



## **Heron Therapeutics Reaches Target Patient Enrollment in MAGIC Phase 3 Study of SUSTOL®**

April 2, 2015

*-Topline Results Expected in May 2015  
-NDA Resubmission Expected Mid-Year 2015*

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Apr. 2, 2015-- Heron Therapeutics, Inc. (NASDAQ:HRTX), a biotechnology company, today announced that it has reached its enrollment target in MAGIC (**M**odified **A**bsorption **G**ranisetron **I**n the Prevention of **C**hemotherapy induced nausea and vomiting (CINV)) and is in the process of closing enrollment of new patients at its clinical sites. MAGIC is Heron's Phase 3 study evaluating the efficacy of SUSTOL® (granisetron injection, extended release) in the prevention of delayed-onset CINV following administration of highly emetogenic chemotherapy (HEC) agents.

This prospective, randomized, placebo-controlled, Phase 3 study compares SUSTOL plus the neurokinin-1 (NK<sub>1</sub>) receptor antagonist fosaprepitant and dexamethasone to the current standard of care for delayed-onset CINV following administration of HEC agents, ondansetron plus fosaprepitant and dexamethasone. The study has enrolled approximately 900 patients receiving various HEC agents, as defined by the 2011 ASCO guidelines, at approximately 200 U.S. sites. The primary endpoint in this study is the proportion of patients who achieved a complete response, defined as no emesis and no rescue medications, in the 24-120 hours following chemotherapy.

"This milestone marks an important step in the development of our lead product candidate, SUSTOL, which has the potential to provide a safe and effective treatment option for the many cancer patients suffering from CINV," commented Barry D. Quart, Pharm.D., Chief Executive Officer of Heron Therapeutics. "With our enrollment goal achieved, we will now turn our focus to collecting all study data as quickly as possible in order to report topline results in May 2015, followed by the resubmission of the SUSTOL NDA to the U.S. Food and Drug Administration (FDA) around the middle of this year."

### **About SUSTOL® and Chemotherapy Induced Nausea and Vomiting**

Heron Therapeutics' lead investigational product candidate, SUSTOL® (granisetron injection, extended release), is being developed for the prevention of both acute- and delayed-onset 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 the most debilitating side effects of such treatments, often attributed as a leading cause of premature discontinuation of cancer treatment. Injectable 5-hydroxytryptamine type 3 (5-HT<sub>3</sub>) 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-onset phase, which typically occurs one-to-five days following administration of chemotherapy agents. For delayed-onset CINV, only one injectable 5-HT<sub>3</sub> receptor antagonist is approved for use following the administration of MEC agents, and none are approved for use following administration of HEC agents. SUSTOL contains the 5-HT<sub>3</sub> receptor antagonist granisetron, selected due to its broad use by physicians based on a well-established record of safety and efficacy, and the fact that it is only currently approved for the prevention of CINV during the acute-onset phase. SUSTOL is formulated with the Company's proprietary Biochronomer® drug delivery technology and in clinical trials has been shown to maintain therapeutic drug levels of granisetron for up to five days with a single subcutaneous injection.

### **About HTX-019 for Chemotherapy Induced Nausea and Vomiting**

HTX-019 is a proprietary injectable formulation of aprepitant, a neurokinin-1 (NK<sub>1</sub>) receptor antagonist for the prevention of CINV. NK<sub>1</sub> receptor antagonists are typically used in combination with 5-HT<sub>3</sub> receptor antagonists. At present, the only injectable NK<sub>1</sub> receptor antagonist approved in the U.S. contains polysorbate 80, a surfactant, which may cause hypersensitivity reactions or other adverse reactions in some patients. Heron Therapeutics' formulation for HTX-019 does not contain polysorbate 80, and may have a lower incidence of infusion-site reactions than reported with the other commercially available injectable NK<sub>1</sub> receptor antagonist.

### **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 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 plans to move HTX-011 into Phase 2 clinical development in the second quarter of 2015.

### **About HTX-003 for Chronic Pain and Addiction**

HTX-003, which utilizes Heron's proprietary Biochronomer drug delivery technology, is a long-acting formulation of buprenorphine for the management of chronic pain and opioid addiction. HTX-003 is designed to maintain therapeutic drug levels of buprenorphine for 30 days following a single subcutaneous injection with a low potential for patient abuse.

#### **About Heron Therapeutics, Inc.**

Heron Therapeutics, Inc. is a biotechnology company using its proprietary technology and innovative efforts to develop products to address unmet medical needs. The Company's proprietary Biochronomer drug delivery technology is designed to improve the therapeutic profile of injectable pharmaceuticals. The Company's product development efforts focus on identifying current therapies with the potential to be reformulated to expand or extend therapeutic effect or duration of action, minimize drawbacks or to apply new delivery methods. In addition, we continually evaluate potential development programs, technologies and product candidates that may be complementary to or synergistic with our existing programs and product development goals.

#### **Forward Looking Statements**

This news release contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. Heron Therapeutics 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 those associated with: the timing of completion of the HEC study, and the results thereof, and the new drug application resubmission for SUSTOL, potential regulatory approval of SUSTOL and the timing for such approval, if approved at all; the progress in research and development of HTX-019, HTX-011, HTX-003 and our other product candidate programs, including the timing of planned toxicology and clinical studies; safety and efficacy data from our clinical studies that may not warrant further development of our product candidates; the launch and acceptance of 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 other products or technologies; 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.

Source: Heron Therapeutics, Inc.

#### **Investor Relations Contact:**

Jennifer Capuzelo, 858-703-6063  
Sr. Manager, Investor Relations  
[jcapuzelo@herontx.com](mailto:jcapuzelo@herontx.com)

or

#### **Corporate Contact:**

Barry D. Quart, 650-366-2626  
Pharm.D., Chief Executive Officer