Spectrum Pharmaceuticals Presents Late Breaker Oral Presentation of Poziotinib Data in First-Line NSCLC Patients with HER2 Exon 20 Insertion Mutations at ESMO Congress 2021

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Early data from Cohort 4 of the ongoing ZENITH20 clinical trial shows ORR of 44% in 48 first-line patients treated with 16mg of poziotinib once daily

HENDERSON, Nev.--(BUSINESS WIRE)--Sep. 18, 2021-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, today announced the presentation of safety and efficacy results from Cohort 4 of the ZENITH20 clinical trial. This data is from 48 first-line patients with non-small cell lung cancer (NSCLC) with HER2 exon 20 insertion mutations who received 16mg of oral poziotinib once daily. These results showed a confirmed objective response rate (ORR) of 44%, as evaluated centrally by an independent image review committee using RECIST 1.1 criteria. The data was presented as a late breaker at the European Society for Medical Oncology (ESMO) Congress 2021 taking place in Paris on September 16-20, 2021.

"The data presented in Paris from Cohort 4 is very encouraging," said Francois Lebel, M.D., Chief Medical Officer of Spectrum Pharmaceuticals. "There currently is no specific approved treatment for NSCLC patients with HER2 exon 20 insertion mutations. This data represents a significant milestone in our development of poziotinib for patients with a significant medical need."

A copy of the ESMO presentation titled, "Efficacy and safety of poziotinib in treatment-naïve NSCLC harboring HER2 exon 20 mutations: A multinational Phase 2 study (ZENITH20-4)" presented by Dr. Robin Cornelissen, from the Erasmus MC Cancer Institute in Rotterdam, is available on Spectrum's corporate website at https://investor.sppirx.com/events-and-presentations.

ZENITH20 Trial Design and Early Safety and Efficacy Data for Cohort 4

Cohort 4 of the ZENITH20 clinical trial is enrolling treatment-naïve NSCLC patients with HER2 exon 20 insertion mutations. This cohort is investigating the efficacy of poziotinib with a QD and BID (ongoing) dosing strategy. Poziotinib 16mg was administered orally once daily for the first 48 patients allowing dose reductions/interruptions for toxicity. The primary endpoint was ORR evaluated centrally by an independent image review committee using RECIST 1.1 criteria. Secondary endpoints included disease control rate (DCR), duration of response (DoR), progression-free survival (PFS) and safety.

The primary endpoint of ORR was 44% (95% CI:29.5-58.8%) in the 48 treated patients including one complete response. 88% of patients (42/48) showed tumor reduction with a DCR of 75%. Median DoR was 5.4 months (range 2.8-19.1+). Median PFS was 5.6 months (range 0-20.2+). 88% of patients had dose interruptions and 77% had reductions from the 16mg QD starting dose, while 13% had adverse event (AE) related discontinuations. The most common treatment related Grade ≥ 3 AEs were rash (35%), stomatitis (20%), diarrhea (14%), and paronychia (8%). In addition, only 1 patient experienced Grade ≥ 3 pneumonitis. Poziotinib demonstrated clinically meaningful anti-tumor activity in newly diagnosed NSCLC patients with HER2 exon 20 mutations with 16mg QD dosing. The safety profile was manageable and similar to previously seen in previous studies and other second-generation tyrosine kinase inhibitors. The 8mg BID portion of Cohort 4 is continuing to actively recruit.

About the ZENITH20 Clinical Trial

The ZENITH20 study consists of seven cohorts of NSCLC patients. Cohorts 1 (EGFR) and 2 (HER2) in previously treated NSCLS 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.

Forward-looking statement — 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, 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, 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 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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