

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): September 9, 2022

SPECTRUM PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-35006
(Commission
File Number)

93-0979187
(IRS Employer
Identification No.)

Pilot House - Lewis Wharf, Atlantic Avenue
(Address of principal executive offices)

6th Floor Boston, MA

02110
(Zip Code)

Registrant's telephone number, including area code: (617) 586-3900

Not Applicable

(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:

- 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, \$0.001 par value	SPPI	The NASDAQ Global Select 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 September 9, 2022, Spectrum Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food and Drug Administration has approved ROLVEDON™ (eflapegrastim-xnst) injection to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia.

A copy of the press release is included as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated September 9, 2022.
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURE

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.

SPECTRUM PHARMACEUTICALS, INC.

Date: September 12, 2022

By: /s/ Nora E. Brennan
Nora E. Brennan
Executive Vice President and Chief Financial Officer



Spectrum Pharmaceuticals Receives FDA Approval for ROLVEDON™ (eflapegrastim-xnst) Injection

First novel Long-Acting GCSF (LA-GCSF) product approved in over 20 years

ROLVEDON™ developed using proprietary LAPSCOVERY™ technology with a differentiated molecular structure and proven safety and efficacy profile

Commercial team ready to launch with product available in the fourth quarter

BOSTON – September 9, 2022 - Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, today announced that the U.S. Food and Drug Administration (FDA) has approved ROLVEDON™ (eflapegrastim-xnst) injection to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia.

“ROLVEDON’s approval marks Spectrum’s transformation to a commercial-stage company with the opportunity to compete in a \$2 billion dollar market, and offers a unique value proposition,” said Tom Riga, President and Chief Executive Officer of Spectrum Pharmaceuticals. “This approval is a significant milestone for our development team and collaboration with Hanmi Pharmaceutical. On behalf of Spectrum, I would like to thank all of the patients, families, health care providers, and our own team members for bringing this goal to fruition.”

“Our commercial team is in place and ready to engage key stakeholders immediately,” said Erin Miller, Senior Vice President, Sales & Marketing of Spectrum Pharmaceuticals. “Equipped with extensive long-acting growth factor market experience, customer connectivity and learnings from in-depth market research insights, we are ready to optimize the launch trajectory. We expect to have product available in the fourth quarter of 2022 following the fulfillment of customary, pre-launch regulatory requirements.”

About ROLVEDON™

ROLVEDON™ (eflapegrastim-xnst) injection is a long-acting granulocyte colony-stimulating factor (G-CSF) with a novel formulation. Spectrum has received an indication to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia. ROLVEDON is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. The BLA for ROLVEDON was supported by data from two identically designed Phase 3, randomized, open-label, noninferiority clinical trials, ADVANCE and RECOVER, which evaluated the safety and efficacy of

ROLVEDON in 643 early-stage breast cancer patients for the management of neutropenia due to myelosuppressive chemotherapy. In both studies, ROLVEDON demonstrated the pre-specified hypothesis of non-inferiority (NI) in mean duration of severe neutropenia (DSN) and a similar safety profile to pegfilgrastim. ROLVEDON also demonstrated non-inferiority to pegfilgrastim in the mean DSN across all four cycles (all NI $p < 0.0001$) in both trials.

Please see the Important Safety Information below and the full prescribing information for ROLVEDON at www.rolvedon.com.

Indications and Usage

ROLVEDON is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia.

Limitations of Use

ROLVEDON is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Important Safety Information

Contraindications

- ROLVEDON is contraindicated in patients with a history of serious allergic reactions to eflapegrastim, pegfilgrastim or filgrastim products. Reactions may include anaphylaxis.

Warnings and Precautions

Splenic Rupture

- Splenic rupture, including fatal cases, can occur following the administration of recombinant human granulocyte colony-stimulating factor (rhG-CSF) products. Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.

Acute Respiratory Distress Syndrome (ARDS)

- ARDS can occur in patients receiving rhG-CSF products. Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue ROLVEDON in patients with ARDS.

Serious Allergic Reactions

- Serious allergic reactions, including anaphylaxis, can occur in patients receiving rhG-CSF products. Permanently discontinue ROLVEDON in patients who experience serious allergic reactions.

Sickle Cell Crisis in Patients with Sickle Cell Disorders

- Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving rhG-CSF products. Discontinue ROLVEDON if sickle cell crisis occurs.

Glomerulonephritis

- Glomerulonephritis has occurred in patients receiving rhG-CSF products. The diagnoses were based upon azotemia, hematuria (microscopic and macroscopic), proteinuria, and renal biopsy. Generally, events of glomerulonephritis resolved after dose-reduction or discontinuation. Evaluate and consider dose reduction or interruption of ROLVEDON if causality is likely.

Leukocytosis

- White blood cell (WBC) counts of $100 \times 10^9/L$ or greater have been observed in patients receiving rhG-CSF products. Monitor complete blood count (CBC) during ROLVEDON therapy. Discontinue ROLVEDON treatment if WBC count of $100 \times 10^9/L$ or greater occurs.

Thrombocytopenia

- Thrombocytopenia has been reported in patients receiving rhG-CSF products. Monitor platelet counts.

Capillary Leak Syndrome

- Capillary leak syndrome has been reported after administration of rhG-CSF products and is characterized by hypotension, hypoalbuminemia, edema and hemoconcentration. Episodes vary in frequency and severity and may be life-threatening if treatment is delayed. If symptoms develop, closely monitor and give standard symptomatic treatment, which may include a need for intensive care.

Potential for Tumor Growth Stimulatory Effects on Malignant Cells

- The granulocyte colony-stimulating factor (G-CSF) receptor through which ROLVEDON acts has been found on tumor cell lines. The possibility that ROLVEDON acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which ROLVEDON is not approved, cannot be excluded.

Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML) in Patients with Breast and Lung Cancer

- MDS and AML have been associated with the use of rhG-CSF products in conjunction with chemotherapy and/or radiotherapy in patients with breast and lung cancer. Monitor patients for signs and symptoms of MDS/AML in these settings.

Aortitis

- Aortitis has been reported in patients receiving rhG-CSF products. It may occur as early as the first week after start of therapy. Consider aortitis in patients who develop generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, and increased inflammatory markers (e.g., c-reactive protein and white blood cell count) without known etiology. Discontinue ROLVEDON if aortitis is suspected.

Nuclear Imaging

- Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. This should be considered when interpreting bone imaging results.

Adverse Reactions

- The most common adverse reactions ($\geq 20\%$) were fatigue, nausea, diarrhea, bone pain, headache, pyrexia, anemia, rash, myalgia, arthralgia, and back pain.
- Permanent discontinuation due to an adverse reaction occurred in 4% of patients who received ROLVEDON. The adverse reaction requiring permanent discontinuation in 3 patients who received ROLVEDON was rash.

To report SUSPECTED ADVERSE REACTIONS, contact Spectrum Pharmaceuticals, Inc. at 1-888-713-0688 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a biopharmaceutical company focused on acquiring, developing, and commercializing novel and targeted oncology therapies. Spectrum has a strong track record of successfully executing across the biopharmaceutical business model, from in-licensing and acquiring differentiated drugs, clinically developing novel assets, successfully gaining regulatory approvals and commercializing in a competitive healthcare marketplace. Spectrum has a late-stage pipeline with novel assets that serve areas of unmet need. This pipeline has the potential to transform the company in the near future. For additional information on Spectrum Pharmaceuticals please visit www.sppirx.com.



Notice Regarding Forward-looking Statements

Certain statements in this press release may constitute “forward-looking statements” within the meaning of the United States Private Securities Litigation Reform Act of 1995, as amended to date. These forward-looking statements relate to a variety of matters, including, without limitation, statements that relate to Spectrum’s business and its future, including the success and timing of the company’s commercialization efforts with respect to ROLVEDON, the satisfaction of pre-launch regulatory requirements, the estimated timing of product availability, the future potential of Spectrum’s existing drug pipeline and other statements that are not purely statements of historical fact. These forward-looking statements are made on the basis of the current beliefs, expectations and assumptions of the management of Spectrum and are subject to significant risks and uncertainties that could cause actual results to differ materially from what may be expressed or implied in these forward-looking statements. Risks that could cause actual results to differ include, but are not limited to, the possibility that ROLVEDON may not be more effective, safer or more cost efficient than competing drugs, the possibility that our efforts to acquire or in-license and develop additional drug candidates may fail, our dependence on third parties for clinical trials, manufacturing, distribution and quality control and other risks that are described in further detail in the company’s reports filed with the Securities and Exchange Commission (SEC). The company does not plan to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release except as required by law. For a further discussion of risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of Spectrum in general, see the risk disclosures in the Annual Report on Form 10-K of Spectrum for the year ended December 31, 2021, and in subsequent reports on Forms 10-Q and 8-K and other filings made with the SEC by Spectrum.

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