NCE & NDDS Development Pipeline

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SUN PHARMACEUTICAL INDUSTRIES LTD.

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Content

- NCE projects
- NDDS
  - Technology platforms
  - Projects
- Summary of milestones

SUN-1334H

- Route of administration : Oral
- Broad therapeutic area : Anti-allergic disorder
- Treatment of
  - Seasonal allergic rhinitis
  - Perennial allergic rhinitis
  - Urticaria
- Current status
  - Phase I completed in India and Europe
    - 127 human exposure
  - Phase II ongoing in US
  - Chronic toxicity studies ongoing

SUN-1334H

- Mechanism of action
  - Selective histamine H-1 receptor antagonist
  - Poor or no affinity for other relevant receptors
- Summary of findings from clinical studies
  - Once-a-day dosing
  - Faster onset of action (within 30 minutes)
  - Efficacy comparable to Cetrizine over a period of 24 hours on wheal and flare model
  - Non-sedating
  - No cardio toxicity seen
- Estimated Phase III beginning : 2008

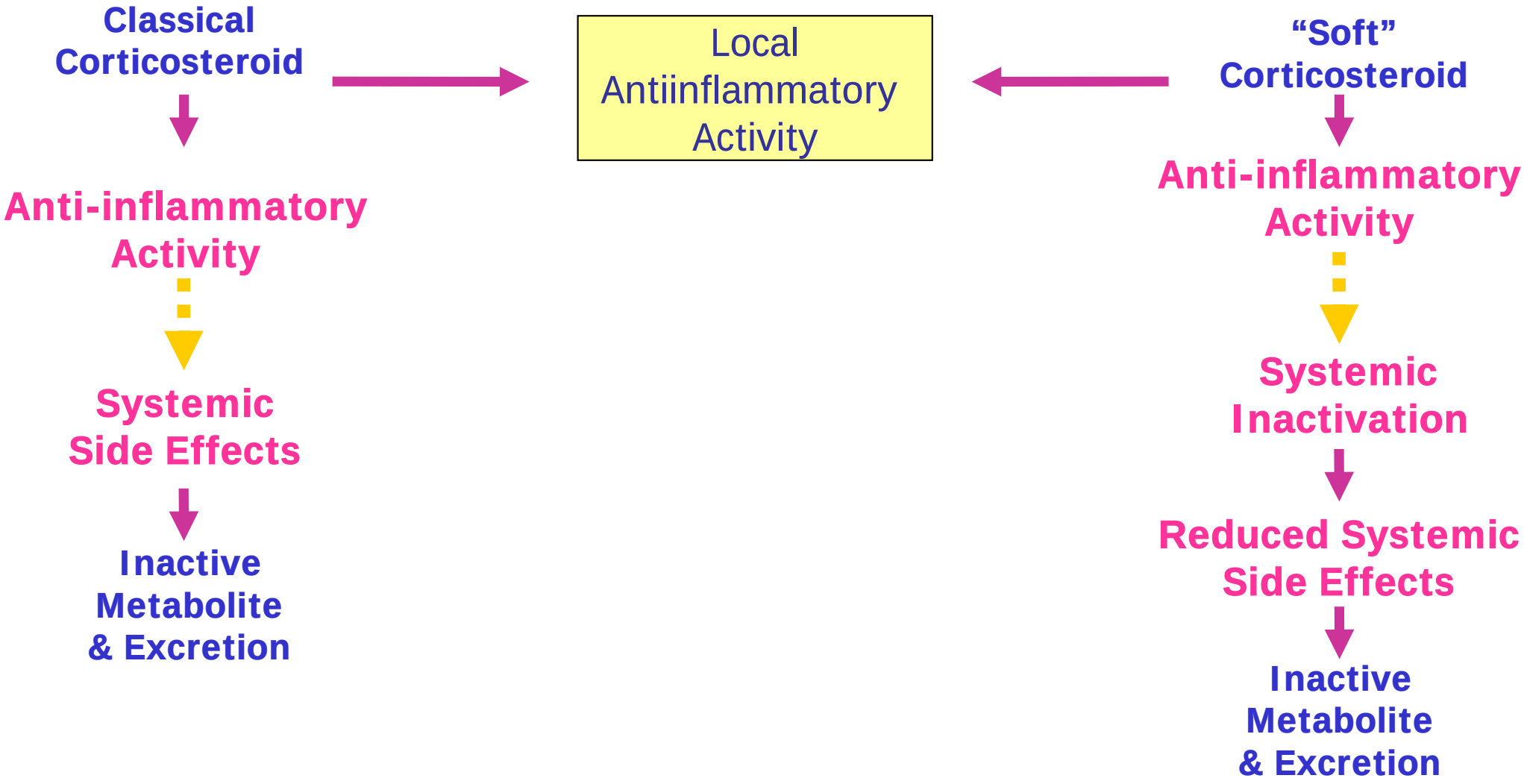
SUN-1334H

- Current global market size : USD 5.5 billion
- Opportunity : Patents expiring on competing products
- Challenge : Justify premium on competing generic products
  - Will need significant investment in studies to prove superiority

SUN-461

- Route of administration : Inhaler
- Broad therapeutic area : Anti-inflammatory
- Indications
  - Asthma
  - COPD
- Mechanism of action
  - Glucocorticoid receptor agonist
  - Suppresses inflammatory response with significantly reduced systemic side effects
- Current status
  - Pre-clinical studies ongoing
  - Acute toxicity studies ongoing
  - Phase I human studies exposure likely to begin in 2008

Inactive Metabolite Approach



- Summary findings / data from studies completed *
  - Anti-inflammatory activity comparable to marketed corticosteriods
  - Side-effect profile superior
    - In Sephadex-induced lung edema model, therapeutic index significantly superior to marketed corticosteroid including budesonide, fluticasone and ciclesonide

Comp No.	ED_{50} Lung edema (mg/kg, i.t.)	ED_{50} Thymus involution (mg/kg, i.t)	Therapeutic index ED_{50} Thymus involution / ED_{50} Lung edema
SUN-S0461	0.22	5.07	23.05
Ciclesonide	0.39	3.13	8.03
Budesonide	0.101	0.68	6.73
Fluticasone propionate	0.086	0.36	4.19

** Data on file*

SUN-461

- Metabolic side effect profile superior to marketed corticosteroid *
  - In liver glycogen deposition screen, deposition of glycogen in liver significantly lower compared to fluticasone and budesonide

Comp No.	Glycogen content (mg/100g liver) at 3mg/kg, i.t.	% Inhibition of thymus
SUN-S0461	160.62	-3.16
Ciclesonide	263.96	61.34
Fluticasone propionate	1514.65	70.17
Budesonide	552.77	65.02

- Current global market data : USD 8 billion
- Estimated IND filing : 2008

** Data on file*

SUN-44

- Prodrug of Gabapentin
- Route of administration : Oral
- Broad therapeutic area : Anti-convulsant / Neuropathy
- Indications : Seizure / CNS related disorders
- Development rationale
  - SUN-44 developed to offer higher bioavailability, enhanced absorption and reduced dosing frequency
- Current status
  - Studies ongoing
    - Pre-clinical
    - Acute toxicity

- Summary findings from animal studies completed *
  - On equivalent dosage, drug concentration 2-3 times higher compared to existing product in the market

Drug levels in plasma		Modified drug (SUN 44) dosed and drug exposure levels in plasma		XP13512 reported dosed and drug exposure levels in plasma	
Dose mg/kg, p.o	Drug Concentration, $AUC_{(0-t)}$ mcg.hr/mL	Equivalent Dose ~ mg/kg, p.o	Drug Concentration $AUC_{(0-t)}$ mcg.hr/mL	Equivalent Dose ~ mg/kg, p.o	Drug Concentration $AUC_{(0-t)}$ mcg.hr/mL
50 mg	85	50 mg	89		
100 mg	99	100 mg	187	100 mg	102 ± 9.16
2000 mg	603	2000 mg	1852	2000 mg	2230 ± 357

  - LD_{50} 2.5 times higher than competing product under development in Phase III (XP13512 #)

LD_0 Drug	2000 mg/kg
LD_0 (SUN 44 as Na)	1000 mg/kg As is of the modified drug
LD_0 (XP13512 as Na, in Phase III)	500 mg/kg As is of the modified drug
LD_{50} (SUN 44 as Na)	1250 mg/kg As is of the modified drug
LD_{50} (XP13512 as Na, in Phase III)	500 mg/kg As is of the modified drug

  - Found to be safer than XP13512 in animal studies

** Data on file*

 # XP13512 is a gabapentin prodrug from Xenoport Inc, currently in Phase III

SUN-44

- Clinical advantages
  - Possible to achieve higher blood level
  - Once-a-day dosing
- Current global market size : USD 1.2 billion (gabapentin is a generic product across most markets)
- Estimated IND filing : 2008
- Phase I human studies exposure likely to begin in 2008

SUN-09

- Pro-drug of a marketed drug
- Route of administration : Oral / Injectable
- Broad therapeutic area : Skeletal muscle relaxants
- Indications : Muscle spasticity
- Development rationale
  - SUN-09 offers quick and improved absorption during entire gastro-intestinal tract
- Current status
  - Studies ongoing
    - Pre-clinical
    - Acute toxicity

SUN-09

- Summary findings from animal studies completed *

Drug as is dosed and drug levels in plasma			Modified drug (SUN 09) dosed and drug exposure levels in plasma		
Dose mg/kg, p.o	Cmax mg/mL	Drug Concentration, $AUC_{(0-t)}$ mcg.hr/mL	Equivalent Dose mg/kg, p.o	Cmax mcg/mL	Drug Concentration, $AUC_{(0-t)}$ mcg.hr/mL
20	3.6	15	20	8	24

  - ❖ At equivalent dosage, AUC 1.6 times higher than existing marketed products
- Substantially improved efficacy seen in muscle coordination in animal model
- Current global market size : USD 200 million (all existing products are generic)
- No. of spastic patients under treatment (US+Europe) : 1.5 million
- Likely IND filing : 2008

** Data on file*

NDDS Technology Platforms

- Dry powder inhalers
- Controlled release systems
  - Gastric retention systems (GRID)
  - Matrix system (Wrap-matrix)
- Targeted drug delivery
  - Nanoemulsion
- Biodegradable injections/implants

DPI

- Inhalers used for Asthma and COPD
- Device can be modified for systemic delivery of drugs to lungs
- Easy to use
  - Simple operating sequence of 3 steps : Open-inhale-close
- Small and convenient to carry
- Multiple dose device
- Being developed to comply with US FDA and European requirements for inhalation device

DPI

- Device engineered to
  - Give visual, audible and tactile feedback
  - Deliver uniform dose over a range of patient effort (flow rates/patient inhalation effort)
  - Eliminate double dosing and dose wastages
  - Deliver multiple doses in one device with fail-safe dose counter
  - Deliver consistently higher drug to lungs
  - Easy use by children, adults and elderly
- Can be used in delivery of
  - Existing combinations of steroid and bronchodilators
  - NCE steroid

DPI based product

- Developing a combination of steroid and bronchodilator with improved formulation
- Current status
  - Semi-regulated markets
    - Design and validation : 2008
    - Human exposure : 2007
    - Expected launch in semi-regulated markets : 2009
  - Regulated markets
    - Expected NDA filing : 2011

Gastro Retentive Innovative Device (GRID)

- Development Rationale
  - Some drugs have narrow zones of absorption in GI tract
    - Poor solubility and degradation in alkaline media of small intestine
    - Carrier mediated transport mechanism
    - Relatively short residence time in stomach and small intestine
    - Decreased absorption hence unsuitable for once a day administration
- Gastro Retentive systems
  - Designed for retention in the stomach for longer time than usual (~about 8 hours)
  - Mechanisms involved
    - Flotation
    - Size expansion
    - Mucoadhesion

GRID

- Key features of GRID
  - Coated multilayered dosage form
  - Floats instantaneously
  - Swells upto 8 times its initial volume
  - Maintains physical integrity
  - Flexible and soft
- Clinical advantages
  - Once-a-day dosing improves patient compliance
  - Reduced side effects
  - Different types of release profiles possible (IR + SR)

Baclofen GRS Capsule

- Once-a-day dosing against 3 to 4 times of marketed product
- Indications : Muscle spasticity
- Current status
  - India
    - Completed Phase I, II & III clinical studies
    - Approved
  - Completed pre-IND meeting with US FDA
    - IND filing : 2007

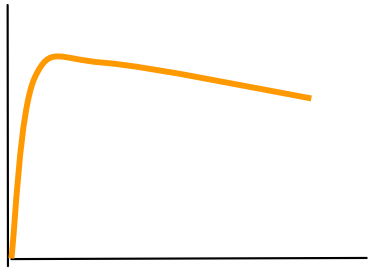
Baclofen GRS Capsule

- Clinical outcome
  - Once-a-day rated better by patients than three-times-a-day
  - Ease of switchover from IR (3 times / day) to GRS (once-a-day)
  - As effective (non-statistically superior)
  - Reduced sedation (statistically superior)
  - No unanticipated significant adverse event

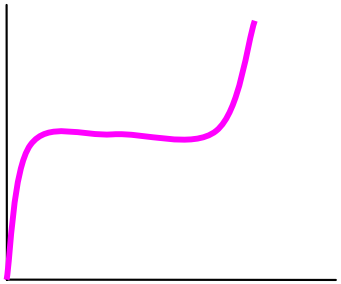
Wrap Matrix System

- Key features
  - Controlled release of drug for once-a-day administration
  - Controlled release of drug for high dose – high solubility drugs
  - pH independent performance
  - Capable of different types of release profiles (IR + SR)

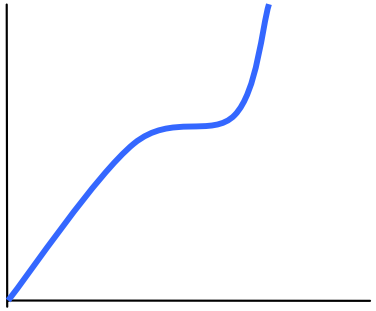
Disease Specific Drug Release Patterns



IR + SR (useful in pain management)



IR + SR + IR (for eg in asthma)



SR + IR (for eg in Heart diseases)

  - High drug to excipient ratio

Wrap Matrix System

- Clinical advantage
  - Once-a-day dosing
  - Reduces the side effects, leading to patient compliance
  - Relatively smaller size of dosage form
  - No residual drug in dosage form on evacuation
  - Minimal effect of food
  - Reproducing similar bio-equivalence difficult for products based on other competing technology
    - Low risk of generics

Wrap Matrix System based products

- Proven technology : Commercially validated and scaled-up
- Metoprolol XL
  - Once-a-day dosing against 2 to 3 times of marketed product
  - Indications : Hypertension / Angina
  - Current status
    - India : Approved
- Based on this technology, a few ANDAs for controlled release dosage form filed with US FDA

Nanoemulsion

- Key features of technology for cytotoxic substances
  - Avoids toxic excipients
  - Better safety index as proven in animal model
  - Increases circulation half life and improved efficacy
  - More drugs can be delivered at target site
  - Avoids hypersensitivity reaction to toxic excipients
  - Uses all approved excipients in injectable products
- Nanoparticle platform technology at preclinical development stage with demonstrated proof of concept
- Based on this technology, 2 cytotoxic products are being developed

Biodegradable implants / injections

- Key Features of technology developed
  - Can produce controlled particle size for facile injection through conventional needle to reduce patient trauma and pain
  - No local anaesthetic required while delivering the drug
  - Closed semi-automatic process to give kilogram scale, reproducible, consistent and uniform microsphere product
  - Technology can be applied to peptides
  - Quantity of the drug product required to be injected is less to get similar profile.
  - No toxic solvents used in the formulation
  - Easy for reconstitution and mixing

Biodegradable implants / injections

- GnRH analogue
  - Comparable to marketed products
    - Achieved comparable profile in animals
    - Injection less painful
    - Easy to use
    - No need of local anaesthesia
  - Current status
    - Preclinical studies ongoing
    - Clinical studies planned in India : 2008
- Somatostatin analogue
  - Comparable to marketed products
    - Achieved comparable profile in animals
    - Easy to use
  - Current status
    - Clinical studies in India ongoing

Tobra + Dexa Ophthalmic Solution

- Development rationale
  - Marketed product available as suspension form
  - SUN product a clear solution, a preferred dosage form
- Indication
  - Prophylaxis of bacterial infection following cataract surgery
- Completed formulation development
- Completed Pre-IND meeting with USFDA
- Likely IND filing : 2007

NCE Milestones

New Chemical Entity	Therapy	IND filing	Pre-clinical	Phase I	Phase II	Phase III
SUN-1334H	Allergic rhinitis Perennial rhinitis Urticaria	Filed 2007				2008
SUN-461	Asthma COPD	2008		2008	2009	
SUN-44	Seizure CNS Related Diorders	2008		2008		2009
SUN-09	Muscle spasticity	2008				2009

Completed

Ongoing

NDDS Milestones

Novel Drug Delivery Systems	IND filing	Pre-clinical	Phase I	Phase II	Phase III	NDA filing	Approved	Launch
DPI								
Semi-regulated markets			2007		2008			2009
Regulated markets						2011		
Baclofen GRS								
India								
US	2007		2008			2009		
Biodegradable implants / injections								
GnRH analogue								
India			2008					
Somatostatin analogue								
India								
Tobra + Dexa Ophthalmic Solution	2007		2008			2009		

Completed

Ongoing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