Heron Therapeutics Announces Financial Results for the Three and Twelve Months Ended December 31, 2018 and Recent Corporate Progress

February 22, 2019

SAN DIEGO, Feb. 22, 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 reported financial results for the three and twelve months ended December 31, 2018 and highlighted recent corporate progress.

Recent Corporate Progress

Pain Management Franchise

- **Acceptance of HTX-011 NDA for Postoperative Pain Management with Priority Review Designation; PDUFA Date of April 30, 2019:** The U.S. Food and Drug Administration (FDA) recently accepted the new drug application (NDA) for Heron's investigational agent, HTX-011, and has granted it a Priority Review designation. The FDA set a Prescription Drug User Fee Act (PDUFA) goal date of April 30, 2019 and indicated that it is not currently planning an advisory committee meeting to discuss this application.

- **90% of Patients Treated with HTX-011 Opioid-Free 72 Hours Post-Surgery in New Multi-center Clinical Study:** In this study, 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.

- **Formal Development Initiated on HTX-034, Our Next-Generation Product Candidate for Postoperative Pain Management:** Based on the positive results of preclinical studies in which HTX-034 demonstrated significant pain reduction for 7 days, Heron has initiated formal development of this next-generation postoperative pain management product candidate.

CINV Franchise

- **2018 Net Sales:** Fourth-quarter 2018 net sales for the chemotherapy-induced nausea and vomiting (CINV) franchise were $28.8 million, up 187% year-over-year and up 46% from the third quarter of 2018. This included net sales of $23.4 million for CINVANTI® (aprepitant) injectable emulsion and $5.4 million for SUSTOL® (granisetron) extended-release injection. Full-year 2018 net sales for the CINV franchise were $77.5 million, up 152% year-over-year. This included net sales of $56.2 million for CINVANTI and $21.3 million for SUSTOL.

- **2019 Net Sales Guidance:** Heron expects 2019 net sales for the CINV franchise of $115 million to $120 million.

"2018 was a year of significant growth for our CINV franchise, and we look forward to continued strong performance this year," said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron. "In pain management, Heron remains committed to making a significant impact on the opioid epidemic through the development and commercialization of innovative non-opioid pain management products. With a PDUFA goal date of April 30, 2019, we look forward to launching HTX-011 in the U.S. later this year, if approved."

Financial Results

Net product sales for the three and twelve months ended December 31, 2018 were $28.8 million and $77.5 million, respectively, compared to $10.1 million and $30.8 million for the same periods in 2017, respectively.

Heron's net loss for the three and twelve months ended December 31, 2018 was $49.6 million and $178.8 million, or $0.63 per share and $2.44 per share, respectively, compared to $62.5 million and $197.5 million, or $1.09 per share and $3.65 per share, for the same periods in 2017, respectively. Net loss for the three and twelve months ended December 31, 2018 included non-cash, stock-based compensation expense of $9.8 million and $33.4 million, respectively, compared to $6.9 million and $30.5 million, for the same periods in 2017, respectively.

As of December 31, 2018, Heron had cash, cash equivalents and short-term investments of $332.4 million, compared to $172.4 million as of December 31, 2017. Net cash used for operating activities for the three and twelve months ended December 31, 2018 was $33.5 million and $191.8 million, respectively, compared to $47.1 million and $170.3 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 postoperative pain management. 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. The FDA set a PDUFA goal date of April 30, 2019.

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 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 sales guidance for the CINV franchise; whether the FDA approves the HTX-011 NDA as submitted; the timing of the FDA's review process for HTX-011; whether the FDA will require an advisory committee meeting for HTX-011 in the future; the anticipated commercial launch of HTX-011; the timing and results of the studies in the HTX-034 development program; 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 December 31,		Twelve Months Ended December 31,	
	2018	**2017**	**2018**	**2017**
	(unaudited)			
Revenues:				
Net product sales	$ 28,844	$ 10,053	$ 77,474	$ 30,767
Operating expenses:				
Cost of product sales	11,572	1,338	27,512	4,588
Research and development	39,891	47,757	140,032	138,582
General and administrative	8,738	6,165	29,263	25,554

Sales and marketing	19,957	16,683	64,604	56,601
Total operating expenses	80,158	71,943	261,411	225,325
Loss from operations	(51,314)	(61,890)	(183,937)	(194,558)
Other income (expense), net	1,755	(600)	5,097	(2,926)
Net loss	$ (49,559)	$ (62,490)	$ (178,840)	$ (197,484)
Basic and diluted net loss per share	$ (0.63)	$ (1.09)	$ (2.44)	$ (3.65)
Shares used in computing basic and diluted net loss per share	78,086	57,585	73,193	54,040

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

	December 31, 2018	December 31, 2017
Cash, cash equivalents and short-term investments	$ 332,371	$ 172,379
Accounts receivable, net	64,652	41,874
Total assets	462,179	234,307
Promissory note payable	-	25,000
Total stockholders' equity	370,160	131,136

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View original content:http://www.prnewswire.com/news-releases/heron-therapeutics-announces-financial-results-for-the-three-and-twelve-months-ended-december-31-2018-and-recent-corporate-progress-300799946.html

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