Heron Therapeutics Receives Complete Response Letter For HTX-011 For The Management Of Postoperative Pain

May 1, 2019

- Complete Response Letter Requests Additional Chemistry Manufacturing and Controls (CMC) and Non-Clinical Information -

- No Clinical Safety or Efficacy Issues Identified, and No Requirement for Further Clinical Data -

- Conference Call and Webcast Today at 8:30 a.m. ET -

SAN DIEGO, May 1, 2019 /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 it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) on April 30, 2019 regarding its New Drug Application (NDA) for HTX-011 for the management of postoperative pain.

The CRL stated that the FDA is unable to approve the NDA in its present form based on the need for additional CMC and non-clinical information. Based on the complete review of the NDA, the FDA did not identify any clinical safety or efficacy issues, and there is no requirement for further clinical studies or data analyses.

"We plan to request a meeting with the FDA to obtain its agreement on our approach to resolve the issues outlined in the CRL and resubmit the NDA as soon as possible," said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron Therapeutics.

Conference Call and Webcast

Heron Therapeutics will host a conference call and webcast today, May 1, 2019, at 8:30 a.m. ET (5:30 a.m. PT). The conference call can be accessed by dialing 877-311-5906 for domestic callers and 281-241-6150 for international callers. Please provide the operator with the passcode 9591606 to join the conference call. The conference call will be available via webcast under the Investor Relations section of Heron's website at www.herontx.com. An archive of today's teleconference and webcast will be available on Heron's website for 60 days following the call.

About HTX-011 for Postoperative Pain

HTX-011, which utilizes Heron's proprietary Biochronomer® drug delivery technology, is an investigational, long-acting, extended-release formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam for the management of postoperative pain. By delivering sustained levels of both a potent anesthetic and a local anti-inflammatory agent directly to the site of tissue injury, HTX-011 was designed to deliver superior pain relief while reducing the need for systemically administered pain medications such as opioids, which carry the risk of harmful side effects, abuse and addiction. HTX-011 has been shown to reduce pain significantly better than placebo or bupivacaine solution in five diverse surgical models: hernia repair, abdominoplasty, bunionectomy, total knee arthroplasty and breast augmentation. 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 CRL was received from the FDA regarding the NDA for HTX-011 on April 30, 2019. An MAA for HTX-011 was validated by the EMA in March 2019 for review under the Centralised Procedure.

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 HTX-011 NDA; the timing of the commercial launch of HTX-011; the timing of the CHMP's review process for HTX-011; whether the EMA authorizes the MAA 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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