Heron Therapeutics Announces Successful Outcome of FDA Type A Meeting to Discuss HTX-011 for the Management of Postoperative Pain

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SAN DIEGO, Sept. 8, 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 a successful Type A meeting with the U.S. Food and Drug Administration (FDA) in which alignment was reached on the plans for the Company to resubmit the New Drug Application (NDA) for HTX-011 for the management of postoperative pain in the fourth quarter of this year.

HTX-011 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.

"Our Type A meeting with the FDA was extremely constructive, with alignment on next steps for the HTX-011 NDA resubmission and with both parties committed to bringing this important non-opioid analgesic to patients in the U.S. as soon as possible. The FDA responded very positively to the information that Heron has generated to resolve the issues contained in the Complete Response Letter and agreed that the proposed specification change was acceptable," said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron. "We expect to resubmit the HTX-011 NDA in the next few months and appreciate the FDA's commitment to an expeditious review for this Breakthrough Therapy product."

About HTX-011 (ZYNRELEF™ in the European Union) for Postoperative Pain

HTX-011, an investigational non-opioid analgesic, 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 2018 and received Priority Review designation in December 2018. A complete response letter (CRL) was received from the FDA regarding the NDA for HTX-011 on June 26, 2020 relating to non–clinical information. No clinical safety or efficacy issues and no chemistry, manufacturing and controls (CMC) issues were identified. The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for ZYNRELEF in July 2020. 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. Heron is working to respond to a list of questions received from Health Canada in July 2020.

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 timing of the submission of the new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for HTX-011; whether the FDA approves the NDA for HTX-011; the timing of the commercial launch of HTX-011 in the U.S.; the timing of the European Commission's (EC) review process for ZYNRELEF; whether the EC authorizes the Marketing Authorisation Application for ZYNRELEF; the timing of the commercial launch of ZYNRELEF in Europe; 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 extent of the impact of the ongoing Coronavirus Disease 2019 (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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