



October 23, 2015

Spectrum Pharmaceuticals Receives Complete Response Letter (CRL) from U.S. Food and Drug Administration (FDA) for EVOMELA™ (melphalan) for Injection

- **The FDA did not identify any clinical deficiency in the CRL**
- **Company plans to meet with FDA and seek clarification on the CRL**

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, announced today that it has received a Complete Response Letter from the U.S. Food and Drug Administration (FDA). A Complete Response Letter is a communication from the FDA that informs companies that an application cannot be approved in its present form. In the letter, the FDA did not identify any clinical deficiency in Spectrum's NDA package.

"We will work swiftly with the FDA to address the Complete Response Letter," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "We remain committed to bringing EVOMELA to the market for patients and plan to work closely with the FDA."

Spectrum Pharmaceuticals gained global development and commercialization rights to EVOMELA from Ligand Pharmaceuticals Incorporated (NASDAQ: LGND) in March 2013. Spectrum assumed responsibility for completing the pivotal Phase 2 clinical trial, and was responsible for filing the NDA. Under the license agreement, Ligand received a license fee and is eligible to receive milestone payments, as well as royalties following potential commercialization.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a leading biotechnology company focused on acquiring, developing, and commercializing drug products, with a primary focus in Oncology and Hematology. Spectrum and its affiliates market five oncology drugs— FUSILEV® (levoleucovorin) for Injection in the U.S.; FOLOTYN® (pralatrexate injection), also marketed in the U.S.; ZEVALIN® (ibrutinomab tiuxetan) Injection for intravenous use, for which the Company has worldwide marketing rights; MARQIBO® (vinCRISTine sulfate LIPOSOME injection) for intravenous infusion, for which the Company has worldwide marketing rights; and BELEODAQ® (belinostat) for Injection in the U.S. Additionally, Spectrum's pipeline includes three drugs targeting blockbuster markets in advanced stages of clinical development. Spectrum's strong track record in in-licensing and acquiring differentiated drugs, and expertise and proven track record 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.

About Multiple Myeloma

Multiple Myeloma is a systemic malignancy of plasma cells that accumulate in the bone marrow, usually associated with monoclonal antibody secretion, and results in bone marrow failure and bone destruction. It is the second most common hematologic disease with nearly 27,000 new cases projected in the U.S. in 2015 and over 11,000 deaths annually (American Cancer Society Stats, 2015). The rate of ASCT for patients with MM is growing by approximately 3.3% annually.

While MM is usually sensitive to cytotoxic chemotherapy, most responses are transient and patients frequently relapse. The demonstrated superiority of high-dose chemotherapy with ASCT over conventional chemotherapy for the treatment of MM has made transplant the current standard of care for patients, particularly the young, with adequate organ function. Melphalan is the most commonly used IV agent for high-dose conditioning for patients undergoing ASCT for MM. The current IV melphalan market is approximately \$100 million annually, with predominant use in ASCT.

About EVOMELA™

EVOMELA is a new, propylene glycol-free melphalan formulation that demonstrated bioequivalence to the standard melphalan formulation (Alkeran) in a Phase 2 clinical study (Aljitawi et al, Bone Marrow Transplant, 2014). EVOMELA has been granted Orphan Drug Designation by the FDA for its use as a high-dose conditioning regimen for patients with MM undergoing ASCT.

EVOMELA's formulation eliminates the need to use a propylene glycol containing custom diluent, which is required with other

intravenous melphalan formulations, and has been reported to cause renal and cardiac side effects. The use of the Captisol® technology to reformulate melphalan also improved its stability, extending its use time to five hours, which is anticipated to simplify preparation and administration logistics, and allow for slower infusion rates and longer administration durations for pre-transplant chemotherapy.

About Captisol®

Captisol is a patent-protected, chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. Captisol was invented and initially developed by scientists in the laboratories of Dr. Valentino Stella at the University of Kansas' Higuchi Biosciences Center for specific use in drug development and formulation. This unique technology has enabled six FDA-approved products, including Amgen's Kyprolis®, Baxter International's Nexterone® and Merck's NOXAFIL IV. There are also more than 30 Captisol-enabled products currently in clinical development.

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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