Heron Therapeutics Reports Positive Top-Line Results from Phase 2 Studies of HTX-011 for Management of Post-Operative Pain

August 1, 2016

-Statistically and clinically significant reductions in pain intensity through 96 hours after bunion surgery and through 48 hours after hernia surgery

-Increase in time to first opioid rescue and decrease in overall opioid use in both studies

-HTX-011 statistically superior to standard-of-care bupivacaine solution on both pain intensity and opioid use

-HTX-011 shown effective when administered by infiltration or by Mayo Block (nerve block)

-Instillation, an easier, less invasive and potentially safer route of administration into the wound, was equally as effective as injection

-Conference call and webcast at 8:30 a.m. ET on August 1

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Aug. 1, 2016-- Heron Therapeutics, Inc. (NASDAQ:HRTX), a biotechnology company focused on improving the lives of patients by developing best-in-class medicines that address major unmet medical needs, announced preliminary, positive, top-line efficacy results from two Phase 2 clinical studies of HTX-011, its lead product candidate for the management of post-operative pain in patients undergoing bunionectomy (Study 208) and inguinal hernia repair (Study 202) and safety data from our ongoing Phase 2 program. HTX-011, which utilizes Heron's proprietary Biochronomer ® drug delivery technology, is the first long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam and is designed to target both post-operative pain and its associated inflammation.

Study 208 – Bunionectomy

Study 208 was a randomized, placebo- and active-controlled, double-blind Phase 2 clinical study in patients undergoing bunionectomy. This study evaluated the efficacy and safety of two formulations of HTX-011 at 200 mg compared to the standard dose of bupivacaine solution and placebo. Bupivacaine solution is the standard-of-care agent for the management of post-operative pain. In addition, HTX-011 was evaluated when administered via Mayo Block (nerve block via closed wound injection) or infiltration (open wound injection).

The primary endpoint was the difference as compared to placebo in pain intensity as measured by the Summed Pain Intensity (SPI) score in the first 24 hours post-surgery (SPI 0-24). Key secondary endpoints included comparison to bupivacaine solution, the time to first use of opioid rescue medication, total opioid consumption and difference in pain intensity compared to placebo or bupivacaine solution when administered as a Mayo Block or infiltration. The major findings for our Phase 3 formulation of HTX-011 are as follows:

- There was a 66% reduction in pain as measured by SPI 0-24 when comparing HTX-011 administered by infiltration to placebo ($p<0.0001$). There was a 64% reduction in pain as measured by SPI 0-24 when comparing HTX-011 administered by infiltration to bupivacaine solution ($p<0.0001$).
- There was a 69% reduction in pain as measured by SPI 0-24 when comparing HTX-011 administered by nerve block to placebo ($p<0.0001$). There was a 71% reduction in pain as measured by SPI 0-24 when comparing HTX-011 administered by nerve block to bupivacaine solution ($p<0.0001$).
- Significant reductions in pain were maintained through 96 hours post-surgery (SPI 0-96) for all groups: HTX-011 by infiltration versus placebo ($p=0.005$), HTX-011 by infiltration versus bupivacaine solution ($p=0.019$), HTX-011 by nerve block versus placebo ($p=0.004$), and HTX-011 by nerve block versus bupivacaine solution ($p=0.007$).
- Mean time to first opioid rescue medication was 716% longer than for placebo ($p<0.0001$) and 167% longer than for bupivacaine solution ($p<0.036$).
- Over the first 24 hours post-surgery, patients receiving HTX-011 consumed 74% less opioids than placebo patients ($p<0.0001$) and 67% less than bupivacaine solution patients. Over the first 96 hours post-surgery, patients receiving HTX-011 consumed 53% less opioids than placebo patients ($p=0.003$) and 50% less than bupivacaine solution patients ($p=0.008$).

Study 202 – Inguinal Hernia Repair

Study 202 was a randomized, placebo-controlled, double-blind Phase 2 clinical study in patients undergoing inguinal hernia repair. The study evaluated the efficacy and safety of two formulations of HTX-011 at two doses (200 mg and 400 mg), compared to placebo.

In addition, two routes of administration into the wound (injection and instillation) were evaluated. Instillation into the incision site is an easier and potentially safer route of administration as it avoids multiple injections around the wound (as many as 10 or more in large operations) that carry the risk of venous puncture.

The primary endpoint was the difference as compared to placebo in pain intensity as measured by SPI 0-24. Key secondary endpoints included the time to first use of opioid rescue medication and total opioid consumption. The major findings for the 400 mg dose of our Phase 3 formulation of HTX-011 as compared to placebo are as follows:

- There was a 29% reduction in pain as measured by SPI 0-24 (p=0.008).
- HTX-011 by instillation (28.4% reduction in SPI 0-24) was equally as effective as HTX-011 by injection (29.2% reduction in SPI 0-24).
- The pain reduction was long-lasting, with a statistically significant, 25% reduction through 48 hours (SPI 0-48; p=0.038).
- Mean time to first opioid rescue medication was 110% longer (13.3 hours versus 27.9 hours).
- Mean total opioid consumption was 36% less through 96 hours post-surgery.
- The number of patients that did not take any opioid rescue medication at all through 96 hours post-surgery was approximately double (21% versus 11%).

HTX-011 has been generally well tolerated in the ongoing Phase 2 program, which has involved more than 250 administrations of HTX-011. The most frequent treatment-related adverse events reported have been nausea and vomiting, which occurred at similar rates in active and control patients.

“With today’s results in hand, we could not be more excited about the potential of HTX-011 to represent a best-in-class therapeutic for post-operative pain,” commented Barry D. Quart, PharmD, Chief Executive Officer of Heron Therapeutics. “HTX-011 is the first extended-release local anesthetic to demonstrate significant benefit over bupivacaine solution, the standard of care for the management of post-operative pain, following bunionectomy, one of the most painful surgeries. As we move toward our broad-based Phase 3 registration program, we remain focused on our goal of delivering a therapeutic tool that can not only greatly reduce pain levels following surgery, but also help address the nationwide burden of opioid abuse and dependence.”

Conference Call and Webcast

Heron Therapeutics will host a conference call and webcast on Monday, August 1, 2016 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 58069081 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. Please connect to Heron's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary. 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 Post-Operative Pain

HTX-011, which utilizes Heron’s proprietary Biochronomer ® drug delivery technology, is a 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 development program designed to target the many patients undergoing a wide range of surgeries who experience significant post-operative pain.

About Heron Therapeutics, Inc.

Heron Therapeutics, Inc. is a 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 involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. These risks and uncertainties include, but are 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, 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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