



Spectrum Pharmaceuticals Provides BLA Filing Update for ROLONTIS® (eflapegrastim)

March 15, 2019

HENDERSON, Nev.--(BUSINESS WIRE)--Mar. 15, 2019-- Spectrum Pharmaceuticals, Inc. (NASDAQ-GS: SPPI) announced today that due to the U.S. Food and Drug Administration's (FDA) request for additional manufacturing-related information for ROLONTIS, the company has voluntarily withdrawn its Biologics License Application (BLA). Spectrum plans to resubmit a revised BLA as soon as possible.

The FDA did not cite concerns related to the pre-clinical and clinical modules of the BLA or the need for additional clinical studies. Spectrum's decision to withdraw the BLA was the result of the company needing more time to provide certain additional manufacturing-related information, which was required before March 29, 2019, the day that the FDA's initial 60-day review period ends.

"We are continuing to have productive discussions with the FDA and will deliver the additional information needed to support the application," said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. "We remain confident in the ROLONTIS program and look forward to a successful resubmission and its ultimate approval."

ROLONTIS is being evaluated as a novel therapy for the management of chemotherapy-induced neutropenia in patients undergoing myelosuppressive chemotherapy.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a biopharmaceutical company focused on acquiring, developing, and commercializing novel and targeted drug products, with a primary focus in hematology and oncology. 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.

Forward-looking statement - 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 timing of the resubmission of the BLA for ROLONTIS, the timing and results of FDA decisions, including with respect to the ROLONTIS BLA, the future potential of Spectrum's existing drug pipeline, Spectrum's ability to identify, acquire, develop and commercialize a broad and diverse pipeline of late-stage clinical and commercial products, 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 uncertainties inherent in new product development, including clinical trial results and additional analysis of existing clinical data, Spectrum's ability to gather and analyze the manufacturing data requested by the FDA in connection with the resubmission of the ROLONTIS BLA, the possibility that Spectrum's 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 Spectrum's existing and new drug candidates, including ROLONTIS, may not ultimately prove to be safe or effective, the possibility that Spectrum's existing and new drug candidates, if approved, may not be more effective, safer or more cost efficient than competing drugs 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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