



FOR IMMEDIATE RELEASE

SPARC Announces U.S. FDA Acceptance of NDA for Taclantis™ (Paclitaxel Injection Concentrate for Suspension) for Filing and Regulatory Review

MUMBAI – July 01, 2019, Sun Pharma Advanced Research Company Ltd. (SPARC) (Reuters: SPRC.BO, Bloomberg: SPADV IN, NSE: SPARC, BSE: 532872) today announced that the U.S. Food and Drug Administration (USFDA) has accepted for review SPARC's New Drug Application (NDA) for Taclantis™ (Paclitaxel Injection Concentrate for Suspension). The NDA filing is based on successful demonstration of clinical bioequivalence of Taclantis™ with Abraxane® and associated clinical safety data. SPARC seeks the same indications as Abraxane® for Taclantis™ in the NDA. The USFDA confirmed that this NDA will be a standard review.

About Taclantis™ (Paclitaxel Injection Concentrate for Suspension):

Taclantis™ (Paclitaxel Injection Concentrate for Suspension) is a Cremophor® and Albumin-free formulation of Paclitaxel. It should be diluted with an appropriate volume of 5% w/v Dextrose injection in either a PVC or non-PVC type sterile infusion bag. Premedication to prevent hypersensitivity is generally not needed prior to administration of Taclantis™.

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

Disclaimer:

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*Taclantis™ is conditionally approved by USFDA as trade name for US market.
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