Heron Therapeutics Announces the Inclusion of ZYNRELEF® as a Qualifying Product Under the Proposed 2025 Non-Opioid Policy for Pain Relief Under the OPPS and the ASC Payment System

July 15, 2024

SAN DIEGO, July 15, 2024 /PRNewswire/ -- Heron Therapeutics, Inc. (Nasdaq: HRTX) ("Heron" or the "Company"), a commercial-stage biotechnology company, today announced that ZYNRELEF® (bupivacaine and meloxicam) is included in the proposed 2025 Non-Opioid Policy for Pain Relief under the Medicare hospital Outpatient Prospective Payment System ("OPPS") and the Medicare Ambulatory Surgical Center ("ASC") payment system (the "Proposed Rule") as a qualifying product effective April 1, 2025. This Proposed Rule for payment within hospital outpatient departments ("HOPDs") and ASCs was issued by the Centers for Medicare & Medicaid Services ("CMS"). Under the Proposed Rule, ZYNRELEF qualified based on its postoperative pain indication and potential to reduce or eliminate the need for opioids.

Currently, ZYNRELEF is reimbursed by CMS through a special payment policy referred to as pass-through payment status. This pass-through payment status will expire on March 31, 2025. The Proposed Rule's April 1, 2025 effective date for ZYNRELEF is expected to allow ZYNRELEF to continue to maintain separate reimbursement in the HOPD and ASC settings without disruption.

Additionally, for calendar year 2025, CMS proposed that payments for qualifying drugs, like ZYNRELEF, will not be reduced by an offset which means Medicare payments will remain at average sales price plus six percent. Given the significant influence of CMS policy on other payer policies, Heron expects that most commercial payers will follow suit.

"We applaud the efforts of CMS to expand access to non-opioid postsurgical pain management options. The inclusion of ZYNRELEF in the Proposed Rule is an important step in ongoing efforts to reduce opioid utilization in the U.S. and ensures patients and providers have access to ZYNRELEF following these often very painful surgical procedures," said Craig Collard, Chief Executive Officer at Heron.

About ZYNRELEF for Postoperative Pain

ZYNRELEF is the first and only dual-acting local anesthetic that delivers a fixed-dose combination of the local anesthetic bupivacaine and a low dose of nonsteroidal anti-inflammatory drug meloxicam. ZYNRELEF is the first and only extended-release local anesthetic to demonstrate in Phase 3 studies significantly reduced pain and significantly increased proportion of patients requiring no opioids through the first 72 hours following surgery compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control. ZYNRELEF was initially approved by the U.S. Food and Drug Administration ("FDA") in May 2021 for use in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy and total knee arthroplasty. In December 2021, the FDA approved an expansion of ZYNRELEF's indication to include foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures. On January 23, 2024, the FDA approved ZYNRELEF for soft tissue and orthopedic surgical procedures including foot and ankle, and other procedures in which direct exposure to articular cartilage is avoided. Safety and efficacy have not been established in highly vascular surgeries, such as intrathoracic, large multilevel spinal, and head and neck procedures.

Important Safety Information for Patients

ZYNRELEF contains an NSAID (non-steroidal anti-inflammatory drug), a type of medicine which:

- **can increase the risk of a heart attack or stroke that can lead to death. This risk increases with higher doses and longer use of an NSAID.**
- **cannot be used during heart bypass surgery.**
- **can increase the risk of gastrointestinal bleeding, ulcers, and tears.**

ZYNRELEF should also not be used:

- if you are allergic to any component of ZYNRELEF, similar local anesthetics, aspirin or other NSAIDs (such as ibuprofen or naproxen), or have had an asthma attack, hives, or other allergic reaction after taking any of these medicines.
- as a paracervical block, during childbirth.

The most common side effects of ZYNRELEF are soft tissue procedures: vomiting and orthopedic procedures: constipation and headache.

The medicines in ZYNRELEF (a local anesthetic and an NSAID) may affect the nervous and cardiovascular system; may cause liver or kidney problems; may reduce the effects of some blood pressure medicines; should be avoided if you have severe heart failure; may cause adverse effects on cartilage; may cause a rare blood disorder, or life-threatening skin or allergic reactions; may harm your unborn baby if received at 20 weeks of pregnancy or later; and may cause low red blood cells (anemia).

Tell your healthcare provider about all your medical conditions and about all the medicines you take including prescription or over-the-counter medicines, vitamins, or herbal supplements to discuss if ZYNRELEF is right for you.

Talk to your healthcare provider for medical advice about side effects. Report side effects to Heron at 1-844-437-6611 or to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

The information provided here is not comprehensive. Please see full Prescribing Information, including Boxed Warning, at www.ZYNRELEF.com.

About Heron Therapeutics, Inc.

Heron Therapeutics, Inc. is a commercial-stage biotechnology company focused on improving the lives of patients by developing and commercializing therapeutic innovations that improve medical care. Our advanced science, patented technologies, and innovative approach to drug discovery and development have allowed us to create and commercialize a portfolio of products that aim to advance the standard-of-care for acute care and oncology patients. 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. Therefore, you should not place undue reliance on forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding the potential market opportunities for ZYNRELEF®, APONVIE®, CINVANTI® and SUSTOL®; revenue, adjusted EBITDA and other financial guidance provided by the Company; the results of the commercial launch of APONVIE; the potential additional market opportunity for the expanded U.S. label for ZYNRELEF or inclusion of ZYNRELEF under the OPPS and the ASC payment system; the timing of the Company's development of the VAN program and receipt of required regulatory approvals, including any potential delays in the anticipated PDUFA goal date; our ability to establish and maintain successful commercial arrangements like our co-promotion agreement with CrossLink; the realization of anticipated benefits from our co-promotion agreement with CrossLink; the outcome of the Company's pending abbreviated new drug application litigation; whether the Company is required to write-off any additional inventory in the future; the expected future balances of Heron's cash, cash equivalents and short-term investments; the expected duration over which Heron's cash, cash equivalents and short-term investments balances will fund its operations and the risk that future equity financings may be needed; and any inability or delay in achieving profitability. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q, and in our other reports filed with the Securities and Exchange Commission, including under the caption "Risk Factors." 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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