



FOR IMMEDIATE RELEASE

Sun Pharma and SPARC enter into a license agreement for commercialization of phenobarbital for injection in the US

- *Product awaiting US FDA approval, targeted at treating seizures in neonatal patients*
- *Benzyl alcohol and propylene glycol-free formulation to minimize gasping syndrome risk*

Mumbai, India, November 9, 2022 – A wholly-owned subsidiary of Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" and includes its subsidiaries and/or associate companies) and Sun Pharma Advanced Research Company Ltd. (Reuters: SPRC.BO, Bloomberg: SPADV IN, NSE: SPARC, BSE: 532872, "SPARC") today announced the signing of a licensing agreement for commercialization of benzyl alcohol and propylene glycol-free phenobarbital sodium powder for injection in the United States. SPARC submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (US FDA) for this product for the treatment of neonatal seizures in February 2022. Currently, there are no phenobarbital injection products approved by the US FDA for the treatment of seizures in newborns.

Under the terms of the license agreement, Sun Pharma will pay SPARC an upfront payment of US \$10 million. SPARC will also be eligible to receive milestone payments contingent upon the achievement of regulatory and sales milestones, as well as tiered royalties on sales.

"SPARC's benzyl alcohol and propylene glycol-free formulation of phenobarbital for injection is an exciting addition to our growing portfolio of specialty branded products in the U.S. Through our existing relationships with hospitals and other institutional customers, we are well-positioned to bring this product to market and make a difference in the lives of patients," said Abhay Gandhi, CEO North America, Sun Pharma.

"SPARC is excited to enter into this collaboration with Sun Pharma and is committed to developing new products to address the needs of patients. SPARC's benzyl alcohol and propylene glycol-free formulation of phenobarbital for injection is designed to minimize the risk of neonatal gasping syndrome, a life-threatening condition, which can be observed with the use of benzyl alcohol containing drug formulations," said Anil Raghavan, CEO, SPARC.



About SPARC's phenobarbital formulation

SPARC's phenobarbital sodium powder for injection is a benzyl alcohol and propylene glycol-free formulation intended for the treatment of seizures in neonates. It was granted orphan drug designation by the US FDA for the treatment of neonatal seizures. The currently marketed phenobarbital formulations are notified under the DESI (Drug Efficacy Study Implementation) program list by the U.S. Department of Health and Human Services.

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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

About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050):

Sun Pharma is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business and a skilled team enables it to deliver high-quality products, trusted by customers and patients in over 100 countries across the world, at affordable prices. Its global presence is supported by manufacturing facilities spread across six continents and approved by multiple regulatory agencies, coupled with a multi-cultural workforce comprising over 50 nationalities. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities across multiple R&D centers, with investments of approximately 6% of annual revenues in R&D. For further information, please visit www.sunpharma.com and follow us on Twitter @SunPharma_Live.

Contact: SPARC

Investors & Media:

Jaydeep Issrani

Tel +91 22 6645 5645, Xtn 5787

Tel Direct +91 22 6645 5787

Mobile +91-98202 16916

E mail jaydeep.issrani@sparcmail.com



Contacts: Sun Pharma

Investors:

Dr. Abhishek Sharma

Tel +91 22 4324 4324, Xtn 2929

Tel Direct +91 22 4324 2929

Mobile +91 98196 86016

E mail abhi.sharma@sunpharma.com

Media:

Gaurav Chugh

Tel +91 22 4324 4324, Xtn 5373

Tel Direct +91 22 4324 5373

Mobile +91 98104 71414

E mail gaurav.chugh@sunpharma.com