Heron Therapeutics Announces Financial Results for the Three Months Ended March 31, 2019 and Highlights Recent Corporate Progress

May 9, 2019

SAN DIEGO, May 9, 2019 /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 financial results for the three months ended March 31, 2019 and highlighted recent corporate progress.

Recent Corporate Progress

Pain Management Franchise

- **Complete Response Letter Received from the FDA Regarding the NDA for HTX-011:** A Complete Response Letter (CRL) was received from the U.S. Food and Drug Administration (FDA) on April 30, 2019 regarding the Company's New Drug Application (NDA) for HTX-011 for postoperative pain management. The CRL stated that the FDA is unable to approve the NDA in its present form based on the need for additional Chemistry, Manufacturing and Controls (CMC) and non-clinical information. Based on the complete review of the NDA, the FDA did not identify any clinical safety or efficacy issues, and there is no requirement for further clinical studies or data analyses.

- **European Medicines Agency Validation of Marketing Authorisation Application for HTX-011 for Postoperative Pain Management:** In April of 2019, Heron announced that the Marketing Authorisation Application (MAA) for its investigational agent, HTX-011, for postoperative pain management, was validated by the European Medicines Agency (EMA). The EMA granted eligibility to the Centralised Procedure for HTX-011 based on it meeting the criteria of a medicinal product constituting a significant scientific innovation. The Centralised Procedure allows applicants to receive a marketing authorisation that is valid throughout the European Union (EU). With the validation of the MAA, an opinion from the EMA Committee for Medicinal Products for Human Use (CHMP) is anticipated in the first half of 2020.

- **77% of Patients Treated with HTX-011 Remain Opioid-Free 72 Hours Post-Surgery in Multi-center Clinical Study in Bunionectomy:** In March of 2019, we reported positive topline results of a multi-center postoperative pain management study in which 31 patients undergoing bunionectomy surgery received HTX-011 together with a regimen of generic, over-the-counter, oral analgesics (acetaminophen and ibuprofen). Seventy-seven percent (77%) of patients were opioid-free 72 hours post-surgery, and 100% of these patients remained opioid-free 28 days post-surgery. Patients mean pain scores stayed in the mild range through 72 hours.

- **90% of Patients Treated with HTX-011 Remain Opioid-Free 72 Hours Post-Surgery in Multi-center Clinical Study in Hernia Repair:** In January of 2019, we reported positive topline results of a multi-center postoperative pain management study in which 63 patients undergoing hernia repair surgery received HTX-011 together with a regimen of generic, over-the-counter, oral analgesics (acetaminophen and ibuprofen). Ninety percent (90%) of patients were opioid-free 72 hours post-surgery, and 81% were still opioid-free 28 days post-surgery.

CINV Franchise

- **FDA Approval of sNDA to Expand CINVANTI® Label for IV Push:** In February of 2019, the FDA approved Heron's supplemental New Drug Application (sNDA) for CINVANTI (aprepitant) injectable emulsion, for intravenous (IV) use. The sNDA requested FDA approval to expand the administration of CINVANTI beyond the already approved administration method (a 30-minute IV infusion) to include a 2-minute IV injection.

- **First Quarter 2019 Net Product Sales:** First-quarter 2019 net product sales for the chemotherapy-induced nausea and vomiting (CINV) franchise were $31.6 million, up 173% and 10% from the first and fourth quarters of 2018, respectively. This included net product sales of $28.0 million for CINVANTI® injectable emulsion and $3.6 million for SUSTOL® (granisetron) extended-release injection. Heron reaffirms full-year 2019 net product sales guidance for the CINV franchise of $115 million to $120 million.

"We are focused on resubmitting the NDA for HTX-011 as soon as possible to bring this important medicine to market to help patients manage their postoperative pain without the need for opioids," said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron. "Our CINV franchise remains strong, highlighted by our strong net product sales in the first quarter and our label expansion for CINVANTI for IV push."

Financial Results

Net product sales for the three months ended March 31, 2019 were $31.6 million compared to $11.6 million for the same period in 2018.

Heron's net loss for the three months ended March 31, 2019 was $63.0 million, or $0.80 per share, compared to $52.3 million, or $0.81 per share for the same period in 2018. Net loss for the three months ended March 31, 2019 included non-cash, stock-based compensation expense of $17.9 million compared to $7.7 million for the same period in 2018.

As of March 31, 2019, Heron had cash, cash equivalents and short-term investments of $289.2 million, compared to $332.4 million as of December 31, 2018. Net cash used for operating activities for the three months ended March 31, 2019 was $49.0 million compared to $61.7 million for the same period in 2018. Heron expects to end the year with more than $190 million in cash, cash equivalents and short-term investments.

About HTX-011 for Postoperative Pain

HTX-011, which utilizes Heron's proprietary Biochronomer® 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 management 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. HTX-011 has been shown to reduce pain significantly better than placebo or bupivacaine solution in five diverse surgical models: hernia repair, abdominoplasty, bunionectomy, total knee arthroplasty and breast augmentation. HTX-011 was granted Fast Track designation from the FDA in the fourth quarter of 2017 and Breakthrough Therapy designation in the second quarter of 2018. Heron submitted an NDA to the FDA for HTX-011 in October of 2018 and received Priority Review designation in December of 2018. A CRL was received from the FDA regarding the NDA for HTX-011 on April 30, 2019 relating to CMC and non-clinical information. No issues related to clinical efficacy or safety were noted. An MAA for HTX-011 was validated by the EMA in March 2019 for review under the Centralised Procedure.

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, and nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). CINVANTI is an IV formulation of aprepitant, a substance P/neurokinin-1 (NK_1) 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_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). CINVANTI is the only IV formulation of an NK_1 RA indicated for the prevention of acute and delayed nausea and vomiting associated with HEC and nausea and vomiting associated with MEC that is free of polysorbate 80 or any other synthetic surfactant. The FDA-approved dosing administration included in the United States prescribing information for CINVANTI is a 30-minute infusion or a 2-minute injection.

Please see full prescribing information at 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_3 receptor antagonist 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 best-in-class treatments to 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 pain or cancer.

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: the full-year 2019 net product sales guidance for the CINV franchise; whether the FDA approves the NDA for HTX-011; the timing of the commercial launch of HTX-011; the timing of the CHMP's review process for HTX-011; whether the European Commission authorizes the MAA for HTX-011; 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.

HERON THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2019	**2018**
	(unaudited)	
Revenues:		
Net product sales	$ 31,602	$ 11,567
Operating expenses:		
Cost of product sales	14,962	3,133
Research and development	42,972	39,561
General and administrative	9,648	7,028
Sales and marketing	28,720	13,835
Total operating expenses	96,302	63,557
Loss from operations	(64,700)	(51,990)
Other income (expense), net	1,688	(275)
Net loss	$ (63,012)	$ (52,265)
Basic and diluted net loss per share	$ (0.80)	$ (0.81)
Shares used in computing basic and diluted net loss per share	78,419	64,724

HERON THERAPEUTICS, INC.
Condensed Consolidated Balance Sheet Data
(in thousands)

	March 31, 2019	**December 31, 2018**
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 289,238	$ 332,371
Accounts receivable, net	74,007	64,652
Total assets	435,794	462,179
Total stockholders' equity	331,814	370,160

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