UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 22, 2019

Heron Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-33221**	**94-2875566**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

4242 Campus Point Court, Suite 200, San Diego, CA	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code (858) 251-4400

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	**HRTX**	**The Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On October 22, 2019, Heron Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has approved the Company's supplemental New Drug Application for CINVANTI® (aprepitant) injectable emulsion for intravenous (IV) use, expanding the recommended dosage to include the 130 mg single-dose regimen for patients receiving moderately emetogenic chemotherapy, as described in the press release furnished herewith as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated October 22, 2019
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Heron Therapeutics, Inc.

Date: October 22, 2019

/s/ David Szekeres

David Szekeres
Senior Vice President, General Counsel,
Business Development and Corporate Secretary

Exhibit 99.1

Heron Announces FDA Approval of Supplemental New Drug Application to Expand CINVANTI® Label for Single-Dose Regimen for Patients Receiving Moderately Emetogenic Chemotherapy (MEC)

SAN DIEGO, Calif. -- (PR NEWSWIRE) – October 22, 2019 -- 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 that the U.S. Food and Drug Administration (FDA) has approved Heron's supplemental New Drug Application (sNDA) for CINVANTI (aprepitant) injectable emulsion for intravenous (IV) use. The sNDA requested FDA approval to expand the recommended dosage to include the 130 mg single-dose regimen for patients receiving MEC.

CINVANTI is the first and only IV formulation of a substance P/neurokinin-1 (NK_1) receptor antagonist (RA) that is free of synthetic surfactants, including polysorbate 80, and that is approved for use as a 2-minute IV injection (also referred to as an IV push). CINVANTI is indicated for the prevention of acute and delayed chemotherapy-induced nausea and vomiting (CINV) following both highly emetogenic cancer chemotherapy (HEC) and MEC. 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 CINV in both the acute phase (0–24 hours after chemotherapy) and the delayed phase (24–120 hours after chemotherapy).

CINVANTI was initially approved based on data demonstrating the bioequivalence of CINVANTI to EMEND IV® (fosaprepitant), supporting its efficacy for the prevention of acute and delayed CINV following HEC and MEC. Results from two pivotal, randomized, cross-over, bioequivalence studies of CINVANTI and EMEND IV showed subjects receiving CINVANTI reported fewer adverse events than those receiving EMEND IV, including substantially fewer infusion-site reactions. In February 2019, the FDA approved Heron's sNDA to expand the administration of CINVANTI beyond the already approved administration method (a 30-minute IV infusion) to include a 2-minute IV injection (also referred to as an IV push). This 2-minute IV push for CINVANTI was approved based on a third study demonstrating bioequivalence and a comparable safety profile to CINVANTI given as a 30-minute IV infusion.

The CINVANTI label expansion standardizes the CINVANTI 130 mg single-dose regimen for patients receiving HEC and/or MEC as an injection over 2 minutes or an infusion over 30 minutes, further simplifying dosing and administration and eliminating the need to take oral aprepitant on Days 2 and 3 following MEC administration. Furthermore, this label expansion builds on the prior label expansion that introduced the 2-minute IV push, which enables physicians to leverage the operational advantages of this method of administration and contributes to a reduction in total patient time spent at the infusion site.

"This most recent label expansion to offer a simplified dosing regimen for MEC adds to the important advantages CINVANTI provides to patients as the only FDA-approved, IV NK_1 RA available as a convenient 2-minute IV push for MEC and HEC," said Rudolph M. Navari, M.D., Ph.D., University of Alabama, Birmingham School of Medicine, Division of Hematology and Oncology. "The simplified dosing in MEC removes the need for patients to take oral aprepitant

on Days 2 and 3, which can improve compliance and reduce costs. These benefits continue to improve the overall patient experience with CINVANTI."

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 HEC, including high-dose cisplatin, and nausea and vomiting associated with initial and repeat courses of MEC. CINVANTI is an IV formulation of aprepitant, an NK1 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 NK1 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 United States prescribing information for CINVANTI is a 30-minute IV infusion or a 2-minute IV injection.

Please see full prescribing information at www.CINVANTI.com.

Important Safety Information

Contraindications

CINVANTI is contraindicated in patients with hypersensitivity to any of the components of CINVANTI.

Concurrent use of pimozide with CINVANTI is contraindicated.

Warnings and Precautions

Clinically Significant CYP3A4 Drug Interactions

Aprepitant is a substrate, weak-to-moderate (dose-dependent) inhibitor, and an inducer of CYP3A4.

- Use of CINVANTI with other drugs that are CYP3A4 substrates may result in increased plasma concentration of the concomitant drug.
  - Use of pimozide with CINVANTI is contraindicated due to the risk of significantly increased plasma concentrations of pimozide, potentially resulting in prolongation of the QT interval, a known adverse reaction of pimozide.
- Use of CINVANTI with strong or moderate CYP3A4 inhibitors (*e.g.*, ketoconazole, diltiazem) may increase plasma concentrations of aprepitant and result in an increased risk of adverse reactions related to CINVANTI.
- Use of CINVANTI with strong CYP3A4 inducers (*e.g.*, rifampin) may result in a reduction in aprepitant plasma concentrations and decreased efficacy of CINVANTI.

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, during or soon after administration of CINVANTI have occurred. Symptoms including dyspnea, eye swelling, flushing, pruritus, and wheezing have been reported. If hypersensitivity reactions occur, discontinue CINVANTI. Do not reinitiate CINVANTI in patients who experience these symptoms with previous use.

Decrease in INR with Concomitant Warfarin

Co-administration of CINVANTI with warfarin, a CYP2C9 substrate, may result in a clinically significant decrease in the International Normalized Ratio (INR) of prothrombin time. Monitor the INR in patients on chronic warfarin therapy in the 2-week period, particularly at 7 to 10 days, following initiation of CINVANTI with each chemotherapy cycle.

Risk of Reduced Efficacy of Hormonal Contraceptives

The efficacy of hormonal contraceptives may be reduced during administration of and for 28 days following the last dose of CINVANTI. Advise patients to use effective alternative or back-up methods of non-hormonal contraception during treatment with CINVANTI and for 1 month following administration of CINVANTI or oral aprepitant, whichever is administered last.

Use in Specific Populations

Avoid use of CINVANTI in pregnant women as alcohol is an inactive ingredient for CINVANTI. There is no safe level of alcohol exposure in pregnancy.

Adverse Reactions

The most common adverse reactions are:

- Single-dose fosaprepitant with MEC (≥2%): fatigue, diarrhea, neutropenia, asthenia, anemia, peripheral neuropathy, leukopenia, dyspepsia, urinary tract infection, pain in extremity.
- 3-day oral aprepitant with MEC (≥1% and greater than standard therapy): fatigue and eructation.
- Single-dose fosaprepitant with HEC: generally similar to 3-day oral aprepitant. In addition, infusion site reactions (3%) occurred.
- Single-dose CINVANTI (≥2%): headache and fatigue. The safety profile of CINVANTI in healthy subjects who received a single 2-minute injection was similar to that seen with a 30-minute infusion.

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 commercial opportunity for CINVANTI; 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.

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