Spectrum Pharmaceuticals Announces Acceptance of New Drug Application Filing for Poziotinib

February 11, 2022

HENDERSON, Nev.--(BUSINESS WIRE)--Feb. 11, 2022-- Spectrum Pharmaceuticals (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, today announced that its New Drug Application (NDA) for poziotinib has been accepted for review by the U.S. Food and Drug Administration (FDA).

The NDA acceptance is based on the positive Phase 2 study results in patients with previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring HER2 exon 20 insertion mutations. There is currently no treatment specifically approved by the FDA for this indication. The product has received Fast Track designation and the agency has set a Prescription Drug User Fee Act (PDUFA) date of November 24, 2022. The FDA reiterated the importance of having the confirmatory trial substantially enrolled at the time of approval and requested additional information around dosing. The FDA also indicated that it is not currently planning to hold an advisory committee meeting for the application.

“The NDA acceptance is a major step toward advancing the treatment for patients with HER2 exon 20 insertion mutations in lung cancer,” said Tom Riga, President and Chief Executive Officer of Spectrum Pharmaceuticals. “This remains an area of high unmet medical need as there are no treatments specifically approved for these patients. We are actively working with the agency to support the review process.”

About the Phase 2 Study Results (Cohort 2 of ZENITH20 Study)

The Phase 2 study enrolled 90 patients who received an oral once daily dose of 16 mg of poziotinib. The intent-to-treat analysis demonstrated a confirmed objective response rate (ORR) of 27.8% (95% Confidence Interval (CI), 18.9%-38.2%). The observed lower bound of 18.9% exceeded the pre-specified lower bound of 17%. The median duration of response was 5.1 months and the median progression free survival was 5.5 months. In this cohort, 87% of patients had drug interruptions with 11 patients (12%) permanently discontinuing due to adverse events. 13 patients (14%) had treatment-related serious adverse events.

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 FDA’s acceptance of Spectrum’s NDA submission for poziotinib for review, poziotinib’s potential to significantly advance the treatment of NSCLC patients with HER2 exon 20 insertion mutations, the timing and results of the FDA’s substantive review, the company’s ability to advance and fund the development and commercialization of its late-stage pipeline assets and such assets’ ability to serve areas of unmet need, the future potential of the company’s existing drug pipeline and its ability to transform the company in the near future, and other statements that are not purely statements of historical fact. These forward-looking statements are based on management's current beliefs, assumptions and expectations, 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 Spectrum’s existing and new drug candidates may not prove to be safe or effective, 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 existing and new drug candidates, if approved, may not be more effective, safer or more cost efficient than competing drugs, the possibility that our efforts to acquire or in-license and develop additional drug candidates may fail, our dependence on third parties for clinical trials, manufacturing, distribution and quality control 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, 2020, and in subsequent reports on Forms 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

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