Anjeso™ (meloxicam) – New drug approval

- On February 20, 2020, Baudax Bio announced the FDA approval of Anjeso (meloxicam) injection, in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics.
    - Because of delayed onset of analgesia, Anjeso alone is not recommended for use when rapid onset of analgesia is required.
- Anjeso is the first intravenous (IV) formulation of meloxicam. Meloxicam is also available as a generic oral tablet, branded oral capsule (Vivlodex®), and branded orally disintegrating tablet (Qmiiz™ ODT).
    - The tablet formulation and Qmiiz ODT are approved for osteoarthritis (OA), rheumatoid arthritis (RA), and pauciarticular or polyarticular course juvenile RA.
    - Vivlodex is only approved for OA.
- The efficacy of Anjeso was established in two randomized, double-blind, placebo-controlled, studies. In the first study of adult patients with postoperative pain who underwent bunionectomy surgery, 201 patients were treated with Anjeso 30 mg or placebo administered once daily for two days starting on the day after surgery.
    - A statistically significant difference demonstrating efficacy was observed in the primary efficacy endpoint of the summed pain intensity difference over the first 48 hours.
- In the second study of adult patients with postoperative pain who underwent elective abdominoplasty surgery, 219 patients were treated with Anjeso 30 mg or placebo administered once daily for two days starting on the day of surgery.
    - A statistically significant difference demonstrating efficacy was observed in the primary efficacy endpoint of the summed pain intensity difference over the first 24 hours as well as over the first 48 hours.
- Anjeso carries a boxed warning for risk of serious cardiovascular and gastrointestinal events.
- Anjeso is contraindicated in patients with:
    - Known hypersensitivity (eg, anaphylactic reactions and serious skin reactions) to meloxicam or any components of the drug product.
    - History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal anaphylactic-like reactions to NSAIDs have been reported in such patients.
    - In the setting of coronary artery bypass graft surgery.
    - Moderate to severe renal insufficiency patients who are at risk for renal failure due to volume depletion.
- Additional warnings and precautions for Anjeso include hepatotoxicity; hypertension; heart failure and edema; renal toxicity and hyperkalemia; anaphylactic reactions; exacerbation of asthma related to aspirin sensitivity; serious skin reactions; premature closure of fetal ductus arteriosus; hematologic toxicity; and masking of inflammation.

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- The most common adverse reactions (≥ 2% and > placebo) with Anjeso use were constipation, increased gamma-glutamyltransferase, and anemia.

- The recommended dose of Anjeso is 30 mg once daily, administered by IV bolus injection over 15 seconds.

    — Anjeso should be used for the shortest duration consistent with individual patient treatment goals.
    — Patients must be well hydrated before Anjeso administration.

- Baudax Bio plans to launch Anjeso in late April or early May 2020. Anjeso will be available as a 30 mg/mL single-dose vial.