Xatmep™ (methotrexate) – New drug approval

- On April 26, 2017, Silvergate Pharmaceuticals announced the FDA approval of Xatmep (methotrexate) oral solution for the following:
    - Treatment of pediatric patients with acute lymphoblastic leukemia (ALL) as part of a multi-phase, combination chemotherapy maintenance regimen.
    - Management of pediatric patients with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs).
- Methotrexate is also available as tablets and various injection formulations. Refer to individual drug labels for specific indication information.
- The safety and effectiveness of Xatmep in pediatric patients with ALL were established as part of a multi-phase, combination chemotherapy maintenance regimen, and for the management of pediatric patients with active pJIA. The clinical trials in patients with pJIA were performed using other formulations of methotrexate.
- Xatmep carries a boxed warning for severe toxic reactions, including embryo-fetal toxicity.
- Xatmep is contraindicated in pregnancy in patients with non-malignant diseases and in patients with severe hypersensitivity to methotrexate.
- Warnings and precautions of Xatmep include bone marrow suppression, serious infections, renal toxicity and increased toxicity with renal impairment, gastrointestinal toxicity, hepatic toxicity, pulmonary toxicity, hypersensitivity and dermatologic reactions, secondary malignancies, ineffective immunization and risks associated with live vaccines, effects on reproduction, increased toxicity due to third-space accumulation, soft tissue and bone toxicity with radiation therapy, laboratory tests, and risk of improper dosing.
- The most common adverse reactions with methotrexate use are ulcerative stomatitis, leukopenia, nausea, abdominal distress, and elevated liver function tests. Other frequently reported adverse reactions are malaise, fatigue, chills and fever, dizziness, and decreased resistance to infection.
- The recommended dosing regimen of Xatmep for the treatment of ALL in multi-agent combination therapy maintenance regimens is 20 mg/m^2 administered orally once weekly.
- The recommended dosing regimen of Xatmep for the treatment of pJIA is 10 mg/m^2 administered orally once weekly.
- Silvergate Pharmaceuticals' launch plans for Xatmep are pending. Xatmep will be available as a 2.5 mg/mL oral solution. Xatmep will be available through an extensive network of pharmacies and a qualified mail-order service.