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18 November 2022.

National Stock Exchange of India Limited,
Exchange Plaza, 5th Floor,
Plot No. C/1, G Block,
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Scrip Symbol: SUNPHARMA

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

Scrip Code: 524715

Sub: Press Release

Dear Sir / Madam,

Please find enclosed herewith our Press Release relating to US FDA approval for phenobarbital sodium powder for injection, which we shall be releasing after sending this letter to you.

This is for your information and dissemination.

Thanking you,

Yours faithfully,

For **Sun Pharmaceutical Industries Limited**

(Anoop Deshpande)
Company Secretary and Compliance Officer

Enclosed: As above

FOR IMMEDIATE RELEASE

SEZABY™ (phenobarbital sodium powder for injection) approved by US FDA for the treatment of neonatal seizures

- *First and only product approved for treating seizures in neonatal patients*
- *Approval triggers a milestone payment for SPARC*

Mumbai, India, November 18, 2022 – 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 that the U.S. Food and Drug Administration (US FDA) has approved SEZABY™ (phenobarbital sodium powder for injection) for the treatment of neonatal seizures. With this approval, SEZABY becomes the first and only product specifically indicated in the U.S. for the treatment of neonatal seizures in term and preterm infants. SEZABY is expected to be available in the U.S. in Q4FY23.

SEZABY is a benzyl alcohol-free and propylene glycol-free formulation of phenobarbital sodium powder for injection. It was granted orphan drug designation by the US FDA for the treatment of neonatal seizures.

SEZABY was recently licensed by SPARC to Sun Pharma. Under the terms of the license agreement, SPARC is eligible to receive a milestone payment on approval of SEZABY by the US FDA.

"SEZABY is an exciting addition to our growing portfolio of specialty branded products in the U.S.," said Abhay Gandhi, CEO North America, Sun Pharma. "As the first and only product specifically indicated to treat seizures in term and preterm infants, SEZABY has the potential to make a difference in the lives of patients and their families."

"For years, physicians have had limited treatment options to manage neonates with seizures. SPARC is proud to have developed benzyl alcohol-free and propylene glycol-free phenobarbital sodium powder for injection as the first treatment option now approved by the US FDA," said Anil Raghavan, CEO, SPARC.

SEZABY was approved based on the results of NEOLEV2, a phase 2 study that evaluated levetiracetam compared to phenobarbital in the first-line treatment of neonatal seizures.

About Neonatal Seizures

Seizures are more common in the neonatal period (first 28 days of life) than at any other time during life. The incidence of seizures during the first month of life is approximately 1 to 4 per thousand babies.[1] Their occurrence is associated with poor outcomes such as cerebral palsy, global developmental delay, and epilepsy in up to 40 to 60% of babies who suffer seizures.[2]

About the NEOLEV2 Trial

Phenobarbital has been commonly used to treat neonatal seizures. NEOLEV2 was a phase 2 study that evaluated levetiracetam compared to phenobarbital in the first-line treatment of neonatal seizures. The randomized controlled trial compared the incidence of recurrent seizures in neonates treated with phenobarbital vs. levetiracetam in 94 neonates. Twenty-four hours following the administration of phenobarbital or levetiracetam, 73% vs. 25% were seizure-free in the respective groups.

The most common adverse reactions (incidence > 5% patients overall) were abnormal respiration, sedation, feeding disorder, and hypotension.

About SEZABY (phenobarbital sodium powder for injection)

SEZABY is a benzyl alcohol-free and propylene glycol-free formulation of phenobarbital sodium powder for injection. It was granted orphan drug designation by the US FDA for the treatment of neonatal seizures.

Important Safety Information

WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS; DEPENDENCE AND WITHDRAWAL REACTIONS AFTER USE OF SEZABY FOR A LONGER DURATION THAN RECOMMENDED; and ABUSE, MISUSE, AND ADDICTION WITH UNAPPROVED USE IN ADOLESCENTS AND ADULTS

- **Concomitant use of phenobarbital products, including SEZABY, and opioids may result in profound sedation, respiratory depression, coma, and death. If a decision is made to use concomitantly, limit dosages and durations to the minimum required, and monitor patients for respiratory depression and sedation.**
- **Although SEZABY is indicated only for short-term use, if used for a longer duration than recommended, abrupt discontinuation or rapid dosage reduction may precipitate acute withdrawal reactions, which can be life-threatening. For patients receiving SEZABY for a longer duration than recommended, to reduce the risk of withdrawal reactions, use a gradual taper to discontinue SEZABY.**

- **SEZABY is not approved for use in adolescents or adults. The unapproved use of SEZABY in adolescents and adults exposes them to risks of abuse, misuse, and addiction, which can lead to overdose or death.**

The most common adverse reactions (incidence > 5% patients overall) are abnormal respiration, sedation, feeding disorder, and hypotension.

Please see full Prescribing Information, including Boxed WARNING, for SEZABY.

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.

References:

1. Vasudevan C, Levene M. Epidemiology and aetiology of neonatal seizures. Semin Fetal Neonatal Med. 2013 Aug;18(4):185-91

2. Uria-Avellanal C, Marlow N, Rennie JM. Outcome following neonatal seizures Semin Fetal Neonatal Med 2013 Aug;18(4):224-32

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 Limited (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.

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