July 7, 2014

FDA Grants Spectrum Pharmaceuticals Accelerated Approval of Beleodaq™ (belinostat) fo Injection

- **Early Action before PDUFA date of August 9, 2014 follows Priority Review**
- **Beleodaq to be launched through Spectrum's existing sales force**
- **Beleodaq is expected to be available to patients in less than 3 weeks**

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 the U.S. Food and Drug Administration (FDA) has granted Accelerated Approval of Beleodaq™ for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). This indication is approved under accelerated approval based on Tumor Response Rate and Duration of Response. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.

Beleodaq was approved by the FDA on July 3rd, nearly 5 weeks before the PDUFA date (August 9th). This indication was approved based on data from the multi-center, single-arm BELIEF trial in 120 evaluable patients, refractory to or who had failed at least one prior systemic therapy. In this trial, Beleodaq was associated with hematologic toxicity, infections, hepatotoxicity, tumor lysis syndrome, gastrointestinal toxicity, and embryo-fetal toxicity.

PTCL comprises a group of rare and aggressive non-Hodgkin's Lymphomas (NHL) that develop from mature T-cells and accounts for approximately 10 to 15% of all NHL cases in the United States. These patients generally have a poor prognosis with a low response rate (25-27%) to available treatment options, and commonly experience repeated treatment failures until drug resistance or death. Therefore, there has been an important unmet medical need for these patients with PTCL for additional new treatment options that are specifically effective for this disease.

"This FDA approval enables us to help address this unmet medical need, and provide a new treatment option for patients with this difficult-to-treat and ultimately fatal disease," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "First with Folotyn® (pralatrexate injection) and now with Beleodaq, we are very proud to be able to offer patients and clinicians two approved treatment options for R/R PTCL, and be a leader in the treatment of T-cell lymphomas. We will be able to effectively leverage our existing Hematology clinical and sales infrastructure to expedite the launch of Beleodaq. Now with a total of five approved Hematology/Oncology drugs and a strong and maturing development pipeline, Spectrum is well positioned for continued future growth."

"Peripheral T-cell lymphoma (PTCL) is a poor prognosis subtype of non-Hodgkin's lymphoma with no accepted standard of care," said Owen A. O'Connor, MD, PhD, Director of Lymphoid Malignancies, Professor of Medicine and Experimental Therapeutics at Columbia Medical Center, New York Presbyterian Medical Center, one of the lead investigators in the BELIEF study. "Relapse is common after initial treatment, and there are limited options for patients in 2nd line and beyond. Histone deacetylase inhibitors have emerged as one promising class of drugs for patients faced with this disease. One interesting observation in the study was the tolerability of Beleodaq in these heavily treated patients. Beleodaq was associated with myelosuppression with an overall rate of anemia of 32%, thrombocytopenia of 16.3% and neutropenia of 9.3% and Grade 3/4 adverse reactions were reported in 10.9%, 7.0% and 6.2% of patients, respectively. The associated severity of hematologic toxicities may prove to be useful in previously treated patients who have poor bone marrow reserve."

"Interestingly, Beleodaq was shown to have an Overall Response Rate of 25.8% with a high response rate (45.5%) in patients with Angioimmunoblastic T-cell Lymphoma, one of the common PTCL subtypes. In addition, 17% of the patients enrolled in this trial had low Baseline platelet counts (< 100,000/mm^3) and tolerated therapy with some (15%) attaining partial and complete responses. I believe Beleodaq will be a valuable new option for physicians who treat patients with relapsed or refractory PTCL. This safety profile makes it a potential candidate for the development of new combination treatment paradigms for patients with PTCL," added Dr. O'Connor.

A review of data from a planned confirmatory Phase III trial of Beleodaq in combination with CHOP (cyclophosphamide, vincristine, doxorubicin, prednisone), to characterize the efficacy and safety of the Beleodaq combination versus CHOP alone,

is required by FDA to convert this Accelerated Approval to a Full Approval.

BELIEF STUDY

The BELIEF study was an open-label, single-arm, non-randomized, international trial conducted at 62 centers that enrolled 129 patients with relapsed or refractory PTCL; 120 patients had histologically confirmed PTCL by central review and were evaluable for efficacy. Patients received treatment with Beleodaq (1,000 mg/m^2), administered over 30 minutes via IV infusion, once daily on Days 1-5 of a 21-day cycle. Treatment cycles were repeated every three weeks until disease progression or unacceptable toxicity.

The primary efficacy endpoint of the BELIEF study was Overall Response Rate (complete and partial responses) as assessed by an Independent Review Committee (IRC) using the International Workshop Criteria (IWC) (Cheson, 2007). The key secondary efficacy endpoint was Duration of Response. In all evaluable patients (N = 120) treated with Beleodaq, the Overall Response Rate (CR + PR) per central review using IWC was 25.8% (n = 31; 95% CI, 18.3 - 34.6); with rates of 23.4% for PTCL, NOS and 45.5% for AITL, the two largest subtypes enrolled. The median Duration of Response based on the first date of response to disease progression or death was 8.4 months (95% CI: 4.5 - 29.4).

Data from the BELIEF study demonstrated that the most common adverse events (AEs) reported with Beleodaq (> 25%) were nausea (42%), fatigue (37%), pyrexia (35%), anemia (32%), and vomiting (29%). Myelosuppression was observed with an overall rate of anemia of 32%, thrombocytopenia of 16.3% and neutropenia of 9.3%; Grade 3/4 adverse reactions were reported in 10.9%, 7.0% and 6.2% of patients, respectively. Sixty-one patients (47.3%) experienced serious adverse reactions while taking Beleodaq or within 30 days after their last dose of Beleodaq. The most common serious adverse reactions (> 2%) were pneumonia (7%), pyrexia (5%), infection (3%), anemia (2%), increased creatinine (2%), thrombocytopenia (2%), and multi-organ failure (2%).

About BELEODAQ™

Beleodaq is a histone deacetylase (HDAC) inhibitor. HDACs catalyze the removal of acetyl groups from the lysine residues of histones and some non-histone proteins. *In vitro*, belinostat caused the accumulation of acetylated histones and other proteins, inducing cell cycle arrest and/or apoptosis of some transformed cells. Belinostat shows preferential cytotoxicity towards tumor cells compared to normal cells. Belinostat inhibited the enzymatic activity of histone deacetylases at nanomolar concentrations (< 250 nM).

Important Beleodaq Safety Information

Warnings and Precautions

- Beleodaq can cause thrombocytopenia, leukopenia (neutropenia and lymphopenia), and/or anemia; monitor blood counts weekly during treatment, and modify dosage as necessary.
- Serious and sometimes fatal infections, including pneumonia and sepsis, have occurred with Beleodaq. Do not administer Beleodaq to patients with an active infection. Patients with a history of extensive or intensive chemotherapy may be at higher risk of life threatening infections.
- Beleodaq can cause fatal hepatotoxicity and liver function test abnormalities. Monitor liver function tests before treatment and before the start of each cycle. Interrupt or adjust dosage until recovery, or permanently discontinue Beleodaq based on the severity of the hepatic toxicity.
- Tumor lysis syndrome has occurred in Beleodaq-treated patients in the clinical trial of patients with relapsed or refractory PTCL. Monitor patients with advanced stage disease and/or high tumor burden and take appropriate precautions.
- Nausea, vomiting and diarrhea occur with Beleodaq and may require the use of antiemetic and antidiarrheal medications.
- Beleodaq can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised to avoid pregnancy while receiving Beleodaq. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of potential hazard to the fetus.

Adverse Reactions

- The most common adverse reactions observed in the trial in patients with relapsed or refractory PTCL treated with Beleodaq were nausea (42%), fatigue (37%), pyrexia (35%), anemia (32%), and vomiting (29%).

Drug Interactions

- Beleodaq is primarily metabolized by UGT1A1. Avoid concomitant administration of Beleodaq with strong inhibitors of

UGT1A1.

Use in Specific Populations

- It is not known whether Beleodaq is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from Beleodaq, a decision should be made whether to discontinue nursing or discontinue drug, taking into account the importance of the drug to the mother.

Please see Beleodaq Full Prescribing Information at www.beleodaq.com.

About FOLOTYN®

FOLOTYN, (pralatrexate injection), a folate analogue metabolic inhibitor, was discovered by Memorial Sloan-Kettering Cancer Center, SRI International and Southern Research Institute and developed by Allos Therapeutics. In September 2009, the U.S. Food and Drug Administration (FDA) granted accelerated approval for FOLOTYN for use as a single agent for the treatment of patients with relapsed or refractory PTCL. This indication is based on Overall Response Rate. Clinical benefit such as improvement in progression-free survival or overall survival has not been demonstrated. FOLOTYN has been available to patients in the U.S. since October 2009. An updated analysis of data from PROPEL, the pivotal study of FOLOTYN in patients with relapsed or refractory PTCL, was published in the March 20, 2011 issue of the Journal of Clinical Oncology. FOLOTYN has patent protection through July 2022, based on a five-year patent term extension through the Hatch-Waxman Act.

Important FOLOTYN® Safety Information

Warnings and Precautions

FOLOTYN may suppress bone marrow function, manifested by thrombocytopenia, neutropenia, and anemia. Monitor blood counts and omit or modify dose for hematologic toxicities.

Mucositis may occur. If greater-than or equal to Grade 2 mucositis is observed, omit or modify dose. Patients should be instructed to take folic acid and receive vitamin B12 to potentially reduce treatment-related hematological toxicity and mucositis.

Fatal dermatologic reactions may occur. Dermatologic reactions may be progressive and increase in severity with further treatment. Patients with dermatologic reactions should be monitored closely, and if severe, FOLOTYN should be withheld or discontinued. Tumor lysis syndrome may occur. Monitor patients and treat if needed.

FOLOTYN can cause fetal harm. Women should avoid becoming pregnant while being treated with FOLOTYN and pregnant women should be informed of the potential harm to the fetus.

Use caution and monitor patients when administering FOLOTYN to patients with moderate to severe renal function impairment.

Elevated liver function test abnormalities may occur and require monitoring. If liver function test abnormalities are greater-than or equal to Grade 3, omit or modify dose.

Adverse Reactions

The most common adverse reactions were mucositis (70%), thrombocytopenia (41%), nausea (40%), and fatigue (36%). The most common serious adverse events are pyrexia, mucositis, sepsis, febrile neutropenia, dehydration, dyspnea, and thrombocytopenia.

Use in Specific Patient Population

Nursing mothers should be advised to discontinue nursing or the drug, taking into consideration the importance of the drug to the mother.

Drug Interactions

Co-administration of drugs subject to renal clearance (e.g., probenecid, NSAIDs, and trimethoprim/sulfamethoxazole) may result in delayed renal clearance.

Please see FOLOTYN Full Prescribing Information at www.FOLOTYN.com.

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. With the launch of BELEODAQ, Spectrum and its affiliates will be marketing five oncology drugs ─ BELEODAQ™ (belinostat) for Injection in the U.S.; 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 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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