Heron Therapeutics Initiates Second Phase 2 Clinical Trial of HTX-011 for the Treatment of Post-Operative Pain

July 23, 2015

- HTX-011 to be evaluated in approximately 60 patients undergoing inguinal hernia repair

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Jul. 23, 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 that it has initiated a second Phase 2 clinical trial of HTX-011. 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.

The placebo-controlled, dose-finding, Phase 2 clinical trial in approximately 60 patients undergoing inguinal hernia repair will evaluate the efficacy and safety of HTX-011, containing 200 mg or 400 mg of bupivacaine combined with meloxicam, compared to placebo. HTX-011 is also currently being evaluated in a placebo-controlled, dose-finding, Phase 2 clinical trial in patients undergoing bunionectomy. In a previously completed, placebo-controlled, Phase 1 clinical trial, HTX-011 achieved the desired pharmacokinetic profile for both bupivacaine and meloxicam, with therapeutically relevant plasma bupivacaine levels sustained for 2-3 days.

"We are extremely pleased to be expanding our Phase 2 development program for HTX-011 with the initiation of a study in patients undergoing hernia repair," commented Barry D. Quart, Pharm.D., Chief Executive Officer of Heron. "Our ongoing clinical trial in patients undergoing bunionectomy is progressing extremely well, supporting the expansion of the HTX-011 Phase 2 development program. We look forward to reporting data from both the bunionectomy study and the hernia repair study in the second half of 2015."

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 a Phase 1 clinical trial, HTX-011 achieved the desired pharmacokinetic profile for both bupivacaine and meloxicam. Specifically, therapeutically relevant plasma bupivacaine levels were sustained for 2-3 days. The anesthetic effects of HTX-011 persisted through 96 hours, which closely correlated with plasma bupivacaine concentrations, and HTX-011 was well-tolerated with no serious adverse events. Heron is currently conducting two placebo-controlled, dose-finding, Phase 2 clinical trials of HTX-011 in patients undergoing bunionectomy or inguinal hernia repair. Heron expects to report results from both of these trials in the second half of 2015.

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® is Heron's injectable, extended-release formulation of granisetron that 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 and resubmitted its New Drug Application (NDA) for SUSTOL to the U.S. Food and Drug Administration (FDA) in July 2015. 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, Heron's long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam, is currently being evaluated in two Phase 2 trials for the prevention of post-operative pain. Heron expects to report results from both of these trials in the second half of 2015. 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, 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: the acceptance of the Company's resubmission of its New Drug Application (NDA) for SUSTOL ®, 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 undertakes no obligation to update or revise these statements except as may be required by law.

View source version on businesswire.com: http://www.businesswire.com/news/home/20150723005450/en/

Source: Heron Therapeutics, Inc.

Investor Relations Contact:
Heron Therapeutics, Inc.
Jennifer Capuzelo, 858-703-6063
Sr. Manager, Investor Relations
jcapuzelo@herontx.com
or
Corporate Contact:
Barry D. Quart, 650-366-2626
Pharm.D., Chief Executive Officer