Spectrum Pharmaceuticals Announces Positive Topline Results in HER2 Exon20 Insertion Mutations from Cohort 2 of the Poziotinib ZENITH20 Trial

July 27, 2020

Management to host webcast and conference call today at 4:30 p.m. ET / 1:30 p.m. PT

HENDERSON, Nev.--(BUSINESS WIRE)--Jul. 27, 2020-- Spectrum Pharmaceuticals, Inc. (NASDAQ-GS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, today announced that it met the pre-specified primary endpoint in the ZENITH20 Phase 2 clinical trial evaluating poziotinib in previously treated non-small cell lung cancer (NSCLC) patients with HER2 exon 20 insertion mutations (Cohort 2).

“The positive results of Cohort 2 are a significant milestone and we are looking forward to meeting with the FDA,” said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. “We believe that poziotinib is a significant advancement for patients with this deadly disease in an area of high unmet medical need.”

Cohort 2 of the ZENITH20 clinical trial enrolled a total of 90 patients who received an oral, once daily dose of 16 mg of poziotinib. All the patients had failed at least one line of prior systemic therapy with 60 patients (67%) having failed two or more prior therapies, including chemotherapy and immunotherapy. All responses were read independently and confirmed by a central imaging laboratory using RECIST criteria. The intent-to-treat analysis demonstrated a confirmed objective response rate (ORR) of 27.8% (95% Confidence Interval (CI) 18.9%-38.2%). Based on the pre-specified statistical hypothesis for the primary endpoint, the observed lower bound of 18.9% exceeded the pre-specified lower bound of 17% in this heavily pre-treated population.

The median duration of response was 5.1 months (range 1 to >12.3), with a median follow up of 8.3 months. The disease control rate (DCR) was 70% and the median progression free survival was 5.5 months. The safety profile was in-line with the type of adverse events (AEs) seen with other second-generation EGFR tyrosine kinase inhibitors and similar to Cohort 1. Grade 3 treatment related rash was 30% and diarrhea was 26%. In Cohort 2, no pneumonitis was reported (0/90).

“We are pleased with the results of Cohort 2,” said Francois Lebel, M.D., Chief Medical Officer of Spectrum Pharmaceuticals. “There are currently no approved therapies for HER2 patients with exon 20 insertion mutations in NSCLC and we are looking forward to reviewing this data with the FDA to determine the path forward.”

Cohort 2 was designed to be a registrational study. The company is in the process of requesting a meeting with the U.S. Food and Drug Administration (FDA) to discuss the data and its plans for a New Drug Application (NDA) submission. The company plans to present additional study results for Cohort 2 at an upcoming medical meeting.

The ZENITH20 trial is comprised of 7 independent cohorts. Cohorts 1 - 4 are each independently powered for a pre-specified statistical hypothesis with a primary endpoint of ORR. Cohorts 5 - 7 are exploratory. In December 2019, the company reported that the primary endpoint for Cohort 1 (EGFR) was not met but clinical activity was seen. Based on the results of Cohort 1, the company has amended the protocol for ZENITH20 to explore additional twice daily dosing regimens as well as lower single daily dosage amounts. This amendment did not impact Cohorts 2 and 3 as these cohorts were fully enrolled. Results from Cohort 3 are expected in the second half of the year.

Conference Call and Webcast

The company’s management will host a webcast and conference call today, July 27, 2020, at 4:30 p.m. ET / 1:30 p.m. PT to discuss the clinical trial results. The live call may be accessed by dialing (877) 837-3910 for domestic callers and (973) 796-5077 for international callers and entering the conference ID#: 2516797. A live webcast of the call will be available from the Investor Relations section of the company’s website at http://investor.sppirx.com/events-and-presentations and will be archived there shortly after the live event.

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. The company holds an exclusive license from Hanmi Pharmaceuticals 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 Pharmaceuticals 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 Pharmaceuticals 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 the company’s business and its future, including the significance of Cohort 2’s reported results; the timing and outcome of a potential meeting 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 timing and result of future FDA approvals; the timing of the results of Cohort 3; the overall progression of the poziotinib development program; the company’s plans to present additional study result from Cohort 2 at an upcoming medical meeting; the company’s ability to advance development 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 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 the company 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 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; the company’s existing and new drug candidates, including poziotinib, may not prove safe or effective; the possibility that the company’s 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 the company’s existing and new drug candidates, including poziotinib, if approved, may not be more effective, safer or more cost efficient than competing drugs; the possibility that the company’s efforts to acquire or in-license and develop additional drug candidates may fail; the company’s 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. 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 the company in general, see the risk disclosures in the company’s Annual Report on Form 10-K for the year ended December 31, 2019, and in subsequent reports on Forms 10-Q and 8-K and other filings made with the SEC by the company.

View source version on businesswire.com: https://www.businesswire.com/news/home/20200727005679/en/

Robert Uhl
Managing Director, Westwicke ICR
858.356.5932
robert.uhl@westwicke.com

Kurt Gustafson
Chief Financial Officer
949.788.6700
InvestorRelations@sppirx.com

Source: Spectrum Pharmaceuticals, Inc.