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Spectrum Pharmaceuticals Announces Publication of Beleodaq® Data Selected as a Rapid Communication in the Journal of Clinical Oncology

- **Beleodaq is marketed in the U.S. by Spectrum Pharmaceuticals, Inc.**

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 the publication of results from the pivotal **BELIEF** (CLN-19) Study, which was selected as a Rapid Communication in the *Journal of Clinical Oncology (JCO),* the journal of the American Society of Clinical Oncology. The study, led by Dr. Owen O'Connor from the Center for Lymphoid Malignancies, Department of Medicine, Columbia University Medical Center, New York, NY, showed that monotherapy with Beleodaq produced complete and durable responses with manageable toxicity in patients with R/R PTCL across the major subtypes, irrespective of the number or type of prior therapies.

Beleodaq, previously known as belinostat, is a histone deacetylase (HDAC) inhibitor indicated 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.

Peripheral T-cell lymphomas are a diverse group of non-Hodgkin lymphomas with a poor prognosis and no accepted standard of care for relapsed or refractory patients. Unfortunately, current treatment options for most of these patients induce responses in only a minority of cases (< 30%), and thus long-term survival is relatively poor. The **BELIEF** study evaluated the efficacy and tolerability of Beleodaq as a single agent in R/R PTCL. This study was an open-label, single-arm, non-randomized, international trial conducted at 62 centers that enrolled 129 patients with R/R PTCL, who had progressed following ≥1 prior therapy with a median number of prior therapies of two (1-8). These patients received Beleodaq (1,000 mg/m^2) as daily 30-minute infusions on Days 1-5 every 21 days until disease progression or unacceptable toxicity.

The primary endpoint of the **BELIEF** study was ORR as assessed centrally by an Independent Review Committee using the International Working Group (IWG) criteria. The ORR in the 120 evaluable patients was 25.8% (31 patients) (95% CI 18.3 - 34.6), including 13 Complete Responses (10.8%) (95% CI 5.9 - 17.8) and 18 Partial Responses (15%) (95% CI 9.1 - 22.7). Secondary endpoints included a median DoR of 13.6 months by IWG criteria and 8.4 months to disease progression or death, with the longest ongoing patient at ≥36 months. The most common Grade 3/4 adverse events were anemia (10.8%), thrombocytopenia (7%), dyspnea (6.2%), and neutropenia. No clinically relevant ECG changes were identified, and cardiovascular monitoring of ECGs is not required at baseline or during treatment. In this pivotal study, monotherapy with Beleodaq produced complete and durable responses with manageable toxicity in patients with R/R PTCL across the major disease subtypes, irrespective of the number or type of prior therapies and with a low incidence of Grade 3/4 thrombocytopenia.

"We are pleased to have the results of the pivotal Beleodaq study selected for publication as a Rapid Communication in such a prominent journal," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "This is a highly distinguished category that JCO reserves for papers judged to have special impact to their broad clinical readership. Spectrum has a unique PTCL franchise, marketing two FDA approved drugs for this indication, Folotyn® (pralatrexate injection) and Beleodaq. We are very proud to be able to offer patients and clinicians more treatment options with two approved treatments for R/R PTCL."

"This is a very exciting time in the treatment of patients with PTCL," said Dr. Owen A. O'Connor, MD, PhD, Director of the Center for 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. "At long last we finally have tools in the therapeutic armamentarium to help our patients. Belinostat represents the latest drug approved for patients with R/R PTCL that has relatively few side effects and produces long durations of benefit, even in patients who have received multiple conventional treatments in the past. Now that we have several new options to treat the disease when it comes back, we need to use these drugs to make better up-front treatment platforms; Belinostat will be an important part of that future."

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a leading biotechnology company focused on acquiring, developing, and commercializing drug

products, with a primary focus in hematology and oncology. Spectrum markets five hematology/oncology drugs, and expects an FDA decision on another hematology drug later this year. 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 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 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*, Beleodaq caused the accumulation of acetylated histones and other proteins, inducing cell cycle arrest and/or apoptosis of some transformed cells. Beleodaq shows preferential cytotoxicity towards tumor cells compared to normal cells. Beleodaq inhibited the enzymatic activity of histone deacetylases at nanomolar concentrations (< 250 nM).

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

Indications and Usage

Beleodaq is a histone deacetylase inhibitor indicated 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.

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%).
- Sixty-one patients (47.3%) experienced serious adverse reactions while taking Beleodaq or within 30 days after their last dose of Beleodaq.

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.

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.

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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Spectrum Pharmaceuticals
Shiv Kapoor
Vice President, Strategic Planning & Investor Relations
702-835-6300
InvestorRelations@sppirx.com

Source: Spectrum Pharmaceuticals