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SPARC Announces Positive Top-line Results from Pivotal Phase 3 Clinical Trial of SDN-037 for the Treatment of Inflammation and Pain Associated with Ocular Surgery

Met Pre-specified Primary and Secondary Endpoints

MUMBAI – October 14, 2020, Sun Pharma Advanced Research Company Ltd. (SPARC) (Reuters: SPRC.BO, Bloomberg: SPADV IN, NSE: SPARC, BSE: 532872) today reported positive top-line results from its Phase 3 trial for its investigational drug, SDN-037, for the treatment of Inflammation and Pain associated with Ocular Surgery. The trial met its pre-specified primary and secondary objectives, demonstrating that SDN-037 is superior to its vehicle.

The objective of the trial was to assess the efficacy and safety of SDN-037 in clearing the inflammation and pain. To that end, the primary efficacy measure was the proportion of subjects with an anterior chamber cell (ACC) grade of zero (0) on Day 15 (zero inflammation). A statistically significant proportion of patients treated with SDN-037 achieved an ACC grade of 0 versus vehicle with p-values <0.0001 in the Intent-To-Treat population.

A key secondary endpoint was the proportion of subjects with a visual analog scale (VAS) pain score of zero (0) at Day 15, and this was also statistically significant in patients treated with SDN-037 compared to vehicle.

SDN-037 was generally well-tolerated in this study with adverse events consistent with the known safety profile of difluprednate.

"On behalf of everyone at SPARC, I would like to extend my sincere gratitude to the patients, families and investigators involved in this study. We are extremely pleased with the top-line efficacy and safety results," said Anil Raghavan, CEO of SPARC.

About SDN-037:

SDN-037 is a novel, twice-a-day, clear, micellar formulation of difluprednate. SDN-037 is 0.04% difluprednate ophthalmic solution with lower dose (i.e. 0.04% w/v) and reduced dosing frequency (twice-a-day) compared to currently commercialized formulation of difluprednate.

About SPARC (CIN: L73100GJ2006PLC047837):

Sun Pharma Advanced Research Company Ltd. ('SPARC') is a pharmaceutical company focused on continuously improving standards of care for patients globally through innovation in therapeutics and delivery. SPARC consistently aims to 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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