Heron Therapeutics Highlights Progress in Acute Care and Oncology Care Franchises

January 9, 2023

- Preliminary Annual Net Product Sales Across the Company Grew 24% to $106.7 Million in 2022, Compared to Annual Net Product Sales in 2021 -

- Preliminary Fourth-Quarter 2022 Net Product Sales for ZYNRELEF® Increased 40% to Approximately $3.8 Million -

- Preliminary Full-Year 2022 Net Product Sales for Oncology Care Franchise of Approximately $96.6 Million, Versus Guidance of $93 Million to $95 Million -

- Full-Year 2023 Net Product Sales Guidance for Oncology Care Franchise of $99 Million to $103 Million -

SAN DIEGO, Jan. 9, 2023 /PRNewswire/ --Heron Therapeutics, Inc. (Nasdaq: HRTX), a commercial-stage biotechnology company focused on improving the lives of patients by developing and commercializing therapeutic innovations that improve medical care, today highlights progress in its acute care and oncology care franchises.

Recent Corporate Progress

Acute Care Franchise

- **Fourth-Quarter 2022 Net Product Sales:** Preliminary fourth-quarter 2022 net product sales for ZYNRELEF were approximately $3.8 million, a 40% increase compared to $2.7 million for the third quarter of 2022.
- **Full-Year 2022 Net Product Sales:** Preliminary full-year 2022 net product sales for ZYNRELEF were approximately $10.1 million.
- **Fourth-Quarter 2022 Demand Unit Sales:** ZYNRELEF demand unit sales were 20,765 in the fourth quarter, a 38% increase compared to 15,077 units for the third quarter of 2022.
- **Supplemental New Drug Application Submitted for ZYNRELEF:** The supplemental New Drug Application (sNDA) for ZYNRELEF, to support the proposed indication for greatly expanded use of ZYNRELEF in soft tissue and orthopedic surgical procedures, was submitted in December 2022 to the U.S. Food and Drug Administration (FDA). The anticipated action date is 10 months after submission of this sNDA.
- **Approval of Heron's Fourth Drug, APONVIE, in September 2022:** APONVIE is the first and only IV formulation of aprepitant approved for postoperative nausea and vomiting (PONV). This ready-to-use, easy to administer, innovative IV formulation ensures rapid and consistent exposure of aprepitant, a molecule that has been found to be the most effective agent for prevention of vomiting in patients undergoing surgery. APONVIE will be commercialized by the acute care franchise starting this quarter.
- **NOPAIN Act Approval Provides Three Years of CMS Reimbursement Outside the Surgical Bundled Payment Beginning January 2025:** ZYNRELEF currently has pass-through status in the outpatient setting of care through March 31, 2025 and this provision of H.R. 2617 should extend separate reimbursement for ZYNRELEF outside of the packaged surgical payment through December 31, 2027.

Oncology Care Franchise

- **Fourth-Quarter 2022 Net Product Sales:** Preliminary fourth-quarter 2022 net product sales for the oncology care franchise were approximately $25.3 million. This included net product sales of approximately $22.3 million for CINVANTI® (aprepitant) injectable emulsion and approximately $3.0 million for SUSTOL® (granisetron) extended-release injection, compared to $17.3 million and $2.5 million, respectively, for the same periods in 2021.
- **Full-Year 2022 Net Product Sales:** Preliminary full-year 2022 net product sales for the oncology care franchise were approximately $96.6 million versus guidance of $93 million to $95 million. This included net product sales of approximately $86.4 million for CINVANTI and approximately $10.2 million for SUSTOL, compared to $73.5 million and $9.9 million,

respectively, for the same periods in 2021.

- **Full-Year 2023 Net Product Sales Guidance:** Heron expects full-year 2023 net product sales for the oncology care franchise of $99 million to $103 million.

Corporate Update

- **Annual Net Product Sales:** Annual net product sales across the Company grew by approximately 24% in 2022 compared to annual net product sales in 2021, based on preliminary fourth-quarter 2022 results.

"We have made important advances in 2022 in both our acute care and oncology care franchises, highlighted by the submission to the FDA of the sNDA for ZYNRELEF to significantly expand ZYNRELEF's indication for use in soft tissue and orthopedic procedures, 40% growth in net product sales of ZYNRELEF in the fourth quarter compared to third quarter, approval of APONVIE in the U.S., and a 16% increase in 2022 CINV net product sales, compared to annual net product sales in 2021. Importantly, we strengthened our balance sheet with a $75 million private placement to advance our commercial franchises and extend our runway against a challenging external backdrop," said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. "2023 should be a transformational year for Heron with significant growth of ZYNRELEF, the launch of APONVIE in the U.S. in the first quarter for a target population of over 36 million patients, and continued growth of our oncology care franchise."

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. In December 2022, we submitted a sNDA to support the proposed indication for greatly expanded use of ZYNRELEF in soft tissue and orthopedic surgical procedures. ZYNRELEF is 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.

Please see full prescribing information, including Boxed Warning, at www.ZYNRELEF.com.

About APONVIE for PONV

APONVIE (aprepitant) injectable emulsion is a substance NK_1 RA, indicated for the prevention of postoperative nausea and vomiting 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. APONVIE is supplied in a single-dose vial that delivers the full 32 mg dose for PONV. APONVIE was approved by the FDA in September 2022.

Please see full prescribing information at www.APONVIE.com.

About CINVANTI for Chemotherapy Induced Nausea and Vomiting (CINV) Prevention

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_1 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_1 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 include 100 mg or 130 mg administered as a 30-minute IV infusion or a 2-minute IV injection.

Please see full prescribing information at www.CINVANTI.com.

About SUSTOL for CINV Prevention

SUSTOL is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens. SUSTOL is an extended-release, injectable 5-hydroxytryptamine type 3 RA that utilizes Heron's Biochronomer® drug delivery technology to maintain therapeutic levels of granisetron for ≥5 days. The SUSTOL global Phase 3 development program was comprised of two, large, guideline-based clinical studies that evaluated SUSTOL's efficacy and safety in more than 2,000 patients with cancer. SUSTOL's efficacy in preventing nausea and vomiting was evaluated in both the acute phase (0–24 hours after chemotherapy) and delayed phase (24–120 hours after chemotherapy).

Please see full prescribing information at www.SUSTOL.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, including, but not limited to, those associated with: adjustments to the preliminary fourth-quarter 2022 and full-year 2022 net product sales for the acute care and oncology care franchises in connection with completion of financial closing procedures and an audit for the 2022 fiscal year; risks associated with the full-year 2023 net product sales guidance for the oncology care franchise; the timing of the FDA's review process and whether the FDA approves the sNDA for ZYNRELEF to expand the U.S. label; the potential additional market opportunity for the expanded U.S. label for ZYNRELEF; the timing of the commercial launch of APONVIE in the U.S.; the impact of the NOPAIN Act on reimbursement for ZYNRELEF outside of the packaged surgical payment; 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 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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