Spectrum Pharmaceuticals Provides Update on Poziotinib Following FDA Oncologic Drugs Advisory Committee Meeting

September 22, 2022

BOSTON--(BUSINESS WIRE)--Sep. 22, 2022-- Spectrum Pharmaceuticals (NasdaqGS: SPPI) ("Spectrum" or the "Company"), a biopharmaceutical company focused on novel and targeted oncology therapies, today announced that the U.S. Food and Drug Administration's ("FDA") Oncologic Drugs Advisory Committee ("ODAC") met to review 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 committee voted 9-4 that the current benefits of poziotinib did not outweigh its risks.

"We are disappointed by the outcome of the ODAC meeting, as patients with NSCLC HER2 exon 20 insertion mutations are in need of additional effective and safe therapies," stated Tom Riga, President and Chief Executive Officer of Spectrum Pharmaceuticals. "We plan to carefully evaluate our options for this program as we approach the November 24, 2022, PDUFA date. We would like to thank lung cancer patients and their families, as well as investigators and their staff, for their support."

ODAC is an independent panel of experts that reviews and evaluates data concerning the efficacy and safety of marketed and investigational products for use in the treatment of cancer. The committee makes appropriate recommendations to the FDA, but these recommendations are not binding and the final decision regarding product approval will be made solely by the FDA.

About Poziotinib

Poziotinib is a novel, oral epidermal growth factor receptor tyrosine kinase inhibitor (EGFR TKI) that inhibits the tyrosine kinase activity of EGFR as well as HER2 and HER4, which, in turn, leads to the inhibition of the proliferation of tumor cells that overexpress these receptors. Mutations or overexpression/amplification of EGFR family receptors have been associated with a number of different cancers, including non-small cell lung cancer (NSCLC), breast cancer, and gastric cancer. HER2 exon 20 insertion mutations are a rare subset accounting for approximately 2-4% in NSCLC. There is no approved therapy for either treatment-naïve or previously treated NSCLC with HER2 exon 20 insertion mutations. Spectrum Pharmaceuticals holds an exclusive license from Hanmi Pharmaceutical ("Hamni") to develop, manufacture, and commercialize poziotinib worldwide, excluding Korea and China. Poziotinib is currently being investigated by the Company and Hanmi in several mid-stage trials in multiple solid tumor indications.

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 – Spectrum Pharmaceuticals

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 likelihood and timing of FDA approval of poziotinib, if FDA approval is received, the success and timing of the Company's commercialization efforts, the results of the confirmatory study for poziotinib, the potential therapeutic benefits of poziotinib, the potential market opportunity for poziotinib, 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 poziotinib may not be more effective, safer, or more cost-efficient than competing drugs, our dependence on third parties for clinical trials, manufacturing, distribution and quality control, 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 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 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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