Spectrum Pharmaceuticals Announces Release of Poziotinib Abstract as Part of the IASLC 19th World Conference on Lung Cancer

Sep 5, 2018

- The abstract reported new interim data from the EGFR cohort and, for the first time, the HER2 cohort in the MD Anderson Phase 2 trial
- In the EGFR cohort, an objective response rate of 58% and a disease control rate of 90% were reported
- In the HER2 cohort, an objective response rate of 50% and a disease control rate of 83% were reported
- Updated data will be presented in an oral session at the conference on September 24
- Spectrum will host a live webcast following the oral presentation

HENDERSON, Nev.--(BUSINESS WIRE)--Sep. 5, 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 new interim poziotinib data from the MD Anderson Phase 2 non-small cell lung cancer (NSCLC) study which appeared in an online abstract as part of the IASLC 19th World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer. The interim results, which include data from the EGFR cohort and, for the first time, the HER2 cohort, are preliminary and based on data through May 3, 2018. More robust and updated data will be presented in an oral session on September 24 at the conference in Toronto, Canada.

"These results add to a growing body of evidence supporting the role of poziotinib in patients with EGFR and HER2 exon 20 mutations, and are a real advance for these patients for whom no targeted therapies have been effective so far," said John Heymach, M.D., Ph.D., Chairman and Professor, Department of Thoracic/Head and Neck Medical Oncology, University of Texas, MD Anderson Cancer Center. "I am highly encouraged by these results and the evolution of poziotinib data. Our study is the single largest data set in this high unmet need patient population and I am excited to present updated data during an oral session at the IASLC World Conference on Lung Cancer."

Data appearing in the abstract were current as of May 3, 2018. 40 patients of the 50 patient EGFR cohort had data available for the efficacy analysis. In the 40 patients, poziotinib continued to show robust efficacy with an objective response rate (ORR) of 58% in this heavily pre-treated population. Median progression free survival (PFS) was 5.6 months (95%-CI 5.06-NA). The disease control rate was 90%. In the HER2 cohort the ORR was 50% and the disease control rate was 83%. The most common adverse events were skin-rash (27.5%), diarrhea (12.5%), and paronychia (7.5%). 45.0% of patients required dose reduction to 12mg, while 17.5% of patients required dose reduction to 8mg. Updated data will be presented at the conference and will include data into September.

"We are thrilled with the data presented in the abstract and look forward to a more robust data set on

September 24th," said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. "Additionally, we believe the treatment potential of poziotinib may go well beyond the previously treated lung cancer setting. We are actively expanding the poziotinib clinical program to explore poziotinib in new areas including first-line treatment of NSCLC, treatment of other solid tumors with EGFR or HER2 mutations, and combination therapies."

Spectrum Pharmaceuticals will be hosting a live webcast on September 24 following the oral presentation.

Abstract: A Phase II Trial of Poziotinib in EGFR and HER2 exon 20 Mutant Non-Small Cell Lung Cancer

Background

Insertions/mutations in exon 20 of EGFR and HER2 occur in ~1% and ~3% of all lung adenocarcinomas, respectively. These alterations are characterized by primary resistance to approved tyrosine kinase inhibitors (TKIs) with response rates of <12%. We have previously shown that exon 20 insertions restrict the size of the drug-binding pocket, limiting binding of large inhibitors. However, poziotinib can circumvent these steric changes and is a potent inhibitor of EGFR and HER2 exon 20 mutants (Robichaux et al. Nat Med). Herein, we report the results of an investigator-initiated study of poziotinib in EGFR and HER2 exon 20 mutant NSCLC (NCT03066206).

Methods

Patients ?18yrs with locally advanced/metastatic NSCLC bearing mutations/insertions in EGFR or HER2 exon 20 (except EGFR T790M) were eligible. Unlimited prior systemic and targeted therapies were permitted. Poziotinib 16mg PO daily was administered until progression, death, or withdrawal. The primary endpoint was objective response rate (ORR) based on RECIST v1.1. Response was evaluated every eight weeks. A Bayesian design was used with a plan to enroll patients in cohorts of 10 and to terminate the study if ORR was ?20%. Secondary endpoints included disease control rate (DCR); progression-free survival (PFS); overall survival; and safety.

Results

As of May 3, 2018, the planned EGFR cohort of 50 patients was fully enrolled, and 40 patients were evaluated for response. Median age was 55yrs (range 29-78). 65.1% of patients had received at least two prior lines of therapy for metastatic disease. 60% of patients had ?grade 3 adverse events; most common were skin-rash (27.5%), diarrhea (12.5%), and paronychia (7.5%). 45.0% of patients required dose reduction to 12mg, while 17.5% of patients required dose reduction to 8mg. One patient stopped the treatment due to grade 3 skin rash. The ORR at eight weeks was 58% (95%-CI 40.9-73.0) and the DCR was 90% (95%-CI 76.3-97.2). Among 23 patients who achieved partial response, 15 responses were confirmed, five responses were unconfirmed, and three patients are pending confirmation. Responses were observed in 8/13 (62%) patients that were previously treated with TKI. Median PFS was 5.6mo (95%-CI 5.06-NA). Furthermore, 13 patients were enrolled in the HER2 cohort. Observed toxicities were similar to the EGFR cohort except one case of grade 5 pneumonitis, assessed to be possibly drug related. Twelve patients were evaluated for response with an ORR of 50% (95% CI 21.1-78.9) at eight weeks and a DCR of 83%.

Conclusion

The trial exceeded the stopping boundary of ORR of 20%. In a heavily pre-treated population with EGFR and HER2 exon 20 mutant NSCLC, poziotinib provides a high ORR, an encouraging PFS, and a manageable toxicity profile.

Conference Call Details:

Monday, September 24, 2018 @ 4:30 p.m. Eastern/1:30 p.m. Pacific

Domestic: (877) 837-3910, Conference ID# 1993267
International: (973) 796-5077, Conference ID# 1993267

The conference call will also be webcast live. To access the webcast and additional documents related to the call, please visit the Investor Relations page of the Spectrum Pharmaceuticals website at http://investor.sppirx.com/events-and-presentations.

For interested individuals unable to join the call, a replay will be available from September 24, 2018 @ 7:00 p.m. ET/4:00 p.m. PT through October 1, 2018, until 7:30 p.m. ET/4:30 p.m. PT.

Domestic Replay Dial-In: (855) 859-2056, Conference ID# 1993267
International Replay Dial-In: (404) 537-3406, Conference ID# 1993267

About Poziotinib

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

The poziotinib NSCLC clinical program for patients with EGFR or HER2 exon 20 insertion mutations currently consists of a Phase 2 investigator-initiated study at The University of Texas MD Anderson Cancer Center and 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.

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 Statements

Certain statements in this press release may constitute “forward-looking statements” within the meaning

of the United States Private Securities Litigation Reform Act of 1995, as amended to date. These forward-looking statements relate to a variety of matters, including, without limitation, statements that relate to Spectrum's business and its future, including the role of poziotinib in treating NSCLC patients with EGFR and HER2 exon 20 mutations and the advancement in treatment of such patients, the results of the data scheduled to be presented on September 24, the treatment potential of poziotinib to go beyond the previously treated lung cancer setting, including other solid tumor indications, Spectrum's ability to expand the poziotinib clinical program to explore poziotinib in new areas, Spectrum's ability to expand the NSCLC clinical program to Canada and Europe, the future potential of Spectrum's existing drug pipeline and other statements that are not purely statements of historical fact.These forward-looking statements are made on the basis of the current beliefs, expectations and assumptions of the management of Spectrum and are subject to significant risks and uncertainties. Investors are cautioned not to place undue reliance on any such forward-looking statements. All such forward-looking statements speak only as of the date they are made, and Spectrum undertakes no obligation to update or revise these statements, whether as a result of new information, future events or otherwise. Although Spectrum believes that the expectations reflected in these forward-looking statements are reasonable, these statements involve many risks and uncertainties that may cause actual results to differ materially from what may be expressed or implied in these forward-looking statements, including, without limitation, the uncertainties inherent in new product development, including clinical trial results and additional analysis of existing clinical data, the possibility that poziotinib may not ultimately prove to be safe or effective, the possibility that Spectrum's 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 poziotinib, if approved, may not be more effective, safer or more cost efficient than competing drugs, and Spectrum's dependence on third parties for clinical trials, manufacturing, distribution and quality control. For a further discussion of risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of Spectrum in general, see the risk disclosures in the Annual Report on Form 10-K of Spectrum for the year ended December 31, 2017, as amended, and in subsequent reports on Forms 10-Q and 8-K and other filings made with the SEC by Spectrum.

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