FDA Grants Fast Track Designation to Spectrum Pharmaceuticals' Poziotinib

March 11, 2021

HENDERSON, Nev.--(BUSINESS WIRE)--Mar. 11, 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 granted Fast Track designation for poziotinib for the treatment of non-small cell lung cancer (NSCLC) in previously treated patients with HER2 exon 20 mutations. Spectrum plans to submit a new drug application (NDA) for poziotinib later this year.

"There are currently no approved therapies to treat patients with HER2 exon 20 mutations and we are pleased that the FDA has granted Fast Track designation for poziotinib," said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. "Momentum is building to unlock the potential of poziotinib."

"We are actively preparing the NDA and delighted with this Fast Track designation," stated Francois Lebel, M.D., Chief Medical Officer of Spectrum Pharmaceuticals. "In addition, last week we presented at the European Society for Medical Oncology Targeted Anticancer Therapies (ESMO TAT) Virtual Congress 2021 that twice daily dosing (BID) suggests improved anti-tumor activity and reduced toxicity relative to once daily dosing. We are optimistic about this BID strategy and we will provide a data update at AACR in April."

About Fast Track Designation

Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious and life-threatening conditions and fill unmet medical needs, with the intention of getting important new drugs to patients earlier. Specifically, Fast Track designation facilitates meetings with the FDA to discuss aspects of development to support licensure and provides the opportunity to submit sections of a NDA on a rolling basis as data become available. When Fast Track designation is requested later in development, available clinical data should demonstrate the potential to address an unmet medical need. Additionally, another potential benefit of Fast Track designation is priority review, which reduces the standard 10 months NDA review to six months.

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 significance of the granting of Fast Track designation for poziotinib; the potential for poziotinib to significantly advance the treatment of NSCLC patients with HER2 exon 20 insertion mutations; the timing and results of the company's planned NDA submission; the significance of the preliminary dosing data for poziotinib, including the ability to achieve improved anti-tumor activity and reduced toxicity with BID dosing; the overall progression of the poziotinib development program; the company's ability to advance and fund the development and commercialization of poziotinib; 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 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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