

FOR IMMEDIATE RELEASE

Sun Pharma and Ferring Pharmaceuticals enter into licensing agreement for introducing CARITEC® in India

- *CARITEC® is an innovative obstetric drug for preventing post-partum hemorrhage*
- *It is a Room Temperature Stable (RTS) formulation of Carbetocin and addresses limitations in refrigeration and cold-chain transportation*

Mumbai, India, June 02, 2021 - Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" and includes its subsidiaries and/or associate companies) today announced that one of its wholly owned subsidiaries has entered into a license agreement with Ferring Pharmaceuticals Pvt. Ltd. (Ferring), a subsidiary of Switzerland-based biopharmaceuticals MNC Ferring Pharmaceuticals, to commercialize a Room Temperature Stable (RTS) formulation of obstetric drug, CARITEC® (Carbetocin RTS) in India. CARITEC® is indicated for the prevention of excessive bleeding in women after vaginal or caesarean child birth. The condition is commonly known as post-partum hemorrhage (PPH).

As per agreement terms, Sun Pharma is granted rights for co-marketing of the drug in India in the private market under the brand name CARITEC®. Ferring has developed the drug and received approval from the Drugs Controller General of India (DCGI) for introducing the drug in India.

Kirti Ganorkar, CEO-India business, Sun Pharma, said, "PPH is one of the leading causes of maternal mortality worldwide. As per WHO, 25% of maternal deaths occur due to this condition.ⁱ Through our collaboration with Ferring, we are introducing an innovative medicine that will help in reducing thousands of deaths from PPH every year. We believe this unique RTS formulation of Carbetocin will play an important role in PPH prevention in India."

PPH is leading cause of maternal mortality worldwide and especially in countries like India. India's current Maternal Mortality Ratio (MMR) stands at 113 deaths per 100,000 live births.ⁱⁱ PPH is a frequent complication of child birth and its reported incidence in India is 2% - 4% after vaginal delivery and 6% after caesarean section. As per a survey conducted in India, PPH contributes to 38% of maternal deaths.

Postpartum bleeding is a largely preventable and manageable condition. In the absence of prevention and timely and appropriate action, however, even a healthy woman could die within a few hours."

About CARITEC® (carbetocin RTS)

Currently, WHO recommends oxytocin as the first-choice drug for preventing excessive bleeding after childbirth. Oxytocin, however, must be stored and transported at 2–8 degrees Celsius, which is hard to do, in many low-income countries, depriving many women the access to this lifesaving drug. CARITEC® is a drug similar to oxytocin with longer duration of action. The new Room temperature stable formulation of carbetocin does not require refrigeration and retains its efficacy for 2 years stored at 30 degrees Celsius and 75% relative humidity. A study published in the New England Journal of Medicine with 30,000 patients has shown room temperature stable carbetocin to be as safe and effective as oxytocin in preventing postpartum haemorrhage. The study included almost 7,000 women from India. This new room temperature stable formulation of carbetocin, to prevent excessive bleeding following childbirth, could save thousands of women's lives in low- and lower-middle-income countries like India^{iii,iv}.

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References:

ⁱ National Health Portal: Postpartum haemorrhage. Accessed from <https://www.nhp.gov.in/disease/gynaecology-and-obstetrics/postpartum-haemorrhage#:~:text=About%20830%20women%20die%20from,deaths%20are%20due%20to%20PPH> on dated 05 May 2021.

ⁱⁱ<https://www.pib.gov.in/PressReleasePage.aspx?PRID=1697441>).

ⁱⁱⁱWHO News Release: WHO study shows drug could save thousands of women's lives. As accessed from <https://www.who.int/news/item/27-06-2018-who-study-shows-drug-could-save-thousands-of-women%E2%80%99s-lives> on dated 05 May 2021.

^{iv}Clinical Trial Registry of India. CTRI/2016/05/006969: A phase III, randomized, double-blind, active, controlled, multinational, multicentre, non-inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum haemorrhage during the third stage of labour in women delivering vaginally. As accessed from: http://ctri.nic.in/ClinicalTrials/pdf_generate.php?trialid=14677&EncHid=&modid=&compid=%27,%2714677det%27 on dated 05 May 2021.

Sun Pharmaceutical Industries Limited.

SUN HOUSE, CTS No. 201 B/1,
Western Express Highway, Goregaon (E),
Mumbai 400063, India
Tel.: (91-22) 4324 4324 Fax.: (91-22) 4324 4343
CIN: L24230GJ1993PLC019050
www.sunpharma.com



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 6 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 6-7% of annual revenues in R&D. For further information, please visit www.sunpharma.com & follow us on Twitter @SunPharma_Live

About Ferring Pharmaceuticals

Ferring Pharmaceuticals is a research-driven, speciality biopharmaceutical group committed to helping people around the world build families and live better lives. Headquartered in Saint-Prex, Switzerland, Ferring is a leader in reproductive medicine and women's health, and in speciality areas within gastroenterology and urology. Ferring has been developing treatments for mothers and babies for over 50 years and has a portfolio covering treatments from conception to birth. Founded in 1950, has its own operating subsidiaries in nearly 60 countries and markets its products in 110 countries.

Contacts:

Investors:

Nimish Desai
Tel +91 22 4324 4324, Xtn 2778
Tel Direct +91 22 4324 2778
Mobile +91-98203 30182
E mail nimish.desai@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