Heron Announces Submission of CINVANTI™ NDA for the Prevention of Chemotherapy-Induced Nausea and Vomiting (CINV)

January 12, 2017

- If Approved by the U.S. FDA, CINVANTI Will Strengthen Heron's CINV Franchise by Adding Second, Complementary Therapeutic Agent -

SAN DIEGO--(BUSINESS WIRE)--Jan. 12, 2017-- Heron Therapeutics, Inc. (NASDAQ:HRTX), a commercial-stage biotechnology company focused on developing novel best-in-class treatment solutions to address some of the biggest unmet patient needs, today announced submission of the New Drug Application (NDA) for CINVANTI (HTX-019), the first polysorbate 80-free, intravenous formulation of aprepitant for the prevention of CINV, to the U.S. Food and Drug Administration (FDA). Aprepitant belongs to a class of agents known as NK_1 receptor antagonists, which are often used in combination with 5-HT_3 receptor antagonists for the prevention of CINV.

The NDA filing includes data demonstrating the bioequivalence of CINVANTI to EMEND IV® (fosaprepitant), supporting its efficacy for the prevention of both acute and delayed CINV with both moderately emetogenic chemotherapy (MEC) and highly emetogenic chemotherapy (HEC). Results also showed CINVANTI was better tolerated than EMEND IV, with significantly fewer adverse events reported with CINVANTI.

"The filing of the NDA for CINVANTI is an important milestone, bringing us one step closer to a new NK_1 receptor antagonist treatment option for cancer patients suffering from the debilitating side effects of chemotherapy," said Kimberly J. Manhard, Executive Vice President, Drug Development at Heron Therapeutics. "We look forward to working closely with the FDA during the review of the NDA for CINVANTI in anticipation of FDA approval in late 2017."

"CINVANTI is based on the most widely used NK_1 receptor antagonist, with almost 9 years of safety and efficacy experience," said Barry D. Quart, Pharm.D., Chief Executive Officer of Heron Therapeutics. "Since NK_1 receptor antagonists are used in combination with 5-HT_3 receptor antagonists, CINVANTI offers a strong strategic and operational fit with Heron's existing commercial product, SUSTOL ®, our extended-release, injectable product that incorporates the 5-HT_3 receptor antagonist granisetron and is also indicated for the prevention of CINV."

About CINVANTI (HTX-019) for CINV

CINVANTI is a proprietary intravenous formulation of aprepitant, a NK_1 receptor antagonist for the prevention of CINV. NK_1 receptor antagonists are typically used in combination with 5-HT_3 receptor antagonists. Currently, the only injectable NK_1 receptor antagonist approved in the U.S. contains polysorbate 80, a surfactant, which may cause hypersensitivity reactions, infusion site reactions or other adverse reactions in some patients. Heron's formulation for CINVANTI does not contain polysorbate 80 and may have a lower incidence of certain types of adverse reactions than reported with the other commercially available injectable NK_1 receptor antagonist.

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 MEC or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens. SUSTOL is an extended-release, injectable 5-HT_3 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 efficacy and safety in more than 2,000 patients with cancer. The efficacy of SUSTOL 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). Please see full prescribing information, including additional important safety information, available at www.SUSTOL.com.

About Heron Therapeutics, Inc.

Heron Therapeutics, Inc. is a commercial-stage 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: whether CINVANTI will receive FDA approval, the timing of commercial launch for CINVANTI, 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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