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Spectrum Pharmaceuticals' Pivotal Trial of Captisol-Enabled™ (Propylene Glycol-Free) Melphalan Meets Primary Endpoint

- **CE Melphalan is being developed as a novel version of the well-established conditioning treatment in autologous transplant for patients with multiple myeloma. CE Melphalan does not contain propylene glycol, an ingredient in currently available products which has been associated with renal and cardiac side effects.**
- **In its pivotal trial, CE Melphalan met its primary endpoint. The improved stability profile of CE Melphalan could lead to rapid adoption in the transplant conditioning market.**
- **The company expects to file an NDA in the 3rd quarter and plans to launch this drug with its existing hematology/oncology sales force next year pending approval.**

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, today announced that its pivotal trial of Captisol-enabled™ (propylene glycol-free) Melphalan met its primary end points.

"I am pleased with the focus and alacrity in which our clinical team has executed this trial," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "With the positive results from this trial, we are one step closer to providing patients and healthcare providers with a much needed new formulation of Melphalan. Melphalan is currently a well-established conditioning treatment in autologous transplant for patients with multiple myeloma. Our novel Captisol-enabled Melphalan is free of propylene glycol, which itself is associated with renal and cardiac side effects. Additionally, the improved stability profile of CE Melphalan could be valuable in its rapid adoption in the transplant conditioning market. This product also fits seamlessly into our existing commercial and research infrastructure. With key upcoming catalysts related to CE Melphalan, Beleodaq and SPI-2012, we continue to be committed to building a world-class Hematology/Oncology company."

The phase 2 pivotal trial evaluating CE Melphalan was a multi-center trial evaluating safety and efficacy. The primary objective of the study was to determine the overall safety and toxicity profile in multiple myeloma patients receiving 200 mg/m^2 of CE Melphalan as myeloablative therapy prior to autologous stem cell transplantation (ASCT). The secondary objectives evaluated the efficacy of CE Melphalan in this patient population as measured by multiple myeloma response rate (according to International Myeloma Working Group [IMWG] criteria), and the rates of myeloablation, and engraftment. The primary endpoint of this Phase 2 trial was met, and additional analyses are currently underway. The company plans to file an NDA in the third quarter.

In a previous clinical study, Captisol-enabled Melphalan met the requirements for establishment of bioequivalence to the current commercial intravenous formulation of melphalan.

Spectrum Pharmaceuticals gained global development and commercialization rights to CE Melphalan from Ligand Pharmaceuticals Incorporated (NASDAQ: LGND) in March 2013. Spectrum assumed the responsibility for the pivotal clinical trial and is responsible for filing an 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 Captisol-Enabled Melphalan

Captisol-enabled, PG-free melphalan is a novel intravenous formulation of melphalan being investigated for the multiple myeloma transplant setting, for which it has been granted an Orphan Drug Designation by the FDA. This formulation eliminates the use of propylene glycol, which has been reported to cause renal and cardiac side effects that limit the ability to deliver higher doses of therapeutic compounds. The use of the Captisol® technology to reformulate melphalan also improves its stability and is anticipated to allow for slower infusion rates and longer administration durations, potentially enabling clinicians to safely achieve a higher dose intensity 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 Onyx Pharmaceuticals' Kyprolis®, Baxter International's Nexterone® and Merck's NOXAFIL IV. There are also more than 30 Captisol-enabled products currently in clinical development.

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 four oncology drugs ─ FUSILEV® (levoleucovorin) for Injection in the U.S.; FOLOTYN® (pralatrexate injection), also marketed in the U.S.; ZEVALIN® (ibritumomab tiuxetan) Injection for intravenous use, for which the Company has worldwide marketing rights and MARQIBO® (vinCRIStine sulfate LIPOSOME injection) for intravenous infusion, for which the Company has worldwide marketing rights. Spectrum's strong track record in 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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Source: Spectrum Pharmaceuticals