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## **Spectrum Pharmaceuticals Announces Initiation of a Multicenter Phase 2 Trial of Poziotinib in Non-Small Cell Lung Cancer (NSCLC) Patients with Exon 20 Insertion Mutation in EGFR or HER2**

- | **The study will evaluate Objective Response Rate (ORR) as the primary endpoint.**
- | **Objective Response Rate of 73% was observed in preliminary analysis of an ongoing Phase 2 study being conducted by Dr. John Heymach at the University of Texas MD Anderson Cancer Center. These data were presented earlier this month in Japan at the 18th IASLC World Conference on Lung Cancer.**
- | **Spectrum has worldwide rights to poziotinib, excluding Korea and China.**

HENDERSON, Nev.--(BUSINESS WIRE)-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biotechnology company with fully integrated commercial and drug development operations with a primary focus in Hematology and Oncology, announced today the initiation of a Phase 2 trial evaluating poziotinib in non-small cell lung cancer patients with an exon 20 insertion mutation in EGFR or HER2. The first patient has been enrolled and the Company expects to enroll patients at several leading cancer institutions in the United States.

"Following the promising preliminary data from the University of Texas MD Anderson Cancer Center's study, we are excited to launch this multicenter trial," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "Earlier this month, results presented at the 18th IASLC World Conference on Lung Cancer showed that poziotinib has the potential to address unmet needs of lung cancer patients with EGFR Exon 20 insertion mutations. The efficacy of first-generation tyrosine-kinase inhibitors has been found to be unsatisfactory in such patients, resulting in single digit response rates and a progression-free survival of around two months. We are grateful for the guidance the Food and Drug Administration has provided in designing this trial."

The goal of this Phase 2 trial is to evaluate both the efficacy and safety of poziotinib in patients with non-small cell lung cancer (NSCLC) that is locally advanced or metastatic and have an exon 20 insertion mutation in either EGFR or HER2. This trial will enroll up to 87 patients with EGFR exon 20 insertion mutations and up to 87 patients with HER2 exon 20 insertion mutations in several leading cancer institutions. The study will evaluate objective response rate (ORR) as the primary endpoint, and disease control rate (DCR), duration of response (DOR), and safety as secondary endpoints. In addition, progression-free survival (PFS) and quality of life (QoL) will be evaluated.

Poziotinib is a novel, oral pan-HER inhibitor that irreversibly blocks signaling through the Epidermal Growth Factor Receptor (EGFR, HER) family of tyrosine-kinase receptors, including HER1 (erbB1; EGFR), HER2 (erbB2), and HER4 (erbB4), and importantly, also HER receptor mutations; 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.

### **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](http://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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