



FOR IMMEDIATE RELEASE

SPARC Receives Orphan Drug Designation from the USFDA for SCO-088 for the Treatment of Patients with Chronic Myeloid Leukemia

MUMBAI – July 08, 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 granted Orphan Drug Designation to SCO-088 for the treatment of patients with Chronic Myeloid Leukemia (CML).

“This is an important milestone in SPARC’s journey to provide solution for patients who are not responding to the existing treatments available in the market. SCO-088 will fill the gap in the treatment of resistant CML” said Anil Raghavan, CEO of SPARC.

The Orphan Drug Act provides economic incentives to encourage the development of drugs for diseases affecting fewer than 200,000 people in the United States. Orphan Drug Designation will grant seven years of US market exclusivity upon approval of SCO-088 for the treatment of patients with CML. Incentives include waiver of user fee by USFDA and assistance in clinical trial design by USFDA.

About CML:

CML is a myeloproliferative neoplasm that accounts for approximately 15% of newly diagnosed cases of leukemia in adults. Central to the pathogenesis of CML is the fusion of the Abelson murine leukemia (ABL1) gene on chromosome 9 with the Breakpoint Cluster Region (BCR) gene on chromosome 22. This rearrangement is known as the Philadelphia chromosome¹. The American Cancer Society estimated that in the United States in 2018 there were about 8,430 new cases of CML (4,980 in men and 3,450 in women) and about 1,090 deaths due to CML (620 men and 470 women)².

About SCO-088:

SCO-088 is a novel and highly selective Bcr – Abl kinase inhibitor intended for the treatment of resistant Chronic Myelogenous Leukemia. SCO-088 is a potent inhibitor of Bcr-Abl and its mutant forms.

Sun Pharma Advanced Research Company Ltd.

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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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Reference

1. Elias Jabbour, Hagop Kantarjian; Am J Hematol. 2018;93:442–459.
2. American Cancer Society. Cancer Facts & Figures 2018 [<https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf>.]

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