Spectrum Pharmaceuticals Provides Pipeline Update on Late Stage Programs

December 26, 2019

HENDERSON, Nev.--(BUSINESS WIRE)--Dec. 26, 2019-- Spectrum Pharmaceuticals, Inc. (NASDAQ-GS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, today reported that its pre-specified primary endpoint in its Phase 2 clinical trial evaluating poziotinib in previously treated non-small cell lung cancer (NSCLC) patients with EGFR exon 20 insertion mutations was not met in Cohort 1. The company also announced that the Biologics License Application (BLA) for ROLONTIS® (eflapegrastim) was accepted for review by the U.S. Food and Drug Administration (FDA) and set a Prescription Drug User Fee Act (PDUFA) date of October 24, 2020.

The ZENITH20 trial's Cohort 1 enrolled a total of 115 patients who received 16 mg/day of poziotinib. The intent-to-treat analysis showed that 17 patients had a response (by RECIST) and 62 patients had stable disease for a 68.7% disease control rate (DCR). The confirmed objective response rate (ORR) was 14.8% (95% Confidence Interval (CI) 8.9%-22.6%). The median duration of response was 7.4 months. The safety profile was in-line with other second-generation EGFR tyrosine kinase inhibitors.

Joe Turgeon, President and CEO of Spectrum Pharmaceuticals said, "While the response rate of Cohort 1 in this trial was lower than we expected, the positive signals observed for this cohort provide support for the continued clinical evaluation of poziotinib in this patient population with significant unmet medical need. We look forward to providing read outs from Cohorts 2 and 3 in 2020, and plan to provide an update on the overall program strategy during the first quarter of 2020 after a full evaluation of the data from Cohort 1 is completed."

The ZENITH20 trial is made up of 7 independent cohorts. Cohorts 1 - 4 are each independently powered for a pre-specified statistical hypothesis with a primary endpoint of ORR. Cohorts 5 - 7 are exploratory studies. The futility analysis has been completed for Cohorts 2 and 3 which met their minimum threshold of responses to continue. The company expects to report results for these cohorts in 2020. Cohorts 4, 5, 6 and 7 are continuing per protocol.

"In Cohort 1, poziotinib has shown unequivocal biologic activity. Although we are disappointed by the ORR, we are highly encouraged by other measures including the disease control rate, the duration of response and the predictable safety profile," said Francois Lebel, M.D., Chief Medical Officer of Spectrum Pharmaceuticals. "A full review of Cohort 1 is underway and we plan to present the data at a future medical meeting."

The company also announced today that the FDA has accepted for review the BLA for ROLONTIS for the treatment of chemotherapy-induced neutropenia. The PDUFA target action date for the ROLONTIS BLA has been set for October 24, 2020.

"If approved, ROLONTIS could be the first novel granulocyte colony-stimulating factor (G-CSF) available to healthcare providers in over 15 years," said Joe Turgeon. "We have confidence in the future of ROLONTIS and are looking forward to potentially competing in this multibillion-dollar market."

The BLA for ROLONTIS is supported by data from two successful large pivotal Phase 3 clinical trials, ADVANCE (conducted under a SPA) and RECOVER. These trials evaluated the safety and efficacy of ROLONTIS in a total of 643 early-stage breast cancer patients for the treatment of neutropenia due to myelosuppressive chemotherapy. In both trials, ROLONTIS demonstrated the pre-specified hypothesis of non-inferiority (NI) in duration of severe neutropenia (DSN) and a similar safety profile to pegfilgrastim. ROLONTIS also demonstrated non-inferiority (NI) to pegfilgrastim in the DSN across all 4 cycles of chemotherapy (all NI $p<0.0001$) in both trials.

About Poziotinib

Poziotinib is a novel, oral 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 holds an 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 mid-stage trials in multiple solid tumor indications.

About ROLONTIS and the ADVANCE and RECOVER Clinical Trials

The ROLONTIS ADVANCE trial was a Phase 3, multicenter, randomized, active-controlled, open label trial that enrolled 406 early-stage breast cancer patients, who received docetaxel and cyclophosphamide chemotherapy every 21 days for four cycles. Patients were randomized in a 1:1 ratio to receive eflapegrastim (n=196) or pegfilgrastim (n=210). The primary endpoint was the duration of severe neutropenia (DSN) in Cycle 1 of absolute neutrophil count [ANC] <0.5×109/L, as measured by ANC. Secondary endpoints included the DSN in Cycles 2, 3 and 4, time to ANC recovery, depth of ANC nadir and incidence of febrile neutropenia at Cycle 1. Patients with early stage breast cancer were treated on Day 1 of each of the four cycles with (adjuvant/neo-adjuvant) docetaxel and cyclophosphamide. On Day 2 of each cycle, patients received a single dose of either eflapegrastim or pegfilgrastim subcutaneously. The ADVANCE trial was conducted under a special protocol assessment (SPA) with the FDA.

The RECOVER trial was a Phase 3, multicenter, randomized, active-controlled, open label trial that enrolled 237 breast cancer patients who received docetaxel and cyclophosphamide chemotherapy every 21 days. Patients were randomized in a 1:1 ratio to receive eflapegrastim (n=118) or pegfilgrastim (n=119). The primary endpoint was the duration of severe neutropenia (DSN) in Cycle 1 of absolute neutrophil count [ANC] <0.5×109/L, as measured by ANC. Secondary endpoints included the DSN in Cycles 2, 3 and 4, time to ANC recovery, depth of ANC nadir and incidence of febrile neutropenia in Cycle 1. Patients with early stage breast cancer were treated on Day 1 of each of the four cycles with (adjuvant/neo-adjuvant) docetaxel and cyclophosphamide. On Day 2 of each cycle, patients received a single dose of either eflapegrastim or pegfilgrastim subcutaneously.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a biopharmaceutical company focused on acquiring, developing, and commercializing novel and targeted oncology therapies. 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. For additional information on Spectrum Pharmaceuticals please visit www.sppirx.com.

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 treatment potential of poziotinib for NSCLC patients with EGFR and HER2 exon 20 mutations, as well as for other solid tumor indications and combination therapy, the success and timing of Spectrum's clinical trials generally, including the results of subgroups and Spectrum's ability to meet secondary endpoints in Cohort 1 and the results from Cohorts 2 through 7 of the ZENITH20 study, the likelihood of success and timing of the Company's BLA submission to the U.S. Food and Drug Administration for ROLONTIS, the timing of and Spectrum's ability to execute on its clinical development strategy for poziotinib, including establishing a second and first-line position in NSCLC, the potential of the Company's FIT Platform molecules in the interferon space, the future potential of Spectrum's existing drug pipeline, including ROLONTIS, 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, Spectrum's available cash and cash equivalents, 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, Spectrum's ability to obtain and maintain intellectual property protection on its product candidates, the possibility that poziotinib, if approved, may not be more effective, safer or more cost efficient than competing drugs, the market acceptance of and availability of reimbursement for Spectrum's products, 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, 2018, 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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