Spectrum Announces Expansion of the Poziotinib Clinical Program

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- Recent pre-clinical data supports development of poziotinib for osimertinib resistance, as well as atypical mutations.
- Three new cohorts are currently open to patient enrollment in the ZENITH20 trial: Cohort 5 (Expansion Study), Cohort 6 (EGFR osimertinib failures), and Cohort 7 (Atypical EGFR or HER2 mutations).
- Topline results from cohort 1 (previously treated NSCLC patients with EGFR exon 20 insertion mutations) are expected in Q4 2019.

HENDERSON, Nev.--(BUSINESS WIRE)--Jul. 22, 2019-- Spectrum Pharmaceuticals, Inc. (NASDAQ-GS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, announced today that it is further expanding its poziotinib clinical program by adding three new cohorts in its cornerstone poziotinib clinical trial, ZENITH20. The ZENITH20 trial is an open-label, multi-center, global phase 2 trial with sites in the U.S., Canada, and Europe, evaluating the impact of poziotinib treatment on non-small cell lung cancer (NSCLC) patients.

“With increased use of osimertinib as the treatment of first-line NSCLC patients with classical EGFR mutations, the emergence of osimertinib resistance is a growing occurrence in this setting,” said Jeffrey Clarke, MD, Assistant Professor of Medicine at Duke University Hospital/Duke Cancer Institute. “One resistance pattern that is emerging is through the development of an additional EGFR mutation and recent pre-clinical publications suggest that poziotinib may be active against EGFR-dependent resistance mechanisms. Exploring the role of poziotinib as an investigational therapeutic option for those patients who fail first-line osimertinib and for those who have de novo atypical mutations is an exciting development and requires clinical confirmation.”

Three new cohorts are currently open to patient enrollment in the ZENITH20 trial. 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. All three new cohorts are now open to enrollment.

“Strong preclinical evidence led to the development of poziotinib in exon 20 mutations. Similarly guided by elegant science, we are expanding the poziotinib program to evaluate its potential in patients with additional difficult to treat mutations in non-small cell lung cancer,” said Francois Lebel, M.D., F.R.C.P.C., Chief Medical Officer of Spectrum Pharmaceuticals. “The emergence of osimertinib resistance and the lack of effective treatments for atypical mutations are growing treatment voids that poziotinib may be uniquely suited to fill.”

The ZENITH20 trial now consists of seven cohorts of NSCLC patients. Cohorts 1 (EGFR) and 2 (HER2) are in previously-treated NSCLC setting and are fully enrolled. Cohort 3 (EGFR) and 4 (HER2) are in the first-line setting and are currently enrolling patients. Cohorts 1- 4 are each independently powered for a pre-specified statistical hypothesis and the primary endpoint is objective response rate (ORR). Additional endpoints include duration of response (DOR), disease control rate (DCR), progression-free survival (PFS), and safety. Topline results from cohort 1 are expected in Q4 2019.

“Our poziotinib clinical program is aggressive, proactive and designed to provide us with a full understanding of poziotinib's potential impact on non-small cell lung cancer,” said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. “Thus far, we are pleased with the rapid recruitment and are eagerly awaiting our first topline readout in patients with previously treated EGFR exon 20 insertion mutations in the fourth quarter of this year.”

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.

AboutSpectrum 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 clinical trial, 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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