PRIME THERAPEUTICS®

Drug Pipeline MONTHLY UPDATE

Critical updates in an ever-changing environment

May 2021

NEW DRUG INFORMATION

- **Kloxxado™ (naloxone hydrochloride) nasal spray 8mg:** The U.S. Food and Drug Administration (FDA) approved Hikma Pharms' Kloxxado nasal spray 8mg for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult and pediatric patients. Kloxxado contains twice as much naloxone per spray as Emergent's Narcan® Nasal Spray 4mg in a ready-to-use nasal spray to reverse the effects of opioid overdose. This provides an important new treatment option in addressing the opioid epidemic. The FDA-approved Kloxxado was approved under the 505(b)2 pathway using Emergent's Narcan injection as its reference product.[1] Kloxxado will be available the second half of 2021 with pricing to follow.

- **Zynrelef® (bupivacaine and meloxicam extended-release solution, formerly HTX-011):** Heron Therapeutics' Zynrelef was approved by the FDA for soft tissue or periarticular instillation into the surgical site to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy and total knee arthroplasty in adults. Zynrelef is an extended-release dual-acting local anesthetic (DALA) using Heron's Biochronomer technology to deliver a fixed-dose combination of local anesthetic and low-dose nonsteroidal anti-inflammatory drug (NSAID). The FDA approval of Zynrelef was based on a Phase 3 control trial which demonstrated a significant reduction in pain intensity for unilateral simple bunionectomy patients treated with Zynrelef compared to either bupivacaine HCl or saline placebo for up to 72 hours. Treatment with Zynrelef had 29% of patients forgoing opioid analgesia post-surgery compared to 11% treated with bupivacaine HCL and 2% of patients treated with saline placebo. Additionally, Zynrelef demonstrated a significant reduction in pain intensity with Zynrelef compared to saline placebo for the first 48-hour and 72-hour postoperative periods in patients who underwent primary unilateral total knee arthroplasty.[2] Zynrelef is planning to launch July 2021 in four dosage strengths with pricing to follow.

GENERIC DRUG INFORMATION

- **Absorica® (isotretinoin caps):** Actavis/Teva launched their generic version of Ranbaxy's Absorica for the treatment of severe recalcitrant nodular acne in patients 12 years of age and older. Absorica generated $176 million in U.S. annual sales in 2020.

+Specialty medication

REFERENCES

1. https://www.prnewswire.com/news-releases/hikma-announces-us-fda-approval-of-kloxxadotm-naloxone-hydrochloride-nasal-spray-8mg-301280855.html
2. https://www.prnewswire.com/news-releases/heron-therapeutics-announces-us-fda-approval-of-zynrelef-htx-011-for-the-management-of-postoperative-pain-for-up-to-72-hours-301290467.html