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

August 5, 2019

SAN DIEGO, Aug. 5, 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 six months ended June 30, 2019 and highlighted recent corporate updates.

Recent Corporate Updates

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.
- **95% of Postoperative Patients Remain Opioid-Free when HTX-011 Is Given with an Over-the-Counter Analgesic Regimen in Real-world Study in Hernia Repair Surgery:** In May 2019, we announced the results of a multi-center postoperative pain management study in 93 patients that provides real-world evidence of opioid-free recovery in patients undergoing outpatient inguinal hernia repair surgery who received the investigational agent, HTX-011, together with a scheduled background regimen of generic over-the-counter (OTC) oral analgesics (acetaminophen and ibuprofen). Ninety-one percent (91%) of patients receiving HTX-011 with the OTC analgesic regimen were discharged without an opioid prescription, and none of these patients subsequently requested an opioid for postoperative pain.
- **Results of Phase 3 EPOCH 1 Study Published:** In May 2019, the results from the pivotal Phase 3 EPOCH 1 bunionectomy study of HTX-011 were published by the *Regional Anesthesia & Pain Medicine* journal.

CINV Franchise

- **CINV 2019 Net Product Sales:** For the three months ended June 30, 2019, chemotherapy-induced nausea and vomiting (CINV) franchise net product sales were $36.7 million, up 112% from the same period in 2018, and up 16% from the three months ended March 31, 2019. For the six months ended June 30, 2019, CINV franchise net product sales were $68.3 million, up 137% from the same period in 2018. Heron reaffirms full-year 2019 CINV franchise net product sales guidance of $115 million to $120 million.
    - **CINVANTI® Net Product Sales:** Net product sales of CINVANTI (aprepitant) injectable emulsion for the three and six months ended June 30, 2019 were $33.2 million and $61.2 million, respectively, compared to $11.2 million and $16.4 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 six months ended June 30, 2019 were $3.5 million and $7.1 million, respectively, compared to $6.1 million and $12.4 million for the same periods in 2018.

"We expect to meet with the FDA shortly to discuss our responses to the CRL for HTX-011, and we remain focused on resubmitting the NDA as soon as possible," said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron. "Our CINV franchise continues to perform well, highlighted by strong net product sales in the second quarter."

Financial Results

Net product sales for the three and six months ended June 30, 2019 were $36.7 million and $68.3 million, respectively, compared to $17.3 million and $28.8 million, respectively, for the same periods in 2018.

Heron's net loss for the three and six months ended June 30, 2019 was $50.2 million and $113.2 million, or $0.63 per share and $1.43 per share, respectively, compared to $38.7 million and $90.9 million, or $0.54 per share and $1.33 per share, respectively, for the same periods in 2018. Net loss for the three and six months ended June 30, 2019 included non-cash, stock-based compensation expense of $12.7 million and $30.6 million, respectively, compared to $7.8 million and $15.5 million, respectively, for the same periods in 2018.

As of June 30, 2019, Heron had cash, cash equivalents and short-term investments of $276.0 million, compared to $332.4 million as of December 31, 2018. Net cash used for operating activities for the six months ended June 30, 2019 was $72.1 million compared to $122.4 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 for HTX-011 to the FDA 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 June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Net product sales	$ 36,659	$ 17,277	$ 68,261	$ 28,844
Operating expenses:				

Cost of product sales	13,588	5,231	28,550	8,364
Research and development	41,425	30,159	84,397	69,720
General and administrative	9,778	6,209	19,426	13,237
Sales and marketing	23,647	14,531	52,367	28,366
Total operating expenses	88,438	56,130	184,740	119,687
Loss from operations	(51,779)	(38,853)	(116,479)	(90,843)
Other income (expense), net	1,557	183	3,245	(92)
Net loss	$ (50,222)	$ (38,670)	$ (113,234)	$ (90,935)
Basic and diluted net loss per share	$ (0.63)	$ (0.54)	$ (1.43)	$ (1.33)
Shares used in computing basic and diluted net loss per share	79,548	71,952	78,987	68,358

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

	June 30, 2019	December 31, 2018
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 276,005	$ 332,371
Accounts receivable, net	66,821	64,652
Total assets	411,666	462,179
Total stockholders' equity	305,359	370,160

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View original content:http://www.prnewswire.com/news-releases/heron-therapeutics-announces-financial-results-for-the-three-and-six-months-ended-june-30-2019-and-highlights-recent-corporate-updates-300895868.html

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