



Spectrum Pharmaceuticals Announces FDA Acceptance of BLA Resubmission for Eflapegrastim

April 11, 2022

FDA has assigned September 9, 2022 as the PDUFA date

HENDERSON, Nev.--(BUSINESS WIRE)--Apr. 11, 2022-- Spectrum Pharmaceuticals (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, today announced that the resubmitted Biologics License Application (BLA) for eflapegrastim has been accepted for filing. The U.S. Food and Drug Administration (FDA) has set a Prescription Drug User Fee Act (PDUFA) goal date of September 9, 2022. Spectrum is seeking an indication to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia.

"The acceptance of the BLA resubmission is an important incremental step forward in the regulatory review process," said Tom Riga, President and Chief Executive Officer of Spectrum Pharmaceuticals. "We are actively working with the agency as they conduct their review and look forward to the potential approval of this novel product."

About Eflapegrastim

Eflapegrastim is a novel, long-acting granulocyte colony-stimulating factor (G-CSF), Spectrum is seeking an indication to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia. The BLA for eflapegrastim is supported by data from two identically designed Phase 3 clinical trials, ADVANCE and RECOVER, which evaluated the safety and efficacy of eflapegrastim in 643 early-stage breast cancer patients for the management of neutropenia due to myelosuppressive chemotherapy. In both studies, eflapegrastim demonstrated the pre-specified hypothesis of non-inferiority (NI) in duration of severe neutropenia (DSN) and a similar safety profile to pegfilgrastim. Eflapegrastim also demonstrated non-inferiority to pegfilgrastim in the DSN across all 4 cycles (all NI $p < 0.0001$) in both trials.

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.sprix.com.

Notice Regarding Forward-looking Statements

This press release may contain forward-looking statements regarding future events and the future performance of Spectrum Pharmaceuticals that involve risks and uncertainties that could cause actual results to differ materially. These statements are based on management's current beliefs and expectations. These statements include, but are not limited to, statements that relate to Spectrum's business and its future, including certain company milestones, Spectrum's ability to identify, acquire, develop and commercialize a broad and diverse pipeline of late-stage clinical and commercial products, the timing and results of FDA decisions, and any statements that relate to the intent, belief, plans or expectations of Spectrum or its management, or that are not a statement of historical fact. Risks that could cause actual results to differ include the possibility that Spectrum's existing and new drug candidates may not prove safe or effective, the possibility that our existing and new applications to the FDA and other regulatory agencies may not receive approval in a timely manner or at all, the possibility that our existing and new drug candidates, if approved, 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. 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.

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