Heron Therapeutics Initiates Phase 3 Label Expansion Study of SUSTOL™

March 31, 2014

Study will evaluate the prevention of delayed-onset chemotherapy-induced nausea and vomiting in patients receiving highly emetogenic chemotherapy

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Mar. 31, 2014-- Heron Therapeutics, Inc. (NASDAQ: HRTX), a specialty pharmaceutical company, today announced the initiation of a Phase 3 clinical trial of SUSTOL™ (APF530), the Company's lead product candidate for the prevention of chemotherapy-induced nausea and vomiting (CINV) associated with moderately and highly emetogenic chemotherapy. This Phase 3 clinical trial will evaluate SUSTOL for the prevention of delayed-onset CINV in patients receiving highly emetogenic chemotherapy (HEC) agents and is designed to support expansion of the expected label for SUSTOL in the delayed-onset HEC setting.

The label-expansion study is a prospective, randomized, placebo-controlled two-arm study of approximately 1000 HEC-treated patients comparing SUSTOL plus the NK-1 inhibitor fosaprepitant and dexamethasone to ondansetron plus fosaprepitant and dexamethasone. Currently, there is no long-acting 5-HT_3 receptor antagonist approved for the prevention of delayed-onset CINV after the administration of HEC agents. Published results of large clinical trials show that approximately 35 percent of patients receiving HEC agents experience CINV in the delayed phase with the currently available standard three-drug regimen, leaving a significant unmet medical need for better therapy. Based on the results of a previously completed Phase 3 trial, Heron is currently pursuing the approval of SUSTOL for the prevention of acute and delayed CINV in patients receiving moderately emetogenic chemotherapy (MEC) agents and the prevention of acute CINV in HEC. The Company anticipates submission of a new drug application (NDA) for SUSTOL to the U.S. Food and Drug Administration (FDA) mid-2014.

“We are excited to have this important label-expansion study underway, which is focused on an area of significant unmet medical need,” commented Barry D. Quart, PharmD, Chief Executive Officer of Heron Therapeutics. “Based on very strong interest from community oncologists, we anticipate rapid enrollment, with data to be available before the end of 2014. Furthermore, if successful, this study will allow us to further differentiate SUSTOL as the only 5-HT_3 receptor antagonist with demonstrated activity for the prevention of delayed-onset CINV in patients receiving the most highly emetogenic chemotherapy agents.”

About SUSTOL

Heron's lead product candidate, SUSTOL™ (formerly known as APF530), is being developed for the prevention of both acute- and delayed-onset chemotherapy-induced nausea and vomiting (CINV). One of the most debilitating side effects of cancer chemotherapy, CINV is a leading cause of premature discontinuation of treatment. There is only one injectable 5-HT_3 antagonist approved for the prevention of delayed-onset CINV in patients receiving moderately emetogenic chemotherapy (MEC); none are approved for delayed-onset CINV in patients receiving highly emetogenic chemotherapy (HEC). SUSTOL contains the 5-HT_3 receptor antagonist granisetron formulated in the Company's proprietary Biochronomer™ polymer-based drug delivery platform, which allows therapeutic drug levels to be maintained for five days with a single subcutaneous injection. Currently available intravenous and oral formulations of granisetron are approved only for the prevention of acute-onset CINV. Granisetron was selected for SUSTOL because it is widely prescribed by physicians based on a well-established record of safety and efficacy.

About Heron Therapeutics, Inc.

Heron Therapeutics, Inc. (formerly A.P. Pharma, Inc.) is a specialty pharmaceutical company developing products using its proprietary Biochronomer™ polymer-based drug delivery platform. This drug delivery platform is designed to improve the therapeutic profile of injectable pharmaceuticals by converting them from products that must be injected once or twice per day to products that need to be injected only once every one or two weeks. The Company's lead product, SUSTOL (formerly known as APF530), is being developed for the prevention of both acute- and delayed-onset chemotherapy-induced nausea and vomiting.

In addition to SUSTOL, Heron is also utilizing its proprietary, extended-release Biochronomer™ technology to develop other drugs designed to extend the duration of action of known active ingredients to address important unmet medical needs. In November 2013, the Company announced movement into full development of the first of these new drug programs - the Biochronomer extended release of an established local anesthetic for the treatment of post-surgical pain. In recently completed, post-surgical animal models of pain, the Company's drug candidates demonstrated statistically significant pain relief for five days, representing the potential to significantly reduce the need for opiates post-surgery and the length of post-surgical hospital stays. Heron expects to move its pain program into human clinical studies in mid-2014.

Forward Looking Statements

This news release contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve risks and uncertainties, including uncertainties associated with the potential approval of SUSTOL (formerly APF530) and the potential timing for such approval, if approved at all, as well as risks and benefits relating to listing on the NASDAQ Capital Market, progress in research and development programs, launch and acceptance of new products 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:
For Heron Therapeutics, Inc.
Michael Rice, 646-597-6979
mrice@lifesciadvisors.com
or
Jennifer Capuzelo, 858-703-6063
jcapuzelo@herontx.com
or
Corporate:
Heron Therapeutics, Inc.
Stephen R. Davis, 650-366-2626
Executive Vice President and Chief Operating Officer