Spectrum Pharmaceuticals Announces Release of Updated Poziotinib Data From MD Anderson Phase 2 Study in Non-Small Cell Lung Cancer Patients

Sep 24, 2018

- Data were featured in an oral presentation at the IASLC 19th World Conference on Lung Cancer
- Spectrum will host a live webcast today at 4:30 p.m. Eastern/1:30 p.m. Pacific

HENDERSON, Nev.--(BUSINESS WIRE)--Sep. 24, 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 preliminary poziotinib data from the University of Texas, MD Anderson Cancer Center Phase 2 non-small cell lung cancer (NSCLC) study which were released today during an oral presentation at the IASLC 19th World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer. The MD Anderson study is the single largest data set of patients with an exon 20 mutation in EGFR or HER2.

"There are currently no approved targeted therapies for this hard-to-treat population," 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. "For this reason, it is especially exciting to observe that poziotinib is highly active, with a manageable safety profile, in these heavily pre-treated patients. The study is ongoing with nineteen EGFR patients remaining on treatment, six of which have been on drug for longer than a year. Poziotinib may offer a much needed option to NSCLC patients with exon 20 mutations in EGFR or HER2."

In the interim analysis presented at the WCLC, the following observations were made:

- This phase II study demonstrates high anti-tumor activity for poziotinib in metastatic, heavily pretreated EGFR exon 20 mutant NSCLC, a group for which no targeted agents have proven effective to date (other than patients bearing T790M or S768I mutations) with best response of PR in 55% of evaluable patients (43% confirmed ORR to date; 19 patients remain on treatment).
    - Median PFS 5.5m; durable responses observed with 6 treated for >1year thus far.
    - Compares favorably to historical ORR rates of <8% approved TKIs and <19% for standard of care 2L agents (docetaxel, PD-1/PD-L1 inhibitors).
- Significant activity also observed in HER2 exon 20-mutant NSCLC with initial responses observed in 50% (6/12) evaluable patients and median PFS 5.1m.
- EGFR-related toxicities (including rash, diarrhea, & paronychia) were manageable and required dose reductions in 60%. Discontinuation due to poor tolerance was rare (3%).
- Encouraging activity has prompted a confirmatory, international, multicenter study in EGFR and HER2 exon 20 mutant NSCLC patients which is currently enrolling (NCT03318939), including a first-line cohort, and development of a separate pan-tumor basket study.

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. The overall poziotinib clinical development program is focused on four pillars, including previously treated NSCLC, first-line treatment of NSCLC, combination therapy and treatment of other solid tumors.

Following the oral presentation of data, Spectrum Pharmaceuticals will be hosting a live webcast featuring Dr. John Heymach.

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.

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 treatment potential of poziotinib to consistently deliver high response and disease control rates for NSCLC patients with EGFR and HER2 exon 20 mutations, the likelihood and timing of obtaining BTD for poziotinib, Spectrum's ability to execute on its clinical development strategy of establishing a second and first-line position in NSCLC, the treatment potential of poziotinib to go beyond the previously treated lung cancer setting, including other solid tumor indications and combination therapy, 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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