Spectrum Pharmaceuticals Announces Integrated Results from Two Phase 3 ROLONTIS® (eflapegrastim) Trials Being Presented at the ASCO Annual Meeting

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- Integrated efficacy and safety results in 643 patients were consistent with individual trial results (ADVANCE and RECOVER)
- The integrated data demonstrated that eflapegrastim provided an absolute risk reduction of severe neutropenia of 6.5% compared to pegfilgrastim in Cycle 1

HENDERSON, Nev.--(BUSINESS WIRE)--Jun. 2, 2019-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biotechnology company with a primary focus in hematology and oncology, today announced integrated analysis results from two Phase 3 clinical trials of ROLONTIS. ROLONTIS is a long-acting granulocyte colony-stimulating factor (G-CSF) being studied as a treatment for neutropenia in patients undergoing myelosuppressive cytotoxic chemotherapy.

The analysis found that integrated efficacy and safety data from the two identically designed Phase 3 trials – ADVANCE and RECOVER – were consistent with results from the individual trials, demonstrating that ROLONTIS was non-inferior to pegfilgrastim in the reduction of duration of severe neutropenia (DSN) in all four cycles of treatment. The summary was presented today during a poster session at the American Society of Clinical Oncology 2019 Annual Meeting in Chicago.

“These integrated analyses confirm non-inferiority in efficacy and a similar safety profile between eflapegrastim and pegfilgrastim across all cycles of treatment, including a 95 percent confidence interval of the difference in the DSN below zero in favor of ROLONTIS in the first cycle of treatment,” said Lee Schwartzberg, M.D., FACP, lead investigator, executive director, University of Tennessee West Cancer Center. “Additionally, the integrated data demonstrated that eflapegrastim provided an absolute risk reduction of severe neutropenia of 6.5 percent compared to pegfilgrastim in Cycle 1. The incidence of febrile neutropenia was low and similar between treatment arms. Adverse events, irrespective of causality and grade, were also similar between the treatment arms. These data strengthen our understanding of the clinical profile of eflapegrastim and help establish it as a possible new supportive care treatment option for patients undergoing myelosuppressive chemotherapy.”

Integrated data derived from the two Phase 3 clinical trials, demonstrated that in Cycle 1, the mean DSN±SD was 0.24±0.581 days for ROLONTIS (n=314) and 0.36±0.789 days for pegfilgrastim (n=329), demonstrating non-inferiority ($p<0.0001$). The non-inferiority of ROLONTIS for DSN was maintained across all four treatment cycles (all $p<0.0001$). The ROLONTIS arm had an absolute risk reduction of severe neutropenia of 6.5% (95% CI: 0.2%, 13%) versus pegfilgrastim in Cycle 1. Absolute risk reduction was defined as the difference in the percentage of patients who experienced severe neutropenia (ROLONTIS 17.5%; pegfilgrastim 24%). Febrile neutropenia (3.2% vs. 3%; p=NS) and neutropenic complications (5.7% vs. 5.8%; p=NS) were similar between the ROLONTIS and pegfilgrastim arms. Integrated safety data presented today also showed that the adverse events in general, regardless of causality, were not significantly different between the two treatment arms.

“Neutropenia remains a significant complication for people undergoing myelosuppressive chemotherapy, potentially causing hospitalizations and delays in much needed cancer treatment,” said Francois Lebel, M.D., F.R.C.P.C., chief medical officer, Spectrum Pharmaceuticals. “ROLONTIS is the first rhG-CSF innovation in over 15 years. The integrated analysis results, which included 643 patients combined, demonstrated reproducible efficacy and an acceptable safety profile. We look forward to potentially providing a new therapy to the patients and physicians managing chemotherapy-induced neutropenia in the near future.”

Spectrum Pharmaceuticals is currently working on a revised Biologics License Application (BLA) to submit to the FDA.

About ADVANCE

The ADVANCE trial is 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 ROLONTIS or pegfilgrastim (eflapegrastim n=196; pegfilgrastim n=210). The primary trial endpoint was the DSN (absolute neutrophil counts [ANC] $<0.5\times10^9$/L) in Cycle 1 of chemotherapy, based on central laboratory assessment of ANC over the 21-day cycle. 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 stage I to stage IIIA 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 subcutaneous dose of either eflapegrastim 13.2 mg/0.6 mL (3.6 mg G-CSF) or pegfilgrastim (6 mg) in a 1:1 ratio.

About RECOVER

The RECOVER trial is 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 ROLONTIS (n=118) or pegfilgrastim (n=119). The primary trial endpoint was the DSN in Cycle 1 of chemotherapy (absolute neutrophil count [ANC] <0.5×10^9/L), based on central laboratory assessment of ANC over a 21-day cycle. There were a total of four cycles evaluated in this trial. 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 stage I to stage IIIA 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 subcutaneous dose of either eflapegrastim 13.2 mg/0.6 mL (3.6 mg G-CSF) or pegfilgrastim (6 mg) in a 1:1 ratio.

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 ROLONTIS to meet currently unaddressed medical needs and the size of the potential market, the timing of the results of the clinical trials run by Spectrum, the future potential of Spectrum's existing drug pipeline, the timing of the BLA filing with the FDA, the availability of therapies related to ROLOTINIS 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 ROLONTIS, 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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