



FOR IMMEDIATE RELEASE

SPARC Announces Top-line Results of Pivotal Bioequivalence Study for Paclitaxel Injection Concentrate for Suspension

- *Pivotal Bioequivalence (BE) study showed Paclitaxel Injection Concentrate for Suspension to be bioequivalent to Abraxane® in patients with locally recurrent or metastatic breast cancer*
- *New Drug Application filing through 505(b)(2) pathway with USFDA targeted in next few months*

Mumbai (India), Nov 26, 2018 - Sun Pharma Advanced Research Company Ltd. (SPARC) (Reuters: SPRC.BO, Bloomberg: SPADV IN, NSE: SPARC, BSE: 532872) today announced top-line results of the pivotal BE study for Paclitaxel Injection Concentrate for Suspension (PICS).

The pivotal BE study was a randomized, open label, two period, single dose, crossover study of PICS and Abraxane® in subjects with locally recurrent or metastatic breast cancer. A total of 142 patients were randomized to characterize the pharmacokinetic (PK) profile of PICS for both unbound and total paclitaxel compared with Abraxane®. The study also provided information on the safety profile of PICS.

The study met all the required pharmacokinetic endpoints for both unbound and total paclitaxel. There were no new adverse events observed in this study.

According to Anil Raghavan, CEO, SPARC, "We are very pleased with the results of the PICS BE study, and it provides a validation of our Nanotecton™ technology. The study results pave the way forward for us, with a USFDA NDA filing using 505(b)(2) approval pathway planned in the coming months. Overall US Paclitaxel market is estimated to be about \$700 million (IQVIA MAT Sep 2018). The current market is dominated by Cremophor® based Paclitaxel formulations, which accounts for ~70% of unit sales. With launch of novel formulations, market for nano-formulations of Paclitaxel is expected to grow."

About Paclitaxel Injection Concentrate for Suspension

Paclitaxel Injection Concentrate for Suspension (PICS) is a novel formulation of Paclitaxel developed using SPARC's proprietary Nanotecton™ technology. PICS is a Cremophor® and Albumin-free formulation of Paclitaxel. PICS offers the convenience of a quick and easy "one step" dilution and infusion preparation. PICS, unlike solvent based formulations, does not require premedication with steroids or antihistamines.

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About SPARC (CIN: L73100GJ2006PLC047837):

Sun Pharma Advanced Research Company Ltd. (SPARC) is a global pharmaceutical company focused on continuously improving standards of care for patients globally, through innovation in therapeutics and delivery. SPARC aims to consistently lower costs and improve operational efficiencies to advance availability and affordability of cures for patients across the world. More information about the company can be found at www.sparc.life

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