Heron Therapeutics Announces Financial Results for the Three Months Ended March 31, 2021 and Highlights Recent Corporate Updates

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- Labelling Discussions with the FDA are Underway for HTX-011; Prescription Drug User Fee Act (PDUFA) Goal Date is May 12, 2021 -

SAN DIEGO, May 10, 2021 /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 months ended March 31, 2021 and highlighted recent corporate updates.

Recent Corporate Updates

Acute Care Franchise

- **New Drug Application Resubmission for HTX-011 Under Review:** The New Drug Application (NDA) resubmission for HTX-011, an investigational agent for the management of postoperative pain, submitted November 12, 2020 to the U.S. Food and Drug Administration (FDA), continues under review. The FDA set a PDUFA goal date of May 12, 2021.
- **Initiation of Expanded Phase 2 Clinical Study of HTX-034 for the Treatment of Postoperative Pain:** In March 2021, Heron initiated the expanded Phase 2 clinical study in patients undergoing bunionectomy with HTX-034, Heron's next-generation product for the treatment of postoperative pain.
- **NDA for HTX-019 Planned in Late 2021 for Prevention of PONV in Adults:** In the Phase 1 bioequivalence study, HTX-019 32 mg as a 30-second intravenous (IV) injection was bioequivalent to oral aprepitant 40 mg, which is approved for the prevention of postoperative nausea and vomiting (PONV). A 505(b)(2) NDA for HTX-019 for PONV in adults is planned for late 2021.

Oncology Care Franchise

- **2021 Net Product Sales:** For the three months ended March 31, 2021, oncology care franchise net product sales were $20.0 million, compared to $25.4 million for the same period in 2020. The Coronavirus Disease 2019 (COVID-19) pandemic reduced cancer screening procedures and new patient treatment starts in 2020 resulting in fewer clinic anti-emetic administrations during the first quarter of 2021 compared to the prior year and last quarter. Heron is assisting Community Oncology Alliance with its campaign to get patients back into screening. With the greater availability of COVID-19 vaccines and the declining rates of infection, Heron believes that the number of patients receiving cancer treatment will begin to return to normal levels.
    - **CINVANTI® Net Product Sales:** Net product sales of CINVANTI (aprepitant) injectable emulsion for the three months ended March 31, 2021 were $18.5 million, compared to $25.2 million for the same period in 2020. Based on recently signed agreements with key customers, Heron believes the most significant impact of the generic arbitrage is over and expects to grow CINVANTI market share in 2021 and beyond.
    - **SUSTOL® Net Product Sales:** Net product sales of SUSTOL (granisetron) extended-release injection for the three months ended March 31, 2021 were $1.5 million, compared to $0.2 million for the same period in 2020. In the first quarter of 2021, Heron reinstated promotion and contracting of SUSTOL to restore growth in 2021 and beyond.
- **Full-Year 2021 Net Product Sales Guidance:** Heron expects full-year 2021 net product sales for the oncology care franchise of $130 million to $145 million.

"We have no outstanding questions on the pending NDA and are currently in labelling discussions with the FDA, as we prepare for the anticipated commercial launch of HTX-011 in the U.S.," said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. "For the oncology care franchise, we expect the market to pick up in the second quarter and we recently signed a large, multi-year contract for CINVANTI that will help increase net product sales throughout 2021."

Financial Results

Net product sales for the three months ended March 31, 2021 were $20.0 million, compared to $25.4 million for the same period in 2020.

Heron's net loss for the three months ended March 31, 2021 was $52.6 million, or $0.58 per share, compared to $51.6 million, or $0.57 per share for

the same period in 2020. Net loss for the three months ended March 31, 2021 included non-cash, stock-based compensation expense of $11.5 million, compared to $12.0 million for the same period in 2020.

As of March 31, 2021, Heron had cash, cash equivalents and short-term investments of $166.5 million, compared to $208.5 million as of December 31, 2020. Net cash used for operating activities for the three months ended March 31, 2021 was $41.9 million, compared to $32.9 million for the same period in 2020. Heron expects that its current cash, cash equivalents and short-term investments will be sufficient to fund its operations into 2022.

About HTX-011 for Postoperative Pain (ZYNRELEF™ in Europe)

HTX-011, an investigational non-opioid analgesic, 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. The FDA granted Breakthrough Therapy designation to HTX-011 and the NDA received Priority Review designation. A complete response letter was received from the FDA regarding the NDA for HTX-011 in June 2020 relating to non-clinical information. No clinical safety or efficacy issues and no chemistry, manufacturing and controls issues were identified. Heron resubmitted an NDA to the FDA for HTX-011 in November 2020 and the FDA set a PDUFA goal date of May 12, 2021. In September 2020, the European Commission granted a marketing authorization for ZYNRELEF (also known as HTX-011) for the treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults. As of January 1, 2021, ZYNRELEF is approved in 31 European countries including the countries of the European Union and European Economic Area and the United Kingdom.

About HTX-034 for Postoperative Pain

HTX-034, an investigational non-opioid analgesic, is a triple-acting, fixed-dose combination of the local anesthetic bupivacaine with a low dose of the nonsteroidal anti-inflammatory drug meloxicam and aprepitant, an additional agent that further potentiates the activity of bupivacaine. HTX-034 is formulated in the same proprietary polymer as HTX-011. By combining two different mechanisms that each enhance the activity of the local anesthetic bupivacaine, HTX-034 is designed to provide superior and prolonged analgesia. Local administration of HTX-034 in a validated preclinical postoperative pain model resulted in sustained analgesia for 7 days.

About HTX-019 for PONV

HTX-019 is an IV injectable emulsion formulation designed to directly deliver aprepitant, the active ingredient in EMEND® (aprepitant) capsules, which is the only substance P/neurokinin-1 (NK_1) receptor antagonist (RA) to be approved in the U.S. for the prevention of PONV in adults.

The FDA-approved dose of oral EMEND is 40 mg for PONV, which is given within 3 hours prior to induction of anesthesia for surgery. In a Phase 1 clinical trial, 32 mg of HTX-019 as a 30-second IV injection was demonstrated to be bioequivalent to oral aprepitant 40 mg.

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 as a single-dose regimen, delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single-dose regimen, and nausea and vomiting associated with initial and repeat courses of MEC as a 3-day regimen. CINVANTI is an IV formulation of aprepitant, an NK_1 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). The FDA-approved dosing administration included in the U.S. prescribing information for CINVANTI is a 30-minute IV infusion or a 2-minute IV injection.

CINVANTI is under investigation for the treatment of COVID-19 as a daily 2-minute IV injection when added to the current standard of care.

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-hydroxytryptamine type 3 RA 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. Our advanced science, patented technologies, and innovative approach to drug discovery and development have allowed us to create and commercialize a portfolio of products that aim to advance the standard of care for acute care and oncology patients. 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: whether the FDA approves the NDA for HTX-011; whether the scope of the label for HTX-011, if approved, will be as desired; the timing of the commercial launch of HTX-011 in the U.S., if approved; the timing and results of studies for the HTX-034 and HTX-019 development programs; the full-year 2021 net

product sales guidance for the oncology care franchise; 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; the extent of the impact of the ongoing COVID-19 pandemic on our business; 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.
Consolidated Statements of Operations
(In thousands, except per share amounts)

	Three Months Ended March 31,	
	2021	2020
	(Unaudited)	
Revenues:		
Net product sales	$ 20,018	$ 25,400
Operating expenses:		
Cost of product sales	9,207	10,622
Research and development	38,116	36,894
General and administrative	9,573	10,422
Sales and marketing	15,236	20,196
Total operating expenses	72,132	78,134
Loss from operations	(52,114)	(52,734)
Other income (expense)	(500)	1,155
Net loss	$ (52,614)	$ (51,579)
Basic and diluted net loss per share	$ (0.58)	$ (0.57)
Shares used in computing basic and diluted net loss per share	91,388	90,409

Heron Therapeutics, Inc.
Consolidated Balance Sheets
(in thousands)

	March 31, 2021	December 31, 2020
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 59,739	$ 105,138
Short-term investments	106,727	103,353
Accounts receivable, net	38,525	41,850
Inventory	42,629	41,905
Prepaid expenses and other current assets	24,668	21,950
Total current assets	272,288	314,196
Property and equipment, net	22,704	22,737
Right-of-use lease assets	15,594	16,277
Other assets	346	346
Total assets	$ 310,932	$ 353,556
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,689	$ 525
Accrued clinical and manufacturing liabilities	54,219	49,962
Accrued payroll and employee liabilities	9,629	13,597
Other accrued liabilities	24,744	28,369
Current lease liabilities	3,081	2,997
Convertible notes payable to related parties	7,555	7,053
Total current liabilities	100,917	102,503
Non-current lease liabilities	13,790	14,561
Total liabilities	114,707	117,064
Stockholders' equity:		
Common stock	914	913
Additional paid-in capital	1,640,552	1,628,070
Accumulated other comprehensive income	121	257
Accumulated deficit	(1,445,362)	(1,392,748)
Total stockholders' equity	196,225	236,492
Total liabilities and stockholders' equity	$ 310,932	$ 353,556

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