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Sun Pharma launches INFUGEM in the U.S.

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



India-based Sun Pharmaceutical Industries Ltd. has 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.”

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.