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# Spectrum Pharmaceuticals Presents New Data on EVOMELATM (CE-Melphalan), at the Annual Meeting of the American Pharmacists Association (APhA) in San Diego, Highlighting Stability

- EVOMELA stability shown to be significantly longer than current Melphalan HCl for Injection in an oral presentation at the annual American Pharmacists Association (APhA) meeting.
- The increased stability of EVOMELA allows a longer use time, and could importantly simplify clinical administration logistics.
- EVOMELA is free of propylene glycol, a diluent which is present in current Melphalan formulations and is associated with renal and cardiac toxicities.
- PDUFA decision date is October 23, 2015; if approved, the Company plans to launch EVOMELA with its existing hematology/oncology sales force.

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 results of a clinical study of the stability of Captisol-enabled Melphalan versus the currently marketed, propylene glycol-containing melphalan formulation entitled, *Solution Stability of Captisol-enabled Melphalan vs Marketed Melphalan Products*. These results were presented in an oral presentation at the annual American Pharmacists Association (APhA) Annual Meeting & Exposition in San Diego, California (March 27-30).

"The improved stability of EVOMELA may potentially ensure that cancer patients receive the full, intended therapeutic dose of intravenous (IV) melphalan, by increasing the use time and infusion time, and simplifying clinical administration logistics," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "EVOMELA is a new injectable formulation of melphalan that incorporates the Captisol brand of modified β-cyclodextrin improving the solubility and stability of melphalan. It also uses a standard aqueous diluent (normal saline) for reconstitution, instead of propylene glycol, which is associated with toxicities including renal dysfunction and arrhythmias. We look forward to launching EVOMELA with our existing sales force later this year and providing this new treatment option to cancer patients."

The following is the summary of the oral presentation at the APhA annual meeting in San Diego:

**Abstract #377 Solution Stability Comparison of Capitsol-enabled™ Melphalan HCl vs. Marketed Melphalan HCl Products**

**Summary:** Over time, the rate of degradation for reconstituted solutions of marketed IV melphalan HCl in vials was 17X faster than reconstituted solutions in vials prepared from EVOMELA. Similarly, melphalan was shown to degrade 5X faster in infusion bag admixtures prepared from marketed products compared to admixtures prepared from EVOMELA. EVOMELA for Injection can be stored up to 1 hour after reconstitution and is stable for an additional 4 hours after preparation of the infusion solution.

**Conclusions:** Data show that EVOMELA has significantly better stability in solution compared to the marketed melphalan formulations. Reconstituted solution in vials is 17X more stable, and the admixture solution in bags is 5X more stable, respectively, than the same solutions prepared using currently marketed formulations.

In December 2014, Spectrum submitted a NDA to the FDA for the approval of EVOMELA for use as a high-dose conditioning treatment prior to AHCT in patients with Multiple Myeloma (MM). Spectrum is also seeking approval for the palliative treatment of patients with MM for whom oral therapy is not appropriate. The NDA was accepted and a PDUFA decision is expected October 23, 2015, 10 months from NDA filing.

Spectrum Pharmaceuticals gained global development and commercialization rights to EVOMELA from Ligand Pharmaceuticals Incorporated (NASDAQ: LGND) in March 2013. Spectrum assumed the responsibility for the pivotal 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® (ibritumomab 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.. 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.

**About EVOMELA™**

EVOMELA 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 need to use a propylene glycol-containing custom diluent, which has been reported to cause renal and cardiac side effects, and, in turn, limits 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.

*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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