Heron Therapeutics Announces U.S. FDA Approval of SUSTOL® (granisetron) Extended-Release Injection for the Prevention of Chemotherapy-Induced Nausea and Vomiting

August 10, 2016

- SUSTOL is the first extended-release 5-HT3 receptor antagonist approved for the prevention of acute and delayed nausea and vomiting associated with both moderately emetogenic chemotherapy and anthracycline and cyclophosphamide combination chemotherapy regimens
- A standard of care in the treatment of breast cancer and other cancer types, AC-based regimens are among the most commonly prescribed highly emetogenic chemotherapy regimens as defined by both the National Comprehensive Cancer Network (NCCN) and the American Society of Clinical Oncology (ASCO)
- U.S. commercial launch of SUSTOL is planned for the fourth quarter of 2016
- Conference call and webcast at 9 a.m. ET today

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Aug. 10, 2016-- Heron Therapeutics, Inc. (NASDAQ:HRTX), today announced that the U.S. Food and Drug Administration (FDA) has approved SUSTOL® (granisetron) extended-release injection. SUSTOL is a serotonin-3 (5-HT3) receptor antagonist indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens.

SUSTOL is an extended-release, injectable 5-HT3 receptor antagonist that utilizes Heron's Biochronomer ® polymer-based drug delivery technology to maintain therapeutic levels of granisetron for ≥5 days, covering both the acute and delayed phases of chemotherapy-induced nausea and vomiting (CINV).

"Despite advances in the management of CINV, up to half of patients receiving chemotherapy can still experience CINV, with delayed CINV being particularly challenging to control," commented Ralph V. Boccia, MD, FACP, Medical Director, Center for Cancer and Blood Disorders. "In our experience, other 5-HT3 receptor antagonists, including palonosetron, are generally effective for 48 hours or less. SUSTOL, due to its extended-release profile, represents a novel option that can protect patients from CINV for a full 5 days."

The SUSTOL global Phase 3 development program was comprised of two, large, guideline-based clinical trials that evaluated SUSTOL's efficacy and safety in more than 2,000 patients with cancer. SUSTOL's efficacy in preventing nausea and vomiting was evaluated in both the acute phase (day 1 following chemotherapy) and the delayed phase (days 2-5 following chemotherapy).

"The SUSTOL clinical trial populations and results are highly representative of cancer patients in our real-world clinical practice," said Jeffrey Vacirca, MD, FACP, Chief Executive Officer and Director of Clinical Research, North Shore Hematology Oncology Associates and Vice President, Community Oncology Alliance. "Use of MEC regimens is widespread, and AC-based regimens are among the most commonly prescribed highly emetogenic chemotherapy regimens. The most significant challenge for my breast cancer patients receiving AC is chemotherapy-induced nausea and vomiting. SUSTOL represents a better option to manage this devastating side effect of therapy."

"We would like to thank the investigators, caregivers and most of all the patients who have helped us to achieve this important milestone," commented Barry D. Quart, PharmD, Chief Executive Officer of Heron Therapeutics. "In addition to bringing an important product to patients, we are extremely pleased to have obtained the first approval of a product utilizing Heron's Biochronomer polymer-based drug delivery technology."

"The approval of SUSTOL is a major step in Heron's evolution into a fully-integrated biopharmaceutical company with both development and commercial capabilities," said Robert H. Rosen, President of Heron Therapeutics. "Our focus now turns to ensuring patients have access to this important therapy. We look forward to collaborating with the oncology community to make SUSTOL available in the fourth quarter of this year."

Conference Call and Webcast

Heron Therapeutics will host a conference call and webcast on Wednesday, August 10, 2016 at 9 a.m. ET (6 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 64356010 to join the conference call. A slide presentation accompanying today's press release and conference call may also be found on Heron's website at www.herontx.com under the investor relations section. The conference call will also be available via webcast under the investor relations section of Heron's website. 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. An archive of today's teleconference and webcast will be available on Heron's website for 60 days following the call.

About SUSTOL® (granisetron) extended-release injection

SUSTOL is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens. SUSTOL is an extended-release, injectable 5-HT3 receptor antagonist that utilizes Heron's Biochronomer ® polymer-based drug delivery technology to maintain therapeutic levels of granisetron for ≥5 days. The SUSTOL global Phase 3 development program was comprised of two, large, guideline-based clinical trials that evaluated SUSTOL's efficacy and safety in more than 2,000 patients with cancer. SUSTOL's efficacy in preventing nausea and vomiting was evaluated in both the acute phase (day 1 following chemotherapy) and the delayed phase (days 2-5 following chemotherapy).

Important Safety Information for SUSTOL

SUSTOL is contraindicated in patients with hypersensitivity to granisetron, any of the components of SUSTOL, or any other 5-HT3 receptor antagonist.

Injection site reactions (ISRs), including infection, bleeding, pain and tenderness, nodules, swelling, and induration, have occurred with SUSTOL. Monitor for ISRs following SUSTOL injection. Inform patients that some ISRs may occur 2 weeks or more after SUSTOL administration. In patients receiving antiplatelet agents or anticoagulants, consider the increased risk of bruising or severe hematoma prior to the use of SUSTOL.

Monitor for constipation and decreased bowel activity and consider optimizing patients' current bowel regimens used for managing preexisting constipation. Instruct patients to seek immediate medical care if signs and symptoms of ileus occur.

Hypersensitivity reactions have been reported and may occur up to 7 days or longer following SUSTOL administration and may have an extended course. If a reaction occurs, administer appropriate treatment and monitor until signs and symptoms resolve.

Serotonin syndrome has been reported with 5-HT3 receptor antagonists alone but particularly with concomitant use of serotonergic drugs.

Avoid SUSTOL in patients with severe renal impairment. In patients with moderate renal impairment, administer SUSTOL not more frequently than once every 14 days.

Most common adverse reactions (≥3%) are injection site reactions, constipation, fatigue, headache, diarrhea, abdominal pain, insomnia, dyspepsia, dizziness, asthenia, and gastroesophageal reflux.

Please see accompanying Full Prescribing Information at www.SUSTOL.com

About Chemotherapy-Induced Nausea and Vomiting (CINV)

While chemotherapy is one of the most effective and common used therapies to help patients fight cancer, it is accompanied by debilitating side effects, including varying degrees of nausea and vomiting, often attributed as a leading cause of premature discontinuation of cancer treatment. Delayed nausea and vomiting, which occurs 2-5 days following chemotherapy treatment, is considered particularly debilitating for patients. The National Comprehensive Cancer Network (NCCN) and the American Society of Clinical Oncology (ASCO) have categorized chemotherapy regimens based on the degree to which they cause nausea and vomiting: low emetogenic chemotherapy (LEC), moderately emetogenic chemotherapy (MEC) and highly emetogenic chemotherapy (HEC).

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: the potential market opportunity for SUSTOL and expected timing of the SUSTOL commercial launch, safety information for SUSTOL, the progress in the research and development of HTX-019, HTX-011 and our other programs, including the timing of preclinical, clinical, and manufacturing activities, safety and efficacy results from our studies, the commercial acceptance of our products, our financial position, business plans and our ability to raise additional capital, 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.

Investor Relations and Media Contact:
Heron Therapeutics, Inc.
Jennifer Capuzelo, 858-703-6063
Associate Director, Investor Relations
jcapuzelo@herontx.com