



Heron Announces FDA Submission of HTX-011 NDA for Postoperative Pain Management

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SAN DIEGO, Oct. 31, 2018 /PRNewswire/ -- Heron Therapeutics, Inc. (Nasdaq: HRTX), a commercial-stage biotechnology company focused on improving the lives of patients by developing best-in-class treatments to address some of the most important unmet patient needs, today announced the submission of its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for HTX-011. HTX-011 is an investigational, long-acting, extended-release formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam for the management of postoperative pain.

HTX-011 was granted both Breakthrough Therapy and Fast Track designations from the FDA. The NDA filing is based on the results of 7 completed clinical studies in 5 bony and soft tissue surgical procedures that included over 1,000 patients who received HTX-011. These completed clinical studies included two Phase 3 studies in which HTX-011 demonstrated superior, sustained postoperative pain relief for 72 hours and decreased the need for opioids, with more patients who were opioid-free compared to placebo and bupivacaine solution, the current standard-of-care. The overall safety profile of HTX-011, administered locally into the surgical site without a needle, is similar to that of the well-established safety profile of bupivacaine solution, without evidence of meloxicam-related toxicities.

"In the U.S., opioid pain medications prescribed for pain control in over 40 million surgical patients have been directly linked to over 2 million new persistent opioid users every year, and over 400,000 new cases of Opioid Use Disorder annually. This makes postoperative opioid use an important contributor to the opioid epidemic. It must be highlighted that, with more than a billion opioid pills taken home after surgery every year for postoperative pain control, there is an enormous concern about diversion of these pills and a desperate need for effective non-opioid alternatives," said Harold S. Minkowitz, M.D., Associate Professor and Associate Director of Clinical Research at the University of Texas MD Anderson Cancer Center, Department of Anesthesiology and Perioperative Medicine. "The clinical results with HTX-011 suggest it may be one of the most promising new non-opioid analgesics for a wide range of surgical procedures."

"The submission of the NDA for HTX-011 in the U.S. is an important milestone, advancing our efforts to bring a non-opioid alternative to patients suffering from postoperative pain," said Barry D. Quart, Pharm.D., Chief Executive Officer of Heron Therapeutics. "As a company, this represents the third NDA filed by Heron. We have appreciated the frequent advice from the FDA during the development of HTX-011 and look forward to working closely with them during the NDA review process."

About HTX-011 for Postoperative Pain

HTX-011, which utilizes Heron's proprietary Biochronomer® drug delivery technology, is an investigational, long-acting, extended-release formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam for the management of postoperative pain. By delivering sustained levels of both a potent anesthetic and a local anti-inflammatory agent directly to the site of tissue injury, HTX-011 was designed to deliver superior pain relief while reducing the need for systemically administered pain medications such as opioids, which carry the risk of harmful side effects, abuse and addiction. HTX-011 has been shown to reduce pain significantly better than placebo or bupivacaine alone in five diverse surgical models: hernia repair, abdominoplasty, bunionectomy, total knee arthroplasty and breast augmentation. HTX-011 was granted Fast Track designation from the FDA in the fourth quarter of 2017 and Breakthrough Therapy designation in the second quarter of 2018. Heron recently submitted an NDA to the FDA for HTX-011.

About Heron Therapeutics, Inc.

Heron Therapeutics, Inc. is a commercial-stage biotechnology company focused on improving the lives of patients by developing best-in-class treatments to address some of the most important unmet patient needs. Heron is developing novel, patient-focused solutions that apply its innovative science and technologies to already-approved pharmacological agents for patients suffering from cancer or pain. For more information, visit www.heronrx.com.

Forward-looking Statements

This news release contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. Heron cautions readers that forward-looking statements are based on management's expectations and assumptions as of the date of this news release and are subject to certain risks and uncertainties that could cause actual results to differ materially, including, but not limited to, acceptance of the HTX-011 NDA as submitted; whether the FDA approves the HTX-011 NDA as submitted; the anticipated commercial launch of HTX-011; and other risks and uncertainties identified in the Company's filings with the U.S. Securities and Exchange Commission. Forward-looking statements reflect our analysis only on their stated date, and Heron takes no obligation to update or revise these statements except as may be required by law.

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