Heron Therapeutics Announces Financial Results for the Three and Nine Months Ended September 30, 2018 and Recent Corporate Progress

November 7, 2018

- Heron Raises Full-Year 2018 CINV Franchise Net Product Sales Guidance to $70 Million to $72 Million -

SAN DIEGO, Nov. 7, 2018 /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 reported financial results for the three and nine months ended September 30, 2018 and highlighted recent corporate progress.

Recent Corporate Progress

Pain Management Franchise

- **Submitted NDA for HTX-011.** On October 31, 2018, the Company announced the submission of its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for HTX-011. HTX-011 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.

CINV Franchise

- **CINV Sales.** Chemotherapy-induced nausea and vomiting (CINV) franchise net product sales for the three and nine months ended September 30, 2018 were $19.8 million and $48.6 million, respectively, compared to $8.6 million and $20.7 million for the same periods in 2017, respectively. Heron has increased full-year 2018 CINV franchise net product sales guidance to $70 million to $72 million.
    - **CINVANTI® Sales.** Net product sales of CINVANTI (aprepitant) injectable emulsion for the three months ended September 30, 2018 were $16.4 million. This compares to $11.2 million for the three months ended June 30, 2018 and $5.2 million for the three months ended March 31, 2018. CINVANTI was approved by the FDA on November 9, 2017 and became commercially available in the U.S. on January 4, 2018. Net product sales for CINVANTI were $32.8 million for the nine months ended September 30, 2018.
    - **SUSTOL® Sales.** Net product sales of SUSTOL (granisetron) extended-release injection for the three and nine months ended September 30, 2018 were $3.4 million and $15.8 million, respectively. The entry of generic palonosetron in the first quarter of 2018 has had, and is expected to have, a several-quarter negative impact on provider demand for SUSTOL.

- **Permanent J-Code Assigned for CINVANTI.** On November 5, 2018, a product-specific billing code, or permanent J-code, for CINVANTI was assigned with an effective date of January 1, 2019. 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 CINVANTI.

"We are pleased with the advances made during the third quarter of 2018 in both our pain management and CINV franchises, highlighted by our recent NDA submission for HTX-011 and the increase in our full-year 2018 CINV franchise net product sales guidance," said Barry D. Quart, Pharm.D., Chief Executive Officer of Heron Therapeutics. "We look forward to preparing to launch HTX-011 in the U.S. for postoperative pain management, if approved, in 2019 and achieving our increased full-year 2018 CINV franchise net product sales guidance of $70 million to $72 million."

Financial Results

Net product sales for the three and nine months ended September 30, 2018 were $19.8 million and $48.6 million, respectively, compared to $8.6 million and $20.7 million for the same periods in 2017, respectively.

Heron's net loss for the three and nine months ended September 30, 2018 was $38.3 million and $129.3 million, or $0.49 per share and $1.81 per share, respectively, compared to $41.9 million and $135.0 million, or $0.77 per share and $2.55 per share, for the same periods in 2017, respectively. Net loss for the three and nine months ended September 30, 2018 included non-cash, stock-based compensation expense of $8.1 million and $23.6 million, respectively, compared to $7.5 million and $23.6 million, for the same periods in 2017, respectively.

As of September 30, 2018, Heron had cash, cash equivalents and short-term investments of $364.8 million, compared to $172.4 million as of December 31, 2017. Net cash used for operating activities for the three and nine months ended September 30, 2018 was $35.9 million and $158.3

million, respectively, compared to $40.5 million and $123.2 million for the same periods in 2017, respectively.

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 alone 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 recently submitted an NDA to the FDA for HTX-011.

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 intravenous formulation of aprepitant, a substance P/neurokinin-1 (NK_1) receptor antagonist. CINVANTI is the first intravenous (IV) formulation to directly deliver aprepitant, the active ingredient in EMEND® capsules. Aprepitant (including its prodrug, fosaprepitant) is the only single-agent NK_1 receptor antagonist 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 receptor antagonist 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. 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.

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 cancer or pain.

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 2018 net product sales guidance for the CINV franchise; acceptance of the HTX-011 NDA as submitted; whether the FDA approves the HTX-011 NDA as submitted; the anticipated commercial launch of HTX-011; 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
(unaudited)
(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Net product sales	$ 19,786	$ 8,572	$ 48,630	$ 20,714
Operating expenses:				
Cost of product sales	7,576	1,051	15,940	3,250
Research and development	30,421	28,844	100,141	90,825
General and administrative	7,288	6,462	20,525	19,389
Sales and marketing	16,281	13,529	44,647	39,918

Total operating expenses	61,566	49,886	181,253	153,382
Loss from operations	(41,780)	(41,314)	(132,623)	(132,668)
Other income (expense), net	3,434	(552)	3,342	(2,326)
Net loss	$ (38,346)	$ (41,866)	$ (129,281)	$ (134,994)
Basic and diluted net loss per share	$ (0.49)	$ (0.77)	$ (1.81)	$ (2.55)
Shares used in computing basic and diluted net loss per share	77,811	54,176	71,544	52,846

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

	September 30, 2018	December 31, 2017
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 364,800	$ 172,379
Accounts receivable, net	53,633	41,874
Total assets	470,896	234,307
Promissory note payable	-	25,000
Total stockholders' equity	406,808	131,136

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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-30-2018-and-recent-corporate-progress-300745746.html

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