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FOR IMMEDIATE RELEASE

SPARC Updates on Innovation

Mumbai, June 14, 2011: In a conference call 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 9 NDDS platform technologies and 4 NCEs were discussed.

Novel Drug Delivery System

Phase III of SPARC's **novel Dry Powder Inhaler (DPI)** delivering a glucocorticoid and beta agonist combination that delivers equivalent efficacy at half the dose, has been completed in India. A product based on this novel DPI is likely to be launched in India in Q2 FY12. For the US, pre IND meeting completed and IND filing is likely in FY12.

SPARC, deploying its **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 short-acting drug, has developed Octreotide depot 1M Inj. capable of maintaining therapeutic plasma levels for one month following a single injection. Based on the clinical studies undertaken on Acromegaly patients, Octreotide depot injection has been launched in India. An Octreotide three- month depot injection is currently under development at SPARC. SPARC expects to file an IND for Octreotide Depot Inj in FY12.

Paclitaxel Injection Concentrate for Nanodispersion (PICN) formulated using SPARC novel **self dispersing Nanoparticle technology platform**, which showed 30% higher concentration in tumor tissues, has completed Phase I in India and has demonstrated a superior safety profile when compared to the marketed drug Abraxane®. Dose limiting toxicity was seen at higher dose level. No hypersensitivity was seen, less neuropathy was seen. No premedication with high dose corticosteroids, antihistamines or anti-emetics was required. Interim analysis of phase II data using two doses of PICN compared with Abraxane® shows much higher objective response rate.

This product is being developed for the US through 505 b(2) route. IND filing with USFDA has been completed, and ethics committee approval obtained. Phase I of combination of PICN with carboplatin will be initiated in Q3 FY12. For India, a phase II/III study in metastatic breast cancer has been initiated in FY11.

Phase I in solid tumor patients has 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 preclinical studies, and the maximum tolerated dose in Phase I was found to be significantly higher than that of Taxotere. Phase II study in NSCLC patients is planned in Q3 FY12. For the US, a pre IND meeting with the USFDA is planned in FY12.

Latanoprost BAK-free ophthalmic solution, using SPARC's **Swollen Micelle Microemulsion (SMM)** technology, is a non-infringing formulation to the market leader Xalatan®. This product is stable at room temperature, with lower risk of eye surface damage.IND has been approved by the USFDA. USFDA requires two Phase III studies, and the target study completion date is Q3 2012. Latanoprost has been launched in India after clinical studies, with excellent response.

Gel Free Reservoir (GFR) technology 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 the product has been launched. Additionally, a formulation based on NCE and other products are in development.

An ophthalmic combination of a water insoluble and a water soluble drug, Latanoprost and Timolol, uses two combination platforms, GFR technology and BAK-free technology. Preclinical proof of concept study has been completed. The Phase III efficacy and safety study is ongoing in India.

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Based on **Gastro Retentive Innovative Device (GRID)** a once-a-day system for drugs that are otherwise absorbed only from the upper part of the small intestine**, Baclofen GRS** capsules to treat muscle spasticity have been developed with 6 strengths i.e., 10 / 20 / 30 / 40 / 50 / 60 mg for individualized dosing and greater dose flexibility. Baclofen GRS has been launched in India. For the US, a protocol for Phase III clinical trials in 300 patients is awaiting special protocol assessment (SPA) agreement by the USFDA, the study will commence by Q3 FY12. Two more studies including an open label study in hundred patients are planned.

A study of Baclofen GRS in alcohol dependence is also planned, and regulatory approval has been sought for a multicentric double blind trial.

SPARC's proprietary **Wrap Matrix technology** offers controlled release with just once a day dosing in a multi-layered matrix-based coated tablet. It offers an option of incorporating large doses of drug into relatively smaller sized controlled release tablets. Levetiracetam, an anti-epileptic with high solubility and very large dose, has completed pivotal pharmacokinetic studies in India and will be filed as a 505 b(2) for the US in Q3 FY12. Pharmacokinetic studies are ongoing for a cardiovascular drug. Phase II studies are underway for a skeletal muscle relaxant with an ultra short half life. An anticancer combination is awaiting Phase I studies. Several CNS drugs are also being studied. Three ANDAs based on wrap matrix have been filed by Sun Pharma for the US, of which one has reached market.

Based on other novel technologies, two cardioprotective agents are also being developed.

New Chemical Entity Research

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

SUN 1334H, an antiallergic selective histamine receptor antagonist, is being developed in two 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. Pilot cardiac safety studies are slated for completion by Q3FY12. Renal safety studies are planned.

Sun 1334 H eyedrop formulation showed excellent inhibition of allergen and histamine induced conjunctivitis in preclinical studies. Phase I clinical study was completed in India in Q4FY11. IND was filed in US, Phase II studies are ongoing.

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 compared to currently marketed steroids.

For the nasal product, Phase I B clinical trials are ongoing and are likely to be completed by Q2 FY12.

For SUN-597 inhalation product, the preclinical toxicity is ongoing, likely to be completed by Q3 FY12. IND filing is likely in Q4 FY12.

For the topical cream containing SUN 597, preclinical development is ongoing, and formulation development is likely by Q2 FY12. IND filing is likely by Q4 FY12.

Ophthalmic steroids are widely used in the treatment of post-operative inflammation and inflammatory conditions of eyes such as allergic conjunctivitis. SUN-597 reduces eye inflammation, however has negligible incidence of local side effects. Preclinical studies for selection of appropriate strength and formulation are ongoing. Formulation development is expected to be done by Q2FY12. IND filing is expected by Q4FY12.

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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. IND has been approved by DCGI. Sun 09 IR tablet is in Phase I clinical studies, likely completion is by Q3 FY12.

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 approved in India. Phase I is to commence in FY12.

SUN K 706, a novel tyrosine kinase inhibitor for the treatment of chronic myelogenous leukemia, is in preclinical studies, and toxicity studies are likely to be done by Q4 FY12. IND filing is planned for FY13.

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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