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## FOR IMMEDIATE RELEASE

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

Dec 1, 2014, Mumbai: 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 (FDA) has issued a Complete Response letter to its New Drug Application (NDA) for Latanoprost BAK-free eyedrops.

While the FDA did not seek any additional information for supporting clinical data, it sought additional information on certain labeling and other deficiencies for processing the NDA.

SPARC believes that this additional information request from the FDA can be addressed on priority.

# **About Latanoprost BAK-Free**

Latanoprost BAK-free is a preservative-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 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.

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