Heron Therapeutics Announces Initiation of Phase 3 Program for HTX-011 in Postoperative Pain Following Successful End-of-Phase 2 Meeting with FDA

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-Phase 3 Program Expected to Enable Broad Indication-

-NDA Filing Planned for 2018-

-Final Phase 2 Results Demonstrate Clear Superiority to Bupivacaine Solution across All Surgical Models Evaluated-

-Conference Call and Webcast Today at 5:00 p.m. ET-

SAN DIEGO--(BUSINESS WIRE)--Aug. 9, 2017-- Heron Therapeutics, Inc. (Nasdaq: HRTX) (the Company or Heron), a commercial-stage biotechnology company focused on developing novel, best-in-class treatments to address some of the most important unmet patient needs, today announced the positive outcome of a recent End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) regarding the Company's investigational agent, HTX-011, to prevent postoperative pain for the first 72 hours after surgery.

General agreement was reached with the FDA on the design and key elements for HTX-011's Phase 3 program that will be required to support a New Drug Application (NDA). The program includes two pivotal Phase 3 efficacy studies in bunionectomy and hernia repair, representing a bony model and a soft tissue model, respectively.

Heron recently initiated patient enrollment in the HTX-011 Phase 3 program and anticipates completing the Phase 3 program in the first half of 2018. Heron expects to file an NDA for HTX-011 in 2018.

The Phase 3 program is designed to achieve a broad indication for the reduction in postoperative pain for 72 hours following surgery. The primary endpoints of the Phase 3 efficacy studies will be the difference in mean area under the curve (AUC) of pain intensity scores through 72 hours compared with placebo. The first key secondary endpoints will be the difference in mean AUC of pain intensity scores through 72 hours compared with bupivacaine. Additional key secondary endpoints measuring reduction in opioid use and proportion of subjects who are opioid-free are included to support an opioid-sparing claim. In addition to the Phase 3 efficacy studies, approximately 200 patients will be enrolled in a Phase 3 safety and pharmacokinetics study to meet the target patient numbers established by the FDA and to provide further evidence of the broad utility of HTX-011 across multiple surgical models. Importantly, the FDA noted that, beyond the agreed-upon Phase 3 studies, no additional clinical work is needed to meet the "Combination Rule" for fixed-dose combination products.

"Inadequate pain management during the first 72 hours following surgery may lead to chronic post-surgical pain and an increased risk of opioid addiction. This places a greater economic burden on the healthcare system, and it potentially results in millions of opioids flooding our communities," said Harold S. Minkowitz, MD, Diplomat American Board of Anesthesiology, Department of Anesthesiology, Memorial Hermann Memorial City Medical Center. "New treatments, such as HTX-011, are addressing how we can prevent, not just react to, the overuse and abuse of opioids in so many of our neighborhoods. HTX-011 provides a highly effective, non-opioid analgesic option before the problem starts. Effectively managing post-surgical pain and prioritizing treatments that can reduce the need for opioid prescriptions are critical steps toward getting ahead of the opioid epidemic."

HTX-011 is the first and only long-acting anesthetic designed to address both postoperative pain and inflammation in a single administration at the surgical site. HTX-011 leverages meloxicam in our proprietary polymer formulation to potentiate the local anesthetic activity of bupivacaine over 72 hours. The unique synergy of bupivacaine and meloxicam in HTX-011 has been shown to reduce pain significantly better than placebo or bupivacaine alone in three diverse surgical models: bunionectomy, hernia repair and abdominoplasty.

Final Phase 2 Results from Bunionectomy, Hernia Repair and Abdominoplasty Studies for HTX-011

As part of our End-of-Phase 2 meeting update, Heron is presenting final Phase 2 results for HTX-011 using the doses, route of administration and statistical methodology that will be used in the Phase 3 studies. These results indicate that HTX-011 has consistently demonstrated superiority over placebo and bupivacaine, the current standard-of-care, in all surgical models evaluated.

- **Bunionectomy:** HTX-011 60 mg reduced pain through 72 hours significantly better than placebo (P=0.0003) and bupivacaine 50 mg (P=0.0166)
  - HTX-011's pain reduction through 72 hours, as compared to placebo, was 24 times greater than a similar dose of bupivacaine
- **Hernia Repair:** HTX-011 300 mg reduced pain through 72 hours significantly better than placebo (P=0.0045) and bupivacaine 75 mg (P=0.0427)
  - HTX-011's pain reduction through 72 hours, as compared to placebo, was more than 4 times greater than bupivacaine

- **Abdominoplasty:** HTX-011 400 mg reduced pain through 72 hours significantly better than placebo (P=0.0041) and bupivacaine 100 mg (P=0.0399)
    - HTX-011's pain reduction through 72 hours, as compared to placebo, was more than 5 times greater than bupivacaine

The final Phase 2 results seen in bunionectomy and hernia repair correspond with the primary and first key secondary endpoints for the Phase 3 efficacy studies agreed to by the FDA.

"We are pleased to announce the positive outcome of the End-of-Phase 2 meeting for HTX-011 and the recent initiation of patient enrollment in our Phase 3 program," said Barry D. Quart, Pharm.D., Chief Executive Officer of Heron Therapeutics. "In bunionectomy and hernia repair, the surgical models planned for Phase 3, we have demonstrated consistent efficacy against both placebo and bupivacaine solution, the standard-of-care used for local administration in more than 11 million surgical procedures per year for postoperative pain control."

Conference Call and Webcast

Heron Therapeutics will host a conference call and webcast today, August 9, 2017, at 5:00 p.m. ET (2:00 p.m. PT). 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 67789688 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 prevention 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. The Phase 2 development program for HTX-011 was designed to target the many patients undergoing a wide range of surgeries who experience significant postoperative pain. Heron has recently initiated the HTX-011 Phase 3 program and expects to file an NDA in 2018.

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: whether the HTX-011 Phase 2 study results are indicative of the results in future studies, the timing of completion and results of the Phase 3 trials for HTX-011, the timing of the NDA filing for HTX-011, the progress in the research and development of HTX-011, 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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