



Spectrum Pharmaceuticals Announces ROLONTIS™ (eflapegrastim) Met the Primary Endpoint in the Phase 3 ADVANCE Study

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- The ADVANCE study met the primary efficacy endpoint of non-inferiority in Duration of Severe Neutropenia between ROLONTIS and pegfilgrastim; adverse event profile was similar between the two treatment arms.
- RECOVER, the second Phase 3 study, is now fully enrolled. The Company plans to file a Biologics License Application (BLA) in the fourth quarter of this year.
- ROLONTIS is a novel, long-acting granulocyte colony-stimulating factor (G-CSF) that utilizes a proprietary technology.

HENDERSON, Nev.--(BUSINESS WIRE)--Feb. 5, 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, announced today that the first Phase 3 study of ROLONTIS, ADVANCE, has met its primary endpoint of non-inferiority in Duration of Severe Neutropenia in comparison to pegfilgrastim. This study evaluated the safety and efficacy of ROLONTIS in the management of chemotherapy-induced neutropenia in 406 patients with early-stage breast cancer. The incidence of adverse events in this study was similar between the ROLONTIS and the pegfilgrastim arms. The Company also announced that RECOVER, the second Phase 3 study, has completed enrollment.

"The ADVANCE study affirms the efficacy and safety of ROLONTIS that was observed in the Phase 2 study," said Lee S. Schwartzberg, M.D., FACP Professor of Medicine and Division Chief, Hematology Oncology, The University of Tennessee Health Science Center, and Executive Director, UT/West Cancer Center. "If approved, this drug would be a welcome addition to supportive care treatment options for cancer patients receiving myelosuppressive cytotoxic chemotherapy."

"The positive top line data from our Phase 3 study is an important milestone for Spectrum as we continue to move our Company forward," said Joe Turgeon, President and Chief Executive Officer of Spectrum Pharmaceuticals. "Also, the completion of enrollment of our second Phase 3, the RECOVER study, keeps us on track to file a BLA in the fourth quarter of 2018. ROLONTIS has the potential to be an important alternative for physicians and patients within this multibillion dollar market."

In accordance with the FDA Special Protocol Assessment, Phase 3 ADVANCE study was a multicenter, randomized, active-controlled trial that enrolled 406 early-stage breast cancer patients, who receive docetaxel and cyclophosphamide chemotherapy every 21 days. Patients were randomized 1:1 to treatment with ROLONTIS or pegfilgrastim. The primary study endpoint was the Duration of Severe Neutropenia (Absolute Neutrophil Counts [ANC] $<0.5 \times 10^9/L$) in Cycle 1 of chemotherapy, based on central laboratory assessment of ANC over the 21 day cycle.

In January 2012, Spectrum entered into a licensing agreement with Hanmi Pharmaceuticals, gaining global rights for ROLONTIS (except Korea, China, and Japan).

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 six 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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