Spectrum Pharmaceuticals Presents Additional Twice Daily Dosing Data for Poziotinib at the AACR Virtual Meeting 2021

April 10, 2021

HENDERSON, Nev.--(BUSINESS WIRE)--Apr. 10, 2021-- Spectrum Pharmaceuticals (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, today presented a data update on the safety and tolerability of twice daily (BID) administered poziotinib in NSCLC patients with EGFR or HER2 exon 20 insertion mutations. These preliminary data, from Cohort 5 of the ZENITH20 clinical trial, continue to show improved tolerability with BID dosing, reduced dose interruption compared to once daily (QD) dosing, and a reduction in treatment emergent Grade 3 or higher adverse events. The preliminary data also demonstrate improved anti-tumor activity with 8mg BID dosing. The presentation is part of the AACR Virtual Meeting 2021 taking place April 10-15, 2021.

"The 8mg BID dosing arm is showing the best performance we have seen across the various dosing arms for a mixed population of EGFR and HER2 exon 20 insertion mutations in NSCLC patients. There is clearly an improved therapeutic effect and a lower adverse event rate which is highly encouraging," said Francois Lebel, M.D., Chief Medical Officer of Spectrum Pharmaceuticals. "We are currently expanding the 8mg BID dataset and look forward to evaluating this dose in additional NSCLC patients and other solid tumors."

A copy of the AACR presentation titled "Poziotinib administered twice daily improves safety and tolerability in patients with EGFR or HER2 exon 20 mutations" is available on Spectrum's website at https://investor.sppirx.com/events-and-presentations.

ZENITH20 Trial Design and Preliminary Safety and Efficacy Data for Cohort 5

Cohort 5 of the ZENITH20 trial includes previously treated NSCLC patients with EGFR or HER2 exon 20 insertion mutations. This cohort is investigating the efficacy of poziotinib with various dosing levels including BID administration. For the 38 patients randomized to poziotinib 16mg QD or 8mg BID in Cohort 5, improved responses were reported in the BID arm with 31.6% of patients (6/19) reaching a partial response. For the 38 patients randomized to poziotinib 12mg QD or 6mg BID, these dosing levels were not as active as 8mg BID but showed improved tolerance with BID dosing relative to QD dosing.

Improved tolerability was also observed for the typical TKI related adverse events, with a clinically meaningful reduction in Grade 3 or higher adverse events for the 8mg BID dose relative to 16mg QD. In addition, there were fewer dose interruptions and dose reductions for the BID arms relative to the same QD dose. Cohort 5 is now enrolling exclusively in the 8mg BID arm and data collection is ongoing.

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 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 significance of the preliminary dosing data for poziotinib, including the ability to achieve an improved therapeutic effect and a lowered adverse event rate with BID dosing; the demonstration of improved anti-tumor activity; the reduction in dose interruptions and dose reductions; poziotinib's potential to significantly advance the treatment of NSCLC patients with EGFR or HER2 exon 20 insertion mutations; the timing and results of the company's planned NDA submission; the overall progression of the poziotinib development program; 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. 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 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 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 (the "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-K, 10-Q and 8-K and other filings made with the SEC by Spectrum.

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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