Heron Therapeutics Receives Positive CHMP Opinion for ZYNRELEF™ (HTX-011) for the Management of Postoperative Pain

July 24, 2020

SAN DIEGO, July 24, 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 European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for ZYNRELEF (formerly known as HTX-011), intended for the treatment of postoperative pain.

ZYNRELEF is a non-opioid, dual-acting analgesic, utilizing a fixed-dose combination of the local anesthetic bupivacaine with a low dose of the nonsteroidal anti-inflammatory drug meloxicam, where meloxicam enhanced the efficacy of bupivacaine. ZYNRELEF uses Heron's proprietary Biochronomer® polymer delivery system to slowly release these drugs over approximately 72 hours.

The CHMP's positive opinion is based on the results of Heron's two Phase 3 studies of ZYNRELEF. The primary endpoint and all 4 key secondary endpoints were met in both Phase 3 studies. ZYNRELEF demonstrated significantly reduced pain and opioid use through 72 hours compared to bupivacaine solution, the current standard-of-care anesthetic for postoperative pain control. ZYNRELEF significantly reduced pain intensity through 72 hours post–surgery, significantly reduced the use of opioid medications following surgery and significantly increased the proportion of patients who required no postoperative opioid medications. In both studies, ZYNRELEF was generally well tolerated, with a safety profile comparable to placebo and bupivacaine solution.

The CHMP's positive opinion will now be reviewed by the European Commission (EC), with a final decision on the Marketing Authorisation Application expected in the coming months. An EC marketing authorisation through the centralized procedure is valid in all 27 European Union (EU) member countries as well as the European Economic Area countries. The CHMP recommended that ZYNRELEF be indicated for treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults.

"Managing postoperative pain remains a major challenge for many physicians, given that up to 80% of patients across Europe report moderate to severe pain for several days after surgery. Postoperative pain causes avoidable suffering, resulting in longer hospital stays and higher healthcare costs," said Richard Langford M.D., FRCA, FFPMRCA, Honorary Consultant, Pain and Anaesthesia Research Centre, St. Bartholomew's Hospital, Barts Health NHS Trust, London, United Kingdom. "The indication recommended by the CHMP will allow surgeons to use the product for a wide range of surgeries, enabling a broad range of patients to benefit from the prolonged action of this important product."

"Obtaining a positive opinion from the CHMP for ZYNRELEF is a major regulatory milestone and confirms the superiority of ZYNRELEF over bupivacaine solution, the current standard of care," said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron. "We believe that the CHMP's positive opinion of ZYNRELEF is an important step forward to help improve the lives of patients across the EU by significantly reducing the proportion of patients who experience severe pain after surgery."

About ZYNRELEF (HTX-011) for Postoperative Pain

ZYNRELEF, 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: 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 in the U.S.; whether the European Commission (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; 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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