Spectrum Pharmaceuticals Announces Submission to the U.S. Food and Drug Administration of Updated Biologics License Application for ROLONTIS®

October 24, 2019

ROLONTIS BLA filing is based on two large pivotal randomized controlled studies that met all primary and secondary endpoints.

ROLONTIS is a novel, long-acting granulocyte colony-stimulating factor (G-CSF) seeking an indication for the treatment of neutropenia in patients receiving myelosuppressive anti-cancer drugs.

HENDERSON, Nev.--(BUSINESS WIRE)--Oct. 24, 2019-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biotechnology company with a primary focus in hematology and oncology, announced today that the company submitted an updated Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for ROLONTIS (eflapegrastim).

The BLA for ROLONTIS is supported by data from two identically designed Phase 3 clinical trials, ADVANCE and RECOVER, which evaluated the safety and efficacy of ROLONTIS in 643 early-stage breast cancer patients for the treatment of neutropenia due to myelosuppressive chemotherapy. In both studies, 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 to pegfilgrastim in the DSN across all 4 cycles (all NI $p<0.0001$) in both studies.

“We have submitted a robust package to the FDA that incorporates strong clinical data and addresses previously communicated FDA requests relating to manufacturing processes,” said Joe Turgeon, President and CEO of Spectrum. “ROLONTIS could be the first novel G-CSF available to healthcare providers in over 15 years and, if approved, we are looking forward to competing in this multibillion-dollar market.”

In March 2019, Spectrum voluntarily withdrew the ROLONTIS BLA that it filed with the FDA in 2018. The updated BLA filed today includes additional information in the Chemistry, Manufacturing and Controls (CMC) section.

About ADVANCE

The 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 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, 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 with four cycles of adjuvant/neo-adjuvant docetaxel and cyclophosphamide. On Day 2 of each cycle, patients received a single dose of either eflapegrastim 13.2 mg/0.6 mL (3.6 mg G-CSF) or pegfilgrastim (6 mg) subcutaneously. ADVANCE was conducted under a special protocol assessment (SPA) with the FDA.

About RECOVER

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 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. 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 dose of either eflapegrastim 13.2 mg/0.6 mL (3.6 mg G-CSF) or pegfilgrastim (6 mg) subcutaneously.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a biopharmaceutical company focused on acquiring, developing, and commercializing novel and targeted 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

This press release may contain forward-looking statements regarding future events and the future performance of Spectrum Pharmaceuticals that involve risks and uncertainties that could cause actual results to differ materially. These statements are based on management's current beliefs and expectations. These statements include, but are not limited to, statements that relate to Spectrum’s business and its future, including certain company milestones, Spectrum's ability to identify, acquire, develop and commercialize a broad and diverse pipeline of late-stage clinical and commercial products, the timing and results of FDA decisions, and any statements that relate to the intent, belief, plans or expectations of Spectrum or its management, or that are not a statement of historical fact. Risks that could cause actual results to differ include the possibility that Spectrum’s existing and new drug candidates may not prove safe or effective, the possibility that our existing and new applications to the FDA and other regulatory agencies may not receive approval in a timely manner or at all, the possibility that our existing and new drug candidates, if approved, may not be more

effective, safer or more cost efficient than competing drugs, the possibility that our efforts to acquire or in-license and develop additional drug candidates may fail, our dependence on third parties for clinical trials, manufacturing, distribution and quality control 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.

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