Spectrum Pharmaceuticals Announces Results from the RECOVER Phase 3 Study of ROLONTIS® (eflapegrastim) at the 2018 SABCS Annual Meeting

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- Primary endpoint of non-inferiority in the Duration of Severe Neutropenia (DSN) between ROLONTIS and pegfilgrastim was met
- No statistically significant differences in adverse event rates between treatment groups
- RECOVER is the second ROLONTIS Phase 3 study to meet the primary efficacy endpoint of non-inferiority in the DSN as compared to pegfilgrastim
- ROLONTIS is a novel, long-acting granulocyte colony-stimulating factor (G-CSF) that utilizes a proprietary platform technology to maximize the pharmacological activity of G-CSF, resulting in increased biological activity and a prolonged half-life
- ROLONTIS Biologics License Application (BLA) filing is expected by the end of the year

HENDERSON, Nev.--(BUSINESS WIRE)--Dec. 6, 2018-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biotechnology company with fully integrated commercial and drug development operations with a primary focus in hematology and oncology, today announced that data from the Phase 3 RECOVER clinical study was presented during the 2018 San Antonio Breast Cancer Symposium® (SABCS). These data confirm the efficacy and safety of ROLONTIS® (eflapegrastim) in reducing the Duration of Severe Neutropenia (DSN) in breast cancer patients treated with chemotherapy. ROLONTIS is a novel, long-acting granulocyte colony-stimulating factor (G-CSF) being studied as a treatment for neutropenia in patients undergoing treatment with myelosuppressive cytotoxic chemotherapy.

"Despite available treatments, neutropenia remains a critical issue for patients undergoing chemotherapy that puts them at risk for developing life threatening infections," said Lee Schwartzberg, MD, FACP, lead investigator, professor of medicine and division chief, hematology/oncology, University of Tennessee Health Science Center, and executive director, UT/West Cancer Center. "The robust data from both Phase 3 studies demonstrate that ROLONTIS has the potential to be a valuable option in the management of neutropenia for patients undergoing treatment with chemotherapeutic agents."

The data released yesterday in a poster presentation from the ROLONTIS Phase 3 RECOVER study (n=237) showed that in Cycle 1, the mean DSN±SD was 0.31±0.688 days for ROLONTIS and 0.39±0.949 days for pegfilgrastim, demonstrating non-inferiority ($p<0.0001$). The non-inferiority of ROLONTIS for DSN was maintained across all four treatment cycles (all ($p<0.0001$)). Incidence of severe neutropenia was 20 percent versus 24 percent in the eflapegrastim and pegfilgrastim arms respectively, with a relative risk reduction of 14 percent in favor of eflapegrastim. There were no statistically significant differences on secondary endpoints such as time to absolute neutrophil count (ANC) recovery, depth of ANC nadir, and incidence of febrile neutropenia between treatment arms across all cycles. None of the ?Grade 3 study drug related adverse events (AE) occurred in >2% of the patients and included

hematologic and bone pain related AEs in both arms.

The RECOVER trial is the second ROLONTIS Phase 3 study to meet the primary efficacy endpoint of non-inferiority in mean DSN. Results from ADVANCE, the first ROLONTIS Phase 3 study, were announced at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting and presented at the Multinational Association in Supportive Care in Cancer Annual Meeting (MASCC) earlier this year.

“The RECOVER study is the second Phase 3 study to confirm non-inferiority data and comparable safety profile between ROLONTIS and the current standard of care,” said Joe Turgeon, chief executive officer of Spectrum Pharmaceuticals. “Data from both studies, which enrolled 643 patients combined, will be used to support the BLA filing which is expected to be submitted by the end of the year. If approved, we look forward to having a unique opportunity to launch and compete in this large market with the first novel G-CSF in more than 15 years.”

About RECOVER

The RECOVER study is a Phase 3, randomized, open-label, active-controlled, multicenter study 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 either ROLONTIS (n=118) or pegfilgrastim (n=119). The primary study endpoint was the DSN in Cycle 1 of chemotherapy (absolute neutrophil count [ANC] <0.5×109/L), based on central laboratory assessment of ANC over a 21 day cycle. There were a total of four cycles evaluated in this study. 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 one. Patients with stage I to stage IIIA breast cancer were treated on day one of each of the four cycles with adjuvant/neo-adjuvant docetaxel and cyclophosphamide. On day two of each cycle, patients received a single subcutaneous dose of either eflapegrastim 13.2 mg/0.6 mL (equivalent to 3.6 mg G-CSF) or pegfilgrastim (6 mg).

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a leading biotechnology company focused on acquiring, developing, and commercializing drug products, with a primary focus in hematology and oncology. Spectrum currently markets seven hematology/oncology drugs, and has an advanced stage pipeline that has the potential to transform the company. Spectrum's strong track record for in-licensing and acquiring differentiated drugs, and expertise in clinical development have generated a robust, diversified, and growing pipeline of product candidates in advanced-stage Phase 2 and Phase 3 studies. More information on Spectrum is available at www.sppirx.com.

Forward-looking statement — 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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