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Spectrum Pharmaceuticals Begins Enrolling Patients in Registrational Trial of SPI-2012, a Novel, Long Acting G-CSF in Patients with Breast Cancer

- **The study is being conducted under Special Protocol Assessment (SPA) agreement with the FDA.**
- **This registrational, randomized, controlled Phase 3 study (ADVANCE) will evaluate SPI-2012 as a treatment for chemotherapy-induced neutropenia in approximately 580 patients with breast cancer.**
- **The Company expects to have approximately 100 investigators in the U.S. and Canada participate in this study; the goal is to complete enrollment in 2017.**
- **SPI-2012 is a novel, long-acting granulocyte colony-stimulating factor (G-CSF) that utilizes a proprietary technology to maximize the pharmacological activity of G-CSF, resulting in increased potency and a prolonged half-life.**
- **The worldwide commercial opportunity for the treatment of chemotherapy-induced neutropenia is over $6 billion, and the approval of SPI-2012 would provide the first novel, long-acting treatment option to healthcare providers and their patients.**

HENDERSON, Nev.--(BUSINESS WIRE)-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biotechnology company with fully integrated commercial and drug development operations and a primary focus in Hematology and Oncology, announced today the Company has initiated the planned registrational trial for SPI-2012 (eflapegrastim), its novel, long-acting G-CSF. This trial will evaluate the safety and efficacy of SPI-2012 as a treatment for chemotherapy-induced neutropenia in patients with breast cancer, and will serve as the basis for the Biologics License Application (BLA) filing.

"The initiation of the registration trial for SPI-2012 is a significant milestone in the history of our company," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "Revenues from our current marketed drugs have helped us invest in this exciting technology that opens the door for us to a blockbuster oncology market. In parallel, Spectrum has built a strong commercial infrastructure with specialized expertise in this indication that positions us well to aggressively compete in this market."

"I am excited to be the lead investigator for this important study, and about the potency and safety of SPI-2012 as demonstrated in Phase 2," 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. "The LAPSCOVERY technology confers long-acting properties and increased bone marrow uptake through decreased renal and vascular clearance, as well as Fc-mediated transport of G-CSF. We look forward to a successfully conducted Phase 3 trial of SPI-2012. I believe this novel biologic drug, if approved, would be a very valuable addition to our supportive care armamentarium for cancer patients receiving myelosuppressive cytotoxic chemotherapy."

"SPI-2012 is a third generation agent for the treatment of neutropenia that has shown promising results in Phase 2 trials," said, Jeffrey L. Vacirca, M.D., FACP CEO, Managing Partner & Chief of Clinical Research at North Shore Hematology/Oncology Associates and Vice-President, Community Oncology Alliance. "In the Phase 2 trial, the duration of severe neutropenia was equivalent to pegfilgrastim at the medium dose and superior at the high dose. No new or significant dose-related toxicities have been observed in over 230 patients who have been treated with SPI-2012, and the incidence of adverse events has been similar to pegfilgrastim."

In accordance with the SPA, this registrational, Phase 3 or ADVANCE study (R*A*n*D*omized Trial of SPI-2012 *V*ersus Pegfilgrastim in the Management of Chemotherapy Induced Neutropenia in Breast C*ANCE*r Patients Receiving Docetaxel and Cyclophosphamide) is a multicenter, randomized, active controlled trial that will enroll 580 newly diagnosed early-stage breast cancer patients, who will receive adjuvant or neoadjuvant chemotherapy every 21 days. Adjuvant chemotherapy is treatment given after primary surgical therapy to kill any remaining cancer cells and increase the chance of long-term disease-free survival; neoadjuvant chemotherapy is the administration of cytotoxic agents before surgical resection in early-stage breast cancer to shrink the tumor and potentially allow for breast-conserving surgery. SPI-2012 will be administered subcutaneously as a fixed dose equivalent to 3.6 mg of GCSF, which was selected based on the robust pharmacological and pharmacodynamic data from Phase 2. The primary study endpoint is the Duration of Severe Neutropenia (Absolute Neutrophil Counts [ANC] < 0.5×10^9/L) in Cycle 1 of chemotherapy, based on central laboratory assessment of ANC over the

21 day cycle. Secondary endpoints include the incidence of neutropenic complications, incidence of Febrile Neutropenia, Relative Dose Intensity, and safety.

About Special Protocol Assessments

A Special Protocol Assessment is a written agreement between a Sponsor and the U.S. Food and Drug Administration on the design, execution and analysis for a clinical trial that may form the basis of a new Biologics License Application or BLA. Final marketing approval depends upon the efficacy results, safety profile and an evaluation of the risk/benefit of treatment demonstrated in the Phase 3 clinical program.

About Breast Cancer

According to the American Cancer Society (ACS), breast cancer is the second most common form of cancer in women after skin cancer, and the second highest cause of female cancer deaths after lung cancer. Unfortunately, it is estimated that about 1 in 8 (12%) of women in the US will develop invasive breast cancer during their lifetime. In 2015 in the United States (US), an estimated 231,840 new cases of invasive breast cancer and 60,290 additional cases of *in situ* breast cancer will be diagnosed, and approximately 40,290 US women are expected to die from breast cancer. In addition, ~2,350 men are also expected to be diagnosed with breast cancer in 2015 with an estimated 440 deaths.

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 five hematology/oncology drugs, and expects an FDA decision on another hematology drug in the first half of 2016. Additionally, Spectrum's pipeline includes three drugs targeting blockbuster markets in advanced stages of clinical development. 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 our 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, leveraging the expertise of partners and employees around the world to assist us in the execution of our strategy, 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 our 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 lack of sustained revenue history, our limited marketing experience, 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. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this press release except as required by law.

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