Spectrum Pharmaceuticals Announces Full Enrollment of the Poziotinib EGFR Cohort for Previously Treated Non-Small Cell Lung Cancer Patients with Exon 20 Insertion Mutations

January 2, 2019

- Results are expected in the second half of 2019

HENDERSON, Nev.--(BUSINESS WIRE)--Jan. 2, 2019-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biotechnology company with fully integrated commercial and drug development operations with a primary focus in hematology and oncology, today announced full enrollment of cohort 1 (N=87) for previously treated Non-Small Cell Lung Cancer (NSCLC) patients with EGFR exon 20 insertion mutations with sites across the U.S., Europe, and Canada. The EGFR previously treated cohort is part of the ZENITH20 trial – an open-label, multi-center, global Phase 2 trial evaluating NSCLC patients with EGFR or HER2 exon 20 insertion mutations. Results from this cohort are expected by the second half of 2019.

“The rapid rate at which we enrolled our Phase 2 previously treated EGFR exon 20 insertion mutations cohort speaks to the critical unmet medical need and demonstrates that the poziotinib program is aggressively advancing,” said Joe Turgeon, President and Chief Executive Officer of Spectrum Pharmaceuticals. “We are pleased with the results seen in smaller poziotinib trials and look forward to data from this larger, multi-center trial in the second half of the year.”

The EGFR previously treated cohort is the first to fully enroll in the ZENITH20 trial. This study consists of four cohorts, each of which is independently powered for a pre-specified statistical hypothesis. There are two cohorts in the previously-treated NSCLC setting and two in the first-line setting. The primary endpoint is objective response rate (ORR). Additional endpoints include duration of response (DOR), disease control rate (DCR), progression-free survival (PFS) and safety.

“Full enrollment of the first cohort marks an important milestone as this cohort is intended to provide the data required for the NDA filing,” said Francois Lebel, M.D., F.R.C.P.C, Chief Medical Officer of Spectrum Pharmaceuticals. “Our poziotinib development program is investigating the treatment of exon 20 mutations across tumor types as these mutations are among the most difficult-to-treat and currently have no targeted FDA-approved therapies, leaving patients and physicians with very limited options.”

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 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 full poziotinib targeted therapy clinical program is focused on four development areas for EGFR and HER2 mutations, including previously treated NSCLC, first-line NSCLC, treatment of other solid tumors and combination therapy.

Spectrum received exclusive license from Hanmi Pharmaceuticals to develop, manufacture, and commercialize poziotinib worldwide, excluding Korea and China. Poziotinib is currently being investigated by Spectrum and Hanmi in several trials in multiple solid tumors.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a leading biotechnology company focused on acquiring, developing, and commercializing drug products, with a primary focus in hematology and oncology. Spectrum currently markets seven hematology/oncology drugs, and has an advanced stage pipeline that has the potential to transform the company. Spectrum's strong track record for in-licensing and acquiring differentiated drugs, and expertise in clinical development have generated a robust, diversified, and growing pipeline of product candidates in advanced-stage Phase 2 and Phase 3 studies. More information on Spectrum is available at www.sppirx.com.

Forward-Looking Statements

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, Spectrum's ability to identify, acquire, develop and commercialize a broad and diverse pipeline of late-stage clinical and commercial products, 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 the possibility that Spectrum’s existing and new drug candidates 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 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.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.

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