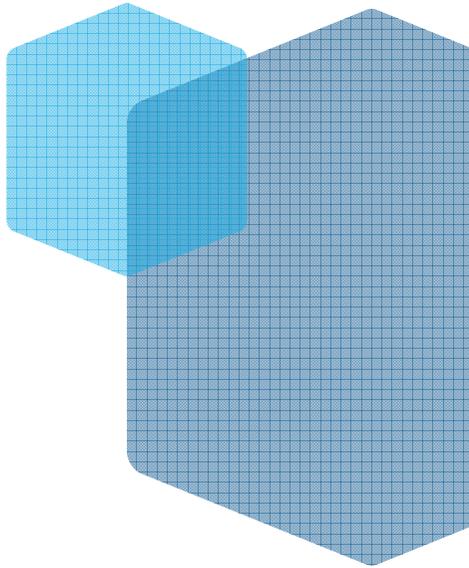
# SUN-597 Topical Development Status Update

- Pre-IND meeting with USFDA completed
- IND filing by Q2, 2015-16\*
- Phase 1 study to be initiated by Q3, 2015-16\*

\*Indicative timeline based on the current estimates of the management and are subject to change. The Company cannot assure that this indicative date will be achieved. The actual results, performance or achievements, could thus differ materially from those projected herein.



Dermatology  
**Minocycline**  
**Topical**



# Minocycline Topical

## Novel Treatment Option for Acne

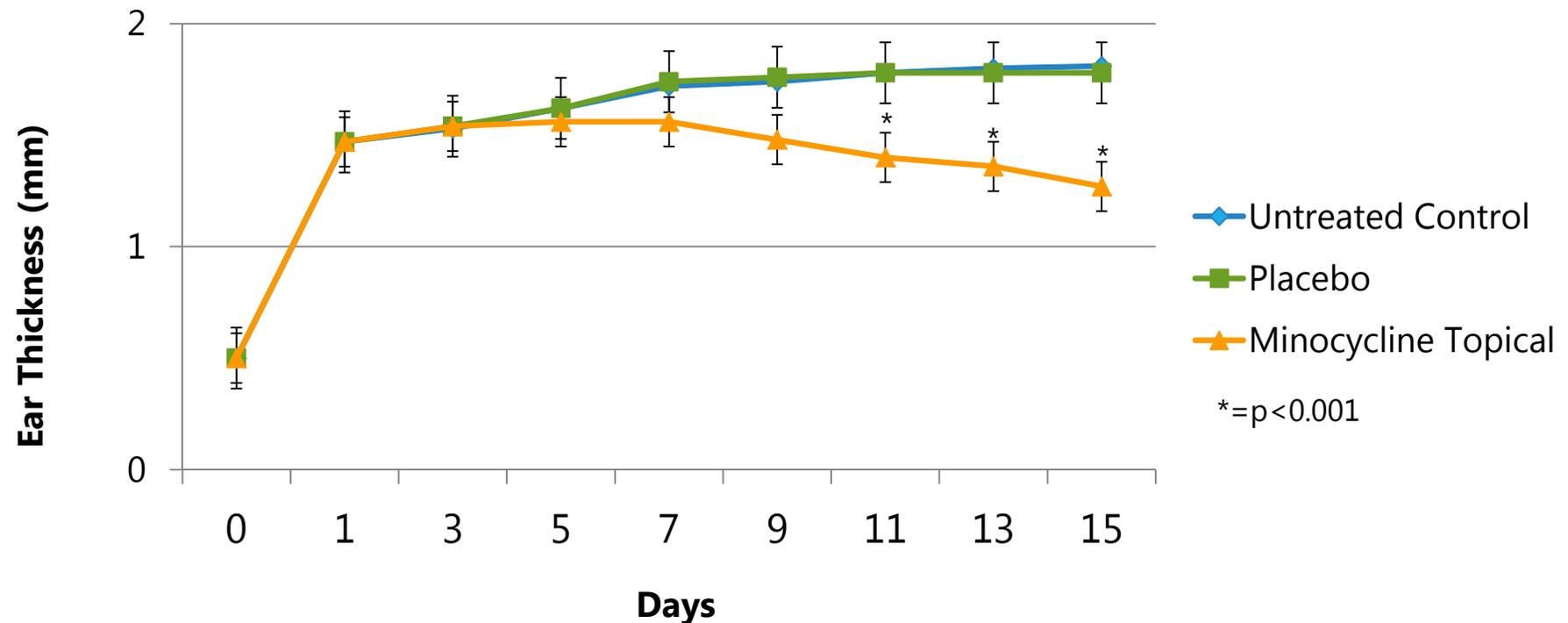
- Minocycline is one of the largest selling oral antibiotics in US for inflammatory Acne
  - In 2014, estimated 3 million prescriptions were generated for oral Minocycline in USA for Acne<sup>#</sup>
- Oral Minocycline is associated with various systemic side effects like, GI upset, candidiasis, benign intracranial hypertension, hepatotoxicity, dizziness etc.\*
- SPARC's novel topical Minocycline provides an effective & safer alternative for Acne
  - Better Dermatokinetics
  - Reduced systemic exposure
  - Potentially active in both inflammatory and non-inflammatory Acne lesions



# Minocycline Topical

## Pre-clinical POC established in Acne model

- In P. Acne SD rat model ~28% reduction in ear thickness compared to placebo at day 15
- Patents filed for the novel composition

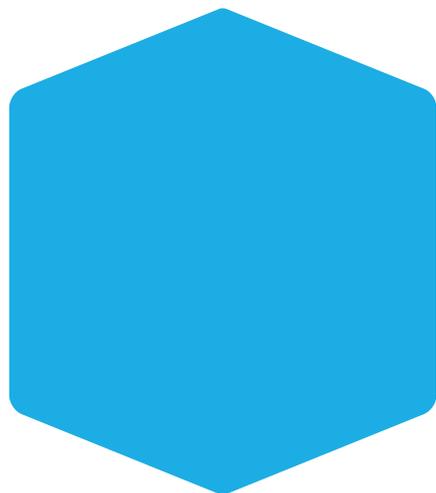


# Minocycline Topical

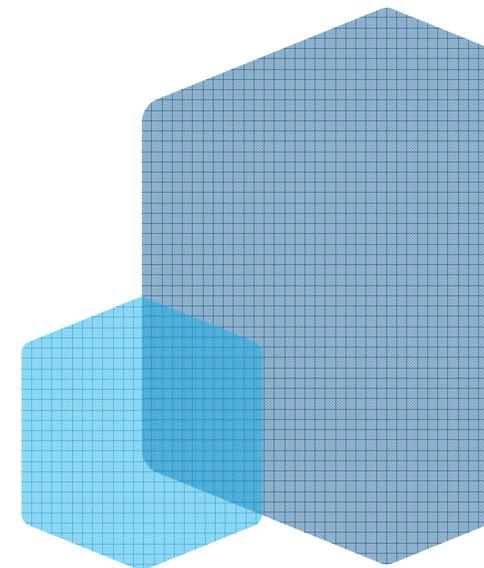
## Development Status Update

- Pre-IND meeting planned in Q3 2015-16\*
- IND filing by Q1 2016-17\*

\* Indicative timeline based on the current estimates of the management and are subject to change. The Company cannot assure that this indicative date will be achieved. The actual results, performance or achievements, could thus differ materially from those projected herein



CNS  
Tizanidine ER

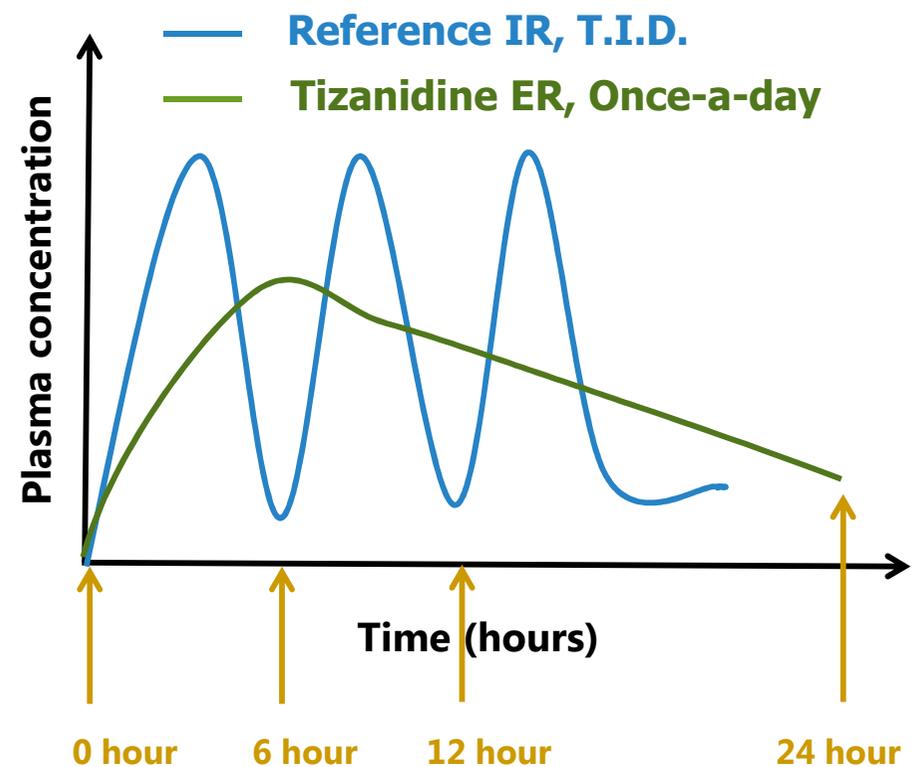


# Tizanidine ER for Musculoskeletal Pain

## Optimizing PK to improve safety profile

- Tizanidine IR is used in management of spasticity and Pain
- Estimated 4.4 million Tizanidine prescriptions generated in US for Musculoskeletal pain\*
- Tizanidine has a short duration of action hence requires 3 to 4 times dosing per day.
- Tizanidine use is limited due to side effects like orthostatic hypotension, somnolence, cognitive function impairment
- 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

- Pre-IND meeting with FDA completed
- Pilot PK study completed
- Phase 2 studies are planned in 2015 – 16\*

\*Indicative timeline based on the current estimates of the management and are subject to change. The Company cannot assure that this indicative date will be achieved. The actual results, performance or achievements, could thus differ materially from those projected herein.



# Abuse Deterrent Formulations (ADF)

# Abuse Deterrent Formulations Opportunity

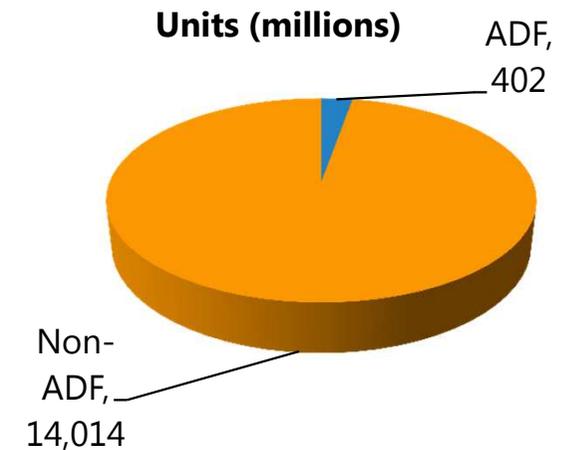
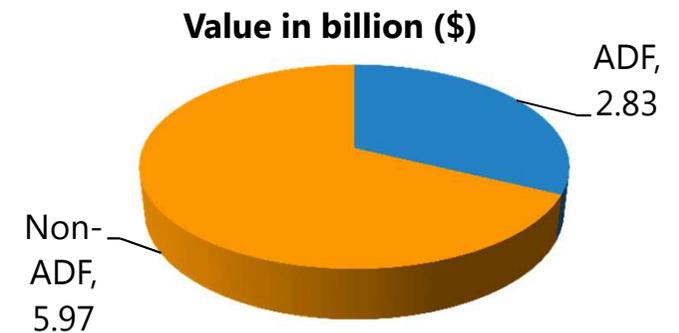
## Opioid abuse: an epidemic in the United States...

- FDA considers the development of abuse deterrent opioid analgesics a high public health priority
- Opioid analgesics were involved in about 348,000 ED visits in 2011 in the USA<sup>@</sup>
- Deaths from prescription painkiller overdose have risen by 300% over the past decade from 1999 to 2012<sup>\*</sup>
- Regulatory environment strongly indicates future development of controlled substance formulations to be abuse-deterrent

## Opioids Market in US

- Prescription opioids hold ~50% market share in the US analgesic market. Total opioids market is estimated to be \$9 billion<sup>^</sup>
- Marketed ADF constitute 3% of unit sales but command 32% of value share

### USA Opioid market ADF Opportunity



# Abuse Deterrent Formulations

## Development Strategy and Plan

- SPARC identified an interesting opportunity in ADF
- Preliminary proof-of-concept results encouraging
- Conceptual meeting with FDA completed
- Patents filed

# SPARC R&D Pipeline



USA/ EU India

For updates and specific queries,  
please visit [www.sunpharma.in](http://www.sunpharma.in) or  
contact

**Mira Desai**

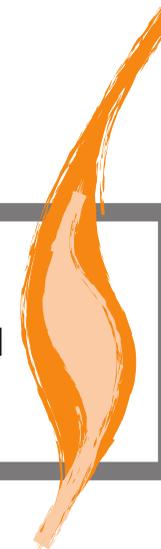
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