



Spectrum Announces Poziotinib ZENITH20 Trial HER2 Cohort (Cohort 2) Has Reached Enrollment Target

May 28, 2019

- Enrollment of cohort 2 was completed six months ahead of schedule
- Cohort 2 had a target enrollment of 87 NSCLC patients with HER2 exon 20 insertion mutations
- Topline results from cohort 2 are expected in mid 2020
- Topline results from cohort 1, which enrolled NSCLC patients with EGFR exon 20 insertion mutations, are expected in Q4 2019

HENDERSON, Nev.--(BUSINESS WIRE)--May 28, 2019-- Spectrum Pharmaceuticals, Inc. (NASDAQ-GS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, announced today the full enrollment of cohort 2 (N = 87) for previously treated non-small cell lung cancer (NSCLC) patients with HER2 exon 20 insertion mutations. Topline results from this cohort are expected by mid 2020. This is the second cohort that has met enrollment target in Spectrum's ZENITH20 trial – an open-label, multi-center, global phase 2 trial evaluating NSCLC patients with EGFR or HER2 exon 20 insertion mutations.

"Our global poziotinib development program is multifaceted and progressing rapidly, which speaks to the high unmet need for patients with this type of lung cancer," said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. "Topline results from cohort 1 in EGFR patients are expected to be available later this year, and are intended to provide the data for regulatory submission. Our goal at Spectrum is to develop novel therapies to serve patients with high unmet medical need, and we are diligently pursuing this goal with our poziotinib program."

The ZENITH20 trial consists of four cohorts of NSCLC patients with EGFR or HER2 exon 20 insertion mutations, with each cohort independently powered for a pre-specified statistical hypothesis. There are two cohorts in the previously-treated NSCLC setting, cohorts 1 (EGFR) and 2 (HER2), and two in the first-line setting, cohorts 3 (EGFR) and 4 (HER2). 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.

"The ZENITH20 trial is a critically important investigation for NSCLC patients harboring exon 20 insertion mutations as these patients have a poor prognosis and very limited treatment options," said Francois Lebel, M.D., F.R.C.P.C., Chief Medical Officer of Spectrum Pharmaceuticals. "A new and targeted treatment is urgently needed. Our brisk enrollment rates are very encouraging for such rare mutations and a strong testimony to the strength of our team."

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. The full poziotinib targeted therapy clinical program is focused on four development areas for EGFR and HER2 mutations, including previously treated NSCLC, first-line NSCLC, treatment of other solid tumors and combination therapy.

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 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 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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