Spectrum Pharmaceuticals and Onxeo Announce Complete Response in 67% of Patients with Peripheral T-Cell Lymphoma in Combination of Belinostat (Beleodaq®) and Standard CHOP

- Data was Highlighted in an Oral Presentation of a Phase 1 Study at the 57th Annual Meeting of the American Society of Hematology (ASH)
- Study Shows 86% Objective Response Rate with 67% Complete Responses in Newly Diagnosed Patients with Peripheral T-cell Lymphoma (PTCL)
- At Full Dose Intensity the Belinostat-CHOP Combination was Well-Tolerated

HENDERSON, Nev. and PARIS (France), COPENHAGEN (Denmark) - December 6, 2015 -- Spectrum Pharmaceuticals (NasdaqGS: SPPI), a biotechnology company with fully integrated commercial and drug development operations and a primary focus in Hematology and Oncology, and Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, today jointly announced the results from their Phase 1 combination trial of belinostat (Beleodaq®) with the CHOP (Cyclophosphamide, Hydroxyl-doxorubicin; Vincristine, and Prednisone) chemotherapy regimen as first-line treatment for newly diagnosed peripheral T-cell lymphoma (PTCL). Beleodaq® is a histone deacetylase (HDAC) inhibitor that received accelerated approval by the U.S. Food and Drug Administration (FDA) for the treatment of relapsed or refractory PTCL in July 2014.

The results were presented today in an oral presentation at the 57th American Society of Hematology (ASH) Annual Meeting & Exposition by Dr. Patrick Johnston, MD, PhD, Assistant Professor of Medicine at the Mayo Clinic, Rochester, MN, USA.

Abstract #253: Safe and Effective Treatment of Patients with Peripheral T-cell Lymphoma (PTCL) with the Novel HDAC Inhibitor, Belinostat, in Combination with CHOP: Results of the Bel-CHOP Phase 1 Trial

This open-label, two-part trial enrolled a total of 23 patients. Eleven were enrolled in **Part A**, the dose-escalation phase, to determine the study's primary endpoint, the maximum tolerated dose (MTD). **Part B** of the study, the Expansion Phase, enrolled 12 additional patients at this dose level. The MTD of belinostat was established at 1,000 mg/m^2 IV infusion on Days 1-5 (the recommended single agent dose) when combined with the CHOP regimen, with each component given at its full recommended dose. Secondary endpoints included safety, tolerability, Objective Response Rate (ORR: Complete Response + Partial Response), and pharmacokinetics.

Results outlined in the oral presentation showed an ORR of 86% with the belinostat and CHOP combination, based on 21 evaluable patients (18/21), with the vast majority, 67%, achieving a Complete Response (14/21), and 19% achieving a Partial Response (4/21). In addition, the belinostat and CHOP combination was shown to have an acceptable safety profile with no new or unexpected toxicities. The most common (>10%) Grade 3-4 hematologic adverse events (AEs) reported with Bel-CHOP were as expected: neutrophil count decreased (30%), anemia (22%), neutropenia (22%), white blood cell (WBC) count decreased (22%), febrile neutropenia (17%) and lymphocyte count decreased (17%). No Grade 3-4 non-hematologic AEs >10% were reported. No patient discontinued therapy due to AEs. One patient died as a result of disease progression during the study.

Dr. Patrick Johnston, MD, PhD, Assistant Professor of Medicine at the Mayo Clinic and investigator on the trial, commented, "PTCL is a very difficult lymphoma to treat due to its heterogeneous nature, and its association with multiple recurrence and poor prognosis; only approximately 37% of patients achieve 5-year overall survival. New combination treatment strategies are undeniably needed to improve efficacy without compromising tolerability, and we are encouraged by these Phase 1 study results indicating that the combination of belinostat and CHOP is a potentially viable treatment option. A good safety profile combined with an Objective Response Rate of 86%, and 67% of patients achieving complete response, are unusual in an early trial of this cancer type. We look forward to further evaluating the combination in a planned Phase 3 trial."

"We are proud to have had several presentations on our products at the ASH meeting, and are optimistic about the new combination data with belinostat," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "Beleodaq was approved for the treatment of patients with relapsed or refractory PTCL based on an Objective Response Rate in the pivotal Phase 2 BELIEF study of 25.8%. The results of this Phase 1 study indicate encouraging safety and efficacy for the combination of belinostat and CHOP in newly diagnosed patients. The clinical activity suggests that earlier treatment with belinostat could be beneficial for the treatment of this devastating disease. Spectrum has a unique PTCL franchise with two FDA approved drugs; we are very proud to be able to offer patients and clinicians additional treatment options for a disease which had no FDA-approved treatments until a few years ago."

Graham Dixon, PhD, Chief Scientific Officer of Onxeo, added, "We are very excited to have these results discussed in an oral presentation at the ASH Annual Meeting. Collectively, the efficacy and safety findings demonstrate the potential value of belinostat plus CHOP, and Onxeo is thrilled to continue the development of belinostat to more broadly assess this promising therapy in PTCL and beyond."

References

1. Johnston, P. "Safe and Effective Treatment of Patients with Peripheral T-cell Lymphoma (PTCL) with the Novel HDAC Inhibitor, Belinostat, in Combination with CHOP: Results of the BelCHOP Phase 1 Trial." Abstract #253 accepted for Oral Presentation at the 2015 ASH Annual Meeting, Dec. 5-8, 2015. Abstract available online at: https://ash.confex.com/ash/2015/webprogram/Paper83281.html

About BELEODAQ®

Beleodaq (belinostat) 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).

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 belinostat 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 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. 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 and proven

track record 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.

About Onxeo

Onxeo has the vision to become a global leader and pioneer in oncology, with a focus on orphan or rare cancers, through developing innovative therapeutic alternatives designed to “make the difference”. The Onxeo team is determined to develop innovative medicines that provide patients with hope and significantly improve their lives.

Key orphan oncology products at the advanced development stage are:

- Livatag® (Doxorubicin Transdrug™)
- Validive® (Clonidine Lauriad®)
- Beleodaq® (belinostat)

For more information, visit the website www.onxeo.com

Disclaimer

This communication expressly or implicitly contains certain forward-looking statements concerning Onxeo and its business. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Onxeo to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Onxeo is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise. For a discussion of risks and uncertainties which could cause actual results, financial condition, performance or achievements of Onxeo to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the 2014 Reference Document filed with the AMF on April 14, 2015, which is available on the AMF website (http://www.amf-france.org) or on the company’s website (www.onxeo.com).

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