Belinostat phase I/II results in soft tissue sarcoma to be presented at the 2015 Annual ASCO Meeting

Paris (France), Copenhagen (Denmark), April 9, 2015 [6:30 pm CET] – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, today announced that the phase I/II clinical trial of belinostat in combination with doxorubicin (PXD101-CLN-14) in patients with soft tissue sarcoma (STS) was accepted for presentation in the Poster Discussion Session at the 2015 Annual Meeting of the American Society of Clinical Oncology (ASCO), taking place in Chicago, USA from May 29 to June 2, 2015.

The PXD101-CLN-14 study was an open-label, multicenter, dose-escalation phase I/II to evaluate the safety and efficacy of the combination of belinostat with doxorubicin in patients with advanced solid tumors (the phase I part of the study) and STS (the phase II part of the study).

The trial demonstrated that belinostat in combination with doxorubicin has an acceptable safety profile, allowing the combination of belinostat at the dose of 1000 mg/m^2 on days 1-5 with 75 mg/m^2 doxorubicin on day 5 in a three-week schedule. Signals of efficacy in STS patients were also demonstrated, in this highly severe disease.

> *"We are delighted to be able to present belinostat data at ASCO, which is a recognition for the team's quality work. These additional clinical data complete and reinforce our knowledge and understanding of belinostat, as a anti-cancer compound and on its potential association with a standard chemotherapy like doxorubicin. This is of great interest while we are finalizing Beleodaq's development plan"*, comments Judith Greciet, CEO of Onxeo.

In July 2014, belinostat (Beleodaq®) was granted accelerated approval in the USA by the Food and Drug Administration (FDA) for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL) in 2nd-line treatment after failure of standard chemotherapy. A phase III trial is planned to be initiated in H1 2016 to expand the indication from 2nd to 1st line of treatment of PTCL in collaboration with Onxeo's US partner, Spectrum Pharmaceuticals, Inc.

Beyond PTCL, belinostat's profile, supported by clinical data, advocates for its development in new promising orphan oncology indications. The company is currently reviewing potential indications in order to define the optimal development plan for belinostat.

About soft tissue sarcoma (STS)

Sarcomas are a group of solid tumors in the connective tissue of the body that are treated with surgery, chemotherapy, and/or radiation. Reported objective response rates are very low with complete responses being rare or absent in the trials that have led to the registration of anticancer treatments in this indication over the past six years. Doxorubicin as a single agent or in combination with ifosfamide is the most commonly used chemotherapeutic regimen in patients with advanced STS.

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 preliminary top-line results
Beleodaq® (belinostat): registered in the US in peripheral T-cell lymphoma
For more information, visit the website www.onxeo.com

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