Heron Therapeutics Presents New Results from Real-world Study Showing 95% of Postoperative Patients Remain Opioid-Free when HTX-011 Is Given with an Over-the-Counter Analgesic Regimen

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SAN DIEGO, May 14, 2019 /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 results of a multi-center postoperative pain management study in 93 patients that provides real-world evidence of opioid-free recovery in patients undergoing outpatient inguinal hernia repair surgery who received the investigational agent, HTX-011, together with a scheduled background regimen of generic over-the-counter (OTC) oral analgesics (acetaminophen and ibuprofen). This study is the initial phase of the HOPE (**H**elping **O**pioid **P**rescription **E**limination) Project, which is designed to substantially reduce opioid prescriptions following surgery with HTX-011 as the foundation of a multimodal analgesic regimen. Currently, the average patient in the U.S. undergoing inguinal hernia repair surgery receives a discharge prescription for 30 opioid pills. Patients in this real-world outpatient study were discharged approximately 2-3 hours following surgery, and those who met prespecified criteria were discharged without a prescription for opioid analgesics.

The goal of this study was to provide real-world confirmation of the treatment algorithm developed in our Phase 3 hernia repair surgery follow-on study (Study 215), in which 90% of patients receiving HTX-011 with an OTC analgesic regimen remained opioid-free during a 72-hour inpatient assessment period, and to optimize the OTC analgesic regimen used with HTX-011.

Topline results of the study include the following:

- 95% of patients receiving HTX-011 with the OTC analgesic regimen did not require opioids to manage their postoperative pain through recovery (Day 15).
- 91% of patients receiving HTX-011 with the OTC analgesic regimen were discharged without an opioid prescription, and none of these patients subsequently requested an opioid for postoperative pain.
- HTX-011 was well tolerated with no serious adverse events associated with the addition of the OTC analgesic regimen.
- Patients indicated an overall high satisfaction with the HTX-011-based analgesic regimen.

"Postoperative pain remains a major problem for surgical patients, and there have been few effective and innovative non-opioid advances for patients who want adequate pain relief without relying on opioids," said Michael Reinhorn, MD, MBA, FACS, President, Boston Hernia & Pilonidal Center. "These results provide evidence that HTX-011 may be an important tool that will allow healthcare providers to significantly reduce the use of unnecessary postoperative opioids and have a substantial impact on the opioid crisis we are facing in the U.S."

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 solution in five diverse surgical models: hernia repair, abdominoplasty, bunionectomy, total knee arthroplasty and breast augmentation. HTX-011 was granted Fast Track designation from the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2017 and Breakthrough Therapy designation in the second quarter of 2018. Heron submitted a New Drug Application (NDA) to the FDA for HTX-011 in October of 2018 and received Priority Review designation in December of 2018. A Complete Response Letter was received from the FDA regarding the NDA for HTX-011 on April 30, 2019 relating to chemistry, manufacturing and controls and non-clinical information. No issues related to clinical efficacy or safety were noted. A Marketing Authorisation Application for HTX-011 was validated by the European Medicines Agency in March 2019 for review under the Centralised Procedure.

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 pain or cancer. For more information, visit www.herontx.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, those associated with: whether the FDA approves the NDA for HTX-011; the timing of the commercial launch of HTX-011; the timing of the CHMP's review process for HTX-011; whether the

European Commission authorizes the MAA for 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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