FDA Approves the Removal of the Bioscan Requirement for ZEVALIN® Treatment

- *The Removal of the Bioscan Requirement Was Approved by the FDA After the Market Close on November 18, 2011, and is Effective Immediately*
- *A Major Revision to the Package Insert Will Permit Simplified Access to ZEVALIN® for Patients with Follicular Non-Hodgkin Lymphoma*
- *Until Now, the Bioscan Requirement Had Been a Burden That Limited Adoption of ZEVALIN*
- *Based on This FDA Action and Recent Studies Supporting Its Efficacy and Safety, Spectrum Will Unveil a Repositioning Campaign for ZEVALIN at the American Society of Hematology Meeting in San Diego (December 9-13, 2011)*

HENDERSON, Nev.--(BUSINESS WIRE)-- Spectrum Pharmaceuticals (NasdaqGS: SPPI), a biotechnology company with fully integrated commercial and drug development operations with a primary focus in hematology and oncology, received approval from the U.S. Food and Drug Administration (FDA) on November 18, 2011 to remove the pre-treatment biodistribution evaluation requirement using Indium-111 ZEVALIN imaging dose followed by a gamma scan before administering the ZEVALIN therapeutic dose. This pre-treatment biodistribution evaluation requirement is more commonly referred to as the "bioscan."

Prior to the bioscan removal, treatment with ZEVALIN was complex. Typically, patients received an infusion of rituximab on Day 1, followed by a diagnostic dose of radiolabeled Indium-111 ZEVALIN and a full-body scan at a nuclear imaging center within ten minutes and again on Day 3 or 4. Patients would then receive another infusion of rituximab and a 10-minute injection of the therapeutic dose of ZEVALIN on Day 7, 8, or 9. With the bioscan requirement removed, patients undergoing treatment with ZEVALIN will receive the two infusions of rituximab followed by a 10-minute injection of ZEVALIN. This simplified regimen will now be called "RRZ" — rituximab, rituximab, ZEVALIN.

"We are pleased to announce that for both the patients and treating physicians ZEVALIN treatment just became much simpler. Non-Hodgkin lymphoma patients undergoing treatment with ZEVALIN no longer need to be exposed to unnecessary radiation with Indium-111 or be burdened by the inconvenience of the bioscan requirement. The need for coordination between physicians and nuclear imaging centers for the bioscan will also be eliminated," said Rajesh C. Shrotriya, MD, Chairman, Chief Executive Officer, and President of Spectrum Pharmaceuticals.

ZEVALIN was first approved in February 2002 for the treatment of follicular NHL patients who had recurred or progressed after other systemic therapies. In September 2009, ZEVALIN was approved as part of the first-line setting based on results from a 414-patient study that showed a 54% decreased risk of progression with ZEVALIN. A 130-patient multicenter, randomized, open-label clinical study comparing the efficacy of the ZEVALIN therapeutic regimen versus rituximab in patients with relapsed or refractory low-grade or follicular NHL showed that ZEVALIN therapeutic regimen produced an overall response rate of 83% compared to 55% with rituximab.

According to the SEER Cancer Statistics provided by the National Cancer Institute, on January 1, 2008, in the United States there were approximately 454,378 men and women alive who had a history of non-Hodgkin lymphoma.

"Despite ZEVALIN's excellent therapeutic profile, as recognized by ZEVALIN's inclusion in the NCCN guidelines for appropriate patients with follicular lymphoma, there has been a limited penetration of the potential market. With this approval, we believe that physicians, patients and payers will find ZEVALIN to be an exceedingly more attractive treatment option. Spectrum is committed to unlocking ZEVALIN's clinical value for patients and financial value for shareholders. Removal of the bioscan is an important step toward our fulfilling these objectives," Dr. Shrotriya added. "With another significant FDA milestone reached today, Spectrum has once again demonstrated its ability to succeed in complex regulatory filings to support the safety and efficacy of its therapies."

Spectrum plans to unveil a new marketing campaign for ZEVALIN at the upcoming annual meeting of the American Society of Hematology to be held in San Diego on December 9-13, 2011. Additional new clinical data from ZEVALIN will also be presented at ASH 2011.

About Non-Hodgkin Lymphoma

According to the National Cancer Institute (www.cancer.gov), there are expected to be 66,360 new cases of non-Hodgkin lymphoma diagnosed and approximately 19,320 deaths in the United States in 2011. Non-Hodgkin lymphoma is defined as any of a large group of cancers of lymphocytes (white blood cells). Non-Hodgkin lymphomas can occur at any age and are often

marked by lymph nodes that are larger than normal, fever, and weight loss. There are many different types of non-Hodgkin lymphoma. These types can be divided into aggressive (fast-growing) and indolent or low grade (slow-growing) types, and they can be formed from either B-cells or T-cells. Prognosis and treatment depend on the stage and type of disease.

About ZEVALIN® and the ZEVALIN Therapeutic Regimen

ZEVALIN (ibritumomab tiuxetan), injection for intravenous use is indicated for the treatment of patients with previously untreated follicular non-Hodgkin Lymphoma (NHL), who achieve a partial or complete response to first-line chemotherapy. ZEVALIN is also indicated for the treatment of patients with relapsed or refractory, low-grade or follicular B-cell non-Hodgkin lymphoma.

ZEVALIN is a CD20-directed radiotherapeutic antibody. The ZEVALIN therapeutic regimen consists of two components: rituximab, and Yttrium-90 (Y-90) radiolabeled ZEVALIN for therapy. The ZEVALIN therapeutic regimen is a form of cancer therapy called radioimmunotherapy. ZEVALIN builds on the combined effect of a targeted biologic monoclonal antibody augmented with the therapeutic effects of a beta-emitting radioisotope.

Important ZEVALIN® Safety Information

Deaths have occurred within 24 hours of rituximab infusion, an essential component of the ZEVALIN therapeutic regimen. These fatalities were associated with hypoxia, pulmonary infiltrates, acute respiratory distress syndrome, myocardial infarction, ventricular fibrillation, or cardiogenic shock. Most (80%) fatalities occurred with the first rituximab infusion. ZEVALIN administration can result in severe and prolonged cytopenias in most patients. Severe cutaneous and mucocutaneous reactions, some fatal, can occur with the ZEVALIN therapeutic regimen.

Please see full Prescribing Information, including Boxed WARNINGS, for ZEVALIN and rituximab. Full prescribing information can be found at www.ZEVALIN.com.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a biotechnology company with fully integrated commercial and drug development operations with a primary focus in hematology and oncology. The Company's strategy is to acquire, develop and commercialize a broad and diverse pipeline of late-stage clinical and commercial products. The Company markets two oncology drugs, FUSILEV and ZEVALIN, and has two drugs, apaziquone and belinostat, in late stage development along with a diversified pipeline of novel drug candidates. The Company has assembled an integrated in-house scientific team, including clinical development, medical research, regulatory affairs, biostatistics and data management, formulation development, and has established a commercial infrastructure for the marketing of its products. The Company also leverages the expertise of its worldwide partners to assist in the execution of its strategy. For more information, please visit the Company's website 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 may not receive approval, and other regulatory agencies 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.

Spectrum Pharmaceuticals, Inc.

Paul Arndt
Senior Manager, Investor Relations
702-835-6300

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