77% of Patients Remain Opioid-Free When HTX-011 Is Given with an Over-the-Counter Analgesic Regimen in New Multi-center Postoperative Pain Management Study in Bunionectomy

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- Bunionectomy Results Complement Opioid-Free Results from the Previously Reported Hernia Repair Study -

SAN DIEGO, March 11, 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 which 31 patients undergoing bunionectomy surgery received the investigational agent, HTX-011, together with a regimen of generic over-the-counter (OTC) oral analgesics (acetaminophen and ibuprofen). Designed as a follow-up to the Phase 3 study in bunionectomy that investigated HTX-011 without the OTC analgesic regimen, this study was led by one of the lead investigators in the Phase 3 study and had the same entry criteria as the Phase 3 study. The goal of the current study was to increase the proportion of patients who did not require opioids by combining HTX-011 with an OTC analgesic regimen.

Topline results of the study include the following:

- 77% of patients receiving HTX-011 with the OTC analgesic regimen did not require opioids to manage their postoperative pain through 72 hours post-surgery, compared to 29%, 11% and 2% of patients receiving HTX-011, bupivacaine solution and placebo, respectively, in the Phase 3 study.
- 100% of patients receiving HTX-011 with the OTC analgesic regimen who were opioid-free through 72 hours remained opioid-free through 28 days post-surgery.
- The increase in patients who did not require opioids was associated with a large reduction in the percentage of patients experiencing severe pain. 29% of patients receiving HTX-011 with the OTC analgesic regimen experienced severe pain, compared to 53%, 76% and 83% of patients receiving HTX-011, bupivacaine solution and placebo, respectively, in the Phase 3 study.
- Over 72 hours post-surgery, patients receiving HTX-011 plus the OTC analgesic regimen consumed an average of only 1.6 morphine milligram equivalents (MME), which compares to 18.8 MME, 25.1 MME and 30.1 MME for patients receiving HTX-011, bupivacaine solution and placebo, respectively, in the Phase 3 study.
- HTX-011 was well tolerated with no serious adverse events associated with the addition of the OTC analgesic regimen.

The results from this bunionectomy study complement the opioid-free results from the hernia repair follow-up study reported in January 2019. In this hernia repair study, Heron reported that 90% of patients were opioid-free 72 hours post-surgery, and 81% were still opioid-free 28 days post-surgery when receiving HTX-011 together with the OTC analgesic regimen.

"In 2017, more than 47,000 individuals died due to an opioid overdose in the U.S., an increase of more than 100% over the past five years," said Richard Pollak, D.P.M., M.S., Director of Endeavor Clinical Trials and Clinical Assistant Professor, Podiatry Service, Department of Orthopedics at the University of Texas Health Science Center. "These recent study results suggest that HTX-011, if approved, when combined with an OTC analgesic regimen, has the potential to significantly reduce pain following surgery as well as the percentage of patients that are discharged with opioids."

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. The FDA set a Prescription Drug User Fee Act (PDUFA) goal date of April 30, 2019.

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 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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