Heron Announces Positive Topline Results from Phase 3b Clinical Study of HTX-011 in Total Knee Arthroplasty

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- Mean Pain Scores Remain in Mild Range for 72 Hours following Surgery -

- 75% of Patients Were Discharged without Opioids -

SAN DIEGO, Oct. 2, 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 positive topline results of a multi-center postoperative pain management study in which 51 patients undergoing total knee arthroplasty (TKA) surgery received the investigational agent, HTX-011, together with a scheduled postoperative regimen of generic, oral analgesics (acetaminophen and celecoxib). A follow-on study to the Phase 2b study of HTX-011 in TKA (Study 209) that was completed in 2018, this study was designed to evaluate the decrease in pain and opioid use with HTX-011 when used together with a regimen of generic oral analgesics. In Study 209, HTX-011 significantly reduced pain and opioid use compared to placebo through 72 hours and significantly reduced pain compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control, using a last observation carried forward (LOCF) analysis. The Phase 3b study included the same multimodal, oral analgesic regimen as a prior published study with liposomal bupivacaine in TKA (Mont doi: 10.1016/j.arth.2017.07.024).

Topline results of this Phase 3b study include the following:

- Mean pain scores remained in the mild range through 72 hours post-surgery.
- Median consumption of opioids was 4-to-5 pills of oxycodone (22.5 morphine milligram equivalents) through 72 hours.
- 75% of patients were discharged from the hospital without a prescription for opioids.
- HTX-011, together with the multimodal, oral analgesic regimen, was well tolerated in this study. There were no deaths, serious adverse events or premature discontinuations due to adverse events.

These Phase 3b study results in TKA complement the positive results of HTX-011 studies in hernia repair and bunionectomy. In January 2019, Heron reported that 90% of patients who received HTX-011 together with a regimen of over-the-counter (OTC) oral analgesics (acetaminophen and ibuprofen) did not require opioids through 72 hours post-hernia repair surgery. In March 2019, Heron reported that 77% of patients that received HTX-011 together with the OTC oral analgesic regimen did not require opioids through 72 hours post bunionectomy.

"Without appropriate multimodal analgesic postoperative pain management, TKA is usually a very painful procedure, especially for patients with end-stage arthritis," said Paul Lachiewicz, M.D., Consulting Professor, Department of Orthopedic Surgery, Duke University. "This study provides strong evidence that HTX-011, together with a standard multimodal analgesic pain regimen, may play an essential role in not only providing superior pain relief with reduction of severe pain, but also reducing opioid consumption and the need for opioid discharge prescriptions for patients undergoing TKA. With the majority of patients only requiring 4-to-5 opioid pills and 75% being discharged without an opioid prescription, these results also demonstrate that new innovative non-opioid pain medications, like HTX-011, can substantially improve patient care, change current prescribing practices and help to stem the overreliance on opioids after major orthopedic surgery."

"In 2017, more than 47,000 individuals died due to an opioid overdose in the U.S. This dire statistic is fueled by the more than one-billion opioid pills prescribed to patients following surgery and the lack of effective alternative regimens," said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron. "The results from recent studies in TKA, hernia repair and bunionectomy demonstrate that HTX-011 can effectively reduce pain and allow the majority of patients to be discharged without opioids."

About HTX-011 for Postoperative Pain

HTX-011, an investigational agent, is a dual-acting, fixed-dose combination of the local anesthetic bupivacaine with a low dose of the nonsteroidal anti-inflammatory drug meloxicam. It is the first and only extended-release local anesthetic to demonstrate in Phase 3 studies significantly reduced pain and opioid use through 72 hours compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control. 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 (CRL) 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. Heron resubmitted an NDA to the FDA for HTX-011 in September 2019. A Marketing Authorisation Application (MAA) for HTX-011 was validated by the European Medicines Agency (EMA) 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 EMA Committee for Medicinal Products for Human Use (CHMP) 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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