Spectrum Pharmaceuticals Submits New Drug Application for Poziotinib

December 6, 2021

Fast Track application is based on positive data in NSCLC HER2 exon 20 insertion mutations in previously treated patients

Positive Results for Cohort 2 of ZENITH20 clinical trial published in Journal of Clinical Oncology

HENDERSON, Nev.--(BUSINESS WIRE)--Dec. 6, 2021-- Spectrum Pharmaceuticals (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, today announced that it has submitted its New Drug Application (NDA) for poziotinib to the U.S. Food and Drug Administration (FDA) for use in patients with previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC) with HER2 exon 20 insertion mutations. The NDA submission is based on the positive results of Cohort 2 from the ZENITH20 clinical trial, which assessed the safety and efficacy of poziotinib. The product has received Fast Track designation and there is currently no treatment specifically approved by the FDA for this indication.

“The NDA submission for poziotinib marks an important step in achieving a first treatment for patients with HER2 exon 20 insertion mutations in lung cancer,” said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. “I want to thank the patients, investigators and our internal staff who have passionately worked to achieve this important milestone in an area of high unmet medical need.”

ZENITH20 Cohort 2 Clinical Results Summary

Results for Cohort 2 of the ZENITH20 clinical trial have been published in the Journal of Clinical Oncology (November 29, 2021), and can be accessed by clicking here.

Cohort 2 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. As previously announced, the company had a successful pre-NDA meeting with the FDA which resulted in an agreement to submit an NDA for poziotinib. During the meeting, Spectrum confirmed with the FDA that Cohort 2 data could serve as the basis of an NDA submission. The company will continue to work with the FDA as appropriate, while the agency conducts its review.

About the ZENITH20 Clinical Trial

The ZENITH20 study consists of seven cohorts of NSCLC patients. Cohorts 1 (EGFR) and 2 (HER2) in previously treated NSCLC patients with exon 20 mutations and Cohort 3 (EGFR) in first-line patients have completed enrollment. Cohort 4 (HER2) in first-line NSCLC patients with exon 20 mutations is still enrolling patients. Cohorts 1- 4 are each independently powered for a pre-specified statistical hypothesis and the primary endpoint is objective response rate (ORR). Cohort 5 includes previously treated or treatment-naïve NSCLC patients with EGFR or HER2 exon 20 insertion mutations. Cohort 6 includes NSCLC patients with classical EGFR mutations who progressed while on treatment with first-line osimertinib and developed an additional EGFR mutation. Cohort 7 includes NSCLC patients with a variety of less common mutations in EGFR or HER2 exons 18-21 or the extracellular or transmembrane domains.

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

This press release may contain “forward-looking statements” within the meaning of the United States Private Securities Litigation Reform Act of 1995, as amended. These statements include, but are not limited to, statements that relate to Spectrum’s business and its future, including the significance of the NDA submission for poziotinib, 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 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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