Heron Therapeutics Announces Positive Topline Results From Phase 2 Clinical Trial of HTX-011 in Abdominoplasty

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- HTX-011 produced statistically significant reductions in both pain intensity and need for opioids following abdominoplasty (tummy tuck) through 96 hours post-surgery -

- Results confirm broad utility of HTX-011 with successful use across wide range of surgeries, from small to very large incisions -

- Conference call and webcast at 8:30 a.m. ET on January 5, 2017 -

SAN DIEGO--(BUSINESS WIRE)--Jan. 4, 2017-- Heron Therapeutics, Inc. (NASDAQ: HRTX), a commercial-stage biotechnology company focused on developing novel best-in-class treatment solutions to address some of the biggest unmet patient needs, today announced positive topline results from its Phase 2 study of the investigational agent HTX-011 in subjects undergoing abdominoplasty (Study 203). HTX-011 demonstrated statistically significant reductions in both pain intensity and the use of opioid rescue medications through 96 hours following surgery.

Study 203 is a randomized, placebo-controlled, dose-finding, Phase 2 clinical study evaluating the efficacy and safety of locally administered HTX-011 for post-operative anesthesia following abdominoplasty surgery. The Summed Pain Intensity (SPI) score through 96 hours post-surgery (SPI 0-96) was significantly reduced with HTX-011 and produced a statistically significant 36.6 percent reduction in pain through 96 hours following surgery, as measured by SPI 0-96 (p=0.0104). Pain was consistently reduced through 96 hours with statistically significant reductions observed between 24 to 48 hours (p=0.007), 48 to 72 hours (p=0.038), and 72 to 96 hours (p=0.016) after a single administration of HTX-011.

Additionally, HTX-011 produced significant reductions (p=0.011) in the use of opioid rescue medication through 96 hours following abdominoplasty, as compared to placebo. To date, HTX-011 continues to be generally well-tolerated in Phase 2.

“The most painful period following surgery is the first three to four days. Currently available local anesthetics do not have the duration of action to provide analgesia for these critical first few days. Poorly managed post-operative pain can result in impaired patient function, increased cost of care and potentially lead to chronic pain and long-term opioid use,” commented Harold S. Minkowitz, MD, Diplomat American Board of Anesthesiology, Department of Anesthesiology, Memorial Hermann Memorial City Medical Center. “However, the efficacy of HTX-011 in even one of the largest surgical incisions, like abdominoplasty, demonstrates its potential to provide durable post-operative pain relief in a wide variety of surgical procedures, reducing or eliminating the need for opioids.”

“Today’s abdominoplasty results, combined with previously reported data from our Phase 2 programs in bunionectomy and hernia repair, demonstrate the potential for HTX-011 to provide broad utility and efficacy across multiple surgery types, from the smallest to one of the largest surgical incisions,” said Barry D. Quart, Pharm.D., Chief Executive Officer of Heron Therapeutics. “The robust, long-lasting results seen across multiple surgical settings indicate that HTX-011 has the necessary attributes to be a best-in-class therapeutic for post-operative pain, extending relief following surgery and, in turn, reducing the need for, and risks associated with, opioid intervention.”

HTX-011 is the first long-acting anesthetic that is designed to address both post-operative pain and accompanying inflammation by combining the local anesthetic bupivacaine and the anti-inflammatory meloxicam in a single administration. Targeting both pain and inflammation has allowed HTX-011 to demonstrate an advantage over current standard of care in multiple surgical models in Phase 2 studies.

Conference Call and Webcast

Heron Therapeutics will host a conference call and webcast on Thursday, January 5, 2017 at 8:30 a.m. ET (5:30 a.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 47808780 to join the conference call. A slide presentation accompanying tomorrow’s conference call may also be found on Heron’s website at www.herontx.com under the investor relations section following the conference call. The conference call will also be available via webcast under the investor relations section of Heron's website. An archive of the teleconference and webcast will be available on Heron’s website for 60 days following the call.

About HTX-011 for Post-Operative Pain

HTX-011, which utilizes Heron’s proprietary Biochronomer® drug delivery technology, is an investigational, long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam for the prevention of post-operative pain. By delivering sustained levels of both a potent anesthetic and an anti-inflammatory agent directly to the site of tissue injury, HTX-011 was designed to deliver superior pain relief while potentially reducing the need for systemically administered pain medications such as opioids, which carry the risk of harmful side effects, abuse and addiction. HTX-011 is the subject of a broad-based Phase 2 development program designed to target the many patients undergoing a wide range of surgeries who experience significant post-operative pain. Following a planned End of Phase 2 meeting with the Food and Drug Administration, Heron anticipates initiating Phase 3 studies in 2017 and filing a New Drug Application 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 medicines that address major unmet medical 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 Phase 2 study results are indicative of the results in future studies related to HTX-011, the sufficiency of the Phase 2 data to allow the commencement of Phase 3 registration studies for HTX-011, the potential market opportunity for HTX-011, the timing of initiating Phase 3 studies for HTX-011, the timing of filing a New Drug Application for 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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Source: Heron Therapeutics, Inc.

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