



CORRECTING and REPLACING Spectrum Pharmaceuticals Announces Detailed Results from Phase 3 Study of ROLONTIS® (eflapegrastim) Published in an ASCO Abstract

May 16, 2018

- Primary endpoint of non-inferiority of ROLONTIS to pegfilgrastim was met
- All secondary endpoints were met
- Adverse events were similar between ROLONTIS and pegfilgrastim
- ROLONTIS is a novel, long-acting granulocyte colony-stimulating factor (G-CSF) that utilizes a propriety technology

HENDERSON, Nev.--(BUSINESS WIRE)--May 16, 2018-- Fourth paragraph, first sentence of release dated May 16, 2018, should read: "The ADVANCE study is a cornerstone in the ROLONTIS clinical program, which includes one Phase 2 and two Phase 3 clinical studies involving approximately 800 patients" (instead of "The ADVANCE study is a cornerstone in the ROLONTIS clinical program, which includes two Phase 3 clinical studies involving approximately 800 patients").

The corrected release reads:

SPECTRUM PHARMACEUTICALS ANNOUNCES DETAILED RESULTS FROM PHASE 3 STUDY OF ROLONTIS® (EFLAPEGRASTIM) PUBLISHED IN AN ASCO ABSTRACT

- Primary endpoint of non-inferiority of ROLONTIS to pegfilgrastim was met
- All secondary endpoints were met
- Adverse events were similar between ROLONTIS and pegfilgrastim
- ROLONTIS is a novel, long-acting granulocyte colony-stimulating factor (G-CSF) that utilizes a propriety technology

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 detailed results from ADVANCE, a Phase 3 trial of ROLONTIS, demonstrating that it was non-inferior to pegfilgrastim in the reduction of duration of severe neutropenia (DSN) in all four cycles of the study. ROLONTIS is a novel long-acting granulocyte colony-stimulating factor (G-CSF) being studied as a treatment for neutropenia in patients undergoing myelosuppressive cytotoxic chemotherapy. The data released online today in an abstract as part of the American Society of Clinical Oncology 2018 Annual Meeting, also showed similar safety profiles between the treatment groups. The abstract can be find online at <https://meetinglibrary.asco.org/record/163382/abstract>.

"These data expand our understanding of the clinical profile of eflapegrastim and help establish it as a possible supportive care treatment option for the multitude of patients undergoing chemotherapy," said

Lee Schwartzberg, M.D., 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 study demonstrated strong non-inferiority of ROLONTIS to pegfilgrastim, including a 95 percent confidence interval of the difference in the DSN below zero in the first cycle of treatment, helping further define the clinical profile of this novel treatment.”

In the ROLONTIS Phase 3 ADVANCE study (n=406), mean DSN±SD was 0.19±0.478 days for ROLONTIS and 0.34±0.668 days for pegfilgrastim, demonstrating non-inferiority with 95 percent confidence interval (CI) of ?DSN: [-0.260, -0.035]; p<0.0001) in Cycle 1. The non-inferiority of ROLONTIS for DSN was maintained across all four treatment cycles. There were no statistically significant differences in all secondary endpoints including time to absolute neutrophil count (ANC) recovery, depth of ANC nadir and incidence of febrile neutropenia in Cycle 1. The most common adverse events, which were observed in less than 10 percent of patients, were similar across both treatment groups and were mainly hematologic, including neutropenia, lymphopenia, anemia and leukopenia.

“The ADVANCE study is a cornerstone in the ROLONTIS clinical program, which includes one Phase 2 and two Phase 3 clinical studies involving approximately 800 patients,” said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. “We are pleased that ROLONTIS has shown strong non-inferiority data and comparable safety profile to the current standard of care. ROLONTIS has the potential to be the first novel drug in this multibillion dollar market in more than 15 years.”

Spectrum is currently conducting a second Phase 3 ROLONTIS trial, RECOVER, a multi-center study being conducted in the USA, Europe and Asia. The study is fully enrolled and expected to complete later this year. The company plans to conduct a pre-BLA meeting with the FDA in preparation for a planned BLA filing in the fourth quarter of 2018.

About ADVANCE

The ADVANCE study is a Phase 3 multicenter, randomized, active-controlled trial that enrolled 406 early-stage breast cancer patients, who received docetaxel and cyclophosphamide chemotherapy every 21 days for four cycles. Patients were randomized 1:1 to treatment with ROLONTIS or pegfilgrastim (eflapegrastim n=196; pegfilgrastim n=210). The primary study endpoint was the DSN (absolute neutrophil counts [ANC] <0.5×10⁹/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 (equivalent to 3.6 mg G-CSF) or pegfilgrastim (6 mg) in a 1:1 ratio.

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.

SPECTRUM PHARMACEUTICALS, INC.[®] and ROLONTIS[®] are registered trademark of Spectrum Pharmaceuticals, Inc and its affiliate. REDEFINING CANCER CARE[™] and the Spectrum Pharmaceuticals logos are trademarks owned by Spectrum Pharmaceuticals, Inc. Any other trademarks are the property of their respective owners.

© 2018 Spectrum Pharmaceuticals, Inc. All Rights Reserved

View source version on
businesswire.com: <https://www.businesswire.com/news/home/20180516006517/en/>

Source: Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals, Inc.
Shiv Kapoor
Vice President, Strategic Planning & Investor Relations
702-835-6300
InvestorRelations@sppirx.com