Heron Therapeutics Announces FDA Acceptance of New Drug Application for SUSTOL®

September 18, 2015

-FDA assigns PDUFA goal date of January 17, 2016

-SUSTOL has potential to be first 5-HT_3 antagonist approved for delayed nausea and vomiting associated with highly emetogenic chemotherapy

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Sep. 18, 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 the U.S. Food and Drug Administration (FDA) has accepted for review Heron's New Drug Application (NDA) resubmission for SUSTOL ® (granisetron) Injection, extended release, for the prevention of acute and delayed chemotherapy-induced nausea and vomiting (CINV) associated with moderately emetogenic chemotherapy (MEC) or highly emetogenic chemotherapy (HEC) regimens. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of January 17, 2016.

The NDA filing includes data from the MAGIC study, Heron's recently completed, multi-center, placebo-controlled, Phase 3 study of SUSTOL for the prevention of delayed CINV in more than 900 patients receiving HEC regimens. Data from an earlier Phase 3 study of more than 1,300 patients, which were previously submitted to the FDA, demonstrated SUSTOL's efficacy in the prevention of acute and delayed CINV associated with MEC regimens and acute CINV associated with HEC regimens.

"We believe that the MAGIC study has demonstrated SUSTOL's superior ability to improve the lives of patients suffering from the debilitating effects of nausea and vomiting associated with chemotherapy compared to the current standard-of-care," commented Barry D. Quart, Pharm.D., Chief Executive Officer of Heron. "We look forward to working closely with the FDA during the review of the SUSTOL NDA and moving forward with commercial planning in anticipation of SUSTOL's potential launch early next year."

About SUSTOL® for Chemotherapy-Induced Nausea and Vomiting

SUSTOL® (granisetron) Injection, extended release, which utilizes Heron's proprietary Biochronomer ® drug delivery technology, is Heron's novel, long-acting formulation of granisetron for the prevention of chemotherapy-induced nausea and vomiting (CINV). Granisetron, an FDA-approved 5-hydroxytryptamine type 3 (5-HT_3) receptor antagonist was selected due to its broad use by physicians based on a well-established record of safety and efficacy. SUSTOL has been shown to maintain therapeutic drug levels of granisetron for five days with a single subcutaneous injection. SUSTOL is being developed for the prevention of both acute (day 1 following the administration of chemotherapy agents) and delayed (days 2-5 following the administration of chemotherapy agents) CINV associated with moderately emetogenic chemotherapy (MEC) or highly emetogenic chemotherapy (HEC). While other 5-HT_3 antagonists are approved for the prevention of CINV, SUSTOL is the first agent in the class to demonstrate efficacy in reducing the incidence of delayed CINV in patients receiving HEC, a major unmet medical need, in a randomized Phase 3 study.

Affecting 70-80% of patients undergoing chemotherapy, CINV is one of the most debilitating side effects of such treatments, often attributed as a leading cause of premature discontinuation of cancer treatment. 5-HT_3 receptor antagonists have been shown to be among the most effective and preferred treatments for CINV. However, an unmet medical need exists for patients suffering from CINV during the delayed phase, which occurs on days 2-5 following the administration of chemotherapy agents. Only one 5-HT_3 receptor antagonist is approved for the prevention of delayed CINV associated with MEC, and no 5-HT_3 receptor antagonists are approved for prevention of delayed CINV associated with HEC.

SUSTOL was the subject of a recently completed, multi-center, placebo-controlled, Phase 3 clinical study in patients receiving HEC regimens known as MAGIC. The MAGIC study evaluated the efficacy and safety of SUSTOL as part of a three-drug regimen with the intravenous (IV) neurokinin-1 (NK_1) receptor antagonist fosaprepitant and the corticosteroid dexamethasone. The MAGIC study, which was conducted entirely in the U.S. using the 2011 ASCO guidelines for classification of emetogenic potential, is the only Phase 3 CINV prophylaxis study in a HEC population performed to date to use the currently recommended, standard-of-care, three-drug regimen as a comparator: a 5-HT_3 receptor antagonist, fosaprepitant, and dexamethasone. The study's primary endpoint was achieved. Specifically, the percentage of patients who achieved a Complete Response in the delayed phase was significantly higher in the SUSTOL arm compared with the comparator arm (p=0.014). Adverse events reported in the study were generally mild to moderate in severity and of short duration, with the most common being injection site reactions (ISRs). 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. SUSTOL is not approved by the FDA or any other regulatory authority.

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, 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 clinical 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: 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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Source: Heron Therapeutics, Inc.

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