Heron Therapeutics Announces Financial Results for the Three and Nine Months Ended September 30, 2019 and Highlights Recent Corporate Updates

November 12, 2019

- Heron Raises Full-Year 2019 CINV Franchise Net Product Sales Guidance from $115-120 Million to $135 Million -

SAN DIEGO, Nov. 12, 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 and nine months ended September 30, 2019 and highlighted recent corporate updates.

Recent Corporate Updates

Pain Management Franchise

- **FDA Acceptance of New Drug Application Resubmission for HTX-011:** In October 2019, the U.S. Food and Drug Administration (FDA) accepted Heron's New Drug Application (NDA) resubmission for HTX-011, an investigational agent for the management of postoperative pain. The FDA set a Prescription Drug User Fee Act (PDUFA) goal date of March 26, 2020.
- **Positive Topline Results from Phase 3b Clinical Study of HTX-011 in Total Knee Arthroplasty:** In October 2019, Heron reported positive topline results of a multi-center postoperative pain management study in which 51 patients undergoing total knee arthroplasty (TKA) surgery received HTX-011 together with a scheduled postoperative regimen of generic oral analgesics (acetaminophen and celecoxib). In this study, 75% of patients were discharged from the hospital without a prescription for opioids.

CINV Franchise

- **CINV 2019 Net Product Sales:** For the three months ended September 30, 2019, chemotherapy-induced nausea and vomiting (CINV) franchise net product sales were $42.6 million, up 115% from the same period in 2018, and up 16% from the three months ended June 30, 2019. For the nine months ended September 30, 2019, CINV franchise net product sales were $110.9 million, up 128% from the same period in 2018. Heron is raising its full-year 2019 CINV franchise net product sales guidance from $115–120 million to $135 million.
    - **CINVANTI Net Product Sales:** Net product sales of CINVANTI (aprepitant) injectable emulsion for the three and nine months ended September 30, 2019 were $36.4 million and $97.6 million, respectively, compared to $16.4 million and $32.8 million, respectively, for the same periods in 2018.
    - **SUSTOL® Net Product Sales:** Net product sales of SUSTOL (granisetron) extended-release injection for the three and nine months ended September 30, 2019 were $6.2 million and $13.3 million, respectively, compared to $3.4 million and $15.8 million for the same periods in 2018.
- **FDA Approval of Supplemental NDA for CINVANTI:** In October 2019, the FDA approved Heron's supplemental New Drug Application (sNDA) for CINVANTI (aprepitant) injectable emulsion for intravenous (IV) use. The sNDA approval resulted in a CINVANTI label expansion that standardizes the CINVANTI 130 mg single-dose regimen for patients receiving HEC and/or MEC as an injection over 2 minutes or an infusion over 30 minutes, further simplifying dosing and administration and eliminating the need to take oral aprepitant on Days 2 and 3 in patients receiving MEC.

"We are pleased with the advances made during the third quarter of 2019 in both our pain management and CINV franchises, highlighted by the FDA acceptance of our recent NDA resubmission for HTX-011 and strong net product sales for our CINV franchise, even amid the launch of generic fosaprepitant," said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron Therapeutics. "We look forward to continuing our commercial momentum with the launch of HTX-011 for postoperative pain management in the second quarter of 2020, pending FDA approval."

Financial Results

Net product sales for the three and nine months ended September 30, 2019 were $42.6 million and $110.9 million, respectively, compared to $19.8 million and $48.6 million, respectively, for the same periods in 2018.

Heron's net loss for the three and nine months ended September 30, 2019 was $33.6 million and $146.8 million, or $0.42 per share and $1.85 per share, respectively, compared to $38.3 million and $129.3 million, or $0.49 per share and $1.81 per share, respectively, for the same periods in 2018. Net loss for the three and nine months ended September 30, 2019 included non-cash, stock-based compensation expense of $9.7 million and $40.3

million, respectively, compared to $8.1 million and $23.6 million, respectively, for the same periods in 2018.

As of September 30, 2019, Heron had cash, cash equivalents and short-term investments of $256.3 million. Adjusting for net proceeds of $162.2 million from our October 2019 public offering of common stock, Heron had pro-forma cash, cash equivalents and short-term investments of $418.5 million. This compares to $332.4 million in cash, cash equivalents and short-term investments as of December 31, 2018. Net cash used for operating activities for the nine months ended September 30, 2019 was $97.6 million, compared to $158.3 million for the same period in 2018.

About HTX-011 for Postoperative Pain

HTX-011, an investigational agent, is a dual-acting, fixed-dose combination of the local anesthetic bupivacaine with a low dose of the nonsteroidal anti-inflammatory drug meloxicam. It is the first and only extended-release local anesthetic to demonstrate in Phase 3 studies significantly reduced pain and opioid use through 72 hours compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control. HTX-011 was granted Fast Track designation from the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2017 and Breakthrough Therapy designation in the second quarter of 2018. Heron submitted a New Drug Application (NDA) to the FDA for HTX-011 in October of 2018 and received Priority Review designation in December of 2018. A Complete Response Letter (CRL) was received from the FDA regarding the NDA for HTX-011 on April 30, 2019 relating to chemistry, manufacturing and controls and non-clinical information. No issues related to clinical efficacy or safety were noted. Heron resubmitted an NDA to the FDA for HTX-011 in September 2019, and the FDA set a PDUFA goal date of March 26, 2020. A Marketing Authorisation Application (MAA) for HTX-011 was validated by the European Medicines Agency (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 HEC, including high-dose cisplatin, and nausea and vomiting associated with initial and repeat courses of MEC. CINVANTI is an IV formulation of aprepitant, an NK1 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 NK1 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 United States prescribing information for CINVANTI is a 30-minute IV infusion or a 2-minute IV 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)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Net product sales	$ 42,624	$ 19,786	$ 110,885	$ 48,630

Operating expenses:				
Cost of product sales	17,195	7,576	45,745	15,940
Research and development	34,708	30,421	119,105	100,141
General and administrative	8,597	7,288	28,023	20,525
Sales and marketing	16,977	16,281	69,344	44,647
Total operating expenses	77,477	61,566	262,217	181,253
Loss from operations	(34,853)	(41,780)	(151,332)	(132,623)
Other income, net	1,258	3,434	4,503	3,342
Net loss	$ (33,595)	$ (38,346)	$ (146,829)	$ (129,281)
Basic and diluted net loss per share	$ (0.42)	$ (0.49)	$ (1.85)	$ (1.81)
Shares used in computing basic and diluted net loss per share	79,940	77,811	79,308	71,544

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

	September 30, 2019	December 31, 2018
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 256,278	$ 332,371
Accounts receivable, net	66,955	64,652
Total assets	392,962	462,179
Total stockholders' equity	285,442	370,160

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View original content:http://www.prnewswire.com/news-releases/heron-therapeutics-announces-financial-results-for-the-three-and-nine-months-ended-september-30-2019-and-highlights-recent-corporate-updates-300955867.html

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