Khapzory™ (levoleucovorin) – New Drug Approval

- On October 23, 2018, Spectrum announced the FDA approval of Khapzory (levoleucovorin) injection for rescue after high-dose methotrexate therapy in patients with osteosarcoma, diminishing the toxicity associated with overdosage of folic acid antagonists or impaired methotrexate elimination, and for the treatment of patients with metastatic colorectal cancer in combination with fluorouracil.
    - Khapzory is not indicated for the treatment of pernicious anemia and megaloblastic anemia secondary to lack of vitamin B12 because of the risk of progression of neurologic manifestations despite hematologic remission.
- Levoleucovorin is available generically and as brand Fusilev®.
- The efficacy and safety of Khapzory is based on prior clinical studies evaluating levoleucovorin as rescue therapy after high-dose methotrexate in patients with osteosarcoma and in patients with metastatic colorectal cancer.
- Khapzory is contraindicated in patients who have had severe hypersensitivity to leucovorin products, folic acid, or folinic acid.
- Warnings and precautions of Khapzory include increased gastrointestinal toxicities with fluorouracil and drug interaction with trimethoprim-sulfamethoxazole.
- The most common adverse reactions (≥ 20%) with levoleucovorin use in patients receiving high dose methotrexate therapy with levoleucovorin rescue were stomatitis and vomiting.
- The most common adverse reactions (> 50%) with levoleucovorin use in patients receiving levoleucovorin in combination with fluorouracil for metastatic colorectal cancer were stomatitis, diarrhea, and nausea.
- The recommended dose of Khapzory should be given by intravenous administration only. Do not administer intrathecally.
    - Refer to the Khapzory prescribing information for dosing instructions for all indications.
- Spectrum plans to launch Khapzory in January 2019. Khapzory will be available as a 175 mg and 300 mg single-dose vial.