



## **Heron Therapeutics Secures Pass-through Payment Status for ZYNRELEF® from Centers for Medicare & Medicaid Services, Expanding Separate Reimbursement into the Hospital Outpatient Setting of Care**

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- ZYNRELEF is the only local anesthetic with separate reimbursement in both the Hospital Outpatient and Ambulatory Surgical Center settings of care

SAN DIEGO, March 25, 2022 /PRNewswire/ -- Heron Therapeutics, Inc. (Nasdaq: HRTX), a commercial-stage biotechnology company focused on improving the lives of patients by developing best-in-class treatments to address some of the most important unmet patient needs, today announced that the Centers for Medicare & Medicaid Services (CMS) has approved transitional pass-through status for ZYNRELEF (bupivacaine and meloxicam) extended-release solution, which will be established for three years beginning on April 1, 2022, for separate reimbursement outside of the surgical bundle payment in the Hospital Outpatient Department (HOPD) setting of care. This CMS approval makes ZYNRELEF the only local anesthetic with separate reimbursement in the hospital outpatient market.

CMS grants pass-through status to certain new and innovative medical devices, drugs, and biological products. Drugs that are administered in the HOPD and Ambulatory Surgical Center (ASC) settings can have pass-through and be reimbursed accordingly by Medicare. By having pass-through status, ZYNRELEF will be separately reimbursed by Medicare at Average Sales Price (ASP) +6% in both the HOPD and ASC settings of care. In the ASC setting, since January 1, 2022, ZYNRELEF, under C-code C9088, has been reimbursed at ASP+6% due to recent changes in Medicare non-opioid pain management drugs and biologicals payment policies. Based on third party claims data, 72% of ZYNRELEF indicated procedures were performed in the outpatient settings in 2021, with 59% in the HOPD market and 13% in the ASC setting of care.

"With almost 60% of our indicated procedures occurring in the HOPD and our primary competitor no longer having reimbursement in this setting, receiving pass-through status from CMS is a hugely important milestone in the successful launch of ZYNRELEF," said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. "Pass-through status will help accelerate access to ZYNRELEF for the millions of patients looking for superior postoperative pain relief through 72 hours by providing outpatient providers with superior reimbursement when administering ZYNRELEF."

ZYNRELEF is approved by the U.S. Food and Drug Administration (FDA) for use in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical 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 constipation, vomiting, 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).

**Please see full Prescribing Information, including Boxed Warning.**

### **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 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. ZYNRELEF is now indicated in the U.S. in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures. Safety and efficacy have not been established in highly vascular surgeries, such as intrathoracic, large multilevel spinal, and head and neck procedures. In September 2020, the European Commission granted a marketing authorization for ZYNRELEF for the treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults. As of January 1, 2021, ZYNRELEF is approved in 31 European countries including the countries of the European Union and European Economic Area and the United Kingdom. In March 2022, Health Canada issued a Notice of Compliance for ZYNRELEF for instillation into the surgical wound for postoperative analgesia after bunionectomy, open inguinal herniorrhaphy, and total knee arthroplasty surgical procedures.

Please see full prescribing information, including Boxed Warning, at [www.ZYNRELEF.com](http://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 best-in-class treatments to address some of the most important unmet patient needs. 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.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, the potential market opportunity for ZYNRELEF in the U.S.; the extent of the impact of the ongoing Coronavirus Disease 2019 pandemic on our business; and other risks and uncertainties identified in the Company's filings with the U.S. 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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