Spectrum Pharmaceuticals Receives Complete Response Letter from U.S. Food and Drug Administration for Poziotinib; Reaffirms Focus on the Commercialization of ROLVEDON™ (eflapegrastim-xnst) injection

November 25, 2022

— Immediately de-prioritizes poziotinib program, accelerates cost reductions, including 75% reduction in R&D related workforce —

— Spectrum to explore strategic alternatives for the poziotinib program, including partnerships and business development opportunities —

BOSTON--(BUSINESS WIRE)--Nov. 25, 2022-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI) (“Spectrum” or the “Company”), a biopharmaceutical company focused on novel and targeted oncology therapies, today announced that the Company has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding Spectrum’s New Drug Application (NDA) for poziotinib for the treatment of patients with previously treated locally advanced or metastatic non-small cell lung cancer (“NSCLC”) harboring HER2 exon 20 insertion mutations. The FDA issued a CRL indicating the poziotinib application cannot be approved in its present form. Based on the CRL, the Company would have to generate additional data including a randomized controlled study prior to approval.

“While we are not surprised by the CRL given the ODAC recommendation in September, we are disappointed. After multiple interactions with the FDA since ODAC, and following careful consideration, we have made the strategic decision to immediately de-prioritize the poziotinib program,” said Tom Riga, President and Chief Executive Officer of Spectrum Pharmaceuticals. “We continue to believe that poziotinib could present a meaningful treatment option for patients with this rare form of lung cancer, for whom other therapies have failed.”

Mr. Riga continued, “We are committed to exploring potential strategic alternatives for poziotinib, including partnerships and business development opportunities, and will determine the best path forward in support of patients. We are grateful to the patients, families, and clinicians who participated in the poziotinib program and to the team members who have dedicated their time and efforts.”

The Company will de-prioritize poziotinib program activities, effective immediately, and is in the process of reducing its R&D workforce by approximately 75%. Based on the anticipated cost savings from the restructuring, Spectrum believes it will be able to generate the working capital required to support its strategic refocusing through 2024.

The Company will focus efforts on driving growth for its recently launched commercial drug, ROLVEDON. ROLVEDON was approved by the FDA in September 2022. It is for adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia. Spectrum launched ROLVEDON, which has an estimated market opportunity of approximately $2 billion, shortly following the FDA's approval.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals, Inc. 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 pipeline with novel assets that serve areas of unmet need. For additional information on Spectrum 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 magnitude of its planned reduction in force; the cost savings to be achieved from the planned restructuring and the Company’s ability to fund its projected operating expenses and working capital through 2024; the future potential of poziotinib as a meaningful treatment option for patients; the likelihood and timing of potential strategic alternatives for poziotinib; the success of the Company’s commercial launch of ROLVEDON, including the potential therapeutic benefits of ROLVEDON and the potential market opportunity for ROLVEDON; the potential of the Company’s pipeline to transform the Company in the near future 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; our dependence on third parties for manufacturing, distribution and quality control; the possibility that our efforts to acquire or in-license and develop additional drug candidates may fail and other risks that are described in further detail in the company's reports filed with 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, 2021, and in subsequent reports on Forms 10-Q and 8-K and other filings made with the SEC by Spectrum.

trademarks are the property of their respective owners.

View source version on businesswire.com: https://www.businesswire.com/news/home/20221125005059/en/

Tom Riga
Chief Executive Officer
949.788.6700
InvestorRelations@sppirx.com

Lisa Wilson
In-Site Communications, Inc
212.452.2793
lwilson@insitecony.com

Source: Spectrum Pharmaceuticals, Inc.