Heron Therapeutics Reports Positive Top-Line Results from Phase 2 Study of HTX-011 in the Management of Post-Operative Pain

September 22, 2015

-Pain intensity through 24 hours reduced by 69%
-Pain intensity through 72 hours reduced by 40%
-Time to first use of opiate rescue medication increased by 488%
-32% of patients received no opiate rescue through 72 hours compared to 5% for placebo

Conference call and webcast at 8:30 am ET on September 23

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Sep. 22, 2015-- 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, today announced positive, top-line results from its Phase 2 clinical study of HTX-011 in the management of post-operative pain in patients undergoing bunionectomy. 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. The primary and all key secondary endpoints in the study were met with a high degree of statistical significance.

This randomized, placebo-controlled, double-blind, Phase 2 clinical study in 64 patients undergoing bunionectomy evaluated the efficacy and safety of HTX-011, containing 200 mg or 400 mg of bupivacaine combined with meloxicam, compared to placebo. 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). Key secondary endpoints included: the difference in SPI in the first 48 hours post-surgery (SPI 0-48); the difference in SPI in the first 72 hours post-surgery (SPI 0-72); time to the first use of opiate rescue medication; and the percent of patients who received no opiate rescue medication in the first 72 hours post-surgery. The study's major efficacy findings for the more effective, 400 mg dose of HTX-011 as compared to placebo include:

- Pain intensity in the first 24 hours post-surgery was reduced by 69% (SPI of 38.5 versus 124.2, p<0.0001).
- Pain intensity in the first 48 hours post-surgery was reduced by 52% (SPI of 106.9 versus 224.8, p<0.0001).
- Pain intensity in the first 72 hours post-surgery was reduced by 40% (SPI of 170.2 versus 285.9, p=0.0064).
- Time to the first use of opiate rescue medication was increased by 488% (48.2 hours versus 8.2 hours, p<0.0001).
- 32% of patients received no opiate rescue medication during the entire 72-hour period post-surgery, compared to 5% for placebo (p<0.0001).

HTX-011 was generally well tolerated in the study. The most frequent adverse events reported were headache, nausea, vomiting, erythema, cellulitis, dizziness, and hypoxia, none of which were considered drug-related.

"Although opioid analgesics are standard of care for post-operative pain management, too often they are associated with unacceptable adverse effects often prolonging hospitalization and recovery," stated Jeffrey A. Gudin, MD, Director, Pain Management and Palliative Care, Englewood Hospital and Medical Center, Englewood, NJ. "Thus, there is a major unmet need for a pain management treatment that can substantially reduce our dependence on post-operative opioids. The ability of HTX-011, administered once during surgery, to significantly reduce pain and the need for pain medications for three days following surgery (as compared to a control group) is truly promising."

"At Heron, we are dedicated to the development of best-in-class medicines that can have a major impact on patients' lives," commented Barry D. Quart, Pharm.D., Chief Executive Officer of Heron. "We are very pleased with these results, and we now will turn our attention to executing on a broad-based development program designed to enable us to bring HTX-011 to the many patients undergoing a wide range of surgeries who experience significant post-operative pain."

Conference Call and Webcast

Heron Therapeutics will host a conference call and webcast on Wednesday, September 23 at 8:30 a.m. ET (5:30 a.m. PT). The conference call can be accessed by dialing (877) 311-5906 for domestic callers and (281) 241-6150 for international callers. Please provide the operator with the passcode 46461973 to join the conference call. The conference call will also be available via webcast under the investor relations section of Heron's website at www.herontx.com and will be archived there for 90 days following the call. Please connect to Heron's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

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. In September 2015, Heron reported positive top-line results from a Phase 2 study of HTX-011 in patients undergoing bunionectomy. In this study, HTX-011 significantly reduced pain intensity, significantly reduced the need for opioid rescue medications, and significantly increased the time to first use of rescue medications. HTX-011 is the subject of a broad-based 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. Heron's goal is to build on therapeutics with well-known pharmacology by improving their tolerability and efficacy as well as broadening their potential field of use. Heron is currently developing four pharmaceutical products for patients suffering from cancer or pain. SUSTOL® (granisetron) Injection, extended release is being developed for the prevention of both acute and delayed chemotherapy-induced nausea and vomiting (CINV) associated with moderately emetogenic chemotherapy (MEC) or highly emetogenic chemotherapy (HEC). CINV is one of the most debilitating side effects of chemotherapy and is a leading cause of premature discontinuation of cancer treatment. Heron recently reported positive, top-line results from its Phase 3 MAGIC study. In July 2015, Heron resubmitted its New Drug Application (NDA) for SUSTOL to the U.S. Food and Drug Administration (FDA), and the FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of January 17, 2016. HTX-019, also being developed for the prevention of CINV, has the potential to become the first polysorbate 80-free, intravenous formulation of aprepitant, a neurokinin-1 (NK_1) receptor antagonist. Heron intends to file an NDA for HTX-019 using the 505(b)(2) regulatory pathway in the second half of 2016. HTX-011 is Heron's long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam. In September 2015, Heron reported positive, top-line results from a Phase 2 study of HTX-011 in patients undergoing bunionectomy. In this study, HTX-011 significantly reduced pain intensity and the need for opioid rescue medications. HTX-011 is the subject of a broad-based development program designed to target the many patients undergoing a wide range of surgeries who experience significant post-operative pain. HTX-003, a long-acting formulation of buprenorphine, is being developed for the potential management of chronic pain and opioid addiction. All of Heron's product candidates utilize Heron's innovative science and technology platforms, including its proprietary Biochronomer ® drug delivery technology, which can deliver therapeutic levels of a wide range of otherwise short-acting pharmacological agents over a period of days to weeks with a single injection.

For more information, please 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. These risks and uncertainties include, but are not limited to, those associated with: whether the U.S. Food and Drug Administration (FDA) approves the SUSTOL NDA as submitted or supports as broad of a labeled indication for SUSTOL as requested, the progress in the research and development of HTX-019, HTX-011, HTX-003 and our other programs, including the timing of preclinical, clinical, and manufacturing activities, safety and efficacy results from our studies that may not justify the pursuit of further development of our product candidates, the launch and acceptance of SUSTOL and new products generally, our financial position and our ability to raise additional capital to fund operations, if necessary, or to pursue additional business opportunities, strategic business alliances we may pursue or the potential acquisition of products or technologies, and our ability to grow our organization to sustain the commercial launch for SUSTOL, 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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