HTX-011 for Postoperative Pain Management Receives Breakthrough Therapy Designation from FDA

June 21, 2018

-Conference Call and Webcast Today at 8:30 a.m. ET-

SAN DIEGO--(BUSINESS WIRE)--Jun. 21, 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 HTX-011 for postoperative pain management has received Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA). HTX-011 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.

Breakthrough Therapy designation is designed to expedite the development and review of drugs that are intended to treat serious conditions and for which preliminary clinical evidence indicates substantial improvement over available therapies on clinically significant endpoint(s). Breakthrough Therapy designation was granted for HTX-011 based on the results of Phase 2 studies and two recently 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.

“We are pleased that HTX-011 has received Breakthrough Therapy designation from the FDA,” said Barry D. Quart, Pharm.D., Chief Executive Officer of Heron Therapeutics. “HTX-011 is the only long-acting local anesthetic to demonstrate significantly reduced postoperative pain and opioid use through 72 hours compared to bupivacaine solution, the standard-of-care local anesthetic for postoperative pain management, in Phase 3 studies. We look forward to working towards the submission of an NDA to the FDA for HTX-011 in the second half of 2018.”

Conference Call and Webcast

Heron Therapeutics will host a conference call and webcast today, June 21, 2018, at 8:30 a.m. ET (5:30 a.m. PT) to discuss the receipt of Breakthrough Therapy designation and the positive HTX-011 Phase 2b study results that were also announced today in a separate press release. The conference call can be accessed by dialing 877-311-5906 for domestic callers and 281-241-6150 for international callers. Please provide the operator with the passcode 9387615 to join the conference call. A slide presentation accompanying today’s press release and conference call may also be found on Heron’s website at www.herontx.com under the Investor Relations section. The conference call will also be available via webcast under the Investor Relations section of Heron's website. An archive of today’s teleconference and webcast will be available on Heron’s website for 60 days following the call.

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. In the second half of 2018, Heron expects to submit a New Drug Application (NDA) to the FDA for HTX-011.

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 that 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 the timing of the HTX-011 NDA filing and review process, and other risks and uncertainties identified in the Company's filings with the 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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