Spectrum Pharmaceuticals Provides Update on ROLONTIS® (eflapegrastim) Pre-Approval Inspection

March 16, 2021

HENDERSON, Nev.--(BUSINESS WIRE)--Mar. 16, 2021-- Spectrum Pharmaceuticals (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, today announced that the U.S. Food and Drug Administration (FDA) has scheduled the pre-approval inspection at the ROLONTIS® (eflapegrastim) manufacturing site in May 2021. In October 2020, the company received notification from the agency that it would defer its decision on the BLA because an inspection of the Hanmi Bioplant in South Korea could not be conducted during the review cycle due to restrictions on travel related to the COVID-19 pandemic.

"I am thrilled that the FDA informed us that they will be conducting a pre-approval inspection of the ROLONTIS manufacturing facility in May," said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. "We believe the pre-approval inspection marks the final step in the ROLONTIS review process."

About ROLONTIS

ROLONTIS is a novel, long-acting granulocyte colony-stimulating factor (G-CSF) seeking an indication for the treatment of neutropenia in patients receiving myelosuppressive anti-cancer drugs. The BLA for ROLONTIS is supported by data from two identically designed Phase 3 clinical trials, ADVANCE and RECOVER, which evaluated the safety and efficacy of ROLONTIS in 643 early-stage breast cancer patients for the treatment of neutropenia due to myelosuppressive chemotherapy. In both studies, ROLONTIS demonstrated the pre-specified hypothesis of non-inferiority (NI) in duration of severe neutropenia (DSN) and a similar safety profile to pegfilgrastim. ROLONTIS 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.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 timing and outcome of the FDA's inspection of the Hanmi Bioplant in South Korea, the FDA's ability to complete the inspection, the overall likelihood of success and timing of the company's BLA for ROLONTIS, the future potential of Spectrum's existing drug pipeline, including ROLONTIS, and other statements that are not purely statements of historical fact. These forward-looking statements are made on the basis of the current beliefs, understandings, 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 the different methodologies, assumptions and applications the company utilizes to assess particular safety or efficacy parameters may yield different statistical results, and even if the company believes the data collected from the clinical trials of its product candidates, including poziotinib, are positive, these data may not be sufficient to support approval by the FDA; the possibility that success in early clinical trials, especially if based on a small patient sample, might not result in success in later clinical trials, and other unforeseen events during clinical trials which could cause delays or other adverse consequences; other uncertainties inherent in new product development; the possibility that Spectrum's new and existing drug candidates, including poziotinib, may not ultimately prove to be safe or effective; the possibility that Spectrum's new and existing 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 "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, 2019, and in subsequent reports on Forms 10-K, 10-Q and 8-K and other filings made with the SEC by Spectrum.

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Robert Uhl
Managing Director, Westwicke ICR

858.356.5932
robert.uhl@westwicke.com

Kurt Gustafson
Chief Financial Officer
949.788.6700
InvestorRelations@sppirx.com

Source: Spectrum Pharmaceuticals, Inc.