Heron Therapeutics Announces Publication of Results from EPOCH 1 Follow-On Study of HTX-011 in Patients Undergoing Bunionectomy Surgery

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- 77% of Bunionectomy Patients Receiving HTX-011 Required No Opioids to Manage Their Postoperative Pain Through 72 Hours After Surgery and Continued To Be Opioid-Free Through 28 Days of Recovery -

SAN DIEGO, Jan. 21, 2021 /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 results from an EPOCH 1 follow-on study (NCT03718039) of the investigational agent HTX-011 in bunionectomy, have been published online, by the *Journal of the American Podiatric Medical Association* in an article entitled "Opioid-Free Recovery from Bunionectomy with HTX-011, a Dual-Acting Local Anesthetic Combining Bupivacaine and Meloxicam, as the Foundation of Non-Opioid Multimodal Analgesia." In this study, 77% of patients receiving HTX-011, along with postoperative over-the-counter (OTC) oral acetaminophen and ibuprofen, remained opioid-free through the 72-hour period following surgery and continued to be opioid-free through 28 days of recovery. The mean pain intensity never rose above the mild range through 72 hours postoperatively.

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 (EPOCH 1 in bunionectomy and EPOCH 2 in hernia repair) 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 well tolerated, with a safety profile comparable to placebo and bupivacaine solution.

"A bunionectomy is a very painful surgical procedure that often requires opioids, which can come with adverse side effects, including nausea, vomiting, constipation and slowed breathing in addition to being potentially addictive," said Richard Pollak, M.D., DPM, a podiatric surgery specialist at San Antonio Podiatry Associates and an author of the publication. "Our findings from this study suggest that HTX-011 can serve as the foundation of a non-opioid multimodal analgesic (MMA) regimen, providing profound pain reduction and enabling opioid-free recovery for most bunionectomy patients through the 28-day recovery period."

The *Journal of the American Podiatric Medical Association* article can be found here.

About the EPOCH 1 Follow-On Study

The EPOCH 1 follow-on study was an open-label, multi-cohort study evaluating the efficacy and safety of locally administered HTX-011 60 mg bupivacaine / 1.8 mg meloxicam via needle-free application into the surgical site in combination with a postoperative non-opioid MMA regimen of OTC oral acetaminophen and ibuprofen in 31 patients undergoing unilateral bunionectomy with osteotomy. Key results of the study include the following:

- 77% of bunionectomy patients receiving HTX-011 with a scheduled non-opioid MMA regimen of OTC acetaminophen and ibuprofen required no opioids during recovery through 28 days (opioid-free).
- 71% of bunionectomy patients receiving HTX-011 with a scheduled regimen of over-the-counter acetaminophen and ibuprofen did not experience severe pain.
- The mean total opioid consumption over the 72-hour postoperative period was 1.61 morphine milligram equivalents.

HTX-011 was well tolerated and demonstrated no safety concerns when used with postoperative non-opioid MMAs (OTC acetaminophen and ibuprofen).

About HTX-011 for Postoperative Pain (ZYNRELEF in the European Union and European Economic Area)

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. The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to HTX-011 and the New Drug Application (NDA) received Priority Review designation. A complete response letter (CRL) was received from the FDA regarding the NDA for HTX-011 in June 2020 relating to non-clinical information. No clinical safety or efficacy issues and no chemistry, manufacturing and controls (CMC) issues were identified. Heron resubmitted an NDA to the FDA for HTX-011 in November 2020 and the FDA set a Prescription Drug User Fee Act goal date of May 12, 2021. Heron is working to respond to a list of questions received from Health Canada in July 2020. In September 2020, the European Commission (EC) granted a marketing authorization for ZYNRELEF (also known as HTX-011) for the treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults. The EC's centralized marketing authorization is valid for the 27 countries that are members of the European Union, and the other countries in the European Economic Area, including the United Kingdom.

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 in the U.S., if approved; 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.

Investor Relations and Media Contact:

David Szekeres
Executive Vice President, Chief Operating Officer
dszekeres@herontx.com
858-251-4447

View original content:http://www.prnewswire.com/news-releases/heron-therapeutics-announces-publication-of-results-from-epoch-1-follow-on-study-of-htx-011-in-patients-undergoing-bunionectomy-surgery-301212178.html

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