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SUN PHARMA ADVANCED RESEARCH COMPANY LTD.

FOR IMMEDIATE RELEASE

SPARC Update on Innovation Effort

Mumbai, June 8, 2010: In a detailed presentation recently, Sun Pharma Advanced Research Company Ltd. (SPARC, NSE: SPARC, BSE: 532872) management shared updates for its Novel Drug Delivery System (NDDS) and New Chemical Entity (NCE) programs. Information on products based on 7 NDDS platform technologies and 4 promising NCEs were discussed.

Novel Drug Delivery System

- Gastro Retentive Innovative Device
- Wrap Matrix system
- Nanoparticulate formulations
- Biodegradable Depot Injections
- Dry Powder Inhalers
- Swollen Micelle Microemulsion technology for ophthalmic formulations and
- Gel Free Reservoir technology for once-a-day ophthalmic formulations.

Gastro Retentive Innovative Device (GRID) is an ideal once-a-day system for drugs that are otherwise absorbed only in stomach or small intestine. GRID is designed so that drug is retained in the stomach for over an eight-hour span. Longer retention in stomach improves the drug absorption. The tablet offers a combination of instant and sustained drug release profiles, and being once a day improves patient compliance.

Based on **GRID, Baclofen GRS**, a once-a-day capsule to treat muscle spasticity, has been launched in India. For the US, Phase III clinical trials have been initiated for Spasticity. One open label safety study in one more indication is planned.

Wrap Matrix: Usually, controlled release dosage forms of very high dose and high solubility products are either, very large and difficult to swallow, or release its entire drug at the same time ("dose dumping"). A combination of instant and long-term release is also tough to achieve in the same tablet. With **SPARC proprietary Wrap Matrix technology**, a multi-layered matrix-based tablet of such drugs offers controlled release with just once a day dosing without creating too bulky a tablet for products requiring larger daily dose. An anti-epileptic with high solubility and very large dose, an anti-hypertensive, a skeletal muscle relaxant with an ultra short half life, a CNS agent with very high solubility and an anticancer agent are some of the products at different stages of development.

SPARC's novel **self dispersing Nanoparticle technology platform** addresses the challenges posed by water insoluble anticancers drugs – use of toxic surfactants to solubilise the drug and distribution to healthy tissues in addition to tumour tissues. SPARC technology offers higher drug localization to the cancer cells, uses less excipient, and can deliver a higher dose. It avoids the need for pre-medication.

Paclitaxel Injection Concentrate for Nanodispersion (PICN) formulated using SPARC proprietary technology, has completed Phase I in India and has demonstrated a superior safety profile with a 30% higher concentration in tumor tissues when compared to the marketed drug Abraxane®. Phase I of combination chemotherapy of PICN with carboplatin will be initiated this year in the US. A phase II study for metastatic breast cancer is planned in India.

All pre-clinical studies required for Phase I have been completed for **Docetaxel** Injection Concentrate for Nanodispersion (DICN). DICN was found to be safe at 7.5 times the dose of conventional docetaxel. In India, a phase I study in solid tumor patients has been initiated.

Some chronic treatments (e.g. for cancer) require maintenance of drug levels in the body over several months or weeks, with daily or frequent injections that are extremely painful for the patient. Depots or reservoirs under the skin from

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which drug is released over a long period is one solution. Depots from current technology have a high polymer to drug ratio, require special needles and specially trained staff. Even after this, the drug would need a few weeks to reach the desired blood levels. Such drawbacks limit their use. SPARC has developed a **proprietary Depot Technology** with biocompatible and biodegradable micron size polymer particles that contains the drug in its matrix, and offers long term systemic delivery of the drug. Administration is convenient with the use of a conventional needle, absence of patient trauma and pain. No special training or equipment is needed. Even the injection volume is lower. This technology offers rapid onset and prolonged release over months with no peaks and valleys that are seen with frequent daily doses and is extremely well suited for treating chronic conditions like prostrate cancer.

Goserelin depot 1 M injection, for the treatment of hormone dependant tumors (e.g. prostate cancer, breast cancer) has been developed based on this technology. Octreotide and Goserelin depot injection 1M IND filing for the US is likely in 2011-12. In India, clinical trials for Goserelin 1M were begun earlier this year.

SPARC has developed a **Dry Powder Inhaler (DPI)** compliant to USFDA and European requirements. This premetered, 60 dose, inhalation activated device for the administration of combination of inhaled steroids and bronchodilator drugs delivers a uniform dose over a range of patient effort and is easy to operate. In addition, the DPI is designed to eliminate double dosing or dose wastages and can be easily used by children, adults as well as elderly. In clinical trials, drug administered via this DPI achieves the same efficacy as the innovator at 50% of the dose administered.

Phase III of DPI delivering a glucocorticoid and beta agonist combination, has been completed in India. A product based on this novel DPI is likely to be launched in India in 2010-11.

Toxic surfactants like benzalkonium chloride (BAK), harmuful to the eye surface, are often used in eyedrops to solubilize drugs not soluble in water. SPARC has developed **Swollen Micelle Microemulsion (SMM)** technology, a BAK-free platform for solubilizing ophthalmic drugs that are insoluble or have limited solubility. The micelle protects the drug from temperature or light fluctuations. Latanoprost BAK-free ophthalmic solution is a non-infringing formulation to the market leader Xalatan®. This product stable at room temperature, with lower risk of eye surface damage, has demonstrated safety profile and eye comfort in phase III trials in India. The product will be launched soon in India. For US, two Phase III studies are planned to begin in 2010.

SPARC has developed a **Gel Free Reservoir (GFR) technology** that increases the duration of action of drugs, localizes drug action with minimal systemic absorption and creates a clear and non-irritant formulation. This is extremely useful in chronic eye ailments like glaucoma, which typically require short-duration drugs to be instilled several times a day. GFR Timolol Maleate 0.5% once-a-day eyedrops developed at SPARC were found to be equivalent to the brand leader Timolol maleate 0.5% administered twice a day, in a clinical trial. Phase III trials have been completed in India and product launch is likely in 2010-11.

New Chemical Entity Research

SPARC Ltd. shared updates on its four leading NCE candidates.

SUN 1334H, an antiallergic selective histamine receptor antagonist, is being developed in three formulations – oral and eyedrops. Sun 1334 H is non-sedating, with quick onset of action. It is being studied for use in seasonal allergic rhinitis, perennial allergic rhinitis, chronic idiopathic urticaria and allergic conjunctivitis.

Chronic toxicity studies on Sun 1334 H oral are ongoing, with cardiac and renal safety studies planned. Sun 1334 H eyedrop formulation showed excellent inhibition of allergen and histamine induced conjunctivitis in preclinical studies. A Phase I study is expected to begin shortly.

SUN 597, a topical glucocorticoid is an anti-inflammatory for use in inflammations of the airway, skin, eye and gastrointestinal tract. In preclinical studies, Sun 597 was found to have good potency, good selectivity for glucocorticoid receptors, low oral bioavailability and very low liability to systemic side effects. It has a very high therapeutic index

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compared to currently marketed steroids. Preclinical efficacy and safety pharmacological studies have been completed. Phase I trials for the nasal formulation are planned.

SUN 44, a prodrug of gabapentin for the treatment of neuropathy and seizures, uses molecular modifications in its structure for better absorption. In animal models of epilepsy, SUN 44 shows better efficacy compared to gabapentin. Its profile indicates higher blood availability, a once-a-day formulation and higher safety. IND has been filed in India, with Phase I to begin in FY 2010-11.

SUN 09 is a prodrug of baclofen, a skeletal muscle relaxant for spasm related disorders. This molecule's physicochemical and structural features have been modified for better absorption throughout the intestine. In preclinical studies, SUN 09 gets rapidly absorbed, and converted to active drug within 2 hours. In animal studies, oral administration of SUN 09 gives dose dependant muscle relaxation and quick onset of action. An IND has been filed for human clinical trials in India.

About SPARC

Sun Pharma Advanced Research Company Ltd (NSE: SPARC, BSE: 532872) is an international pharmaceutical company engaged in research and development of drugs and delivery systems. More information about the company can be found at www.sunpharma.in.

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