

Heron Submission Statement – National Academy of Medicine's (NAM's) Action Collaborative on Countering the U.S. Opioid Epidemic

Heron Therapeutics is dedicated to countering the opioid epidemic, particularly through reducing or eliminating unnecessary opioid use in the postoperative setting. For millions of people, their first exposure to opioids occurs in the hospital or an outpatient surgery facility as they recover from surgery, opening a door to dependence, misuse and abuse. Despite this risk, opioid medications continue to be used as the primary agents used to treat postoperative pain.

The continuing over-reliance on postoperative opioids fuels the crisis by both exposing opioid naïve patients to the narcotics and by leaving hundreds of millions of leftover pills hiding in our community medicine cabinets. As many as 6.5% of patients who take opioids to manage pain after surgery become persistent opioid users – and hundreds of thousands of those will become addicted. Heron is dedicated to reducing the need of opioids in the postoperative setting through a pipeline of innovative non-opioid postoperative pain therapies.

HTX-011 – the first dual-acting local anesthetic – is an investigational drug that utilizes Heron's proprietary Biochronomer® drug delivery technology, and is a long-acting, extended-release formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam for postoperative pain management. HTX-011 was designed to deliver superior pain relief over 72 hours while reducing the need for systemically administered pain medications including opioids. HTX-011 has been shown to reduce pain, including severe pain, significantly better than standard-of-care bupivacaine solution and placebo in five diverse surgical models: hernia repair, abdominoplasty, bunionectomy, total knee arthroplasty and breast augmentation. Heron was granted Fast Track Designation and Breakthrough Therapy Designation for HTX-011 and it is currently under Priority review at the FDA with a PDUFA date of April 30, 2019.

Additionally, Heron Therapeutics has helped form and sponsors the Surgical Taskforce Organized to Prevent Opioid Abuse (STOP Opioid Abuse) – a coalition dedicated to inspiring healthcare providers, patients and payers across the country to take action and commit to reducing unnecessary exposure to opioids in the surgical setting. As the groups founding sponsor, Heron brought together various medical societies (surgical, anesthesiology and nursing), policy and patient advocate groups to work together and discuss ways to combat the opioid epidemic within the surgical setting. Through the work of the coalition, Heron aims to further understand postoperative prescribing habits. The coalition will use these findings to improve pain management in the surgical setting, create awareness and change around opioid use and develop an online resource center for best practices in reducing the number of opioids prescribed in the postoperative setting.

Heron would be a dedicated member of the Action Collaborative on Countering the U.S. Opioid Epidemic, and work to actively promote the messages and activities of the network to combat the opioid epidemic.