FDA Grants Priority Review Designation for Heron Therapeutics' NDA for HTX-011, a Non-Opioid for Postoperative Pain Management

December 31, 2018

- FDA Assigned PDUFA Goal Date of April 30, 2019 -
- FDA Not Currently Planning Advisory Committee Meeting for NDA -

SAN DIEGO, Calif.–(PR NEWSWIRE)–December 31, 2018– 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 U.S. Food and Drug Administration (FDA) has accepted the new drug application (NDA) for Heron's investigational agent, HTX-011, and has granted it a Priority Review designation. HTX-011 is a 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. HTX-011 is the first and only dual-action fixed-combination product specifically designed to address both postoperative pain and inflammation in a single administration at the surgical site. The NDA for HTX-011, which was submitted on October 30, 2018, comprises data from five Phase 2 clinical trials and two Phase 3 clinical trials that included over 1,000 patients undergoing five different surgical procedures. The FDA also indicated that it is not currently planning to hold an advisory committee meeting to discuss this application. The FDA set a Prescription Drug User Fee Act goal date of April 30, 2019.

"We are pleased to receive Priority Review designation for the HTX-011 NDA," said Barry D. Quart, Pharm.D., Chief Executive Officer of Heron. "We believe that HTX-011 could have a considerable impact on the lives of patients by significantly reducing the proportion of patients who experience severe pain and receive opioids after surgery, especially at discharge. We look forward to continuing to work closely with the FDA during the review process with the goal of bringing this important product to patients in 2019."

The FDA had previously granted Breakthrough Therapy designation for HTX-011 based on the results of Phase 2 studies and two completed Phase 3 studies, which showed that HTX-011 produced significant reductions in both pain intensity and the need for opioids through 72 hours post-surgery compared to placebo and bupivacaine solution, the standard-of-care. The FDA has now granted Priority Review designation to the NDA for HTX-011. Priority Review designation is for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment or prevention of serious conditions. HTX-011 is the first and only non-opioid, long acting local anesthetic to demonstrate in Phase 3 studies a statistically significant reduction in severe pain and an increase in the number of patients who require no opioids for 72 hours postoperatively versus bupivacaine solution, the standard-of-care. The overall safety profile of HTX-011, administered locally into the surgical site without a needle, was similar to that of the well-established safety profile of bupivacaine solution, without evidence of meloxicam-related toxicities.

"Despite ongoing efforts to prevent opioid abuse, patients continue to receive too many opioids for postsurgical pain," said Jay Redan, M.D., FACS, Chief of Surgery, Florida Hospital-Celebration Health, President-Society of Laparoendoscopic Surgeons Governor, Florida Chapter, American College of Surgeons. "There is a significant need for safe, effective and non-addictive options that can decrease opioid exposure and improve the patient recovery experience, as well as make an impact on the opioid epidemic by

significantly reducing the amount of opioids necessary to take home for pain management."

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 alone 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 2018. The FDA set a Prescription Drug User Fee Act goal date of April 30, 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 cancer or pain.

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 as submitted; the timing of the FDA's review process for HTX-011; whether the FDA will require an advisory committee meeting for HTX-011 in the future; the anticipated commercial launch of 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.

Investor Relations and Media Contact:

David Szekeres
Senior VP, General Counsel, Business Development and Corporate Secretary
Heron Therapeutics, Inc.
dszekeres@herontx.com
858-251-4447

View original content:http://www.prnewswire.com/news-releases/fda-grants-priority-review-designation-for-heron-therapeutics-nda-for-htx-011-a-non-opioid-for-postoperative-pain-management-300771412.html

SOURCE Heron Therapeutics, Inc.