



SPARC/Sec/SE/2022-23/70

November 09, 2022

**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.

**Ref:** Scrip Code: NSE: SPARC; BSE: 532872

Dear Sir/Madam,

**Sub:** Press Release: SPARC and Sun Pharma enter into a license agreement for commercialization of phenobarbital for injection in the US

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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 Ltd.**

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

Encl: As above



**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.

#### **Disclaimer:**

Statements in this "Document" describing the Company's objectives, projections, estimates, expectations, plans or predictions or industry conditions or events may be "forward looking statements" within the meaning of applicable securities laws and regulations. Actual results, performance or achievements could differ materially from those expressed or implied. The Company undertakes no obligation to update or revise forward looking statements to reflect developments or circumstances that arise or to reflect the occurrence of unanticipated developments/circumstances after the date hereof.

### **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](http://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](http://www.sunpharma.com) and follow us on Twitter @SunPharma\_Live.

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