



## Heron Therapeutics Highlights Progress in CINV and Pain Management Franchises

January 8, 2018

- SUSTOL<sup>®</sup> Fourth-Quarter 2017 Net Sales of Approximately \$10 Million, Up 16% from Third-Quarter 2017 Net Sales of \$8.6 Million; Full-Year 2017 Net Sales of Approximately \$31 Million, versus Guidance of \$25 Million to \$30 Million -

- 2018 Net Sales Guidance for CINV Franchise of \$60 Million to \$70 Million –

- Enrollment Complete in Both Pivotal Phase 3 Studies for HTX-011; Top-line Results Expected in First Half of 2018 -

SAN DIEGO--(BUSINESS WIRE)--Jan. 8, 2018-- Heron Therapeutics, Inc. (Nasdaq: HRTX), a commercial-stage biotechnology company focused on developing novel, best-in-class treatments to address some of the most important unmet patient needs, today highlighted progress in the Company's pain management and CINV franchises.

### **CINV Franchise**

- **SUSTOL<sup>®</sup> Sales.** SUSTOL (granisetron) extended-release injection fourth-quarter 2017 net product sales were approximately \$10 million, up 16% from third-quarter 2017 net product sales of \$8.6 million. SUSTOL full-year 2017 net product sales were approximately \$31 million, versus guidance of \$25 million to \$30 million.
- **2018 CINV Sales Guidance.** Net product sales guidance for full-year 2018 for the CINV franchise is \$60 million to \$70 million.
- **Permanent J-Code Now Effective.** On January 1, 2018, a product-specific billing code, or permanent J-code, for SUSTOL became available. The new J-code was assigned by the Centers for Medicare and Medicaid Services (CMS) and will help simplify the billing and reimbursement process for prescribers of SUSTOL.
- **CINVANTI<sup>™</sup> Now Available.** In November 2017, the U.S. Food and Drug Administration (FDA) approved the Company's New Drug Application (NDA) for CINVANTI (aprepitant) injectable emulsion, the first and only polysorbate 80-free intravenous (IV) formulation of a neurokinin-1 (NK<sub>1</sub>) receptor antagonist indicated for the prevention of acute and delayed CINV. CINVANTI became commercially available in the United States on January 4, 2018.

### **Pain Management Franchise**

**Enrollment Complete in Phase 3 Pivotal Trials for HTX-011 in Postoperative Pain.** Heron completed enrollment in its two pivotal Phase 3 efficacy studies in bunionectomy and hernia repair. Heron anticipates reporting top-line results in the first half of 2018 and expects to file an NDA with the FDA in the second half of 2018.

"Heron had a strong year in 2017, led by the advancement of the HTX-011 program toward an NDA filing, the success of our commercial team with SUSTOL and the expansion of our CINV franchise with the approval of CINVANTI," said Barry D. Quart, Pharm.D., Chief Executive Officer of Heron. "We expect to build on our momentum in 2018 by reporting top-line pivotal Phase 3 results for HTX-011, filing an NDA for HTX-011 and growing our CINV franchise, which now includes two innovative products."

### **About HTX-011 for Postoperative Pain**

HTX-011, which utilizes Heron's proprietary Biochronomer<sup>®</sup> drug delivery technology, is an investigational, long-acting, extended-release formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam for the prevention of postoperative pain. By delivering sustained levels of both a potent anesthetic and a local anti-inflammatory agent directly to the site of tissue injury, HTX-011 was designed to deliver superior pain relief while reducing the need for systemically administered pain medications such as opioids, which carry the risk of harmful side effects, abuse and addiction. The Phase 2 development program for HTX-011 was designed to target the many patients undergoing a wide range of surgeries who experience significant postoperative pain. Heron completed enrollment in its two pivotal Phase 3 efficacy studies in bunionectomy and hernia repair and anticipates reporting top-line results in the first half of 2018 and expects to file an NDA with the FDA in the second half of 2018.

### **About CINVANTI (aprepitant) injectable emulsion**

CINVANTI is indicated in adults, in combination with other antiemetic agents, 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 and nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). CINVANTI is an intravenous formulation of aprepitant, a substance P/neurokinin-1 (NK<sub>1</sub>) receptor antagonist. CINVANTI is the first intravenous (IV) formulation to directly deliver aprepitant, the active

ingredient in EMEND<sup>®</sup> capsules. Aprepitant (including its prodrug, fosaprepitant) is the only single-agent NK<sub>1</sub> receptor antagonist to significantly reduce CINV in both the acute phase (0 – 24 hours after chemotherapy) and the delayed phase (24 – 120 hours after chemotherapy). CINVANTI does not contain polysorbate 80 or any other synthetic surfactant. Pharmaceutical formulations containing polysorbate 80 have been linked to hypersensitivity reactions, including anaphylaxis and irritation of blood vessels resulting in infusion-site pain. FDA-approved dosing administration included in the United States prescribing information for CINVANTI is a 30-minute infusion.

Please see Full Prescribing Information at [www.CINVANTI.com](http://www.CINVANTI.com).

#### **About SUSTOL (granisetron) extended-release injection**

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-HT<sub>3</sub> receptor antagonist that utilizes Heron's Biochronomer<sup>®</sup> polymer-based 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](http://www.SUSTOL.com).

#### **About Chemotherapy-Induced Nausea and Vomiting (CINV)**

While chemotherapy is one of the most effective and commonly used therapies to help patients fight cancer, it is accompanied by debilitating side effects, including varying degrees of nausea and vomiting, often attributed as a leading cause of premature discontinuation of cancer treatment. The goal of antiemetic therapy is to prevent CINV in both the acute phase (0 – 24 hours after chemotherapy) and delayed phase (24 – 120 hours after chemotherapy). The National Comprehensive Cancer Network (NCCN) and the American Society of Clinical Oncology (ASCO) have categorized chemotherapy regimens based on the degree to which they cause nausea and vomiting: low emetogenic chemotherapy (LEC); moderately emetogenic chemotherapy (MEC); and highly emetogenic chemotherapy (HEC).

#### **About Heron Therapeutics, Inc.**

Heron is a commercial-stage biotechnology company focused on improving the lives of patients by developing best-in-class treatments that address some of the most important unmet patient needs. Heron is developing novel, patient-focused solutions that apply its innovative science and technologies to already-approved pharmacological agents for patients suffering from cancer or pain. 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, those associated with: the potential market opportunities for SUSTOL and CINVANTI; the timing of completion and results of the Phase 3 studies for HTX-011; the timing of the NDA filing for HTX-011; and other risks and uncertainties identified in the Company's filings with the 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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