Brixadi™ (buprenorphine) – New drug approval

- On May 23, 2023, Braeburn announced the FDA approval of Brixadi (buprenorphine), for the treatment of moderate to severe opioid use disorder (OUD) in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine.
    - Brixadi should be used as part of a complete treatment plan that includes counseling and psychosocial support.
- Buprenorphine is also available in an injectable formulation for OUD under the brand name Sublocade®.
- The efficacy of Brixadi was established in a randomized, double-blind, double-dummy, active controlled study in 428 patients with moderate or severe OUD. Patients were randomized to receive either Brixadi injections with placebo sublingual tablets or sublingual buprenorphine/naloxone (SL BPN/NX) tablets with placebo injections. Efficacy (response) was evaluated using urine drug screens combined with self-reported use of illicit opioid use.
    - Brixadi met the primary endpoint of non-inferiority for responder rate vs. daily SL BPN/NX (16.9% vs. 14.0%; treatment difference of 2.9; 95% CI: -3.9, 9.8).
- Additionally, the evidence for Brixadi was supported by an opioid blockade study in 47 patients.
- Brixadi carries a boxed warning for risk of serious harm or death with intravenous (IV) administration.
    - Because of the risk of serious harm or death that could result from IV self- administration, Brixadi is only available through a restricted program called the Brixadi REMS. Healthcare settings and pharmacies that order and dispense Brixadi must be certified in this program and comply with the REMS requirements.
    - Refer to the Brixadi drug label for the complete list of additional warnings and precautions for Brixadi.
- The most common adverse reactions (≥ 5%) with Brixadi use were injection site pain, headache, constipation, nausea, injection site erythema, injection site pruritus, insomnia, and urinary tract infection.
- Brixadi is administered as a weekly or monthly subcutaneous injection by a healthcare provider. Doses of Brixadi (weekly) cannot be combined to yield an equivalent Brixadi (monthly) dose.
    - Refer to the Brixadi drug label for complete dosing and administration recommendations.
- Braeburn plans to launch Brixadi in September 2023. Brixadi will be available as weekly and monthly injections provided in a pre-filled single-dose syringe:
    - Brixadi (weekly): 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, and 32 mg/0.64 mL
    - Brixadi (monthly): 64 mg/0.18 mL, 96 mg/0.27 mL, and 128 mg/0.36 mL.