



Spectrum Pharmaceuticals Announces Data from Poster Presentation for Pozitotinib in NSCLC Patients with G778_P780dup HER2 Exon 20 Mutations at ESMO Congress 2022

September 10, 2022

BOSTON--(BUSINESS WIRE)--Sep. 10, 2022-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPP1), a biopharmaceutical company focused on novel and targeted oncology therapies, today announced data from a poster presentation titled: High Activity of Pozitotinib in G778_P780dup HER2 Exon 20 Insertion Mutations in Non-Small Cell Lung Cancer (NSCLC). The data show that pozitotinib is highly active in G778 mutations in both treatment naïve and previously treated patients with NSCLC.

The poster titled "High Activity of Pozitotinib in G778_P780dup HER2 Exon 20 Insertion Mutations in Non-Small Cell Lung Cancer (NSCLC)" is being presented by Xiuning Le, M.D., Ph.D., Assistant Professor, The University of Texas MD Anderson Cancer Center on September 12, 2022. A poster with the data is available to registered participants at the European Society for Medical Oncology Congress (ESMO) 2022 taking place in Paris from September 9-13, 2022.

"The G778 mutation is one of the frequent HER2 exon 20 insertion mutations and patients with these tumors have a poor prognosis," said Francois Lebel, M.D., Chief Medical Officer of Spectrum Pharmaceuticals. "These findings demonstrate the high activity of pozitotinib in both treatment naïve and heavily pre-treated patients."

Results for Pozitotinib in this Patient Group

The findings are based on an assessment of the activity of pozitotinib in patients with the G778_P780dup HER2 exon 20 insertion mutation in a population of previously treated (Cohort 2) and treatment-naïve (Cohort 4) patients with NSCLC from the ZENITH20 clinical trial. Patients (n=90) in Cohort 2 (C2) received 16 mg of pozitotinib once a day (QD) and patients (n=80) in Cohort 4 (C4) received 16 mg QD or 8 mg twice a day (BID). The primary endpoint was objective response rate (ORR). Fourteen patients had the HER2 G778 insertion (C2, n=7; C4, n=7) mutation.

12 of 14 patients were evaluable and all had partial response, resulting in an ORR of 85.7% (95% CI, 57.2, 98.2) and a median DOR of 5.5 months (range 2.9-14.1). The ORR was 100% in the previously treated C2 patients, and 71.4% in the treatment naïve C4 patients. Median DOR was 5.3 months for the C2 patients and 8.9 months for those in C4. The frequency of adverse events (AEs) was consistent with prior reports and overall AEs were similar to the TKI class.

The poster will be available for viewing by registered participants during the conference via the ESMO [website](#) beginning on September 10, 2022. It will also be available on the Investor Relations section of the company's website at <https://investor.sppix.com/index.php/events-and-presentations>.

About Pozitotinib

Pozitotinib 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 specifically 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 pozitotinib worldwide, excluding Korea and China.

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.sppix.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 potential therapeutic benefits of pozitotinib, the potential market opportunity for pozitotinib for its target indication, Spectrum's expectations that future study results will be consistent with the results to date 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 pozitotinib 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 pozitotinib, 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, 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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