Beleodaq® (belinostat) pivotal BELIEF study results published in the Journal of Clinical Oncology (JCO)

Paris (France), Copenhagen (Denmark), June 23, 2015 – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, today announced the publication of results from the pivotal BELIEF (PXD101-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 JCO is peer-reviewed and is one of the most recognized, selective, and specialized journals within oncology.

The study, led by Dr. Owen O'Connor from the Center for Lymphoid Malignancies, Department of Medicine, Columbia University Medical Center, New York, USA, showed that monotherapy with Beleodaq (belinostat) produced complete and durable responses with manageable toxicity in patients with relapsed or refractory peripheral T-cell lymphoma (R/R PTCL) across the major subtypes, irrespective of the number or type of prior therapies.

Beleodaq is a histone deacetylase (HDAC) inhibitor indicated for the treatment of patients with R/R PTCL. This indication was approved by the US Food and Drug Administration (FDA) in July 2014 based on tumor response rate and duration of response (DOR). A confirmatory trial is in preparation to assess Beleodaq's efficacy and safety in PTCL in the 1st line of treatment in combination with CHOP (Cyclophosphamide, Hydroxydaunorubicin (doxorubicin), Oncovin (vincristine), and Prednisone) standard protocol.

"*We are honored to have the pivotal Beleodaq study results selected as a Rapid Communication in the prominent Journal of Clinical Oncology. This is a highly distinguished category that the JCO reserves for papers judged to have great impact to their broad clinical readership and we at Onxeo are delighted for Beleodaq to be given this recognition*", comments Judith Greciet, CEO of Onxeo.

"*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 new 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 PTCL and the BELIEF 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 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/m2) 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 objective response rate (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). Single-agent belinostat was shown to induce complete and partial responses even in poor prognosis R/R PTCL subtypes, e.g. angioimmunoblastic T-cell lymphoma (AITL) and anaplastic large-cell lymphoma (ALK). Secondary endpoints included a median duration of response 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. 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.

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 second line of treatment in peripheral T-cell lymphoma
For more information, visit the website www.onxeo.com

Disclaimer

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