



SPARC/Sec/SE/2023-24/027

July 13, 2023

National Stock Exchange of India Ltd.,
Exchange Plaza, 5th Floor,
Plot No. C/1, G Block,
Bandra Kurla Complex,
Bandra (East), Mumbai – 400 051.

BSE Limited,
Market Operations Dept.
P. J. Towers,
Dalal Street,
Mumbai - 400 001.

Scrip Symbol: SPARC

Scrip Code: 532872

Dear Sir/ Madam,

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

Pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, we enclose herewith the Press Release on the above mentioned subject, which we shall be releasing after sending this letter to you.

This is for your information and dissemination.

Yours faithfully,

For **Sun Pharma Advanced Research Company Limited**

Dinesh Lahoti
Company Secretary and Compliance Officer
ICSI Membership No.: A22471

Encl: As above



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: SPARC.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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