Spectrum Pharmaceuticals Initiates Same Day Dosing Clinical Trial for ROLONTIS® (eflapegrastim)

April 30, 2020

HENDERSON, Nev.--(BUSINESS WIRE)--Apr. 30, 2020-- Spectrum Pharmaceuticals (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, today announced dosing of the first patient in a clinical trial to evaluate the administration of ROLONTIS on the same day as chemotherapy. The trial will evaluate the duration of severe neutropenia when administered at three different time points on the same day following standard chemotherapy in patients with early stage breast cancer. ROLONTIS is an investigational drug not approved by the U.S. Food and Drug Administration (FDA) and the BLA is currently under active review by the agency for the treatment of chemotherapy induced neutropenia with a PDUFA date of October 24, 2020.

“This study exemplifies our commitment to unlocking the full potential of ROLONTIS, the first novel biologic positioned to enter the G-CSF market since 2001. A same day dosing option would be a unique and meaningful addition to the G-CSF category,” said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. “We will continue to follow the science and explore ways to add value to patients and health care providers. The initiation of this study, despite the pandemic, highlights investigator’s interest and our team’s dedication.”

“This clinical trial will provide information on the pharmacodynamic effects of ROLONTIS given the same day as chemotherapy and it could provide a scientific basis to re-examine the way neutropenia is managed in patients who receive myelosuppressive chemotherapy,” said Francois Lebel, M.D., Chief Medical Officer of Spectrum Pharmaceuticals. “Same day dosing could possibly enhance compliance, lead to better patient outcomes and minimize patient’s burden in terms of simplified logistical issues associated with the administration of currently available growth factors that specify next day dosing following chemotherapy.”

About the ROLONTIS Same Day Dosing Clinical Trial

This clinical trial will compare the effect of ROLONTIS on the duration of neutropenia in patients with early-stage breast cancer when administered at varying intervals following docetaxel and cyclophosphamide. Approximately 45 patients will be enrolled in this Phase 1, open label, trial with 1:1:1 randomization to three dosing time schedule arms. Each treatment cycle will be 21 days and a total of four cycles will be evaluated. On day 1 of cycle 1, patients will receive chemotherapy followed by administration of ROLONTIS at 30 minutes, 3 hours or 5 hours. During cycles 2 – 4, patients will receive ROLONTIS 24 hours after chemotherapy. The primary endpoint is duration of Grade 4 neutropenia in cycle 1. A number of secondary endpoints in cycle 1 will be evaluated including incidence of neutropenia, time to recovery of severe neutropenia, incidence of grade 3 febrile neutropenia, pharmacokinetics, and number of patients with adverse events as a measure of safety. Additional information about this clinical trial can be found at www.clinicaltrials.gov using the identifier NCT04187898.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a biopharmaceutical company focused on acquiring, developing, and commercializing novel and targeted oncology therapies. 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. For additional information on Spectrum Pharmaceuticals please visit 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20200430005111/en/

Robert Uhl

Managing Director, Westwicke ICR
858.356.5932
robert.uhl@westwicke.com

Kurt Gustafson
Chief Financial Officer
949.788.6700
InvestorRelations@sppirx.com

Source: Spectrum Pharmaceuticals