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Spectrum Pharmaceuticals Announces Agreement with FDA on the Special Protocol Assessment (SPA) for the Registrational Trial of SPI-2012, a Novel, Long Acting G-CSF in Patients with Breast Cancer

- **Registrational, randomized, active-controlled Phase 3 study (ADVANCE) will study SPI-2012 as a treatment for chemotherapy-induced neutropenia in approximately 580 patients with breast cancer.**
- **The company expects to start the pivotal trial soon and plans to complete enrollment in 2017.**
- **SPI-2012 is a novel, long-acting granuloctye colony-stimulating factor (G-CSF) that utilizes a proprietary platform 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.**

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 that the company has reached agreement with the U.S. Food and Drug Administration (FDA) on the Special Protocol Assessment (SPA) for the Phase 3 clinical trial of its novel, long-acting G-CSF, SPI-2012 (eflapegrastim). 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.

"We are excited to have reached agreement with the FDA on the SPI-2012 SPA, which is the highest priority program at Spectrum," saidÂ Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer ofÂ Spectrum Pharmaceuticals. "SPI-2012 is a novel proprietary biologic that has been shown in a Phase 2 clinical trial to be more potent than pegfilgrastim, and consists of a novel, recombinant G-CSF conjugated, using a technology that enhances the half-life of this therapeutic protein. Our team has been ready to start this registrational Phase 3 trial, and plans to aggressively drive study enrollment. Spectrum has built a strong clinical team and commercial infrastructure with expertise in the treatment of neutropenia. If approved, we believe this drug will enable us to compete in a blockbuster market and change the face of our Company."

In accordance with the SPA, this registrational, Phase 3 trial, or ADVANCE study (R*A*n*D*omized Trial of SPI-2012 *V*ersus Pegfilgrastim inÂ the Management of Chemotherapy Induced Neutropenia in Breast C*ANCE*r Patients Receiving Docetaxel and Cyclophosphamide) will be 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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