



## **Heron Therapeutics Establishes Synergy of Bupivacaine and Meloxicam with HTX-011 for Prevention of Post-Operative Pain in Phase 2 Clinical Studies**

January 4, 2017

*- Statistically significant synergy demonstrated with unique proprietary combination of bupivacaine and meloxicam in HTX-011 -*

*- 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 data from its Phase 2 study of HTX-011 in patients undergoing bunionectomy (Study 208) that establishes, for the first time, the synergy between the local anesthetic bupivacaine and the anti-inflammatory meloxicam in HTX-011, an extended-release combination product for the prevention of post-operative pain.

HTX-011 is the first long-acting anesthetic developed to address both post-operative pain and accompanying inflammation by combining bupivacaine and meloxicam in a single administration. Utilizing Heron's Biochronomer<sup>®</sup> sustained-release drug delivery technology, HTX-011 has demonstrated a statistically significant benefit over each individual component alone, providing evidence for the synergistic activity of bupivacaine and meloxicam in the HTX-011 formulation. Further data from Study 208 demonstrates that a 60 mg dose of HTX-011 produced a statistically significant reduction in both pain and opioid use compared to a 50 mg dose of bupivacaine solution, further supporting the synergy observed with the two components of HTX-011. In addition to these clinical data, Heron also announced preclinical data from a validated animal model demonstrating that the activity of bupivacaine and meloxicam in HTX-011 cannot be replicated by administering bupivacaine locally along with systemic administration of meloxicam.

"We are very excited to have confirmed the synergy between bupivacaine and meloxicam when co-administered in HTX-011, which was previously demonstrated in animal models," said Barry D. Quart, Pharm.D., Chief Executive Officer of Heron Therapeutics. "The meloxicam component of HTX-011 allows bupivacaine to work throughout the three to four days of drug release, demonstrating unprecedented concordance between bupivacaine drug levels and reduction in pain. With four positive Phase 2 studies in multiple surgical models spanning small to very large incisions, we believe there is a well-defined rationale for advancing HTX-011 into a broad Phase 3 program this year. We expect to conduct an End of Phase 2 meeting with the Food and Drug Administration in the coming months and are planning for the submission of a New Drug Application in 2018."

Study 208 is a randomized, placebo-and active-controlled, double-blind Phase 2 clinical study in patients undergoing bunionectomy. HTX- 011 demonstrated statistically significant superiority in post-operative pain management when compared to treatment with similar doses of bupivacaine solution, bupivacaine alone in the Biochronomer<sup>®</sup> polymer and meloxicam alone in the Biochronomer<sup>®</sup> polymer.

### **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.heronrx.com](http://www.heronrx.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<sup>®</sup> 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.heronrx.com](http://www.heronrx.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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