Spectrum Pharmaceuticals Announces Publication of Positive Poziotinib Data in Cancer Cell

October 4, 2019

Publication highlights pre-clinical and clinical activity of poziotinib in lung cancer patients with HER2 mutations and potential future applications using monotherapy and combinations in many different mutated cancers

HENDERSON, Nev.--(BUSINESS WIRE)--Oct. 4, 2019-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, announced today a publication from The University of Texas, MD Anderson Cancer Center entitled, "Pan-Cancer Landscape and Functional Analysis of *ERBB2* Mutations Identifies Poziotinib as a Clinically Active Inhibitor and Enhancer of T-DM1 Activity." The publication appears in the Oct 3, 2019 online issue at https://www.cell.com/cancer-cell/fulltext/S1535-6108(19)30384-8 and will be published in a future print issue of *Cancer Cell*.

"Our analysis is the largest ever conducted to understand the diversity of HER2 mutations across 25 cancer types, including more than 200,000 patients from cBioPortal, MD Anderson, Foundation Medicine, and Guardant Health," said John Heymach, M.D., Ph.D., Chairman and Professor, Department of Thoracic/Head and Neck Medical Oncology at MD Anderson. "In our pre-clinical study of 11 EGFR/HER2 tyrosine kinase inhibitors, poziotinib was the most potent HER2 mutant-selective TKI tested, and in our initial clinical cohort we found that poziotinib was highly active in NSCLC patients with HER2 exon 20 mutations. Our findings indicate that poziotinib may be well-suited to target HER2 mutations with a constricted binding pocket. Furthermore, we have determined from pre-clinical data that poziotinib is synergistic with a HER2-targeting antibody-drug conjugate, providing a rationale for combinations to move forward into the clinic."

Spectrum is studying poziotinib in ZENITH20, a company-sponsored, open-label, single-arm, multi-center, global Phase 2 study of non-small cell lung cancer (NSCLC) patients.

"The publication of these latest research findings from MD Anderson on poziotinib in the journal Cancer Cell continues to strengthen the evidence of the potential benefit of poziotinib in the treatment of lung cancer," said Joe Turgeon, President and CEO, Spectrum Pharmaceuticals. "This quarter, we plan to disclose topline data from the first cohort of the company-sponsored ZENITH20 study, which is analyzing previously-treated NSCLC patients with exon 20 mutations in EGFR. By mid-2020 we also expect topline data from cohort 2, which is studying previously treated NSCLC patients with exon 20 mutations in HER2. We look forward to the top line data from the ZENITH20 study this quarter and continue to expand the poziotinib program, based on emerging science, to other areas of opportunity."

About Poziotinib

Poziotinib is a novel, oral epidermal growth factor receptor tyrosine kinase inhibitor (EGFR TKI) that inhibits the tyrosine kinase activity of EGFR (HER1) as well as HER2 and HER4. Importantly this 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 from Hanmi Pharmaceuticals to develop, manufacture, and commercialize poziotinib worldwide, excluding Korea and China. Poziotinib is currently being investigated by Spectrum and Hanmi in several trials in multiple solid tumors.

About ZENITH20

The ZENITH20 study consists of seven cohorts of NSCLC patients. Cohorts 1 (EGFR) and 2 (HER2) have completed enrollment of previously-treated NSCLC patients with exon 20 mutations. Cohort 3 (EGFR) and 4 (HER2) are currently enrolling first-line NSCLC patients with exon 20 mutations. Cohorts 1- 4 are each independently powered for a pre-specified statistical hypothesis and the primary endpoint is objective response rate (ORR). In July 2019, three new cohorts were added to the ZENITH20 study that are all currently enrolling patients. Cohort 5 includes previously treated or treatment-naïve NSCLC patients with EGFR or HER2 exon 20 insertion mutations. Cohort 6 includes NSCLC patients with classical EGFR mutations who progressed while on treatment with first-line osimertinib and developed an additional EGFR mutation. Cohort 7 includes NSCLC patients with a variety of less common mutations in EGFR or HER2 exons 18-21 or the extracellular or transmembrane domains.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a biopharmaceutical company focused on acquiring, developing, and commercializing novel and targeted drug products, with a primary focus in hematology and oncology. Spectrum has a strong track record of successfully executing across the biopharmaceutical business model, from in-licensing and acquiring differentiated drugs, clinically developing novel assets, successfully gaining regulatory approvals and commercializing in a competitive healthcare marketplace. Spectrum has a late-stage pipeline with novel assets that serve areas of unmet need. This pipeline has the potential to transform the company in the near future.

Notice Regarding 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 Company's ability to advance development of its late-stage pipeline assets, the ability of poziotinib to meet currently unaddressed medical needs and the size of the potential markets, the timing of the results of cohort 1 and cohort 2 in Spectrum's ZENITH20 study, the future potential of Spectrum's existing drug pipeline, the progression of the poziotinib development program 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 that could cause actual results to differ materially from what may be expressed or implied in these forward-looking statements. Risks that could cause actual results to differ include, but are not limited to, the uncertainties inherent in new product development, including clinical trial results and additional analysis of existing pre-clinical and clinical data, the possibility that Spectrum's new and existing drug candidates, including poziotinib, may not ultimately prove to be safe or effective, the possibility that Spectrum's new and existing drug candidates, if approved, may not be more effective, safer, or more cost efficient than competing drugs, 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. 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, 2018, and in subsequent reports on Forms 10-Q and 8-K and other filings made with the SEC by Spectrum.

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