



Heron Therapeutics Provides Update on SUSTOL® NDA

February 29, 2016

REDWOOD CITY, Calif.--(BUSINESS WIRE)-- Heron Therapeutics, Inc. (HRTX), previously announced that the U.S. Food and Drug Administration (FDA) would not take action on the New Drug Application (NDA) for SUSTOL® (granisetron) Injection, extended release by the original Prescription Drug User Fee Act (PDUFA) goal date of January 17, 2016 and would delay taking action until late February 2016. The FDA has informed the Company that it has not concluded its review of the NDA and could not yet provide the Company with an anticipated action date, but indicated that they will communicate the new action date to the Company later this week.

SUSTOL is a long-acting formulation of the FDA-approved 5-hydroxytryptamine type 3 (5-HT₃) receptor antagonist granisetron 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). SUSTOL is formulated utilizing Heron's proprietary Biochronomer® drug delivery technology, and has been shown to maintain therapeutic drug levels of granisetron for at least five days with a single subcutaneous injection.

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. 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. 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) completes its review within the anticipated time period, whether the FDA approves the SUSTOL NDA as submitted or supports as broad of a labeled indication for SUSTOL as requested, the potential market opportunity for SUSTOL and expected timing of the commercial launch, 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 that may not justify the pursuit of further development of our product candidates, 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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- Health Care Industry
- Food and Drug Administration
- Heron
- New Drug Application

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