



Health Canada Grants Priority Review Status for Heron Therapeutics' New Drug Submission for HTX-011 for Management of Postoperative Pain

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SAN DIEGO, Dec. 3, 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 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. Health Canada grants Priority Review status to drug submissions intended for the treatment, prevention or diagnosis of serious, life-threatening or severely debilitating illnesses or conditions for which there is substantial evidence of clinical effectiveness and a benefit/risk profile that is improved over existing therapies.

"We are appreciative of Health Canada for granting Priority Review status for the HTX-011 NDS," said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron. "Priority Review status was granted based on Health Canada's acknowledgement that reduction in opioid prescribing and consumption is an important medical and public health priority and that the benefit/risk profile of HTX-011 is improved over existing therapies based on the results of the two pivotal Phase 3 studies, EPOCH 1 and EPOCH 2, in which HTX-011 demonstrated superior, longer-lasting pain relief compared to bupivacaine with fewer patients using opioid analgesics."

"The overprescribing of opioids after surgery puts surgical patients at risk for opioid-related adverse events and potential long-term use, which can result in unused pills making their way into communities," said Dr. Ken Leslie, Chief, Division of General Surgery, London Health Sciences Centre, London, Ontario, and Principal Investigator of the Standardization of Outpatient Procedure (STOP) Narcotics Study. "New opioid-free options to more effectively manage postoperative pain, while reducing the need for opioids, are urgently needed, as opioid-related deaths have been on the rise in Canada with more than 12,800 apparent opioid-related deaths occurring between January 2016 and March 2019."

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 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 United States 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; 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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