Zilretta™ (triamcinolone acetonide) – New drug approval

- On October 6, 2017, Flexion Therapeutics announced the FDA approval of Zilretta (triamcinolone acetonide) extended-release injection, for the management of osteoarthritis (OA) pain of the knee.
    - Zilretta is not intended for repeat administration.
- OA, also known as degenerative joint disease, affects more than 30 million Americans. Its effects may range from intermittent discomfort to the loss of function and severe chronic pain associated with irreversible structural damage.
- The efficacy of Zilretta was demonstrated in a placebo- and active-controlled study enrolling 484 patients with OA pain of the knee. Patients received Zilretta, placebo or an immediate-release formulation of triamcinolone acetonide 40 mg. The primary efficacy endpoint for Zilretta vs. placebo was change from baseline at week 12 in the weekly mean of the average daily pain intensity (ADP) scores.
    - Zilretta demonstrated a statistically significant reduction in pain intensity vs. placebo.
    - Zilretta also demonstrated a reduction in pain intensity scores each week from weeks 1 – 12.
    - Zilretta was not statistically significantly better vs. immediate-release triamcinolone for the change from baseline at week 12 in weekly mean ADP.
- Warnings and precautions of Zilretta include warnings and precautions specific for Zilretta, serious neurologic adverse reactions with epidural and intrathecal administration, hypersensitivity reactions, joint infection and damage, increased risk of infections, alterations in endocrine function, cardiovascular effects, renal effects, increased intraocular pressure, gastrointestinal perforation, alterations in bone density, and behavioral and mood disturbances.
- The most common adverse reactions ($\geq$ 1%) with Zilretta use were sinusitis, cough and contusions.
- The recommended dosage of Zilretta is 32 mg (5 mL) administered as a single intra-articular injection in the knee.
    - Zilretta is for intra-articular use only and should not be administered by the following routes: epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous.
    - Zilretta is not suitable for use in small joints, such as the hand.
    - The efficacy and safety of Zilretta for management of osteoarthritis pain of the shoulder and hip have not been evaluated.
- Flexion Therapeutics plans to launch Zilretta by the end of October 2017. Zilretta will be available as a single-dose kit containing one vial of Zilretta 32 mg microsphere powder, one vial of 5 mL diluent, and one sterile vial adapter.