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SPARC Announces Top-line Results of Pivotal Peak Inspiratory Flow (PIF) study and Low Dose Pharmacokinetic (PK) Study for Salmeterol – Fluticasone Dry Powder Inhaler (SPARC DPI)

SPARC DPI meets the end point for PIF study
In the Low dose PK study bio-equivalence established for Fluticasone, however, Salmeterol component not bio equivalent to the comparator arm

Mumbai (India), June 14, 2017 - Sun Pharma Advanced Research Company Ltd. (SPARC) (Reuters: SPRC.BO, Bloomberg: SPADV IN, NSE: SPARC, BSE: 532872) announced the top-line results of the PIF study and Low dose PK study for SPARC DPI.

The PIF study was designed to examine peak inspiratory flow profiles generated with the SPARC DPI and Seretide Accuhaler® in healthy adult subjects, children with asthma, adult patients with asthma and adult patients with Chronic Obstructive Pulmonary Disease. Subjects in all the groups were successfully able to use the Device. The percentage differences observed in mean PIF data between both study arms were well within the acceptable range and considered comparable.

The low dose PK study was a randomized, single dose, crossover, comparative pharmacokinetic study of Salmeterol 25 µg and Fluticasone Propionate 50 µg inhalation powder in SPARC DPI with Seretide Accuhaler® Salmeterol 50 µg + Fluticasone Propionate 100 µg Inhalation Powder in Healthy Volunteers.

The bioavailability of 50 µg fluticasone propionate using the SPARC DPI was comparable to the administration of 100 µg fluticasone propionate using the Seretide Accuhaler® and within the acceptance range for bioequivalence.

The shape of the plasma concentration time curves were similar for salmeterol after administration of 25 µg salmeterol using the SPARC DPI and administration of 50 µg using the Seretide Accuhaler®, however the peak concentration of salmeterol was

higher when using the SPARC DPI compared to the Seretide Accuhaler® and did not meet the criteria for bioequivalence.

A single inhalation of SPARC DPI was safe and well tolerated. The safety profile of SPARC DPI was similar to that of Seretide Accuhaler®.

According to Anil Raghavan, CEO, SPARC, "The results confirms that our device is highly efficient and consistent in delivering more drug to the lungs and suitable for all classes of patients. We will consult the regulatory agencies in Europe to understand the potential path forward for SPARC DPI.

About SPARC DPI
SPARC DPI is a pre-metered, 60 dose, breath activated device containing Salmeterol – Fluticasone. SPARC DPI uses half the dose of the both Salmeterol and Fluticasone compared to Seretide Accuhaler®.

About SPARC (CIN: L73100GJ2006PLC047837):
Sun Pharma Advanced Research Company Ltd. (SPARC) 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.sparc.life

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