Heron Therapeutics Announces Submission of HTX-019 NDA for the Prevention of Postoperative Nausea and Vomiting to FDA

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SAN DIEGO, Nov. 18, 2021 /PRNewswire/ -- Heron Therapeutics, Inc. (Nasdaq: HRTX), a commercial-stage biotechnology company focused on improving the lives of patients by developing best-in-class treatments to address some of the most important unmet patient needs, today announced the submission of its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for HTX-019 (aprepitant) injectable emulsion for the prevention of postoperative nausea and vomiting (PONV) in adults. HTX-019 is a proprietary intravenous (IV) formulation of aprepitant, a substance P/neurokinin-1 (NK_1) receptor antagonist (RA) that is approved for PONV prevention.

The NDA filing includes data demonstrating the bioequivalence of HTX-019 32 mg as a 30-second IV injection to oral aprepitant 40 mg, supporting its efficacy for the prevention of PONV. Results also showed HTX-019 was well-tolerated with a similar safety profile compared to oral aprepitant. Because HTX-019 is administered as an IV injection, it provides convenient, rapid, consistent, and reliable exposure in all patients and overcomes the need to take the oral formulation 1 to 3 hours before anesthesia. The HTX-019 injectable emulsion formulation intended for PONV prevention is identical to the approved CINVANTI® (aprepitant) injectable emulsion formulation for prevention of chemotherapy-induced nausea and vomiting (CINV).

Despite advances in postoperative care, nausea and vomiting has remained a challenge for many patients undergoing surgery. There are approximately 65 million diagnostic and surgical procedures at risk of resulting in PONV in the U.S. each year. More than half of these patients are at moderate to high risk of developing PONV. Recent data has also shown that PONV can lead to increases in medical costs and delays in discharge and recovery following procedures. Aprepitant is the first and only NK_1 RA to be approved for prevention of PONV based on showing superiority to ondansetron, the current standard of care.

"In a recent Cochrane Meta-Analysis, aprepitant was found to be the most effective agent for PONV prevention with activity similar to two-drug combinations. In fact, the use of oral aprepitant has grown by almost 80% in the past three years without any promotional efforts. Our IV formulation is designed to directly deliver the active form of the drug, aprepitant, to patients over 30 seconds so it can take effect much more quickly than when taken orally," said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. "The HTX-019 NDA was filed with the same FDA division that previously approved CINVANTI without delays."

"There remains an important unmet need for effective and convenient products for PONV prevention," said Ashraf Habib, MBBCh, MSc, MHSc, FRCA, Chief, Division of Women's Anesthesia at Duke University Hospital. "If approved, this innovative IV formulation of aprepitant, with rapid achievement of therapeutic drug levels, will enable physicians to provide patients with a well-established agent that effectively prevents nausea and vomiting after surgery, using a route of administration that fits well in the perioperative workflow."

About HTX-019 for PONV

HTX-019 is an IV injectable emulsion formulation designed to directly deliver aprepitant, the active ingredient in EMEND® (aprepitant) capsules, which is the only substance P/neurokinin-1 receptor antagonist to be approved in the U.S. for the prevention of postoperative nausea and vomiting (PONV) in adults. The FDA-approved dose of oral EMEND is 40 mg for PONV prevention, which is given within 3 hours prior to induction of anesthesia for surgery. In a Phase 1 clinical trial, 32 mg of HTX-019 as a 30-second IV injection was demonstrated to be bioequivalent to oral aprepitant 40 mg. The NDA for HTX-019 for PONV was submitted in November 2021.

About CINVANTI for Chemotherapy-Induced Nausea and Vomiting (CINV) Prevention

CINVANTI, in combination with other antiemetic agents, is indicated in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin as a single-dose regimen, delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single-dose regimen, and nausea and vomiting associated with initial and repeat courses of MEC as a 3-day regimen. CINVANTI is an IV formulation of aprepitant, an NK_1 RA.

CINVANTI is the first IV formulation to directly deliver aprepitant, the active ingredient in EMEND® capsules. Aprepitant (including its prodrug, fosaprepitant) is the only single-agent NK_1 RA to significantly reduce nausea and vomiting in both the acute phase (0–24 hours after chemotherapy) and the delayed phase (24–120 hours after chemotherapy). The FDA-approved dosing regimens included in the U.S. prescribing information for CINVANTI include 100 mg or 130 mg administered as a 30-minute IV infusion or a 2-minute IV injection.

Please see full prescribing information at www.CINVANTI.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 treatments to address some of the most important unmet patient needs. Our advanced science, patented technologies, and innovative approach to drug discovery and development have allowed us to create and commercialize a portfolio of products that aim to advance the standard-of-care for

acute care and oncology patients. 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, whether the FDA approves the HTX-019 NDA as submitted; the anticipated commercial launch of HTX-019 in the U.S.; the extent of the impact of the ongoing COVID-19 pandemic on our business; and other risks and uncertainties identified in the Company's filings with the U.S. 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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