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

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- FDA Clears IND for HTX-011

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Jun. 16, 2015-- Heron Therapeutics, Inc. (NASDAQ: HRTX) announced today that it has initiated a Phase 2 clinical trial of HTX-011, the Company's lead product candidate for the prevention of post-operative pain, following clearance from the U.S. Food and Drug Administration (FDA) of its Investigational New Drug (IND) application for 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.

The placebo-controlled, dose-finding, Phase 2 clinical trial in approximately 60 patients undergoing bunionectomy will evaluate the efficacy and safety of HTX-011, containing 200 mg or 400 mg of bupivacaine combined with meloxicam, compared to placebo. In a previously completed, placebo-controlled, Phase 1 clinical trial of HTX-011 in healthy volunteers, the desired pharmacokinetic profile for both bupivacaine and meloxicam was achieved, with therapeutically relevant drug levels of bupivacaine sustained for 2-3 days. Heron anticipates reporting top-line results from this Phase 2 clinical trial in the second half of 2015.

"We are excited to be moving HTX-011, an innovative product candidate targeting the large and growing post-operative pain management market, into a Phase 2 study in an important surgical indication," commented Barry D. Quart, Pharm.D., Chief Executive Officer of Heron. "We believe that HTX-011 has the potential to meet our core goal of developing best-in-class medicines with the potential to significantly improve the lives of patients."

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. The effective management of pain with a reduction in the use of opioids remains an important area of unmet medical need, and HTX-011 could potentially provide a differentiated therapeutic profile with advantages compared to currently available pain management options. In a Phase 1 clinical trial, HTX-011 achieved the desired pharmacokinetic profile for both bupivacaine and meloxicam. Therapeutically relevant plasma bupivacaine levels were sustained for 2-3 days in the absence of the large initial peak that can be observed with commercially available formulations. 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 a placebo-controlled, dose-finding, Phase 2 clinical trial of HTX-011 in patients undergoing bunionectomy.

About Heron Therapeutics, Inc.

Heron Therapeutics, Inc. is a biotechnology company focused on developing and commercializing best-in-class pharmaceutical products that address major unmet medical needs. The Company has four product candidates in development for patients suffering from cancer and pain and has retained commercial rights to each of these in all major markets. SUSTOL® is an injectable, extended-release formulation of granisetron that is being developed for the prevention of both acute and delayed chemotherapy-induced nausea and vomiting (CINV) following the administration of moderately emetogenic chemotherapy (MEC) or highly emetogenic chemotherapy (HEC) agents. Affecting 70-80% of patients undergoing chemotherapy, CINV is one of chemotherapy's most debilitating side effects 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 intends to resubmit its New Drug Application (NDA) for SUSTOL to the U.S. Food and Drug Administration (FDA) in mid-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) pathway in the second half of 2016. HTX-011, a long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam, is in Phase 2 clinical development for the prevention of post-operative pain. HTX-003, a long-acting formulation of buprenorphine, is being developed for the potential management of chronic pain and opioid addiction. Many of Heron's product candidates utilize its proprietary Biochronomer® drug delivery technology, which can deliver therapeutic levels of a wide range of otherwise short-acting drugs 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 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 timing and 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. We caution investors that forward-looking statements reflect our analysis only on their stated date. We do not intend to update them except as required by law.

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