Heron Therapeutics Highlights Progress in Pain Management and CINV Franchises

January 13, 2020

- Marketing Applications for HTX-011 for Postoperative Pain Management Are under Review in the United States, the European Union and Canada -

- Preliminary Fourth-Quarter 2019 Net Product Sales for CINV Franchise of Approximately $34.8 Million, up 21% Year-over-Year -

- Preliminary Full-Year 2019 Net Product Sales for CINV Franchise of Approximately $145.7 Million, versus Guidance of $135.0 Million -

- December 31, 2019 Cash, Cash Equivalents and Short-Term Investments of Approximately $391.0 Million -

- Attending the 38th Annual J.P. Morgan Healthcare Conference -

SAN DIEGO, Jan. 13, 2020 /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 highlighted progress in its pain management and chemotherapy-induced nausea and vomiting (CINV) franchises.

Recent Corporate Progress

Pain Management Franchise

- **New Drug Application Resubmission for HTX-011:** In September 2019, Heron resubmitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for HTX-011, an investigational agent for the management of postoperative pain. The FDA set a Prescription Drug User Fee Act (PDUFA) goal date of March 26, 2020.
- **Marketing Authorisation Application for HTX-011:** In March 2019, Heron's Marketing Authorisation Application (MAA) for HTX-011 for the management of postoperative pain was validated by the European Medicines Agency's (EMA) for review under the Centralised Procedure. An opinion from the EMA Committee for Medicinal Products for Human Use (CHMP) is anticipated in the second quarter of 2020.
- **New Drug Submission for HTX-011:** In December 2019, Heron's New Drug Submission (NDS) for HTX-011 for the management of postoperative pain was granted Priority Review status and accepted by Health Canada. Health Canada's Priority Review status provides an accelerated 6-month review target for the NDS. A decision by Health Canada is anticipated in the third quarter of 2020.

CINV Franchise

- **Fourth-Quarter 2019 Net Product Sales:** Preliminary fourth-quarter 2019 net product sales for the CINV franchise were approximately $34.8 million, up 21% year-over-year. This included net product sales of approximately $34.4 million for CINVANTI® (aprepitant) injectable emulsion and approximately $0.4 million for SUSTOL® (granisetron) extended-release injection.
- **Full-Year 2019 Net Product Sales:** Preliminary full-year 2019 net product sales for the CINV franchise were approximately $145.7 million, versus guidance of $135.0 million and up 88% year-over-year. This included net product sales of approximately $132.0 million for CINVANTI and approximately $13.7 million for SUSTOL.

Corporate Update

- **December 31, 2019 Cash, Cash Equivalents and Short-Term Investments:** As of December 31, 2019, Heron had approximately $391.0 million in cash, cash equivalents and short-term investments.

"We have made important advances in 2019 in both our pain management and CINV franchises, highlighted by the submission of three marketing applications for HTX-011 for postoperative pain management and strong net product sales for CINVANTI, even amid the launch of generic fosaprepitant," said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron. "We ended 2019 in a strong cash position of $391.0 million, which will support the anticipated launch of HTX-011 in the second quarter of 2020, pending FDA approval."

About HTX-011 for Postoperative Pain

HTX-011, an investigational agent, is a dual-acting, fixed-dose combination of the local anesthetic bupivacaine with a low dose of the nonsteroidal anti-inflammatory drug meloxicam. It is the first and only extended-release local anesthetic to demonstrate in Phase 3 studies significantly reduced pain and opioid use through 72 hours compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control. HTX-011 was granted Fast Track designation from the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2017 and Breakthrough Therapy designation in the second quarter of 2018. Heron submitted a New Drug Application (NDA) to the FDA for HTX-011 in October of 2018 and received Priority Review designation in December of 2018. A Complete Response Letter (CRL) was received from the FDA regarding the NDA for HTX-011 on April 30, 2019 relating to chemistry, manufacturing and controls and non-clinical information. No issues related to clinical efficacy or safety were noted. Heron resubmitted an NDA to the FDA for HTX-011 in September 2019 and the FDA set a Prescription Drug User Fee Act (PDUFA) goal date of March 26, 2020. A Marketing Authorisation Application (MAA) for HTX-011 was validated by the European Medicines Agency (EMA) in March 2019 for review under the Centralised Procedure. Heron's New Drug Submission (NDS) for HTX-011 for the management of postoperative pain was granted Priority Review status by Health Canada in October 2019 and accepted by Health Canada in November 2019.

About CINVANTI (Aprepitant) Injectable Emulsion

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 HEC, including high-dose cisplatin, and nausea and vomiting associated with initial and repeat courses of MEC. CINVANTI is an IV formulation of aprepitant, an NK1 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 NK1 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 administration included in the United States prescribing information for CINVANTI is a 30-minute IV infusion or a 2-minute IV injection.

Please see full prescribing information at www.CINVANTI.com.

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 moderately emetogenic chemotherapy (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® 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 studies that evaluated SUSTOL's efficacy and safety in more than 2,000 patients with cancer. SUSTOL's efficacy in preventing nausea and vomiting was evaluated in both the acute phase (0–24 hours after chemotherapy) and delayed phase (24–120 hours after chemotherapy).

Please see full prescribing information 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 treatments to address some of the most important unmet patient needs. Heron is developing novel, patient-focused solutions that apply its innovative science and technologies to already-approved pharmacological agents for patients suffering from pain or cancer.

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: the fourth-quarter 2019 and full-year 2019 net product sales for the CINV franchise; whether the U.S. Food and Drug Administration (FDA) approves the New Drug Application (NDA) for HTX-011; the timing of the commercial launch of HTX-011; the timing of the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) review process for HTX-011; whether the European Commission authorizes the Marketing Authorization Application (MAA) for HTX-011; the timing of Health Canada's New Drug Submission (NDS) review process for HTX-011; whether Health Canada issues a Notice of Compliance for the NDS for HTX-011; the expected balances of Heron's cash, cash equivalents and short-term investments; the expected duration over which Heron's cash, cash equivalents and short-term investments balances will fund its operations; 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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