Heron Therapeutics Announces Financial Results for the Three and Twelve Months Ended December 31, 2020 and Highlights Recent Corporate Updates

February 24, 2021

SAN DIEGO, Feb. 24, 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 and twelve months ended December 31, 2020 and highlighted recent corporate updates.

Recent Corporate Updates

Pain Management 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 Prescription Drug User Fee Act (PDUFA) goal date of May 12, 2021.
- **European Commission Authorization for ZYNRELEF™ for the Treatment of Postoperative Pain:** In September 2020, the European Commission (EC) granted a marketing authorization for ZYNRELEF (formerly known as HTX-011) for the treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults. As Heron builds large-scale manufacturing capacity to meet the anticipated commercial demand in the U.S. and the rest of the world, we are developing a coordinated global marketing strategy. At this time, Heron anticipates making ZYNRELEF available to patients in Europe during 2022.
- **Low-Dose HTX-034 Produced Greater Pain Reduction Compared to Bupivacaine, the Current Standard-of-Care, Through 96 Hours in Bunionectomy Study:** In the Phase 1b portion of this Phase 1b/2 double-blind, randomized, active-controlled, dose-escalation study in 33 patients undergoing bunionectomy, the reduction in pain intensity observed was greater with the lowest dose of HTX-034 evaluated (containing 21.7 mg of bupivacaine plus meloxicam and aprepitant) than with the bupivacaine 50 mg solution through 96 hours.
    - In addition, 45.5% of HTX-034 patients remained opioid-free through Day 15 with median opioid consumption of 2.5 mg morphine equivalents (same as one 5 mg oxycodone pill) through 72 hours, a 71% reduction compared to bupivacaine solution.
    - Heron expects to initiate the expanded Phase 2 portion of the study for HTX-034 in the first quarter of 2021.

CINV Franchise

- **CINV 2020 Net Product Sales:** For the three and twelve months ended December 31, 2020, chemotherapy-induced nausea and vomiting (CINV) franchise net product sales were $20.6 million and $88.6 million, respectively, compared to $35.1 million and $146.0 million for the same periods in 2019.
    - **CINVANTI® Net Product Sales:** Net product sales of CINVANTI (aprepitant) injectable emulsion for the three and twelve months ended December 31, 2020 were $20.3 million and $87.8 million, respectively, compared to $34.6 million and $132.2 million, respectively, for the same periods in 2019. 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 and twelve months ended December 31, 2020 were $0.3 million and $0.8 million, respectively, compared to $0.5 million and $13.8 million for the same periods in 2019. On October 1, 2019, we discontinued all discounting of SUSTOL to improve the reimbursement and net selling price of the product, which resulted in significantly lower SUSTOL net product sales in 2020. Heron expects SUSTOL to return to growth in 2021 and beyond.
- **Full-Year 2021 Net Product Sales Guidance:** Heron expects full-year 2021 net product sales for the CINV franchise of $130 million to $145 million.

HTX-019 for PONV

- **HTX-019 Achieved Bioequivalence to Approved Oral Aprepitant 40 mg Dose for Prevention of PONV:** A new

Investigational New Drug application for HTX-019 (aprepitant injectable emulsion) for postoperative nausea and vomiting (PONV) was approved by the FDA in late September of 2020. In the Phase 1 bioequivalence study, 32 mg of HTX-019 as a 30-second intravenous (IV) injection was bioequivalent to oral aprepitant 40 mg, which is approved for the prevention of PONV. An NDA for HTX-019 is planned in late 2021 for prevention of PONV in adults.

Corporate Update

- **Year-End 2020 Cash Balance:** Heron ended 2020 with $208.5 million in cash, cash equivalents and short-term investments.

"We are very pleased that we exceeded our CINV sales guidance for the year, despite 2020 being a challenging year for Heron, with our CINV franchise impacted by both the COVID-19 global pandemic and the EMEND® IV generic arbitrage. We also achieved several important milestones in 2020, including the authorization of ZYNRELEF in Europe and the advancement of HTX-034 for postoperative pain and HTX-019 for PONV into clinical development," said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. "We believe that 2021 will be a transformational year for Heron, with significant growth expected in our CINV products with net product sales guidance of $130 million to $145 million, the anticipated FDA approval and commercial launch of HTX-011 in the U.S., and the submission of an NDA for HTX-019 for PONV in the fourth quarter."

Financial Results

Net product sales for the three and twelve months ended December 31, 2020 were $20.6 million and $88.6 million, respectively, compared to $35.1 million and $146.0 million, respectively, for the same periods in 2019.

Heron's net loss for the three and twelve months ended December 31, 2020 was $62.3 million and $227.3 million, or $0.68 per share and $2.50 per share, respectively, compared to $57.9 million and $204.7 million, or $0.65 per share and $2.50 per share, respectively, for the same periods in 2019. Net loss for the three and twelve months ended December 31, 2020 included non-cash, stock-based compensation expense of $16.0 million and $50.2 million, respectively, compared to $11.1 million and $51.4 million, respectively, for the same periods in 2019.

As of December 31, 2020, Heron had cash, cash equivalents and short-term investments of $208.5 million compared to $391.0 million as of December 31, 2019. Net cash used for operating activities for the twelve months ended December 31, 2020 was $184.8 million, compared to $124.6 million for the same period in 2019. 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. Heron is working to respond to a list of questions received from Health Canada in July 2020.
In September 2020, the EC 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. The EC's centralized marketing authorization is valid for the 27 countries that are members of the European Union, the other countries in the 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 Postoperative Nausea and Vomiting

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-HT_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. 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: whether the FDA approves the NDA for HTX-011; the timing of the commercial launch of HTX-011 in the U.S., if approved; the timing of the commercial launch of ZYNRELEF in Europe; the timing of Health Canada's New Drug Submission (NDS) review process for HTX-011; whether Health Canada issues a Notice of Compliance for the NDS for HTX-011; 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 CINV 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 Coronavirus Disease 2019 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 December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
	(Unaudited)			
Revenues:				
Net product sales	$ 20,605	$ 35,083	$ 88,638	$ 145,968
Operating expenses:				
Cost of product sales	9,392	15,874	36,189	61,619
Research and development	44,453	48,277	174,533	167,382
General and administrative	12,503	9,874	42,226	37,897
Sales and marketing	15,553	20,420	63,853	89,764
Total operating expenses	81,901	94,445	316,801	356,662
Loss from operations	(61,296)	(59,362)	(228,163)	(210,694)
Other income (expense), net	(985)	1,442	885	5,945
Net loss	$ (62,281)	$ (57,920)	$ (227,278)	$ (204,749)
Basic and diluted net loss per share	$ (0.68)	$ (0.65)	$ (2.50)	$ (2.50)
Shares used in computing basic and diluted net loss per share	91,081	89,112	90,774	81,779

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

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 105,138	$ 71,898
Short-term investments	103,353	319,074
Accounts receivable, net	41,850	39,879
Inventory	41,905	24,968

Prepaid expenses and other current assets	21,950	23,245
Total current assets	314,196	479,064
Property and equipment, net	22,737	19,618
Right-of-use lease assets	16,277	13,754
Other assets	346	346
Total assets	$ 353,556	$ 512,782
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 525	$ 2,758
Accrued clinical and manufacturing liabilities	49,962	34,614
Accrued payroll and employee liabilities	13,597	15,248
Other accrued liabilities	28,369	36,535
Current lease liabilities	2,997	1,926
Convertible notes payable to related parties	7,053	5,624
Total current liabilities	102,503	96,705
Non-current lease liabilities	14,561	12,242
Total liabilities	117,064	108,947
Stockholders' equity:		
Preferred stock	—	—
Common stock	913	903
Additional paid-in capital	1,628,070	1,568,317
Accumulated other comprehensive income	257	85
Accumulated deficit	(1,392,748)	(1,165,470)
Total stockholders' equity	236,492	403,835
Total liabilities and stockholders' equity	$ 353,556	$ 512,782

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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-31-2020-and-highlights-recent-corporate-updates-301234154.html

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