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Investor Update on R&D Pipeline

25th March 2013

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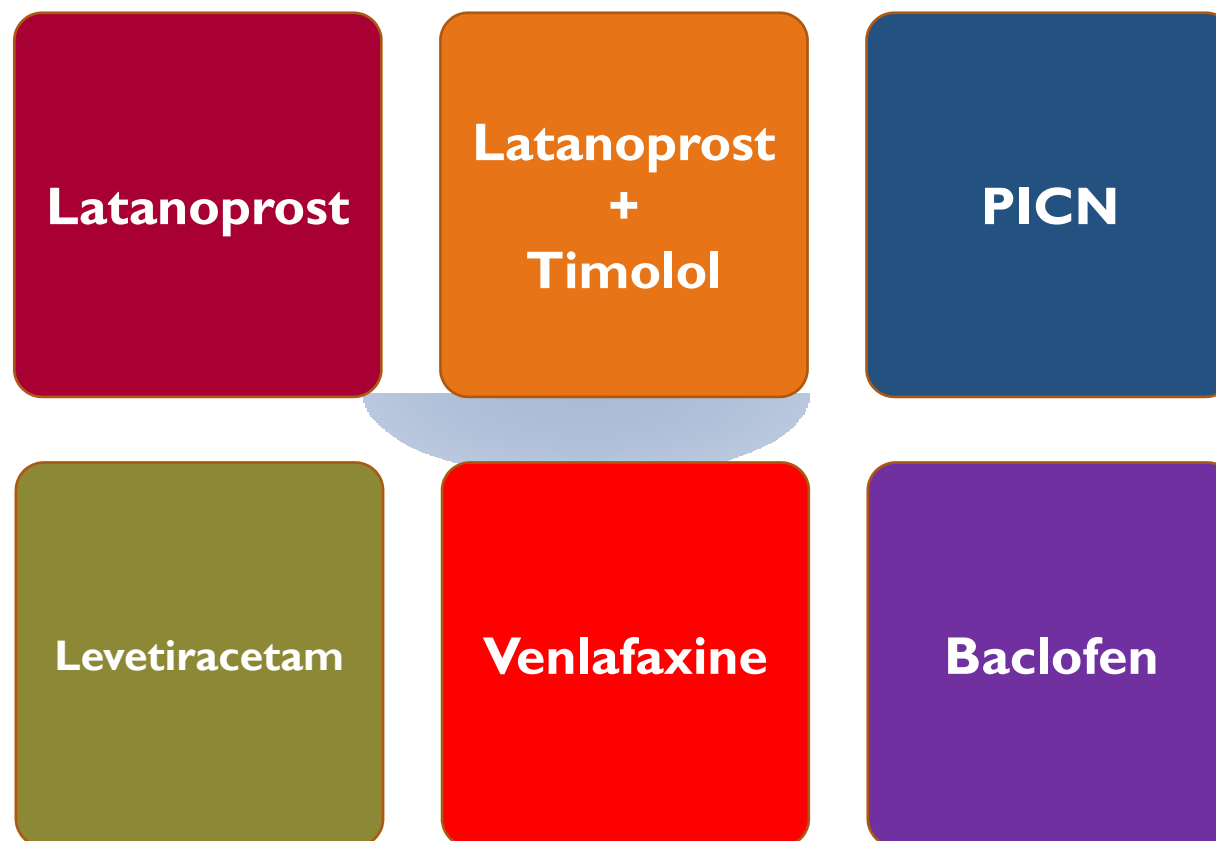
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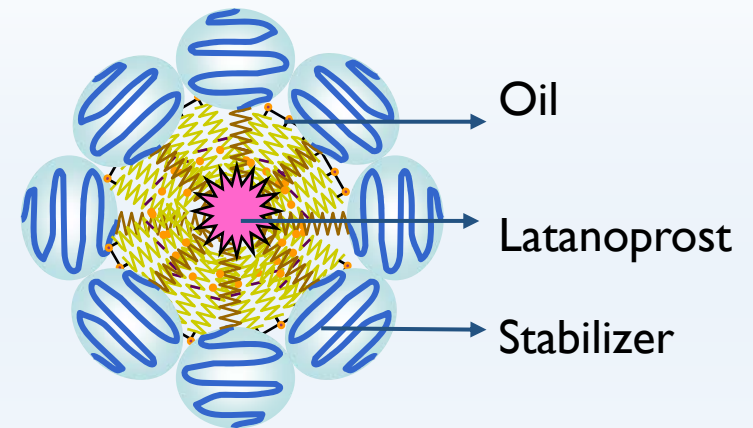
Lead NDDS Programs



Latanoprost “BAK Free” Ophthalmic Solution



- Clear, colorless, BAK-free ophthalmic solution
- Reduced risk of ocular surface damage on chronic use
- Expected to show benefits in Chronic Glaucoma patients with dry eyes
- Storage at room temperature



“Swollen Micelle Microemulsion”

Phase III Studies in US –Data Supports NDA

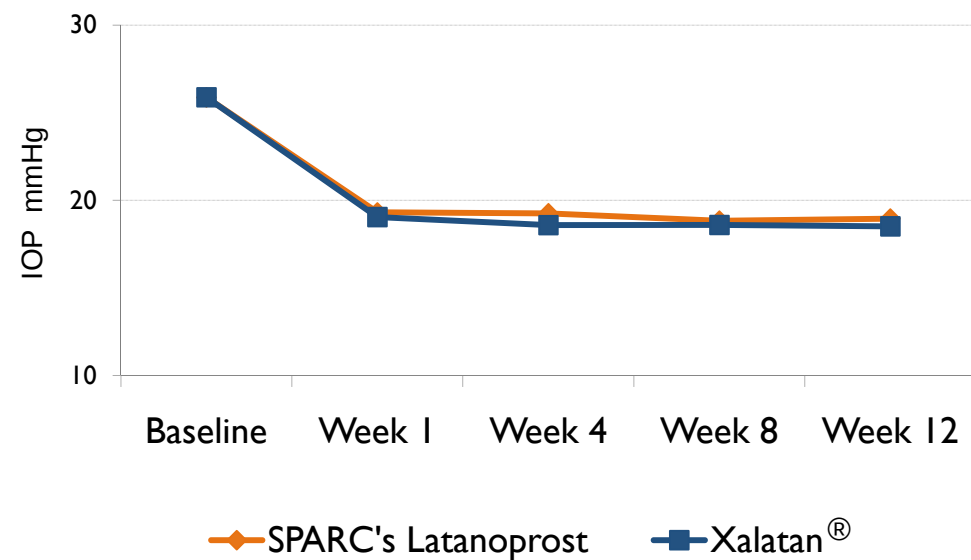


Completed 2 phase III studies in the US

- 590 patients in efficacy and safety study
- 149 patients in open label safety study

- SPARC's Latanoprost could meet the non-inferiority criteria of 1.5 mmHg at all time-points and 1 mmHg at 4 time points
- The reduction in IOP from baseline for SPARC Latanoprost was approx. 6 to 7 mmHg at all 12 time points
- IOP reduction comparable to Xalatan[®]
- Data shared with FDA in a Pre-NDA meeting

Mean IOP with SPARC's Latanoprost and Xalatan[®]



Future development plan



US –505(b)(2) route

- PreNDA meeting completed with USFDA in February 2013
- NDA filing in Q2 FY14

ROW

- Select EM filing planned in FY14

Latanoprost and Timolol OD Ophthalmic Solution



- Combination of essential elements of the two ophthalmic platforms
 - GFR technology
 - BAK-free and Surfactant free
- Once a day dosing
- Product with characteristics similar to natural tears
- Storage at room temperature

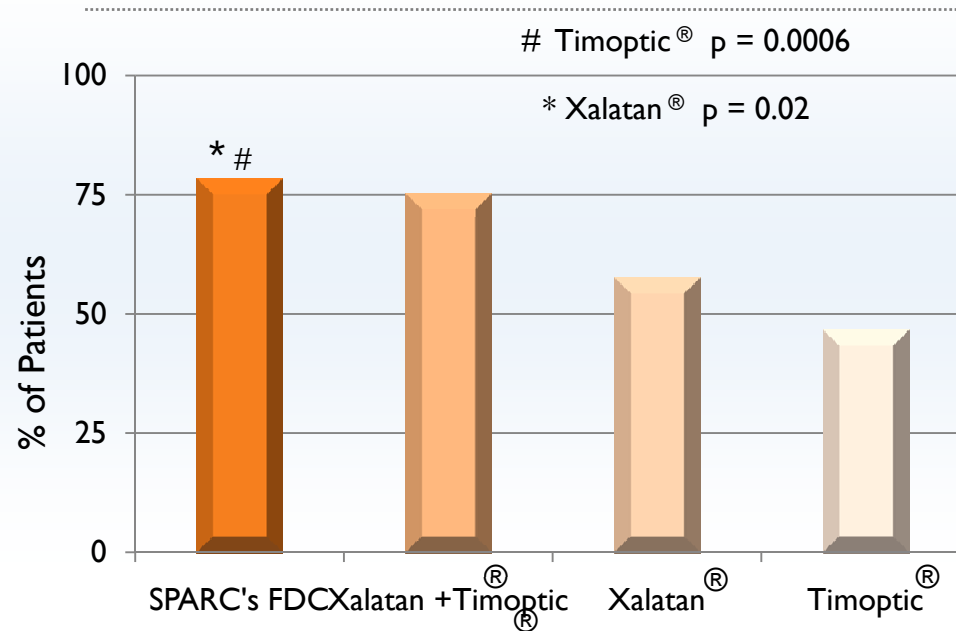
Significantly higher responder rates compared to Xalatan® and Timoptic®



Phase III study in 227 patients comparing SPARC's Latanoprost / Timolol OD FDC with Timoptic®, Xalatan® and Concomitant therapy

- Improved reductions in IOP with SPARC's FDC compared to Xalatan® and Timoptic® alone.
- Significantly higher responder rates compared to Xalatan® and Timoptic®
- Efficacy of SPARC's FDC met non-inferior criterion of +/- 1.5 mmHg with concomitant therapy of Xalatan® once daily + Timoptic® twice daily
- Safety of SPARC's FDC was comparable to concomitant therapy

Responders Rates = % Patients with IOP ≤ 18 mmHg at atleast 2 time points at all visits



Future development plan



- EU scientific advice planned in Q2 FY14
- Filed in India in Q3 FY13

Paclitaxel Injection Concentrate for Nanodispersion (PICN)



Novel formulation of Paclitaxel using SPARC's proprietary nanotectonsTM platform technology

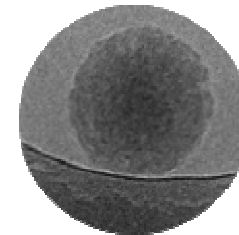
- Cremophor[®] and Albumin free formulation
- Unlike ABRAXANE[®], quick and easy “one step” dilution and infusion preparation



PICN as How Supplied



**PICN after
Reconstitution**



**Electron microscope
image of nano particle**

PICN is now clinically tested in 200 patients in over 959 treatment cycles



- Premedication with steroids or antihistamines – Not required
- No significant hypersensitivity reactions noted in any patient
- No new or previously unreported toxicities with Paclitaxel observed in any patient

Clear efficacy in advanced breast cancer in a Phase 2/3 study

Demonstrated comparable efficacy to ABRAXANE® :
Independent radiological assessment*

	PICN 295mg/m² n= 40 (%)	PICN 260mg/m² n=48 (%)	ABRAXANE® 260mg/m² n=42 (%)
Objective response rate (ORR)	19 (48)	17 (35)	16 (38)
Stable Disease	14 (35)	18 (38)	14 (33)
Progressive disease	7 (18)	13 (27)	12 (29)

* Out of 180 patients, 25 patients were not evaluable for efficacy at Cycle 2. Of the remaining 155 patients, 145 patients data were available for independent radiological assessment. 15 of these did not qualify for response assessment

Lower Grade 3 / 4 AEs at equivalent doses compared to ABRAXANE®



	PICN 295 (N = 58) n (%)	PICN 260 (N = 64) n (%)	ABRAXANE® (N = 58) n (%)
Blood and lymphatic system disorders			
Neutropenia	14 (24)	6 (9)	12 (21)
Leukopenia	7 (12)	5 (8)	8 (14)
Febrile Neutropenia	5 (9)	2 (3)	3 (5)
Nervous system disorders			
Peripheral sensory neuropathy	11 (19)	4 (6)	7 (12)

Grade 3/4 AEs with at least 5 % subjects in any treatment group are presented in this table.

Future development plan

US –505(b)(2) route

- To share safety and efficacy data with FDA and obtain guidance for registration

India

- To file with DCGI for approval in Q1 FY14

Lead Oral NDDS Programs

Levetiracetam

Venlafaxine

Baclofen

Levetiracetam ER 1000mg / 1500mg

- Levetiracetam - An Antiepileptic with high water solubility and very large dose
- Development of 1500 mg and 1000 mg once a day product with SPARC's proprietary *Wrap Matrix*® Technology
- Low Excipient to Drug ratio enabled a relatively small and acceptable size of the tablet
- NDA filed in US under 505(b)(2) route in Q1 FY13



Wrap Matrix®

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

Venlafaxine ER 300mg

- Venlafaxine ER employs SPARC's proprietary *Wrap Matrix*® technology
- Venlafaxine ER lower strengths 37.5mg, 75 mg and 150mg are already approved in US and EU
- NDA filed in US under 505(b)(2) route in Q4 FY13



Other Products with Wrap Matrix™ Technology



A skeletal muscle relaxant with ultra short half-life

- Target product profile includes better therapeutic action over repeat dose available IR product
- Target added benefit - less side effects due to reduced “peak and trough” plasma levels.
- PK studies ongoing
- Clinical trial planned in Q3 FY14

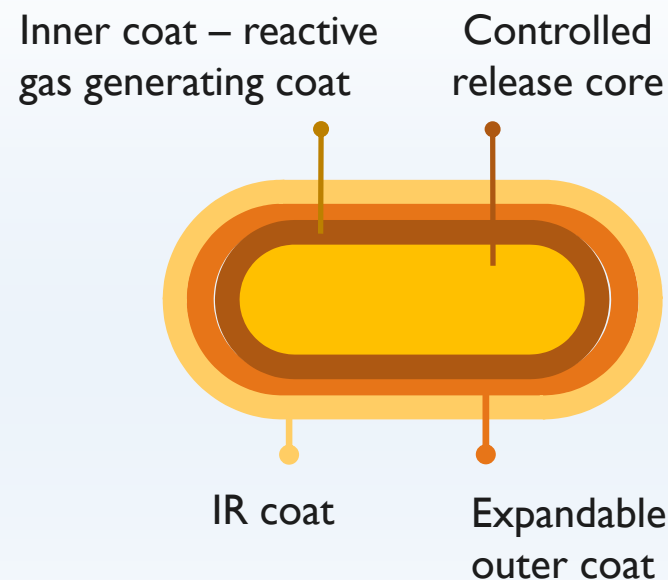
CNS Agent : new indication

- Proof of concept studies completed
- PK studies are ongoing

Baclofen GRS

- Extended release formulation of Baclofen with Proprietary Gastro Retentive Innovative Device (GRID™) technology
- Once daily and 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 for individualized dosing and greater dose flexibility
- Offers a steady therapeutically effective level for spasticity
- Patent portfolio comprising of formulation , once a day therapy and indication patents with last patent expiring in 2027

GRID™ Technology



Baclofen GRS - Current Status for Spasticity

US –505(b)(2) route

- Phase III, randomized, placebo-controlled efficacy study in 300 patients :
 - A special protocol assessment (SPA) was completed with FDA
 - 20 sites actively recruiting patients
 - Plan to increase no. of sites to speed up study completion
- Open label safety study in 200 patients
- 135 patients PD study to prove once a day dosing

India

- Baclofen GRS is registered and marketed in India

Baclofen GRS for Alcohol Dependence

- Clinical study in 180 patients for use of Baclofen GRS to treat Alcohol Dependence is completed in India
 - Results expected in Q1 FY14
 - Phase 2 dose finding study planned in EU in Q2 FY14
-



Lead NCE Programs



SUN-597

SUN-L73 I

SUN-K706

SUN-597 Nasal – Excellent safety demonstrated in a Phase I clinical study



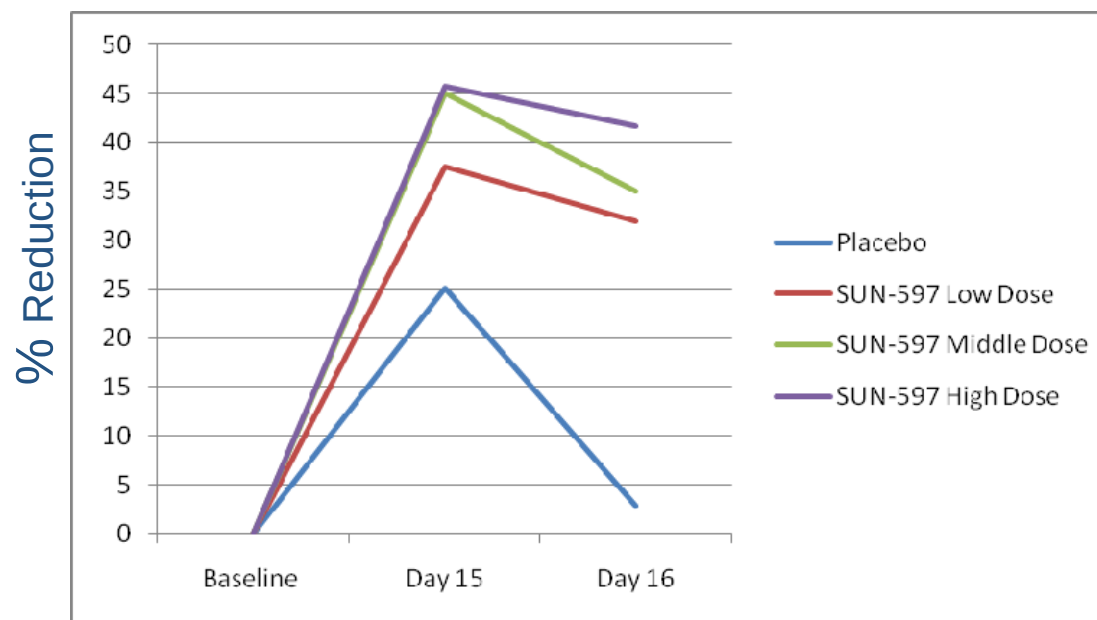
- Phase I studies (dose escalation, both single dose and repeat dose) in healthy human subjects for assessing the safety of SUN-597 nasal have been completed in India.
- In Phase I multiple dose escalating study, SUN-597 was found to be safe and well tolerated when given up to doses of 3200 mcg/day for 14 days.

SUN-597 Nasal – Encouraging efficacy data in a Phase II study in Rhinitis



- At all dose levels SUN-597 demonstrated encouraging efficacy in relieving nasal symptoms
- No significant differences in safety parameters between SUN-597 and placebo.
- Efficacy comparable to literature reported data of Fluticasone and Mometasone.

% Reduction in Nasal Symptoms with 14 days treatment

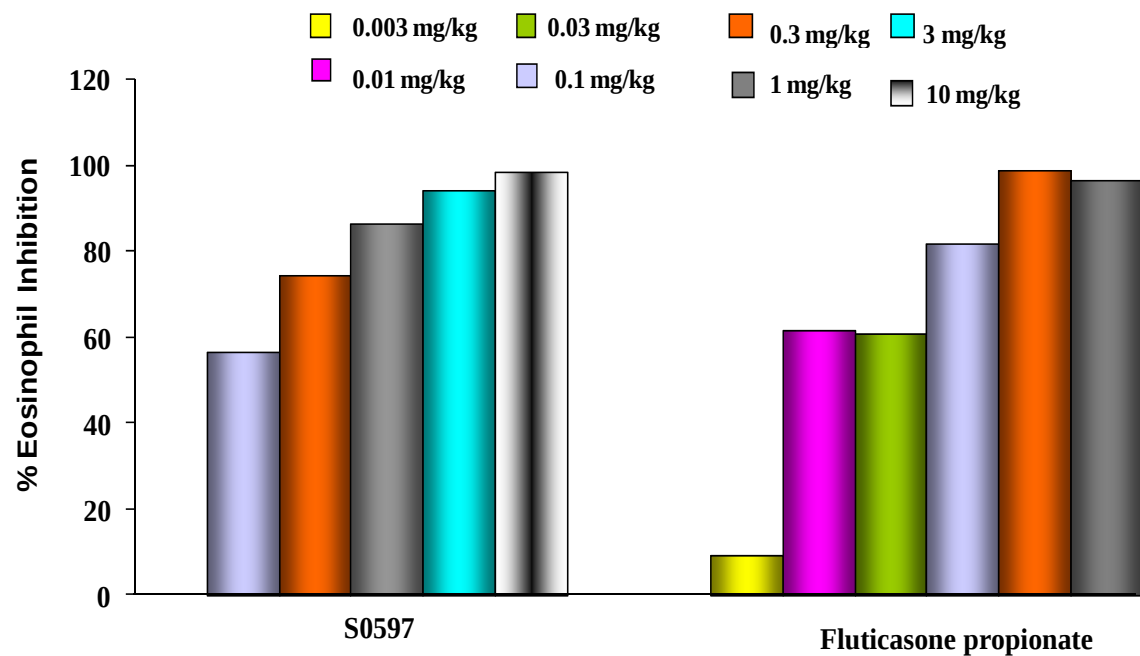


SUN-597 Nasal - Future development plan



- Pre-IND meeting with USFDA with proposed phase IIb study for identification of optimum dosage and dosing regimen - Q2 FY14
- Plan to initiate study in Q3 FY14

SUN-597 Inhalation - Efficacy in Allergen-Induced Asthma



Dose-dependent inhibition of eosinophilia in lung lavage of asthmatic rats by SUN-597

Treatment	ED ₅₀ (mg/kg, i.t.)
SUN-597	0.027
Fluticasone Propionate	0.014

SUN-597 Inhalation- Safety Advantage –Lung inflammation



Therapeutic Indices in Side Effect Models in Rat

Thymus Involution Dose: 3 mg/kg, 2 days, intratracheal

Treatment	ED ₅₀ Thymus/ ED ₅₀ Lung Edema
SUN-597	92.5
Fluticasone Propionate	4.19

Liver Glycogen Deposition Dose: 3 mg/kg, 3 days, intratracheal

Treatment	Glycogen deposition (mg/100g liver wt.)
SUN-597	11
Fluticasone Propionate	1956

**Safety index of SUN -597 is ~ 22 times higher than
Fluticasone Propionate**

SUN-597 Inhalation- Safety Advantage



SUN-597 has extremely low oral bioavailability in rats

As significant proportion of orally inhaled steroids are swallowed and absorbed from the GIT, low oral bioavailability has significance for low systemic side effects.

Some portion of inhaled steroid gets absorbed from lungs.

SUN-597 on direct administration to lungs cause non-significant thymolysis (biomarker of systemic side effect) and glycogen deposition (biomarker of steroid-induced diabetes).

Above outcomes of safety studies coupled with optimal efficacy in asthma model indicate that SUN-597 has a wide therapeutic index for local anti-inflammatory efficacy to undesired systemic side effects.

SUN-597 Inhalation- Future development plan



- Clinical Trial Application filing planned in Q2 FY14
- Proposed clinical studies to be conducted in Europe
 - Phase Ia-Single dose in healthy for tolerance and safety
 - Phase Ib-Multiple dosing in mild asthmatics to assess efficacy trend and dose response. Multiple efficacy and pharmacodynamic parameters will be assessed

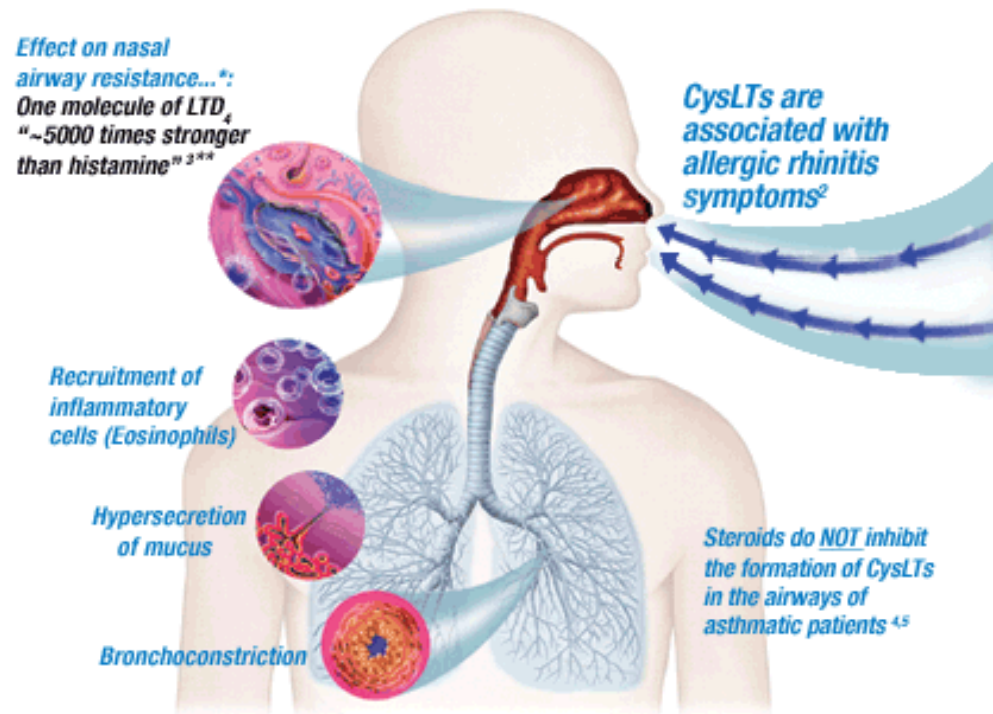
Cys-Leukotrienes (CysLTs) in asthma and allergic rhinitis

In asthma:

- CysLTs-mediated effects include airway edema, smooth muscle contraction, and altered cellular activity associated with the inflammatory process.

In allergic rhinitis:

- CysLTs are released from the nasal mucosa after allergen exposure during both early-and late-phase reactions and are associated with symptoms of allergic rhinitis



LTD₄ antagonists inhibit physiologic actions of LTD₄ at the CysLT₁ receptor without any agonist activity, thereby alleviating the symptoms of asthma and allergic rhinitis

Desired Attributes of a Novel LTD₄-Antagonist



- Potent and Selective to CysLT₁ receptor
- Quick onset and Long duration of action
- Safe and good oral bio-availability
- Superior efficacy to currently marketed LTD₄ antagonists

SUN-L73 I – Preclinical profile



In-vitro

- Potent and selective LTD₄ antagonist; selective to other isoforms by 1000 fold
- Safe to hERG-K
- Does not inhibit major cytochromes CYP3A₄, 2D₆ & 2C₉

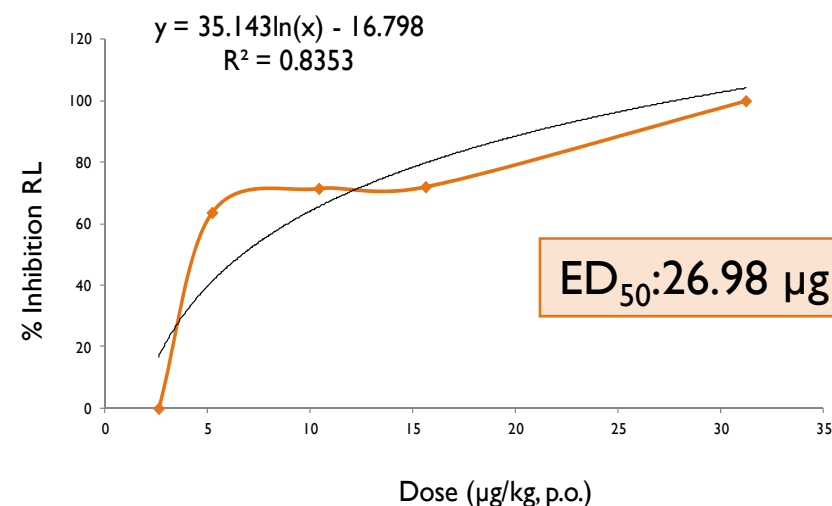
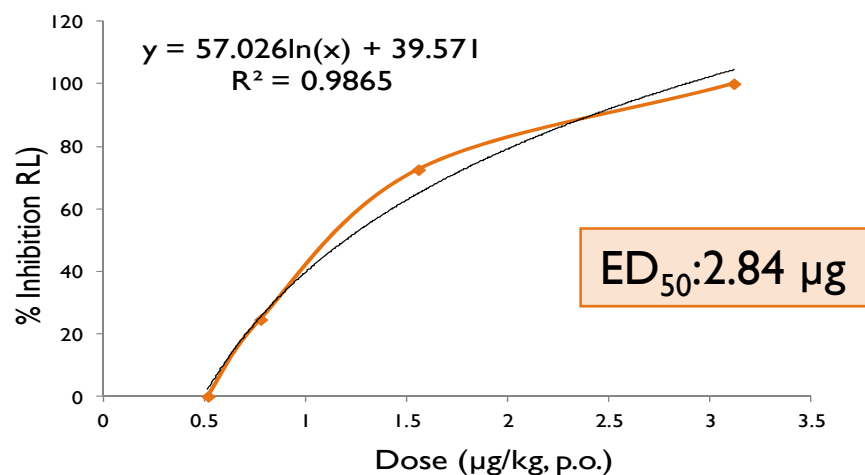
In-vivo

- High potency & efficacy
 - Inhibition of LTD₄ induced bronchospasm in guinea pigs.
 - Inhibition of ovalbumin induced Eosinophilia in BN Rats

- Fast onset & long duration of action
- Good oral bioavailability

SUN-L731 – In vivo potency & efficacy

Inhibition of LTD4-Induced Lung Resistance in Guinea Pigs (Plethysmography)

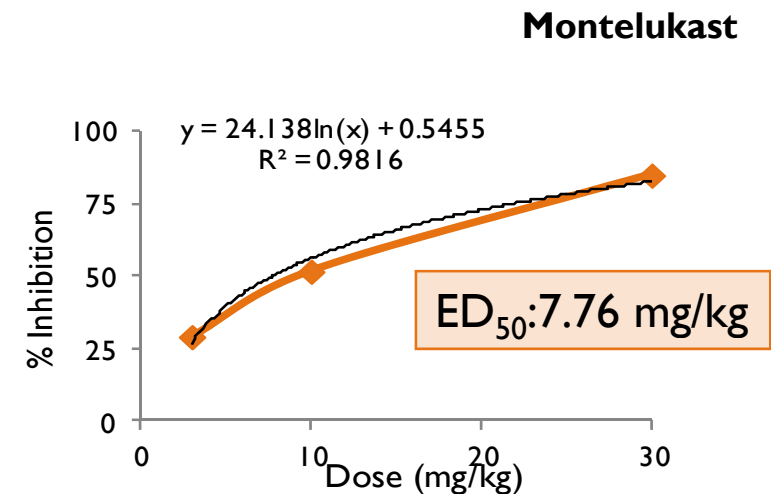
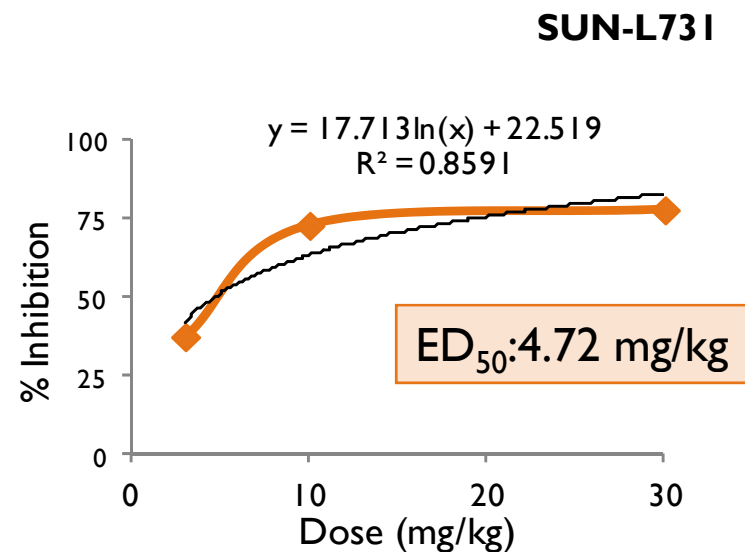


SUN-L731 and montelukast Na were administered 24 hr before induction of bronchoconstriction by LTD₄, n=6/treatment

- SUN-L731 is ~ 10 fold more potent than Montelukast
- Has 24 hrs duration of action- potential for once-a-day dosing

SUN-L731 – In vivo potency & efficacy

Dose-Response in OVA-Induced Eosinophilia in BN Rats



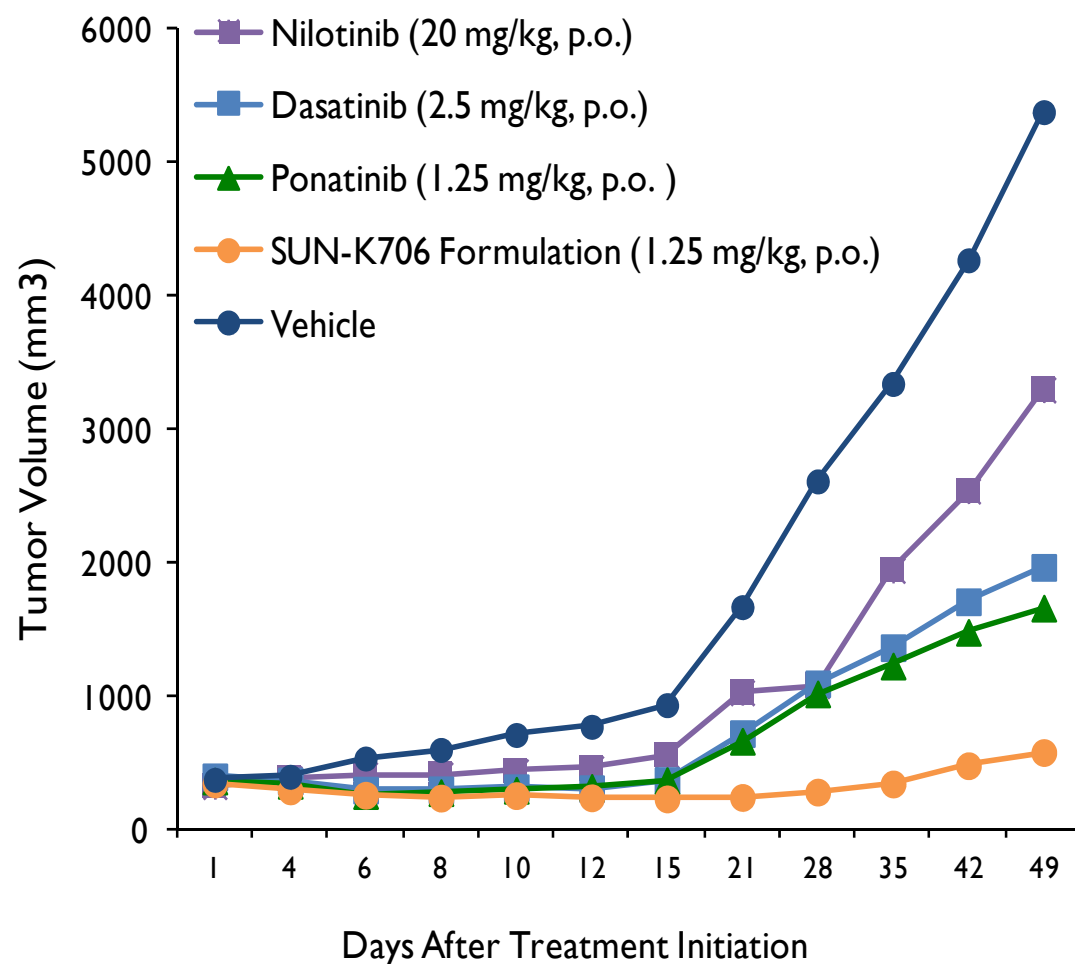
- SUN-L731 has better efficacy than Montelukast in animal model for eosinophilia
- SUN-L731 has ~70% oral bioavailability in rats

L -73 I Future development plan



- Safety pharmacology & toxicity studies for IND by Q3 FY14
- File IND in India in Q1 FY15

SUN-K706 In Vivo Efficacy in Tumor Xenograft Model



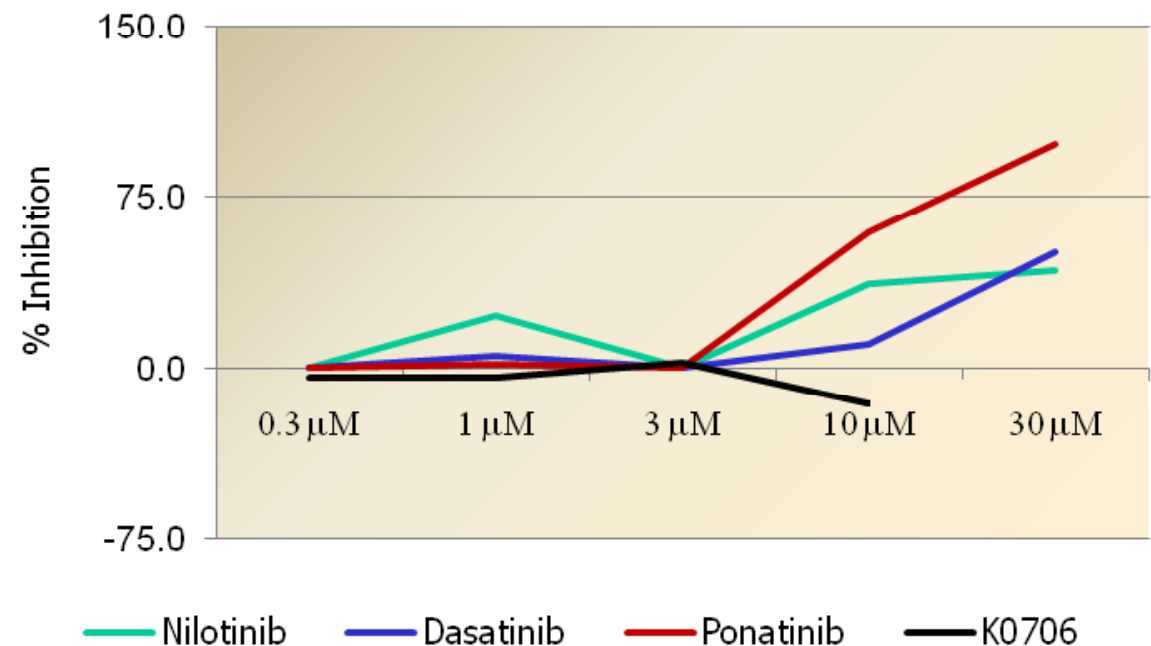
SUN-K706 has higher anti-tumor activity in tumor xenograft model compared with approved drugs at clinically relevant doses

SUN-K706 Safety studies – *in vitro*



hERG K⁺ channel binding

- K0706 did not show inhibition of any of the major cytochromes viz. CYP3A4, CYP2D6 & CYP2C9 (direct or time-dependent)
- K0706 did not show any significant hERG K⁺ channel binding affinity

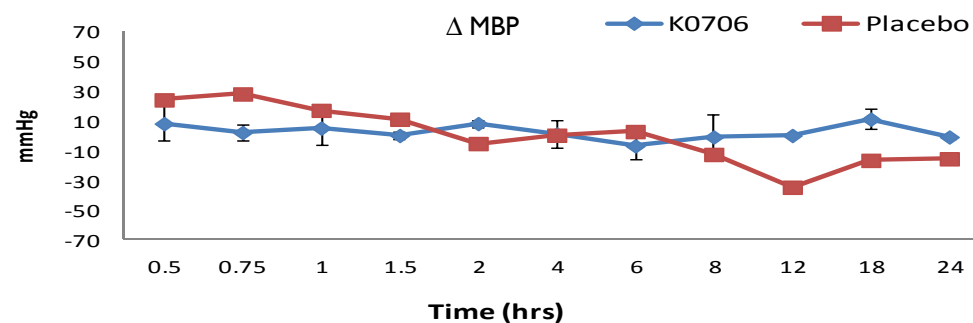
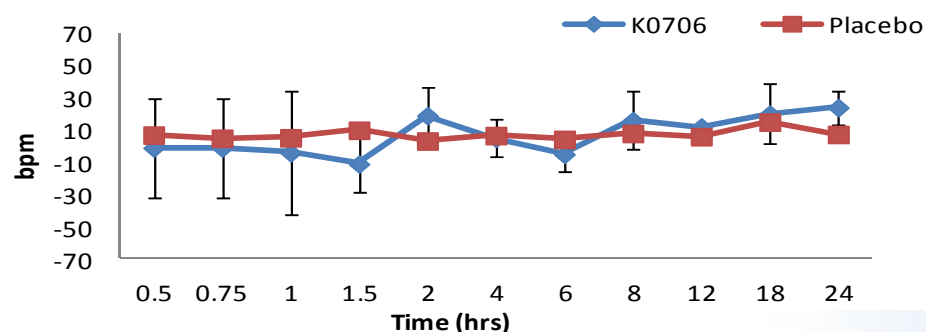


SUN-K706 Safety studies – in vivo

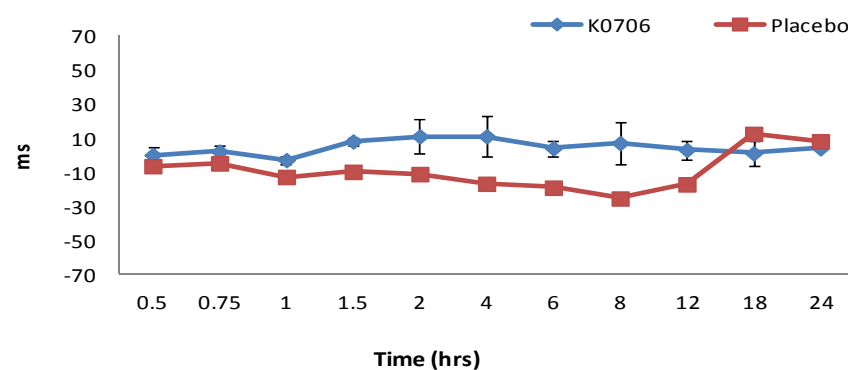
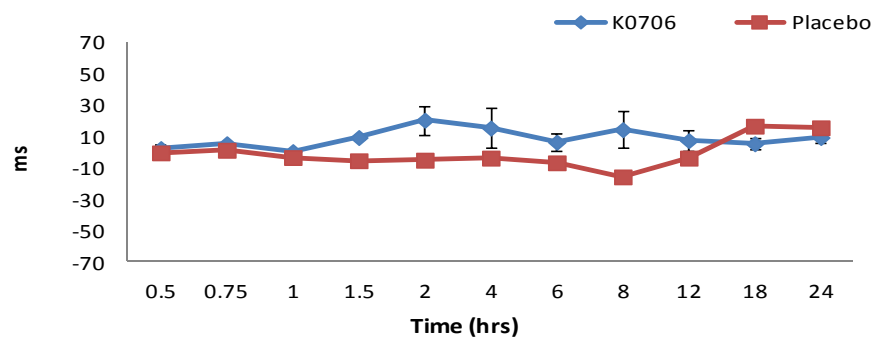


Effect on Heart Rate and Arterial Blood Pressure in Telemetered Beagle Dogs

No significant effect when compared to baseline & placebo



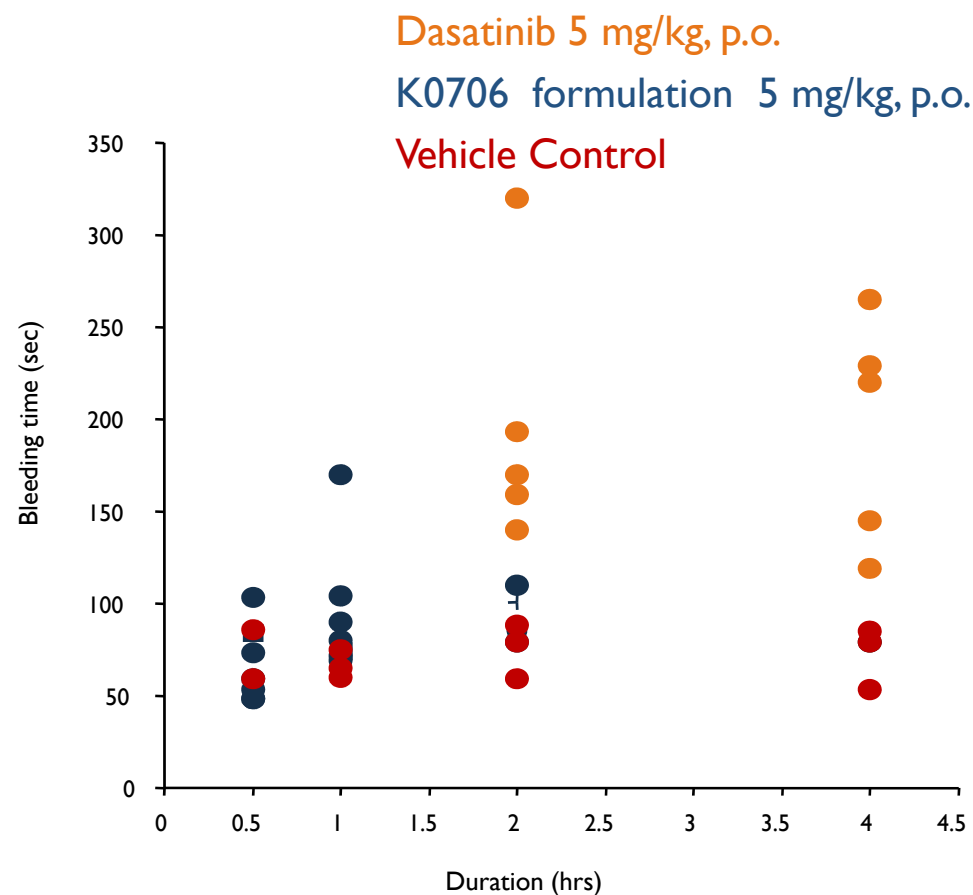
Dose: 10 mg/kg, p.o.



Effect on Corrected QT Intervals in Telemetered Beagle Dogs

No significant effect on “rate corrected” QT intervals, compared to baseline values and placebo

SUN-K706 Safety studies – in vivo



- Thrombocytopenia and effects on platelet function has been indicated in dasatinib therapy
- When assessed at T_{max} time points, at equivalent dose level K706 caused less bleeding indicating low potential for such side effects

K-706 Future development plan



- Optimize oral formulation
- File IND in Q3 FY14

Other Programs



Dry Powder Inhaler

SPARC's DPI is a pre-metered, 60 dose, inhalation 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 for easy to carry
- Compliant to the stringent USFDA and European requirements



Combitide® Starhaler® – Current Status



India

- Approved Q4 FY11
- Launched in Q3 FY12
- SPARC addressed all the functional issues by Aug'12
- Field trial conducted in > 400 patients and 38 doctors across the country – Oct'12 – Jan'13
- Re-launched based on positive field trial opinion – Mar'13

Future development plan



US –505(b)(2) route

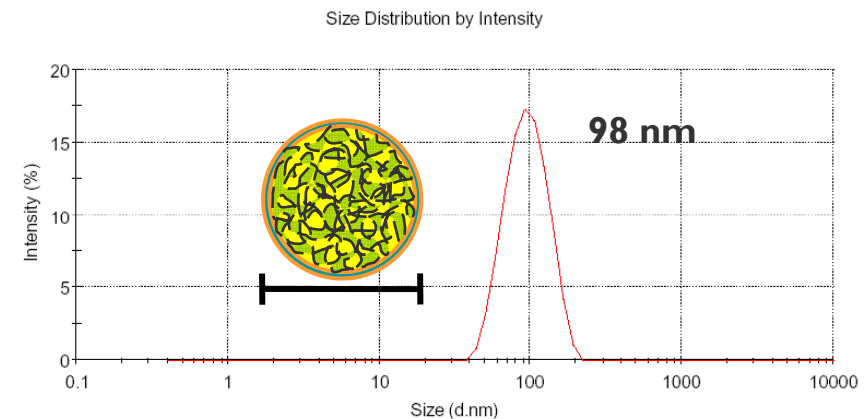
- Pre IND meeting completed Q4 FY11
- US - IND filing in Q4 FY14
- EU – Scientific meeting in Q4 FY14

Docetaxel Injection Concentrate for Nanodispersion (DICN)



A “self-dispersing” nano particle formulation of Docetaxel

- DICN technology is on the same platform as PICN.
- Avoids “toxic” solvents used in conventional docetaxel formulations.
- Avoids limitations of specific bags and in-line filter use
- Usage compliance: simple admixture in infusion bag
- No premedication needed
- No hypersensitivity risk



A typical histogram of Docetaxel nanodispersion showing z-average mean diameter of ~80-120 nm taken on a Malvern's Zetasizer.

DICN – Update on Clinical Trials



Phase I Dose finding and Safety Study

- Completed Phase I clinical trial in solid tumor patients
- Safe dose was established at 150mg/m² which is ~50% higher than Docetaxel
- NO pre-medication with high dose corticosteroids, antihistamines or anti-emetics
- NO hypersensitivity reactions in ANY patients

Phase Ib NSCLC Study

- Clinical study is initiated in advanced NSCLC patients as second line therapy
- Doses from 100mg/m² to 150 mg/m² will tested in this study

DICN Future development plan



US –505(b)(2) route

- Pre-IND meeting with FDA after completion of India NSCLC study

India

- Phase Ib study in NSCLC patients is initiated

Octreotide Depot Inj I M



Octreotide is a Somatostatin analogue used for the treatment of hormone dependant cancers. Somatostatin has a short half life and needs 3-4 injections daily

SPARC has developed Octreotide depot IM Inj. capable of maintaining therapeutic plasma levels for one month following a single injection.

- Octreotide depot Inj. (I Month) has been developed at SPARC with biodegradable depot injection platform
- Based on clinical studies undertaken on Acromegaly patients, Octreotide depot inj. has been launched in India
- Octreotide 3 Month depot Inj. is currently under development at SPARC

Future development plan



US –505(b)(2) route

- Plan to file Octreotide Depot Inj IND in FY15

India

- One month product is already launched in India.

Portfolio reassessment and commercial evaluation

Projects under commercial assessment



- In the current reimbursement scenario, it will be challenging to get appropriate pricing for the product without any clear clinical benefit which will justify the commercial returns.
 - With this view we are making commercial reassessment of the following projects
 - SUN I334H Oral
 - SUN I334H Ophthalmic
 - B 09 Oral Pro-drug
 - G 44 Oral Pro-drug
-

NDDS Programs - Pipeline



USA India

NCE Programs - Pipeline



Product	Route of Administration	Indication	Research	Preclinical	Phase 1	Phase 2	Phase 3	Market
SUN-597	Nasal	Rhinitis						
SUN-597	DPI	Asthma						
SUN-597	Dermal	Dermatoses						
SUN-597	Ophthalmic	Allergic Conjunctivitis						
SUN-K706	Oral	Chronic Myelogenous Leukemia (CML)						
SUN-L731	Oral	Asthma/ Allergic Rhinitis						
SUN-1334H	Oral	Allergic Diseases	Under Commercial Evaluation					
SUN-1334H	Ophthalmic	Allergic Conjunctivitis	Under Commercial Evaluation					
SUN-09	Oral	Spasticity	Under Commercial Evaluation					
SUN-44	Oral	Neuropathic Pain	Under Commercial Evaluation					

Key Programs surpassing critical milestones



- Levetiracetam ER 1000mg and 1500mg Tablets
 - NDA filed
- Venlafaxine ER 300 mg Tablets
 - NDA filed
- Latanoprost “BAK Free” Ophthalmic Solution
 - PreNDA meeting with FDA completed; NDA to be filed in Q2 FY14
- Baclofen GRS for spasticity and chronic alcoholism
 - NDA enabling studies initiated
- Paclitaxel Injection Concentrate for Nanodispersion (PICN)
 - Successfully completed Phase II/III study in advanced breast cancer
- Sun-597 Nasal dosage form for Rhinitis
 - Encouraging results from Phase IIa study

SPARC Value Proposition



- Significant near term opportunities – 2 NDAs filed; 1 to be filed in Q2 FY14
- Latanoprost “BAK Free” Ophthalmic Solution successfully completed phase III studies in USA
- Clinical proof of efficacy established for the SUN-597 nasal dosage form
- PICN continues to advance in clinical trials; successfully completed Phase II/III study in India.
- Baclofen GRS phase III study for Spasticity in USA continues enrolling patients; Completed phase III patient enrolment in Alcoholism indication in India
- Royalty and milestone payments on Liposomal Doxorubicin, Levetiracetam and Venlafaxine sales
- Accomplished funding of INR 1980 million for advancing clinical trials through a rights issue



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