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Heron Therapeutics Provides Update on Sustol Resubmission

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REDWOOD CITY, Calif.--(BUSINESS WIRE)--Heron Therapeutics, Inc. (NASDAQ: HRTX), a specialty pharmaceutical company, today announced an approximate one-quarter delay to the Company's timeline for the resubmission of the new drug application (NDA) for Sustol® to the U.S. Food and Drug Administration (FDA), the Company's product candidate for chemotherapy-induced nausea and vomiting (CINV).

"Subject to the FDA's review and approval of the Sustol NDA, we project being in a position to launch Sustol in early 2015, which presents more optimal timing than potentially launching into the late 2014 holiday season." The Company received notice last week from the supplier of the syringes used for Sustol injections that the production order of syringes manufactured for Heron, and scheduled to be used in the validation of the commercial manufacturing process for Sustol required for resubmission of the NDA, will be delayed due to equipment failure of an in-process quality control check. The equipment failure is not specific to Sustol or Heron, and remedial efforts are underway.

"The manufacturer of our syringe is a well-established global manufacturer of medical products and we are confident that the issue they have identified can and will be rectified within a quarter," said Barry D. Quart, PharmD, Chief Executive Officer of Heron Therapeutics. "Although this delay is extremely frustrating for us, we are looking at every possible alternative to accelerate the timing of resubmission. We expect the delay in delivery of final syringes, which were planned for use in our commercial validation of Sustol and the impact on associated activities to result in an approximate one quarter delay in resubmission of the NDA for Sustol, which we had previously targeted for end of the first quarter of 2014."

"While the timing of our resubmission will be impacted by this delay, we expect it to have minimal impact on our projected timing of the launch of Sustol," continued Dr. Quart. "Subject to the FDA's review and approval of the Sustol NDA, we project being in a position to launch Sustol in early 2015, which presents more optimal timing than potentially launching into the late 2014 holiday season."

Clinical trial supplies of Sustol were produced prior to the delay in syringe manufacturing; therefore, the Company remains on track to commence and complete in 2014 a study of Sustol in the treatment of delayed onset CINV in patients receiving highly emetogenic chemotherapy (HEC) agents. Currently, there is no 5-HT3 receptor antagonist approved for the treatment of delayed HEC.

About Heron Therapeutics

Heron Therapeutics (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, Biochronomer[™], sustained-release 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.

For further information, please visit the Company's web site at www.herontx.com.

About Sustol

Heron's lead product candidate, Sustol, 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-HT3 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-HT3 antagonist granisetron formulated in the Company's proprietary Biochronomer[™] drug delivery system, 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.

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.

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