FOR IMMEDIATE RELEASE

FDA issues complete response letter for PDP-716 NDA due to inspection findings at third-party API manufacturing facility

- *No issues with clinical efficacy or safety were identified in the CRL*
- *No additional clinical data or trials have been requested*

Mumbai, India, July 13, 2023 – Sun Pharma Advanced Research Company Ltd. (Reuters: SPRC.BO, Bloomberg: SPADV IN, NSE: SPARC, BSE: 532872, "SPARC") today announced that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) for the New Drug Application (NDA) for PDP-716 for the treatment of patients with Glaucoma, due to inspection findings at a third-party Active Pharmaceutical Ingredient (API) manufacturing facility. The FDA did not raise any issues with the PDP-176 clinical efficacy or safety and no additional clinical data or trials have been requested. SPARC is committed to work closely with Visiox, the FDA and the third-party manufacturer to resubmit the NDA as quickly as possible.

About PDP-716:

PDP-716 is a novel, once daily, ophthalmic suspension of brimonidine tartrate 0.35%. PDP-716 was developed using SPARC's proprietary TearAct™ technology. SPARC had previously licensed global commercialization rights excluding India and China of PDP-716 to Visiox Pharmaceuticals Inc.

About Sun Pharma Advanced Research Company Ltd. (CIN - L73100GJ2006PLC047837):

Sun Pharma Advanced Research Company Ltd. (SPARC) is a clinical stage bio-pharmaceutical company focused on continuously improving standards of care for patients globally, through innovation in therapeutics and delivery. SPARC aims to advance availability of treatment options for patients across the world. More information about the company can be found at www.sparc.life

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