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**FOR IMMEDIATE RELEASE**

## **Sun Pharma Launches Ready-to-Infuse INFUGEM in the U.S.**

*INFUGEM™ (gemcitabine in sodium chloride injection) is the first and only chemotherapy product in a premixed, ready-to-infuse formulation*

*Use of ready-to-infuse bags eliminates steps in the complex chemotherapy preparation process, reducing exposure and mitigating inherent provider and patient safety risks*

**Mumbai, India & Princeton, NJ, April 8, 2019** -- Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" and includes its subsidiaries and/or associate companies) today announced that INFUGEM™ (gemcitabine in sodium chloride injection), for intravenous use, is now commercially available in the U.S. INFUGEM, the first chemotherapy product that comes in a premixed, ready-to-infuse formulation, was approved by the U.S. Food and Drug Administration (FDA) in July 2018 in combination with other drugs for the treatment of breast, ovarian, non-small cell lung cancers, and as a single agent for the treatment of pancreatic cancer.

INFUGEM is an alcohol-free, clear, colorless, sterile solution of 10mg/mL gemcitabine in 0.9% sodium chloride that is supplied to pharmacists in ready-to-infuse bags as a Spike & Go™ package. It involves dose banding practice, whereby standardized doses of intravenous cytotoxic drugs are used for ranges (or "bands") of doses calculated for individual patients. INFUGEM is the only available gemcitabine formulation that does not require reconstitution and syringe withdrawal prior to intravenous administration. Eliminating these steps reduces complexity and minimizes the inherent risks of hazardous drug exposure, contamination, and medication errors.

"INFUGEM is an example of our focus at Sun Pharma, which is to improve provider and patient experiences by using high-tech delivery systems and/or novel formulations for gold-standard medicines," said Abhay Gandhi, CEO-North America, Sun Pharma. "With an increasing number of organizations strongly recommending the use of premixed parenteral products due to concerns related to manual compounding, and with the broad use of gemcitabine to treat various cancers, the timing couldn't be better to launch INFUGEM in the U.S."

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INFUGEM is the first product using Sun's proprietary technology which allows cytotoxic oncology products to be premixed in a sterile environment and supplied to the prescribers in ready-to-infuse final dosage bags. The product is stable at room temperature storage conditions for two years, even without the use of alcohol and other preservatives in the bag. By contrast, other gemcitabine products require reconstitution and/or dilution for patient use, and remain stable at room temperature for only 24 hours.

"The availability of gemcitabine in ready-to-infuse bags is a welcome development, simplifying the complex delivery of this vital chemotherapy medication," commented Jeff Lombardo PharmD, BCOP, Research Assistant Professor, Center of Integrated Global Biomedical Sciences, University at Buffalo.

For more information about INFUGEM, please visit [www.infugem.com](http://www.infugem.com).

## **INFUGEM™ Prescribing Information**

### **INDICATIONS AND USAGE**

INFUGEM is a nucleoside metabolic inhibitor indicated for:

**Ovarian Cancer:** in combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy.

**Breast Cancer:** in combination with paclitaxel, for first-line treatment of metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated.

**Non-Small Cell Lung Cancer:** in combination with cisplatin for the first-line treatment of patients with inoperable, locally advanced (Stage IIIA or IIIB), or metastatic (Stage IV) non-small cell lung cancer.

**Pancreatic Cancer:** as first-line treatment for patients with locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) adenocarcinoma of the pancreas. INFUGEM is indicated for patients previously treated with fluorouracil.

### **IMPORTANT SAFETY INFORMATION**

#### **CONTRAINDICATIONS**

INFUGEM is contraindicated in patients with a known hypersensitivity to gemcitabine.

## **WARNINGS AND PRECAUTIONS**

**Schedule-Dependent Toxicity:** In clinical trials evaluating the maximum tolerated dose of gemcitabine, prolongation of the infusion time beyond 60 minutes or more frequent than weekly dosing resulted in an increased incidence of clinically significant hypotension, severe flu-like symptoms, myelosuppression and asthenia.

**Myelosuppression:** Myelosuppression manifested by neutropenia, thrombocytopenia and anemia occurs with INFUGEM as a single agent, and the risks are increased when INFUGEM is combined with other cytotoxic drugs. Monitor patients receiving INFUGEM prior to each dose with a complete blood count (CBC), including differential and platelet count, and modify the dosage as recommended.

**Pulmonary Toxicity and Respiratory Failure:** Permanently discontinue INFUGEM in patients who develop unexplained dyspnea, with or without bronchospasm, or have any evidence of pulmonary toxicity.

**Hemolytic Uremic Syndrome:** Hemolytic uremic syndrome (HUS), including fatalities from renal failure or the requirement for dialysis, can occur in patients treated with INFUGEM. Assess renal function prior to initiation of INFUGEM and periodically during treatment. Consider the diagnosis of HUS in patients who develop anemia with evidence of microangiopathic hemolysis, elevation of bilirubin or LDH, or reticulocytosis; severe thrombocytopenia; or evidence of renal failure (elevation of serum creatinine or BUN). Permanently discontinue INFUGEM in patients with HUS or severe renal impairment. Renal failure may not be reversible even with discontinuation of therapy.

**Hepatic Toxicity:** Drug-induced liver injury, including liver failure and death, has been reported in patients receiving gemcitabine alone or in combination with other potentially hepatotoxic drugs. Administration of INFUGEM in patients with concurrent liver metastases or a preexisting medical history of hepatitis, alcoholism or liver cirrhosis can lead to exacerbation of the underlying hepatic insufficiency. Assess hepatic function prior to initiation of INFUGEM and periodically during treatment. Permanently discontinue INFUGEM in patients that develop severe liver injury.

**Embryo-Fetal Toxicity:** INFUGEM can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with INFUGEM and for 6 months after the final dose. Advise male patients with female partners of reproductive potential to use effective contraception during and for 3 months following the final dose of INFUGEM.

**Exacerbation of Radiation Therapy Toxicity:** INFUGEM is not recommended for use in combination with radiation therapy.

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Concurrent (given together or  $\leq 7$  days apart): Life-threatening mucositis, especially esophagitis and pneumonitis, occurred in a trial in which gemcitabine was administered at a dose of 1000 mg/m<sup>2</sup> to patients with non-small cell lung cancer for up to 6 consecutive weeks concurrently with thoracic radiation.

Non-concurrent (given  $>7$  days apart): Excessive toxicity has not been observed when gemcitabine is administered more than 7 days before or after radiation. Radiation recall has been reported in patients who receive gemcitabine after prior radiation

**Capillary Leak Syndrome:** Capillary leak syndrome (CLS) with severe consequences has been reported in patients receiving gemcitabine as a single agent or in combination with other chemotherapeutic agents. Permanently discontinue INFUGEM if CLS develops during therapy.

**Posterior Reversible Encephalopathy Syndrome:** Posterior reversible encephalopathy syndrome (PRES) has been reported in patients receiving gemcitabine as a single agent or in combination with other chemotherapeutic agents. PRES can present with headache, seizure, lethargy, hypertension, confusion, blindness and other visual and neurologic disturbances. Confirm the diagnosis of PRES with magnetic resonance imaging (MRI) and permanently discontinue INFUGEM if PRES develops during therapy.

## **ADVERSE REACTIONS**

The most common adverse reactions for the single agent ( $\geq 20\%$ ) are nausea/vomiting, anemia, hepatic transaminitis, neutropenia, increased alkaline phosphatase, proteinuria, fever, hematuria, rash, thrombocytopenia, dyspnea and peripheral edema.

## **USE IN SPECIFIC POPULATIONS**

Due to the potential for serious adverse reactions in nursing infants from INFUGEM, women should not breastfeed during treatment with INFUGEM and for at least one week after the last dose.

The safety and effectiveness of INFUGEM have not been established in pediatric patients.

Please see Full Prescribing Information for INFUGEM™ at <http://www.infugem.com/infugem-PI>.

INFUGEM is a trademark of Sun Pharma Global FZE.

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**About Sun Pharmaceutical Industries Inc., USA (SPII)**

SPII is a wholly owned subsidiary of Sun Pharmaceutical Industries Ltd, a global specialty generic company based in Mumbai, which provides innovative, high-quality, affordable medicines trusted by customers and patients in more than 100 countries around the world. Sun Pharma's global presence is supported by 44 manufacturing facilities spread across 6 continents, R&D centers across the globe and a multi-cultural workforce comprising over 50 nationalities. In India, the company enjoys leadership across 10 different classes of doctors with 30 brands featuring amongst the top 300 pharmaceutical brands. Its footprint across emerging markets covers over 100 markets and 6 markets in Western Europe, and our Global Consumer Healthcare business is ranked amongst the top 10 across 3 global markets. Sun Pharma's API business footprint is strengthened through 14 world-class API manufacturing facilities across the globe. It 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](http://www.sunpharma.com) & follow us on Twitter @SunPharma\_Live.

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