Spectrum Pharmaceuticals Expands Poziotinib Clinical Trial Into First-Line Therapy and Doses First Patient

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- Spectrum’s Phase 2 non-small cell lung cancer (NSCLC) study expanded to include two new cohorts for first-line NSCLC patients with EGFR or HER2 exon 20 insertion mutations
- Phase 2 study now includes four cohorts with each cohort being an independent study with pre-specified statistical hypotheses and statistical power
- First patient has been dosed in this expanded patient population

HENDERSON, Nev.--(BUSINESS WIRE)--Sep. 12, 2018-- 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 that it has initiated two new cohorts for first-line, locally advanced or metastatic non-small cell lung cancer (NSCLC) patients with EGFR or HER2 exon 20 insertion mutations in its current Phase 2 non-small cell lung cancer (NSCLC) clinical trial. Spectrum also announced that it has dosed the first patient in the expanded patient population.

“Given the exciting preliminary poziotinib clinical data in NSCLC patients with EGFR exon 20 mutations who have received prior systemic therapy, we are happy to extend our participation in Spectrum’s trial to explore poziotinib's activity in the first-line setting,” said Jonathan Goldman, M.D., Associate Professor of Hematology and Oncology, Associate Director of Drug Development and Director of Clinical Trials in Thoracic Oncology at UCLA Health. "Current available therapies for NSCLC patients with exon 20 insertion mutations have been shown to be minimally effective. We do not have good options for these patients as we do in other settings with actionable mutations. This clinical trial expansion is a welcome milestone for patients and physicians battling this disease.”

The poziotinib NSCLC clinical program for patients with EGFR or HER2 exon 20 mutations currently consists of a Phase 2 pivotal, Spectrum-sponsored, multi-center global study (ZENITH20) with active sites in the United States and future centers planned in Canada and Europe, and a Phase 2 investigator-initiated study at the University of Texas MD Anderson Cancer Center. Spectrum’s ZENITH20 study now includes four cohorts, with each cohort being an independent study with pre-specified statistical hypotheses and statistical power. The protocol amendment incorporating the two new cohorts was designed based on input from the FDA. The two previously-treated cohorts will enroll up to 87 patients each, and the two first-line cohorts will enroll up to 70 patients each. For each cohort, the primary endpoint is objective response rate; the secondary endpoints are disease control rate, duration of response, safety and tolerability; and the exploratory endpoints are progression-free survival and quality of life.

About Poziotinib

Poziotinib is a novel, orally administered Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor

(EGFR TKI) that inhibits the tyrosine kinase activity of EGFR (HER1) 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. Spectrum received an exclusive license to develop, manufacture, and commercialize worldwide excluding Korea and China from Hanmi Pharmaceuticals.

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 six 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 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 by law.

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