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SPARC Announces Positive Top-line Results from Pivotal Phase 3 Clinical Trial of PDP-716 for the Treatment of Open Angle Glaucoma or Ocular Hypertension

Met Pre-specified Primary Endpoint

MUMBAI – May 14, 2021, 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 (CLR_16_33) for its investigational drug, PDP-716 ophthalmic suspension, for the treatment of Open Angle Glaucoma or Ocular Hypertension. The trial met its pre-specified primary endpoint, demonstrating that PDP-716 dosed once daily is equivalent to Alphagan® P 0.1% dosed 3 times a day.

The primary endpoint of the trial was to evaluate the efficacy of once daily (QD) dosing of PDP-716 0.35% compared with Alphagan® P 0.1% dosed 3 times a day (TID) in subjects with open-angle glaucoma or ocular hypertension. Equivalence in intraocular pressure was demonstrated across all 9 required timepoints, showing that the 2 formulations of brimonidine are functionally equivalent.

The safety of once daily (QD) dosing of PDP-716 compared with Alphagan® P 0.1% dosed 3 times a day (TID) was also evaluated. Treatment emergent adverse events were similar with 38.8% in the PDP-716 group vs. 33.2% with Alphagan® P 0.1% group.

“We are very pleased by these results for PDP-716. Once daily dosing of PDP-716 can significantly reduce the dosing frequency compared to currently marketed formulation and can have positive impact on quality of life for patients with Glaucoma. On behalf of everyone at SPARC, I would like to extend my sincere gratitude to the patients, families and investigators involved in this study.” said Anil Raghavan, CEO of SPARC.

About PDP-716:

PDP-716 is a novel, once daily, ophthalmic suspension of Brimonidine Tartrate 0.35%. PDP-716 is developed using SPARC's proprietary TearAct™ technology.

About CLR_16_33:

CLR_16_33 is randomized, multi-center, investigator-masked, parallel group, equivalence study of once daily PDP-716 0.35% ophthalmic suspension compared with 3 times a day Alphagan® P 0.1% in subjects with open angle glaucoma or ocular hypertension.

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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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