Spectrum Pharmaceuticals Presents Positive Data for Poziotinib in First-line NSCLC Patients with HER2 Exon 20 Insertion Mutations

March 7, 2022

Data presented at ESMO TAT from Cohort 4 of the ZENITH20 clinical trial met the primary endpoint

HENDERSON, Nev.--(BUSINESS WIRE)--Mar. 7, 2022-- Spectrum Pharmaceuticals (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 70 first-line patients with non-small lung cancer (NSCLC) with HER2 exon 20 insertion mutations who received 16 mg daily, given as 16 mg once daily (48 patients) or 8 mg twice daily (22 patients) of oral poziotinib. These results showed a confirmed objective response rate (ORR) of 41% (95% CI:30%-54%), as evaluated centrally by an independent image review committee using RECIST 1.1 criteria. The evaluable patient population showed an ORR of 50%. The study met its primary endpoint as the observed lower bound of 30% exceeded the pre-specified lower bound of 20%. The safety profile was consistent with the TKI class. The data is part of an oral presentation at the European Society for Medical Oncology Targeted Anticancer Therapies (ESMO TAT) Congress 2022 being held virtually March 7-8, 2022.

“Cohort 4 from our ZENITH 20 study demonstrated positive results for treatment naïve lung cancer patients harboring HER2 Exon 20 insertion mutations. There is currently no approved treatment for NSCLC patients with these mutations,” said Francois Lebel, M.D., Chief Medical Officer of Spectrum. “We are encouraged by these findings and look forward to further discussions with the FDA on the regulatory path forward.”

The presentation is available on the Spectrum Pharmaceuticals website at: https://investor.sppirx.com/index.php/events-and-presentations.

Safety and Efficacy Data for Cohort 4 of the ZENITH20 Clinical Trial

Cohort 4 enrolled treatment-naïve NSCLC patients with HER2 exon 20 insertion mutations. This cohort investigated the efficacy of poziotinib and included patients dosed either with a QD or BID dosing strategy. Poziotinib 16 mg was administered orally once daily for the first 48 patients followed by an additional 22 patients dosed at 8 mg twice daily. Both dosing regimens allowed 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 41% (95% CI:30-54%) in the 70 treated patients including one complete response. The DCR was 73% (95% CI:61-83%). DoR was 5.7 months (range 1.2-19.1+). Median progression free survival (PFS) was 5.6 months (range 0-20.2+). 90% of patients had dose interruptions and 79% had reductions from the 16 mg QD starting dose, while 64% had reductions from the 8mg BID starting dose. The most common treatment related Grade ≥ 3 adverse events were rash (30%), stomatitis (19%), diarrhea (14%), and paronychia (7%). In addition, the incidence of Grade ≥ 3 pneumonitis was low at 3%. The safety profile was consistent with the TKI class and tolerability, dose reductions and interruptions were less frequent with BID dosing.

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, Cohort 3 (EGFR) in first-line patients and Cohort 4 (HER2) in first-line NSCLC patients with exon 20 mutations have completed patient enrollment. Cohorts 1-4 are each independently powered for a pre-specified statistical hypothesis and the primary endpoint is 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

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 outcome and timing of discussions with the FDA regarding poziotinib and the FDA’s determination of a path forward for poziotinib, poziotinib’s potential to significantly advance the treatment of NSCLC patients with HER2 exon 20 insertion mutations, 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. 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 an NDA filing or 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 Spectrum's new and existing drug candidates, if approved, may not be more effective, safer, or more cost efficient than competing drugs, and other risks that are described in further detail in the company's reports filed with the Securities and Exchange Commission. These statements are based on management's current beliefs and expectations as of the date hereof. 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, ICR Westwicke
858.356.5932
robert.uhl@westwicke.com

Kurt Gustafson
Chief Financial Officer
949.788.6700
InvestorRelations@sppirx.com

Source: Spectrum Pharmaceuticals