September 28, 2017

Spectrum Pharmaceuticals Highlights Poziotinib Data in Lung Cancer to be Presented in an Oral Presentation at the 18th IASLC World Conference on Lung Cancer in Yokohama, Japan, October 15-18, 2017

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 the release of an abstract from a clinical study evaluating poziotinib in EGFR Exon 20 Mutant Non-Small Cell Lung Cancer (NSCLC) by scientists from The University of Texas MD Anderson Cancer Center, the sponsor of the trial. This abstract contains limited data as of the submission deadline of June 21, 2017. Additional data from their clinical experience and the ongoing Phase 2 study will be released in an oral presentation at the 18th International Association for the Study of Lung Cancer (IASLC) World Conference on Lung Cancer in Yokohama, Japan, October 15-18, 2017.

Wednesday, October 18th, 2017:

Abstract #	Type	Title	First Author/Presenting Author	Time
10369	Oral	The Preclinical and Clinical Activity of Poziotinib, a Potent, Selective Inhibitor of EGFR Exon 20 Mutant NSCLC	Elamin, Heymach	11:00 AM-11:10 AM JST

Abstract #10369: The Preclinical and Clinical Activity of Poziotinib, a Potent, Selective Inhibitor of EGFR Exon 20 Mutant NSCLC

Background

Approximately 10% of EGFR mutant NSCLCs have an insertion/mutation in exon 20 of EGFR resulting in primary resistance to currently available tyrosine kinase inhibitors (TKIs). We previously reported that the structural features of poziotinib could potentially enable it to circumvent the steric hindrance induced by exon 20 mutations. Here we further characterize the preclinical activity of poziotinib and report on initial clinical activity of poziotinib in patients EGFR exon 20 mutations from an ongoing phase II study.

Methods

We evaluated poziotinib activity in vitro using human NSCLC cell lines and the BAF3 model as well as several patient-derived xenograft (PDX) models and genetically engineered mouse models (GEMMs) of exon 20 insertion. We launched a phase 2 investigator-initiated trial of poziotinib in patients with metastatic NSCLC with EGFR exon 20 insertions (NCT03066206).

Results: In vitro poziotinib was approximately 100x more potent than osimertinib and 40x more potent than afatinib against a common panel of EGFR exon 20 insertions. Furthermore, it had ~65-fold greater potency against common exon 20 insertions compared with EGFR T790M mutations; 3rd generation inhibitors osimertinib, EGF816, and rociletinib were all significantly less potent for exon 20 mutations/insertions compared with T790M. in vivo poziotinib led to > 85% reduction in tumor burden in GEM models of EGFR exon 20 insertion (D770insNPG) NSCLC and the PDX model LU0387 (H773insNPH).

To date, 8 platinum-refractory patients with EGFR exon 20 insertion mutation metastatic NSCLC have been enrolled in the clinical trial and treated with poziotinib at a dose of 16 mg PO daily. Two patients have reached the first interval-imaging time point (at 8 weeks of therapy per protocol). Both patients exhibited dramatic partial response, with one patient reporting improvement in dyspnea and cough at one week of therapy. In this early stage of the study, one case of grade 3 paronchycia was observed. One additional platinum- and erlotinib-refractory patient with EGFR exon 20 insertion was treated with poziotinib on compassionate basis. The patient achieved partial response after three weeks

of treatment.

Conclusion: Poziotinib has selective activity against EGFR exon 20 mutations and potent activity in cell lines, PDX, and GEM models. Three platinum-refractory patients with EGFR exon 20 mutations have been treated thus far and are evaluable for response; all three had partial responses at the time of the initial scan. Updated data from the ongoing phase 2 clinical trial of poziotinib will be presented at the meeting.

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. Spectrum received exclusive license to develop, manufacture and commercialize worldwide excluding Korea and China from Hanmi Pharmaceuticals.

About the WCLC

The World Conference on Lung Cancer (WCLC) is the world's largest meeting dedicated to lung cancer and other thoracic malignancies, attracting over 6,000 researchers, physicians and specialists from more than 100 countries. The goal is to disseminate the latest scientific achievements; increase awareness, collaboration and understanding of lung cancer; and to help participants implement the latest developments across the globe. Organized under the theme of "Synergy to Conquer Lung Cancer," the conference will cover a wide range of disciplines and unveil several research studies and clinical trial results. For more information, visit http://wclc2017.iaslc.org/.

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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