Spectrum Pharmaceuticals Announces Publication of Poziotinib Data in Nature Medicine

April 23, 2018

HENDERSON, Nev.--(BUSINESS WIRE)--Apr. 23, 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 a publication entitled, “Mechanisms and clinical activity of an EGFR and HER2 exon 20–selective kinase inhibitor in non–small cell lung cancer.” The publication appears in the April 23, 2018 online issue at https://www.nature.com/articles/s41591-018-0007-9 and will be published in a future print issue of Nature Medicine.

“We are honored to have data from poziotinib published in this prestigious journal,” said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. “The excitement around poziotinib is palpable among the medical community. For cancer patients that have exon 20 mutations, physicians have very few options. The publication shows that poziotinib has a strong potential to be a promising therapy for such patients. We are collaborating with the medical community, regulatory agencies and corporate partners to expedite the rapid development of this drug.”

The Nature Medicine publication summarizes the current preclinical and clinical data with poziotinib for EGFR and HER2 exon 20 mutations. MD Anderson utilized *in silico, in vitro,* and *in vivo* testing to model structural alterations induced by exon 20 mutations and identify potentially effective inhibitors. 3-D modeling indicated alterations restricted the size of the drug binding pocket, limiting the binding of large, rigid inhibitors. It was found that poziotinib, due to its small size and flexibility, can circumvent these steric changes, and is a potent inhibitor of the most common EGFR and HER2 exon 20 mutants. Poziotinib demonstrated greater activity than approved EGFR TKIs *in vitro* and in *EGFR* or *HER2* exon 20 mutant patient-derived xenograft models, and genetically engineered mouse models of NSCLC.

According to the Nature Medicine publication, the first 11 NSCLC patients with *EGFR* exon 20 mutations receiving poziotinib in MD Anderson’s Phase 2 clinical trial had a confirmed objective response rate of 64%. At the time of the publication, the median progression-free survival had not been reached, with a median follow up of 6.6 months. 55% of patients received a dose reduction, with the two most common adverse events being known EGFR inhibitor-related toxicities: skin rash and diarrhea. At the World Conference on Lung Cancer in October 2017, MD Anderson presented that all of the 11 patients had a radiologic improvement in their disease, and 8 out of the 11 patients had a partial response (73% objective response rate). In the Nature Medicine publication it was reported that 7 out of those 11 patients had confirmed partial response (64% objective response rate).

The MD Anderson Phase 2 clinical trial is nearing completion of enrollment in the EGFR cohort, and the Spectrum Phase 2 study is enrolling at approximately 20 centers in the United States today, with further study center expansion in the U.S. and other countries in progress.

About Poziotinib

Poziotinib is a novel, 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. Spectrum received exclusive license to develop, manufacture, and commercialize worldwide excluding Korea and China from Hanmi Pharmaceuticals. Poziotinib is currently being investigated by Spectrum and Hanmi in several mid-stage trials in multiple solid tumor indications.

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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20180423005964/en/

Source: Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals, Inc.
Shiv Kapoor, 702-835-6300
Vice President, Strategic Planning & Investor Relations
InvestorRelations@sppirx.com