Heron Therapeutics Announces FDA Extension of Review Period for NDA for HTX-011 for the Management of Postoperative Pain

February 19, 2020

- Updated Prescription Drug User Fee Act (PDUFA) Goal Date Is June 26, 2020 -
- Contract Manufacturing Site for HTX-011 Reinspected by FDA with No Observations Issued and a Recommendation for Approval Received -

SAN DIEGO, Feb. 19, 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 announced that the U.S. Food and Drug Administration (FDA) has extended the review period for the New Drug Application (NDA) for HTX-011 by up to three months. The new PDUFA goal date is June 26, 2020.

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. Heron is pleased to report that the contract manufacturing site used to manufacture HTX-011 has been reinspected by the FDA with no Form 483 observations issued and with a recommendation by the FDA inspector for approval of the site. Heron has not been informed of any other manufacturing concerns. There were no clinical efficacy or safety issues in the CRL.

"While the three-month extension of the review clock for the HTX-011 NDA resubmission is very disappointing, the FDA indicated that they will try to complete their work in less time," said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron. "We are gratified with the positive outcome of the FDA reinspection of the HTX-011 contract manufacturing facility, which was an important factor in the CRL."

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 FDA in the fourth quarter of 2017 and Breakthrough Therapy designation in the second quarter of 2018. Heron submitted an 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. The PDUFA goal date is June 26, 2020. A Marketing Authorisation Application for HTX-011 was validated by the European Medicines Agency 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 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: whether the FDA approves the NDA for HTX-011; the timing of the commercial launch of HTX-011; the timing of the European Medicines Agency Committee for Medicinal Products for Human Use review process for HTX-011; whether the European Commission authorizes the Marketing Authorisation Application 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; 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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