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

August 8, 2018

SAN DIEGO, Aug. 8, 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 six months ended June 30, 2018 and highlighted recent corporate progress.

Recent Corporate Progress

Pain Management Franchise

- **Positive Topline Results from Phase 2b Clinical Studies of HTX-011 in Total Knee Arthroplasty and Breast Augmentation**. HTX-011 achieved all primary endpoints in two completed Phase 2b studies: Study 209 (local administration in total knee arthroplasty) and Study 211 (instillation or pectoral pocket nerve block in breast augmentation). In both of these studies:
  - HTX-011 demonstrated statistically significant reductions in both pain intensity and opioid use;
  - HTX-011 demonstrated a strong correlation between pain reduction and pharmacokinetics; and
  - HTX-011 was well tolerated.
- **Breakthrough Therapy Designation Granted for HTX-011.** The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for HTX-011 for local administration into the surgical site. Breakthrough Therapy designation is designed to expedite the development and review of drugs that are intended to treat serious conditions and for which preliminary clinical evidence indicates substantial improvement over available therapies on clinically significant endpoint(s). Breakthrough Therapy designation was granted for HTX-011 based on the results of completed Phase 2 studies and two recently completed Phase 3 studies, which showed that HTX-011 produced significant reductions in both pain intensity and the need for opioids through 72 hours post-surgery compared to placebo and bupivacaine solution, the standard of care.

In the second half of 2018, Heron expects to submit a New Drug Application (NDA) to the FDA for HTX-011.

CINV Franchise

- **CINV Sales.** Chemotherapy-induced nausea and vomiting (CINV) franchise net product sales for the three and six months ended June 30, 2018 were $17.3 million and $28.8 million, respectively. Heron reaffirms full-year 2018 CINV franchise net product sales guidance of $60 million to $70 million, and Heron believes net product sales will be in the upper end of this range.
  - **SUSTOL® Sales.** Net product sales of SUSTOL (granisetron) extended-release injection for the three and six months ended June 30, 2018 were $6.1 million and $12.4 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.
  - **CINVANTI® Sales.** Net product sales of CINVANTI (aprepitant) injectable emulsion for the three and six months ended June 30, 2018 were $11.2 million and $16.4 million, respectively. CINVANTI was approved by the FDA on November 9, 2017 and became commercially available in the U.S. on January 4, 2018.

"We are pleased with the progress we have made in the first half of 2018. In our pain management franchise, the results of completed Phase 2 and Phase 3 studies and the Breakthrough Therapy designation by the FDA of HTX-011 further confirm our belief in the superiority of HTX-011 over the standard of care in reducing pain intensity and opioid use across multiple diverse surgical models. In our CINV franchise, providers are continuing to realize the value of CINVANTI over other injectable NK_1 receptor antagonists, and the number of oncology clinics ordering CINVANTI has increased," said Barry D. Quart, Pharm.D., Chief Executive Officer of Heron Therapeutics. "We look forward to submitting an NDA for HTX-011 to the FDA in the second half of this year and achieving full-year CINV net product sales in the upper end of our $60 million to $70 million guidance."

Financial Results

Net product sales for the three and six months ended June 30, 2018 were $17.3 million and $28.8 million, respectively, compared to $8.5 million and $12.1 million for the same periods in 2017, respectively.

Heron's net loss for the three and six months ended June 30, 2018 was $38.7 million and $90.9 million, or $0.54 per share and $1.33 per share, respectively, compared to $42.8 million and $93.1 million, or $0.80 per share and $1.79 per share, for the same periods in 2017, respectively. Net loss for the three and six months ended June 30, 2018, included non-cash, stock-based compensation expense of $7.8 million and $15.5 million, respectively, compared to $8.2 million and $16.2 million, for the same periods in 2017, respectively.

As of June 30, 2018, Heron had cash, cash equivalents and short-term investments of $423.0 million, compared to $172.4 million as of December 31, 2017. Net cash used for operating activities for the six months ended June 30, 2018 was $122.4 million, compared to $82.6 million for the same period in 2017.

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 FDA in the fourth quarter of 2017 and Breakthrough Therapy designation in the second quarter of 2018. In the second half of 2018, Heron expects to submit a New Drug Application (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 2018 net product sales guidance for the CINV franchise; the timing of the HTX-011 NDA filing and review process; 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 June 30,	Six Months Ended June 30,

	2018	2017	2018	2017
Revenues:				
Net product sales	$ 17,277	$ 8,510	$ 28,844	$ 12,142
Operating expenses:				
Cost of product sales	5,231	1,013	8,364	2,199
Research and development	30,159	28,597	69,720	61,981
General and administrative	6,209	6,185	13,237	12,927
Sales and marketing	14,531	14,770	28,366	26,389
Total operating expenses	56,130	50,565	119,687	103,496
Loss from operations	(38,853)	(42,055)	(90,843)	(91,354)
Other income (expense), net	183	(744)	(92)	(1,774)
Net loss	$ (38,670)	$ (42,799)	$ (90,935)	$ (93,128)
Basic and diluted net loss per share	$ (0.54)	$ (0.80)	$ (1.33)	$ (1.79)
Shares used in computing basic and diluted net loss per share	71,952	53,791	68,358	52,170

HERON THERAPEUTICS, INC.

Condensed Consolidated Balance Sheet Data

(in thousands)

	June 30, 2018	December 31, 2017
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 422,964	$ 172,379
Accounts receivable, net	45,886	41,874
Total assets	510,556	234,307
Promissory note payable	25,000	25,000
Total stockholders' equity	431,891	131,136

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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-30-2018-and-recent-corporate-progress-300693720.html

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