



Onxeo Reports Initial Results of Phase 1 Trial Evaluating Belinostat in Combination with CHOP in Peripheral T-cell Lymphoma (PTCL)

Full results to be reported in Oral Presentation at 2015 ASH (American Society of Hematology) Annual Meeting

- *Data demonstrate 89% objective response rate, 72% complete response rate, and good safety profile of belinostat in combination with CHOP*
- *Study supports the interest of belinostat in combination with CHOP as first-line treatment for PTCL*

Paris (France), Copenhagen (Denmark), November 9, 2015 – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, announced the initial results from its Phase 1 trial of belinostat, its potent, pan-HDAC (histone deacetylase) inhibitor, in combination with CHOP chemotherapy regimen as first-line treatment in patients with peripheral T-cell lymphoma (PTCL). The Bel-CHOP combination has demonstrated to be well-tolerated with all components of belinostat and CHOP given at their approved therapeutic doses. Furthermore, the efficacy data indicate that the combination is a promising new regimen in PTCL that Onxeo together with its partner Spectrum Pharmaceuticals will further evaluate in a Phase 3 randomized trial, planned to begin in 2016.

The abstract has been accepted for oral presentation at the [57th American Society of Hematology \(ASH\) Annual Meeting & Exposition](#), being held December 5-8 in Orlando, FL, USA.

The open-label, randomized, two-part trial enrolled a total of 23 patients, of which 11 were enrolled in the dose-escalation Part A to determine the study's primary endpoint, the maximum tolerated dose (MTD), followed by 12 patients treated in Part B at this dose level. The MTD dose was established at 1000 mg/m² IV infusion on days 1-5.

Secondary endpoints included safety, tolerability, and objective response rate (ORR: Complete response + partial response) and pharmacokinetics.

Results outlined in the accepted abstract (#253)¹ demonstrated an objective response rate of 89% based on 18 evaluable patients (16/18), with the vast majority, 72%, achieving a complete response (13/18) and 17% achieving a partial response (3/18). In addition, the combination was shown to have a manageable safety profile with rates of adverse events consistent with those typically reported with CHOP alone.

Graham Dixon, PhD, Chief Scientific Officer of Onxeo, commented, "Currently, CHOP chemotherapy regimens are recommended for first-line treatment of PTCL, however the prognosis remains poor for many patients who relapse within five years, signifying that improved treatment strategies are still very

much needed to produce better outcomes for these patients. This trial confirms that the potential is high for a synergistic effect of a Bel-CHOP combination treatment regimen for patients with PTCL and the initial results showing 72% of patients achieved disappearance of all signs of cancer are very promising.”

Judith Greciet, Chief Executive Officer of Onxeo, added, “Belinostat was approved in the U.S for the second-line treatment of patients with relapsed or refractory PTCL based on results from our pivotal Phase 2 BELIEF study, which demonstrated tolerability and durable clinical benefit of the drug as a single-agent. The findings we will present at the ASH Annual Meeting go well beyond this and indicate that the combination of belinostat and CHOP therapy as first-line treatment generates a highly potent effect compared to the current CHOP regimen alone. Beyond expanding the potential of Belinostat from second- to first-line treatment of PTCL, this study confirms the validity of combining this drug with other therapies for improved outcomes.”

Logistical details for the Oral Presentation at the ASH Annual Meeting are as follows:

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

Presenting Author:	Patrick B. Johnston, MD, PhD (Mayo Clinic, Rochester, USA)
Oral Session Name:	623. Lymphoma: Chemotherapy, excluding Pre-Clinical Models: NHL – New Drugs
Session Date and time:	Sunday, December 6, 2015
Presentation Time:	12:00 p.m. ET
Location, Room:	Orange County Convention Center, W311

The ASH Annual Meeting is the world’s premier event in malignant and non-malignant hematology. The meeting provides an invaluable educational experience and an opportunity to review thousands of scientific abstracts highlighting updates in the hottest topics in hematology.

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 CHOP

CHOP is a chemotherapy treatment regimen for lymphomas typically consisting of the following drugs: cyclophosphamide, doxorubicin (hydroxydaunomycin), vincristine (Oncovin®), and prednisolone (a steroid).

About belinostat (Beleodaq®)

Belinostat is a novel pan-histone deacetylase (HDAC) inhibitor that has anti-cancer activity associated with the inhibition of cell proliferation, the induction of apoptosis (programmed cell death), the inhibition of angiogenesis and the induction of cellular differentiation.

Belinostat is designated as an orphan drug in Europe and the United States. In July 2014, belinostat (Beleodaq®) was granted accelerated approval in the U.S. by the Food and Drug Administration (FDA) for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL) in second-line treatment after failure of standard chemotherapy. Approval was based on results from the pivotal Phase 2 BELIEF study (O’Connor et al, JCO, 2015) of

belinostat in relapsed or refractory PTCL, which demonstrated durable clinical benefit (objective response rate of 25.8%) and good tolerability. The initiation of a Phase III trial in collaboration with Onxeo's U.S. partner, Spectrum Pharmaceuticals, Inc. is planned in 2016 to expand the indication from second to first-line treatment of PTCL.

Beyond PTCL, belinostat's clinical profile supports further development in new and promising orphan oncology indications. Onxeo is currently reviewing potential indications in order to define the optimal development plan for belinostat.

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™): Phase III in hepatocellular carcinoma

Validive® (Clonidine Lauriad®): Phase II in severe oral mucositis: Positive final results

Beleodaq® (belinostat): Registered in the US in 2nd-line treatment of peripheral T-cell lymphoma

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

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