



## **Heron Therapeutics Announces U.S. Commercial Launch and Availability of ZYNRELEF™ for the Management of Postoperative Pain for up to 72 Hours**

July 1, 2021

- ZYNRELEF, the first and only extended-release local anesthetic, is now available in distribution channels -**
- Heron has deployed new acute care sales representatives across the U.S. -**

SAN DIEGO, July 1, 2021 /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 ZYNRELEF (bupivacaine and meloxicam) extended-release solution, is now commercially available at all national wholesalers and the largest specialty distributors in the United States. ZYNRELEF was approved by the U.S. Food and Drug Administration (FDA) on May 12, 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.

"We are pleased that ZYNRELEF is now available for ordering at hospitals and ambulatory surgical centers (ASCs) across the United States, as the first and only extended-release dual-acting local anesthetic," said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron.

"ZYNRELEF is the only local anesthetic for postoperative pain designated by the FDA to be extended-release for up to 72 hours after surgery, which may help patients and healthcare providers reduce overreliance on opioids but also mitigate exposure to their unwanted side effects and the potential for long-term safety risks like opioid misuse, abuse, or addiction."

Heron's new acute care sales team has extensive operating room, postoperative pain, and hospital launch experience. Heron's commercial organization has a proven track record of hospital success through our launch of CINVANTI® in 2018. The team has been meeting with key customers and has executed contracts for ZYNRELEF with the two largest group purchasing organizations, Vizient and Premier Inc.

ZYNRELEF delivers a fixed-dose combination of the local anesthetic bupivacaine and a low dose of the nonsteroidal anti-inflammatory drug (NSAID) meloxicam. The synergy between bupivacaine and meloxicam in ZYNRELEF has resulted in patients experiencing significantly less pain, including severe pain, and significantly more patients requiring no opioids (opioid-free) after surgery as compared to bupivacaine solution, the current standard-of-care.

### **Important Safety Information for Patients**

**ZYNRELEF contains an NSAID (nonsteroidal 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 components of ZYNRELEF, 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; or 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) can 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 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 (DALA) 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 modified-release local anesthetic to be classified by FDA as an "extended-release" product because ZYNRELEF is also 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 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. 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. For more information visit [ZYNRELEF.com](https://www.zynrelef.com)

## **About CINVANTI (Aprepitant) Injectable Emulsion**

CINVANTI, in combination with other antiemetic agents, is indicated in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin as a single-dose regimen, delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single-dose regimen, and nausea and vomiting associated with initial and repeat courses of MEC as a 3-day regimen. CINVANTI is an IV formulation of aprepitant, an NK<sub>1</sub> receptor antagonist (RA). CINVANTI is the first IV formulation to directly deliver aprepitant, the active ingredient in EMEND® capsules. Aprepitant (including its prodrug, fosaprepitant) is the only single-agent NK<sub>1</sub> RA to significantly reduce nausea and vomiting in both the acute phase (0–24 hours after chemotherapy) and the delayed phase (24–120 hours after chemotherapy). The FDA-approved dosing administration included in the U.S. prescribing information for CINVANTI is a 30-minute IV infusion or a 2-minute IV injection.

CINVANTI is under investigation for the treatment of COVID-19 as a daily 2-minute IV injection when added to the current standard of care.

Please see full prescribing information at [www.CINVANTI.com](http://www.CINVANTI.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.herontx.com](http://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, the timing of the commercial launch of ZYNRELEF in Europe; the potential market opportunity for ZYNRELEF in the U.S. and Europe; 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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