



## **Spectrum Pharmaceuticals Presents ADVANCE Phase 3 ROLONTIS® (eflapegrastim) Data at MASCC 2018 and Announces the Phase 3 RECOVER Study Met the Primary Endpoint**

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- ADVANCE, first Phase 3 study, met the non-inferiority of ROLONTIS to pegfilgrastim endpoint in the Duration of Severe Neutropenia (DSN) across all 4 cycles (all  $p < 0.0001$ )
- ROLONTIS showed an absolute risk reduction of severe neutropenia of 8.5 percent compared to pegfilgrastim in Cycle 1
- No statistically significant differences in adverse events between treatment groups
- RECOVER, the second Phase 3 study, met the primary efficacy endpoint of non-inferiority in Duration of Severe Neutropenia between ROLONTIS and pegfilgrastim
- Investor webcast to take place today, Friday, June 29<sup>th</sup>, at 8:30 a.m. EDT/5:30 a.m. PDT

HENDERSON, Nev.--(BUSINESS WIRE)--Jun. 29, 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 detailed data from the ADVANCE Phase 3 study which showed that ROLONTIS had an absolute risk reduction of severe neutropenia of 8.5 percent (95% CI: 0.2%, 16.2%) versus pegfilgrastim in Cycle 1. Absolute risk reduction was defined as the difference in percentage of the patients experiencing no severe neutropenia (ROLONTIS 84.2 percent; pegfilgrastim 75.7 percent). New safety data presented today also showed that the adverse events were not significantly different between two treatment arms. Data were presented today during an oral session at the Multinational Association of Supportive Care in Cancer (MASCC) 2018 Annual Meeting in Vienna, Austria. Earlier this year, the company revealed ADVANCE study data which demonstrated that ROLONTIS was non-inferior to pegfilgrastim in achieving the endpoint of the duration of severe neutropenia (DSN) across all 4 cycles (all  $p < 0.0001$ ). ROLONTIS is a novel, long acting granulocyte colony-stimulating factor (G-CSF) that utilizes a proprietary technology to treat chemotherapy-induced neutropenia.

“ROLONTIS data presented today demonstrated that adverse events, including severe bone pain, were not statistically different from pegfilgrastim and occurred at rates that are expected for those 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. “Furthermore, the absolute risk of severe neutropenia was lower for the ROLONTIS arm than pegfilgrastim. These new data help us better understand ROLONTIS as a potential new treatment option in supportive care for patients undergoing myelosuppressive chemotherapy.”

The company also announced that the RECOVER study, the second Phase 3 ROLONTIS study, met the primary efficacy endpoint of non-inferiority in DSN between ROLONTIS and pegfilgrastim. The

adverse event profile was also similar between the two treatment arms. The RECOVER study evaluated the safety and efficacy of ROLONTIS in the management of chemotherapy-induced neutropenia in patients with early-stage breast cancer (n=237).

The company previously announced in February 2018 that the ADVANCE study, the first Phase 3 ROLONTIS study, met the primary efficacy endpoint of non-inferiority in DSN between ROLONTIS and pegfilgrastim. Mean DSN $\pm$ SD was 0.19 $\pm$ 0.478 days for ROLONTIS and 0.34 $\pm$ 0.668 days for pegfilgrastim, demonstrating non-inferiority with 95 percent confidence interval (CI) of difference in DSN: [-0.260, -0.035];  $p < 0.0001$ ) in Cycle 1. The ADVANCE study also demonstrated a similar adverse event profile between treatment arms.

“We are pleased that both ROLONTIS Phase 3 studies, which studied more than 600 patients combined, demonstrated non-inferiority and similar safety profiles to the current standard of care,” said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. “The emerging ROLONTIS efficacy and safety profile appears to be strong and we are excited to potentially provide a novel therapy to the patients and physicians managing chemotherapy-induced neutropenia.”

Spectrum Pharmaceuticals will be hosting an investor webcast today, Friday, June 29<sup>th</sup>, at 8:30 a.m. EDT/5:30 a.m. PDT with Dr. Lee Schwartzberg to discuss the ROLONTIS Phase 3 ADVANCE study results that were presented earlier today during an oral session at the MASCC 2018 annual meeting.

### **Conference Call Details**

**Friday, June 29, 2018 @ 8:30 a.m. Eastern/5:30 a.m. Pacific**

Domestic: (877) 837-3910, Conference ID# 6798817  
International: (973) 796-5077, Conference ID# 6798817

The conference call will also be webcast live. To access the webcast and additional documents related to the call, please visit the Investor Relations page of the Spectrum Pharmaceutical website at <http://investor.sppirx.com/events-and-presentations>.

### **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]  $< 0.5 \times 10^9/L$ ) 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 (equivalent to 3.6 mg G-CSF) or pegfilgrastim (6 mg) in a 1:1 ratio. The most common adverse events, which were observed in greater than 5 percent of patients, were similar across both treatment groups and included neutropenia, lymphopenia, anemia, leukopenia, febrile neutropenia and bone pain.

### **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]  $<0.5 \times 10^9/L$ ), based on central laboratory assessment of ANC over a 21 day cycle. There were a total of four cycles evaluated in this 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 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](http://www.sppirx.com).

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