Xifyrm (meloxicam) – New drug approval

- On June 5, 2025, the FDA approved Azurity Pharmaceuticals' Xifyrm (meloxicam), for use in adults for the **management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics**.
    - Because of delayed onset of analgesia, Xifyrm alone is not recommended for use when rapid onset of analgesia is required.
- Meloxicam is currently available generically as an oral tablet and oral suspension.
- Xifyrm carries a boxed warning for risk of serious cardiovascular and gastrointestinal events.
- Xifyrm is contraindicated in patients:
    - 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
    - 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 Xifyrm include hepatotoxicity; hypertension; heart failure and edema; renal toxicity and hyperkalemia; anaphylactic reactions; exacerbation of asthma related to aspirin sensitivity; serious skin reactions; drug rash with eosinophilia and systemic symptoms; fetal toxicity; hematologic toxicity; masking of inflammation and fever; and laboratory monitoring.
- The most common adverse reactions (≥ 2% and greater than placebo) with Xifyrm use in controlled clinical trials include constipation, increased gamma-glutamyl transferase, and anemia.
- The recommended dosage of Xifyrm is 30 mg once daily, administered by intravenous bolus injection over 15 seconds.
    - Some patients may not experience adequate analgesia for the entire 24-hour dosing interval and may require administration of a short-acting, non-NSAID, immediate-release analgesic.
- Azurity Pharmaceuticals' launch plans for Xifyrm are pending. Xifyrm will be available as a 30 mg/mL single-dose vial.