Heron Therapeutics Announces Presentations of Results from Phase 2 Clinical Trial of HTX-011 in Hernia Repair at PAINWeek® 2016

September 8, 2016

--HTX-011 resulted in a statistically significant reduction in pain intensity through 48 hours post-surgery compared to placebo

--Substantial decrease in overall opioid use and in the proportion of patients requiring opioids through 96 hours post-surgery

--Instillation, an easier, less invasive and potentially safer route of administration into the wound, was equally as effective as injection

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Sep. 8, 2016-- Heron Therapeutics, Inc. (NASDAQ:HRTX), a biotechnology company focused on improving the lives of patients by developing best-in-class medicines that address major unmet medical needs, announced that results from the initial portions of Heron's Phase 2 study of HTX-011 in patients undergoing inguinal hernia repair (Study 202) will be presented today in two posters at PAINWeek®, the national conference on pain for frontline practitioners, in Las Vegas, NV. The posters were co-authored by Harold S. Minkowitz, MD, Diplomat American Board of Anesthesiology, Department of Anesthesiology, Memorial Hermann Memorial City Medical Center and Peter J. Winkle, MD, FACP, CPI, FACG, Anaheim Regional Medical Center, Anaheim Clinical Research.

Study 202 was a randomized, placebo-controlled, double-blind Phase 2 clinical study in patients undergoing inguinal hernia repair. The study evaluated the efficacy and safety of three formulations of HTX-011 and two routes of administration into the wound (injection and instillation). Instillation into the incision site is an easier and potentially safer route of administration as it avoids multiple injections around the wound (as many as 10 or more in large operations) that carry the risk of venous puncture.

The primary endpoint was the difference as compared to placebo in pain intensity as measured by the Summed Pain Intensity (SPI) score in the first 24 hours post-surgery (SPI 0-24). Important secondary endpoints included SPI for the first 48 hours post-surgery, total opioid consumption, and the percent of patients opioid-free through 96 hours post-surgery. Today's presentations describe Part B of the study (202B), which compared our planned Phase 3 formulation of HTX-011 (HTX-011B) at 200 mg (n=30) and 400 mg (n=30) to saline placebo (n=31). The major findings for the 400 mg dose of HTX-011B as compared to placebo are as follows:

- There was a 29.5% reduction in pain as measured by SPI 0-24 (p=0.0035).
- Instillation (29.9% reduction in SPI 0-24) was equally as effective as injection (29.1% reduction in SPI 0-24).
- The pain reduction was long-lasting, with a statistically significant, 25.2% reduction through 48 hours (SPI 0-48; p=0.0250).
- Mean total opioid consumption decreased by 22.4% through 96 hours post-surgery.
- The number of patients who were opioid-free through 96 hours post-surgery was substantially higher (24.1% versus 6.5%).

HTX-011 has been generally well tolerated in the ongoing Phase 2 program, which has involved more than 250 administrations of HTX-011. In Study 202B, the frequency of treatment-related adverse events reported was 38.7% in the HTX-011B 200 mg group, 33.3% in the HTX-011B 400 mg group, and 51.6% in the placebo group. The most frequent treatment-related adverse events reported were nausea, constipation and headache.

"I have been working in acute pain research for 25 years and I have worked with many new products. I am extremely impressed with the efficacy of HTX-011," commented Harold S. Minkowitz, MD, Diplomat American Board of Anesthesiology, Department of Anesthesiology, Memorial Hermann Memorial City Medical Center. "Additionally, the unique ability to instill HTX-011 with equal efficacy to a standard infiltration technique provides a fast, easy and safe route of administration."

"The results presented today give us confidence as we prepare for our broad-based Phase 3 registration program," commented Barry D. Quart, PharmD, Chief Executive Officer of Heron Therapeutics. "We remain focused on our goal of delivering a therapeutic tool that can not only greatly reduce pain levels following surgery, but also reduce the burden of opioids."

PAINWeek® 2016 Posters

Heron's posters from PAINWeek ® 2016 are available on Heron's website (www.herontx.com) under Scientific Posters and Presentations under the following titles:

- Local Administration of HTX-011, a Long-Acting Biochronomer®-Based Bupivacaine/Meloxicam Combination, in Hernia Repair: Preliminary Results of an Interim Analysis
- Local Administration of HTX-011, a Long-Acting Biochronomer®-Based Bupivacaine/Meloxicam Combination, in Hernia

Repair Provides Similar Initial Results Whether Injected or Instilled

About HTX-011 for Post-Operative Pain

HTX-011, which utilizes Heron's proprietary Biochronomer ® drug delivery technology, is a long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam for the prevention of post-operative pain. By delivering sustained levels of both a potent anesthetic and an anti-inflammatory agent directly to the site of tissue injury, HTX-011 was designed to deliver superior pain relief while potentially reducing the need for systemically administered pain medications such as opioids, which carry the risk of harmful side effects, abuse and addiction. HTX-011 is the subject of a broad-based Phase 2 development program designed to target the many patients undergoing a wide range of surgeries who experience significant post-operative pain.

About Heron Therapeutics, Inc.

Heron Therapeutics, Inc. is a biotechnology company focused on improving the lives of patients by developing best-in-class medicines that address major unmet medical 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 Phase 2 study results are indicative of the results in future studies related to HTX-011, the sufficiency of the Phase 2 data to allow the commencement of Phase 3 registration studies for HTX-011, the potential market opportunity for HTX-011, and other risks and uncertainties identified in the Company's filings with the 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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