Infugem™ (gemcitabine) – New drug approval

- On July 18, 2018, Sun Pharma announced the FDA approval of Infugem (gemcitabine), for patients with the following indications:
    - In combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy.
    - 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.
    - In combination with cisplatin for the first-line treatment of inoperable, locally advanced (stage IIIA or IIIB), or metastatic (stage IV) non-small cell lung cancer (NSCLC).
    - The first-line treatment of locally advanced (nonresectable stage II or stage III) or metastatic (stage IV) adenocarcinoma of the pancreas, in patients previously treated with fluorouracil.

- Infugem uses proprietary technology which allows cytotoxic oncology products to be premixed in a sterile environment and supplied to the prescribers in ready-to-administer infusion bags.

- Gemcitabine is also available generically as a powder for intravenous (IV) injection and a solution for IV infusion.
    - These products share the same FDA-approved indications as Infugem.

- Warnings and precautions of Infugem include schedule-dependent toxicity, myelosuppression, pulmonary toxicity and respiratory failure, hemolytic-uremic syndrome, hepatic toxicity, embryo-fetal toxicity, exacerbation of radiation therapy toxicity, capillary leak syndrome, and posterior reversible encephalopathy syndrome.

- The most common adverse reactions (≥ 20%) with Infugem use as a single agent were nausea/vomiting, anemia, hepatic transaminitis, neutropenia, increased alkaline phosphatase, proteinuria, fever, hematuria, rash, thrombocytopenia, dyspnea, and peripheral edema.

- The recommended dosage of Infugem is given as an IV infusion as follows:
    - Ovarian cancer: 1,000 mg/m^2 on days 1 and 8 of each 21-day cycle.
    - Breast cancer: 1,250 mg/m^2 on days 1 and 8 of each 21-day cycle.
    - NSCLC: 1,000 mg/m^2 on days 1, 8, and 15 of each 28-day cycle or 1,250 mg/m^2 on days 1 and 8 of each 21-day cycle.
    - Pancreatic cancer: 1,000 mg/m^2 once weekly for the first 7 weeks, then one week rest, then once weekly for 3 weeks of each 28-day cycle.
    - Infugem is provided in premixed bags that are ready for infusion and do not require any further preparation prior to use.
    - The Infugem premixed bag(s) should be selected based on the patient's body surface area range as outlined in Infugem's drug label.
    - Consult the Infugem drug label for additional dosing recommendations, including when used as part of a combination regimen.

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- Sun Pharma's launch plans for Infugem are pending. Infugem will be available as premixed infusion bags containing 10 mg/ml of gemcitabine in 0.9% sodium chloride in the following strengths: 1,200 mg, 1,300 mg, 1,400 mg, 1,500 mg, 1,600 mg, 1,700 mg, 1,800 mg, 1,900 mg, 2,000 mg, and 2,200 mg.