

Sun Pharma Advanced Research Company Ltd.  
17/B, Mahal Industrial Estate,  
Mahakali Caves Road,  
Andheri (East), Mumbai 400 093 India  
Tel.: (91-22) 6645 5645  
Fax.: (91-22) 6645 5685  
CINNo:L73100GJ2006PLC047837



**FOR IMMEDIATE RELEASE**

## **SPARC Receives Complete Response Letter (CRL) from USFDA for Latanoprost NDA**

Mumbai, August 1, 2015 - 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 issued a Complete Response letter (CRL) to its New Drug Application (NDA) for Xelpros, Latanoprost BAK-free eyedrops.

SPARC submitted a response to an earlier CRL it had received from the USFDA, wherein no additional preclinical or clinical data was required. While the USFDA has accepted the clarifications and changes to the labeling, SPARC has now received another CRL from the USFDA seeking minor changes to the proposed labeling. SPARC hopes to address these requirements soon.

This product is to be manufactured at SPIL's Halol facility and the USFDA has indicated that a satisfactory resolution of the cGMP deficiencies at this facility is a prerequisite for the final approval of Xelpros. SPARC had recently out-licensed this product to a subsidiary of Sun Pharmaceutical Industries Ltd (SPIL).

### **About Latanoprost BAK-Free**

Latanoprost BAK-free is a Benzyalkonium Chloride-free, once-a-day formulation of the glaucoma medication Latanoprost using SPARC's novel Swollen Micelle Microemulsion (SMM) technology. Unlike conventional glaucoma eyedrops, Latanoprost BAK-free does not cause or aggravate Ocular Surface Disease (OSD).

Prostaglandin analogues like latanoprost are the first line of treatment for glaucoma. Market estimates place Latanoprost usage at as high as 55% of the US glaucoma market.

Swollen micelle microemulsion technology, or SMM, helps to solubilize drugs that have limited or no solubility, and cuts out the need for a preservative.

### **About SPARC**

Sun Pharma Advanced Research Company Ltd. (SPARC) is an international pharmaceutical company engaged in research and development of drugs and delivery systems. More information about the company can be found at [www.sunpharma.in](http://www.sunpharma.in).

Sun Pharma Advanced Research Company Ltd.  
17/B, Mahal Industrial Estate,  
Mahakali Caves Road,  
Andheri (East), Mumbai 400 093 India  
Tel.: (91-22) 6645 5645  
Fax.: (91-22) 6645 5685  
CINNo:L73100GJ2006PLC047837



**Contact**

Mira Desai  
Tel +91 22 6645 5645, Ext 5606  
Tel Direct +91 22 66455606  
Mobile +91 98219 23797  
Email: [miradesai@sparcmail.com](mailto:miradesai@sparcmail.com)