Sun Pharmaceutical Industries Ltd. 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



# FOR IMMEDIATE RELEASE

# Sun Pharma Announces U.S. FDA Approval of INFUGEM<sup>™</sup> Injection

Ready-to-administer gemcitabine adds to Sun Pharma's growing oncology portfolio of novel products

- Pre-mixed medicines are expected to play an increasing role due to improved safety, convenience & time saving benefits
- First USFDA approval for a product from the Halol facility post receipt of EIR

**Mumbai, India, July 18, 2018** – Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" including its subsidiaries and/or associate companies) today announced that it has received approval from the U.S. Food and Drug Administration (USFDA) for INFUGEM<sup>™</sup> (gemcitabine in 0.9% sodium chloride injection) 10 mg/mL, for intravenous use in a ready-to-administer (RTA) bag. This is the first USFDA approval for a product from Sun Pharma's Halol facility post receipt of Establishment Inspection Report (EIR) in June 2018.

INFUGEM<sup>™</sup> uses a proprietary technology which allows cytotoxic oncology products to be premixed in a sterile environment and supplied to the prescribers in RTA infusion bags. It involves dose banding practice, whereby standardized doses of intravenous cytotoxic drugs are used for ranges (or "bands") of doses calculated for individual patients. The RTA bags will provide greater safety by preventing problems of over or under-dosing, preventing the risk of contamination that can lead to infections, and by taking care of problems associated with, and precautions to be taken while, handling cytotoxic drugs by healthcare providers.

"The technology used to formulate INFUGEM<sup>™</sup> eliminates the risks associated with compounding, an extra step in the administration of cytotoxic infusion products, providing improved safety for healthcare professionals and cancer patients," said Abhay Gandhi, CEO - North America, Sun Pharma. "We're pleased to add this novel product to our expanding oncology portfolio, as gemcitabine is one of the most commonly used cytotoxics in oncology practices."

The addressable market size is approximately US\$ 35 million for the 12 months ending March 2018, as per IQVIA.

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

Sun Pharma is the world's fifth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business, economies of scale and an extremely skilled team enable us to deliver quality products in a timely manner at affordable prices. It provides high-quality, affordable medicines trusted by customers and patients in over 150 countries across the world. Sun Pharma's global presence is supported by 41 manufacturing facilities spread across 6 continents, R&D centres across the globe and a multi-cultural workforce comprising over 50 nationalities. In India, the company enjoys leadership across 13 different classes of doctors with 32 brands featuring amongst top 300 pharmaceutical brands in India. Its footprint across emerging markets covers over 100 markets and 6 markets in Western Europe. Its Global Consumer Healthcare business is ranked amongst Top 10 across 3 global markets. Its API business footprint is strengthened through 14 world class API manufacturing

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facilities across the globe. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities comprising about 2,000 scientists and R&D investments of approximately 8% of annual revenues. For further information, please visit www.sunpharma.com & follow us on Twitter @SunPharma\_Live.

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