



February 6, 2014

## **Spectrum Pharmaceuticals Announces FDA's Acceptance of NDA Filing for Beleodaq™ (belinostat) for Injection, a novel pan-HDAC inhibitor**

- **FDA grants Priority Review Designation**
- **FDA decision date based on PDUFA set for August 9, 2014**

HENDERSON, Nev.--(BUSINESS WIRE)-- Spectrum Pharmaceuticals (NasdaqGS: SPPI), a biotechnology company with fully integrated commercial and drug development operations and a primary focus in Hematology and Oncology, announced today that its New Drug Application (NDA) for Beleodaq, a novel, pan-histone deacetylase (HDAC) inhibitor, has been accepted for filing by the U.S. Food and Drug Administration (FDA). FDA establishes review classification for this application as Priority Review. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) action date of August 9, 2014. Spectrum is seeking FDA approval of Beleodaq for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (R/R PTCL).

"The FDA's acceptance of this NDA submission is another important milestone in our strategy to bring Beleodaq to market, and one step closer to the possible availability of more treatment options to address the unmet medical need for patients with R/R PTCL," said Rajesh C. Shrotriya, MD, Chairman, Chief Executive Officer, and President of Spectrum Pharmaceuticals. "The Priority Review designation for the Beleodaq NDA acknowledges the potential significant improvement in its safety or effectiveness for the treatment for patients with the serious condition of R/R PTCLs when compared to standard applications. Since approximately 70% of R/R PTCL patients fail the currently approved treatments in the course of their therapy, Beleodaq could be an important additional treatment option for these patients. Importantly, several patients treated with Beleodaq were able to go on to potentially curative stem cell transplantation. We expect to use our existing sales force to successfully launch Beleodaq if approved by the FDA."

Beleodaq is differentiated from other HDAC inhibitors that selectively inhibit a single class of HDAC enzymes by virtue of its inhibition of all 3 classes of the zinc-dependent HDAC enzymes (Class I, Class II and Class IV); this leads to different alterations in histone and non-histone protein acetylation that, in turn, could importantly influence chromatin accessibility, gene transcription, and the clinical activity of this drug in different cancer patients, including those who have developed drug-resistant disease.

### **About Peripheral T-Cell Lymphoma**

According to the Lymphoma Research Foundation ([www.lymphoma.org](http://www.lymphoma.org)), lymphoma is the most common blood cancer. Hodgkin's lymphoma and non-Hodgkin's lymphoma (NHL) are the two main forms of lymphoma. Lymphoma occurs when lymphocytes, a type of white blood cell, grow abnormally and accumulate in one or more lymph nodes or lymphoid tissues. The body has two main types of lymphocytes that can develop into lymphomas: B-lymphocytes (B-cells) and T-lymphocytes (T-cells). PTCL comprises a group of rare and aggressive NHLs that develop from mature T-cells. PTCL accounts for approximately 10 to 15% of all NHL cases in the United States.

### **About Beleodaq**

Beleodaq is a pan-HDAC inhibitor being studied in multiple clinical trials as a single agent or in combination with chemotherapeutic agents for the treatment of various hematological and solid cancers. Its anticancer effect is thought to be mediated through multiple mechanisms of action, including the inhibition of cell proliferation, induction of apoptosis (programmed cell death), inhibition of angiogenesis, and the induction of differentiation. Beleodaq has been shown to have activity in tumors that had become resistant to anticancer agents such as the platinum, taxanes and topoisomerase II inhibitors.

### **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](http://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 sales of Spectrum's drug products, 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 customer concentration, the possibility for fluctuations in customer orders, evolving market dynamics, our dependence on third parties for clinical trials, manufacturing, distribution, information 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, Inc.

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