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Spectrum Pharmaceuticals Announces Initiation of a Phase 2 Trial of Poziotinib in Non-Small Cell Lung Cancer Patients with EGFR Exon 20 Insertion Mutations

- | Encouraging results observed in patient with exon 20 insertion mutation treated with poziotinib on a compassionate basis.
- | Phase 2 trial will evaluate Objective Response Rate (ORR) as the primary endpoint.
- | Top-line results are expected before year-end.
- | Spectrum has worldwide rights to poziotinib, excluding Korea and China.

HENDERSON, Nev.--(BUSINESS WIRE)-- Spectrum Pharmaceuticals (NasdaqGS: SPPI), a biotechnology company with fully integrated commercial and drug development operations with a primary focus in Hematology and Oncology, today announced that the University of Texas MD Anderson Cancer Center initiated a Phase 2 trial of poziotinib in non-small cell lung cancer patients with EGFR exon 20 insertion mutations. This Phase 2 trial will evaluate Objective Response Rate (ORR) as the primary endpoint and is expected to yield preliminary results before year-end.

"We are excited to be collaborating with a prominent institution to continue to develop our potential best-in-class, novel, pan-HER inhibitor, poziotinib," said Rajesh C. Shrotriya, M.D., Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "Tumors with exon 20 mutations have generally not been responsive to several other EGFR inhibitors. However, poziotinib, due to its unique structure and characteristics, is hypothesized to inhibit cell growth of EGFR exon 20 insertions. Preclinical results from poziotinib are very encouraging, and poziotinib has the potential to be a transforming therapy for these patients who have few or no options and poor prognosis. We look forward to working closely with MD Anderson Cancer Center on this study."

"Patients who suffer from this rare cancer have very few options for treatment and a poor prognosis with median progression free survival (PFS) of less than 2 months," said John Heymach, M.D., Ph.D., Chairman, Professor, and David Bruton Junior Chair in Cancer Research, Department of Thoracic/Head and Neck Medical Oncology, The University of Texas MD Anderson Cancer Center. "Recently we saw promising preclinical results from poziotinib and based on our preclinical studies, drug screening, and computational modeling, we believe that poziotinib could potentially overcome steric hindrance of the drug binding pocket induced by the exon 20 insertion mutations. We have already seen encouraging results in a patient with this mutation who was recently treated with poziotinib on a compassionate basis. We look forward to further results from this trial later this year."

About Poziotinib

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. Currently, poziotinib is being investigated by Hanmi in several mid-stage trials in different solid tumor indications including HER2-positive breast cancer. (Phase 2 sponsored by National OncoVenture, a funding initiative by the Korean government's National Cancer Center).

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.

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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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