Spectrum Pharmaceuticals to Present Data at 2022 ASCO Highlighting the Potential Predictive Capabilities of ctDNA as a Biomarker for Poziotinib Treatment Response

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Reduced circulating tumor DNA (ctDNA) and circulating free DNA (cfDNA) levels were associated with tumor shrinkage in patients that responded to poziotinib treatment

Poziotinib has received Fast Track designation from FDA and a Prescription Drug User Fee Act (PDUFA) date of November 24, 2022

HENDERSON, Nev.--(BUSINESS WIRE)--May 26, 2022-- Spectrum Pharmaceuticals (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, today announced additional exploratory data for poziotinib in non-small cell lung cancer (NSCLC) patients harboring HER2 exon 20 insertion mutations at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting being held in Chicago from June 3-7.

In poziotinib treated patients with advanced NSCLC harboring HER2 exon 20 insertion mutations, baseline ctDNA presence was associated with the tumor tissue genotyping with a concordance of 95%. In patients who responded to treatment, reduced ctDNA levels were associated with tumor mass reduction by central imaging. Increases in ctDNA were observed prior to confirmation of tumor escape, or disease progression.

“This early data suggests that a reduction in ctDNA may be a predictor of response to treatment with poziotinib,” said Francois Lebel, M.D., Chief Medical Officer of Spectrum Pharmaceuticals. “We are encouraged by these findings and look forward to further investigate ctDNA as a potential predictive biomarker of poziotinib treatment response.”

Poziotinib is currently under review by the U.S. Food and Drug Administration (FDA) with a PDUFA date of November 24, 2022 and has received Fast Track designation from the agency.

Session title and information for the poster is listed below and is available on the ASCO online itinerary planner.

Circulating tumor DNA (ctDNA) in HER2 exon 20 insertion mutations and responses in NSCLC HER2 exon 20 insertion treated with poziotinib
Session Title: Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology
Session Date and Time: Sunday, June 5, 2022, 8-11 a.m. CDT, 6-9 a.m. PT
Location: McCormick Place, Chicago IL
Abstract: 3051 / Poster: 43

Copies of the presentation will be available on Spectrum's website at https://investor.sppirx.com/events-and-presentations following presentation at the meeting.

About the ZENITH20 Clinical Trial

The ZENITH20 study is a multicenter, open-label Phase 2 trial, evaluating poziotinib in patients with advanced or metastatic NSCLC patients with EGFR or HER2 exon 20 insertion mutations. The trial is comprised of 7 independent cohorts. Cohorts 1 - 4 were each independently powered for a pre-specified statistical hypothesis with a primary endpoint of ORR, or objective response rate evaluated by independent review committee (RECIST v1.1). Cohorts 5 - 7 are exploratory. Secondary outcome measures are disease control rate, duration of response, progression-free survival, and safety and tolerability. The patients’ quality of life is also measured and assessed throughout. Cohort 4 includes first-line NSCLC patients with HER2 exon 20 mutations and cohort 5 includes previously treated or treatment-naïve NSCLC patients with EGFR or HER2 exon 20 insertion mutations.

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. Importantly this, 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. The company holds an exclusive license from Hanmi Pharmaceutical 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

This press release may contain forward-looking statements regarding future events and the future performance of Spectrum Pharmaceuticals that involve risks and uncertainties that could cause actual results to differ materially. These statements are based on management's current beliefs and expectations. These statements include, but are not limited to, statements that relate to Spectrum's business and its future, including certain company milestones, Spectrum's ability to identify, acquire, develop and commercialize a broad and diverse pipeline of late-stage clinical and commercial products, the timing and results of FDA decisions, and any statements that relate to the intent, belief, plans or expectations of Spectrum or its management, or that are not a statement of historical fact. Risks that could cause actual results to differ include the possibility that Spectrum's existing and new drug candidates may not prove 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. 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.

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