Heron Therapeutics Announces U.S. FDA Approval of APONVIE™ (HTX-019) for the Prevention of Postoperative Nausea and Vomiting (PONV)

September 16, 2022

- APONVIE is the first and only intravenous (IV) formulation of a substance P/neurokinin-1 (NK_1) receptor antagonist indicated for PONV -

- Delivered via a single 30-second IV injection, APONVIE has demonstrated rapid achievement of therapeutic drug levels ideally suited for the surgical setting -

SAN DIEGO, Sept. 16, 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 U.S. Food and Drug Administration (FDA) has approved APONVIE (aprepitant) injectable emulsion, for intravenous use for the prevention of postoperative nausea and vomiting (PONV) in adults.

APONVIE is the first and only IV formulation of aprepitant for PONV prevention. Administered via a single 30-second IV injection, APONVIE reaches drug levels associated with ≥97% receptor occupancy in the brain within five minutes and maintains therapeutic plasma concentrations for at least 48 hours. APONVIE is provided in a single-dose vial that delivers the full 32 mg dose approved for PONV. This ready-to-use, easy to administer, innovative IV formulation ensures rapid and consistent exposure in patients undergoing surgery.

An important component of the FDA approval of APONVIE were results from two multicenter, randomized, double-blind clinical studies comparing oral aprepitant to current standard of care, IV ondansetron, for the prevention of PONV in patients during the 48 hours following open abdominal surgery demonstrating that aprepitant was more effective than ondansetron in preventing vomiting. Treatment with aprepitant resulted in approximately 50% fewer patients vomiting in the first 24 and 48 hours compared to ondansetron. In clinical studies, APONVIE was well-tolerated and presented a safety profile comparable to oral aprepitant.

In a 2020 Cochrane meta-analysis, aprepitant was ranked as the most effective drug approved for PONV prophylaxis, being the most effective for the prevention of vomiting in the first 24 hours post-surgery and the drug with the fewest adverse events.

"With the approval of APONVIE our acute care portfolio now addresses the two most common concerns of patients and clinicians after surgery, postoperative pain and postoperative nausea and vomiting. This marks an important milestone for our expanding acute care portfolio and is a testament to our ongoing commitment to developing innovative solutions to help improve the overall patient experience after surgery," said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. "With approximately 36 million procedures in the U.S. each year in patients with high to moderate risk for PONV, the approval of APONVIE provides an easy to use, highly effective option for these patients that fits seamlessly into our acute care franchise."

PONV are common adverse effects of anesthesia and surgery, with an estimated 30 percent of patients receiving general anesthesia and up to 80 percent of high-risk patients experiencing these symptoms, necessitating more effective preventative agents. PONV is a major cause of patient dissatisfaction after surgery, with patients frequently ranking vomiting as the most undesirable outcome of anesthesia. Additionally, PONV presents a significant risk in outpatient surgeries as patients are often discharged within hours after surgery and no longer have access to highly effective antiemetics.

"PONV is commonly experienced after surgery and may result in increased hospital stays, prolonged recovery time, and decreased patient satisfaction" said Ashraf Habib, MBBCh, MSc, MHSc, FRCA, Chief, Division of Women's Anesthesia at Duke University Hospital. "Oral aprepitant has been used to prevent postoperative nausea and vomiting for more than 16 years and it is exciting to see that, with the approval of APONVIE, physicians can now offer patients a more convenient IV injection that delivers the same effective treatment, with a 48-hour duration of effect, in a rapid, consistent and reliable way, ensuring a better experience for patients postoperatively."

Conference Call and Webcast

Heron will host a conference call and webcast on September 19, 2022 at 8:30 a.m. ET. The conference call can be accessed by dialing 646-307-1963 for domestic callers and 800-715-9871 for international callers. Please provide the operator with the passcode 4538096 to join the conference call. The conference call will also be available via webcast under the Investor Relations section of Heron's website at www.herontx.com. An archive of the teleconference and webcast will also be made available on Heron's website for 60 days following the call.

Important Safety Information

APONVIE should not be used:

- if you are allergic to aprepitant or any of the ingredients in APONVIE

- if you are taking pimozide

APONVIE may cause serious side effects. Tell your doctor or nurse right away if you have any of these signs or symptoms of an allergic reaction:

- trouble breathing or swallowing, shortness of breath or wheezing
- swelling of your eyes, face, tongue, or throat
- flushing or redness of your face or skin
- hives, rash, or itching
- dizziness, a rapid or weak heartbeat, or you feel faint

APONVIE may affect how other medicines work. Other medicines may affect how APONVIE works. Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, or herbal supplements. If you take the blood-thinner medicine warfarin, your doctor may do blood tests after you receive APONVIE to check your blood clotting.

Women who use birth control medicines containing hormones to prevent pregnancy (birth control pills, skin patches, implants, and certain IUDs) should also use back-up methods of birth control (such as condoms and spermicides) for 1 month after receiving APONVIE.

Before you receive APONVIE, tell your doctor if you are pregnant or plan to become pregnant. APONVIE contains alcohol and may harm your unborn baby.

Before you receive APONVIE, tell your doctor if you are breast-feeding or plan to breastfeed because it is likely APONVIE passes into your milk, and it is not known if it can harm your baby. You and your doctor should decide if you will receive APONVIE, if breast-feeding.

The most common side effects of APONVIE are constipation, low blood pressure, tiredness, and headache.

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.**

About APONVIE for PONV

APONVIE (aprepitant) injectable emulsion is a substance P/neurokinin-1 (NK_1) receptor antagonist, indicated for the prevention of postoperative nausea and vomiting (PONV) in adults. Delivered via a 30-second intravenous (IV) injection, APONVIE 32 mg was demonstrated to be bioequivalent to oral aprepitant 40 mg with rapid achievement of therapeutic drug levels. APONVIE is the same formulation as Heron's approved CINVANTI® (aprepitant) injectable emulsion formulation for prevention of chemotherapy-induced nausea and vomiting (CINV). APONVIE is supplied in a single-dose vial that delivers the full 32 mg dose for PONV. APONVIE was approved by the U.S. Food and Drug Administration (FDA) in September 2022.

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.

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 APONVIE; the potential market opportunity for APONVIE; the extent of the impact of the ongoing COVID-19 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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