90% 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

January 3, 2019

SAN DIEGO, Jan. 3, 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 63 patients undergoing hernia repair 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 hernia repair completed in 2018, this study included many of the same investigators and the same entry criteria as the Phase 3 study. The goal of the current study was to increase the proportion of opioid-free patients by combining HTX-011 with a regimen of readily available, oral analgesics.

Topline results of the study include the following:

- 90% 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 51%, 40% and 22% of patients receiving HTX-011, bupivacaine and placebo, respectively, in the prior Phase 3 study.
- 81% of patients receiving HTX-011 with the OTC analgesic regimen remained opioid-free through 28 days post-surgery.
- Over 72 hours post-surgery, patients receiving HTX-011 plus the OTC analgesic regimen consumed an average of 0.9 morphine milligram equivalents (MME), which compares to 10.8 MME, 14.5 MME and 17.5 MME for patients receiving HTX-011, bupivacaine and placebo, respectively, in the prior Phase 3 study.

"Overprescribing of opioids not only puts patients at risk of persistent use, addiction or dependence, but also results in unused pills available for potential misuse or abuse by others," 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. "Recently, a U.S. Food and Drug Administration Advisory Committee reported that, at time of discharge, patients receive an average of 30 opioid pills (range of 15-120 opioid pills) following open hernia repair surgery, while only 9 of these opioid pills are used. This suggests that, with a drug that substantially reduces the need for postoperative opioids such as HTX-011, surgeons could eliminate opioid prescriptions for almost all of their patients and in turn significantly reduce excess opioid pills going out into communities. For hernia repair alone, this would mean a reduction of almost 30 million opioid pills every year."

"Reducing discharge prescriptions for opioids after surgery, while providing appropriate pain management, remains a high priority in the battle against the opioid epidemic," said Barry D. Quart, Pharm.D., Chief Executive Officer of Heron. "The results announced today show us that, with HTX-011 as the backbone of a multimodal approach to pain management, patients experience less pain and few need an opioid prescription when they are sent home following outpatient surgery. We look forward to presenting these results in more detail during the upcoming 37th Annual J.P. Morgan Healthcare Conference on Monday, January 7, 2019, at 5:00 p.m. PST at the Westin St. Francis hotel in San Francisco, CA."

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 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 cancer or pain.

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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