## Xipere® (triamcinolone acetonide) – New drug approval

- On October 25, 2021, Bausch + Lomb and Clearside Biomedical announced the FDA approval of Xipere (triamcinolone acetonide), for the treatment of macular edema associated with uveitis.
- Xipere is an injection formulation of triamcinolone that is administered in the suprachoroidal space.
- The efficacy of Xipere was established in a 6-month, randomized, double-masked, sham-controlled study in patients with macular edema associated with anterior-, intermediate-, posterior-, or pan-uveitis. Patients were treated at baseline and week 12. The primary endpoint was the proportion of patients in whom best corrected visual acuity (BCVA) had improved by ≥ 15 letters from baseline after 24 weeks of follow-up.
    - Overall, 47% and 16% of patients met the primary endpoint in the Xipere and control groups, respectively (treatment difference 31%, 95% CI: 15, 46; $p < 0.01$).
- Xipere is contraindicated in patients with ocular or periocular infections and in patients with known hypersensitivity to triamcinolone acetonide or any other components of this product.
- Warnings and precautions for Xipere include potential corticosteroid-related effects and alterations in endocrine function.
- The most common adverse reactions (≥ 10% and at a rate greater than control) with Xipere use were elevated intraocular pressure and eye pain.
- The recommended dose of Xipere is 4 mg (0.1 mL of the 40 mg/mL injectable suspension) administered via suprachoroidal injection.
- Bausch + Lomb and Clearside plan to launch Xipere in the first quarter of 2022. Xipere will be available as a 40 mg/mL suspension in a single-dose glass vial.