



Onxeo announces positive DSMB recommendation for its Phase III trial with Livatag® in primary liver cancer

Paris (France), Copenhagen (Denmark), November 24, 2014 – Onxeo SA (Euronext Paris, NASDAQ OMX Copenhagen - ONXEO), an innovative company specializing in the development of orphan oncology drugs, today announced that the European Independent Board of Experts (Data Safety and Monitoring Board, DSMB) in charge of the safety monitoring of the Livatag® Phase III trial has once again unanimously recommended continuing the study without modification.

“Each new positive recommendation from our DSMB further strengthens our confidence about Livatag® safety profile and confirms that so far, the product safety profile is as expected. This is of course of great importance for one of our most promising programs”, comments Judith Greciet, CEO of Onxeo.

ReLive is an international, randomized Phase III trial aiming at demonstrating the efficacy of Livatag® on survival in 400 patients with advanced HepatoCellular Carcinoma (primary liver cancer) after failure of intolerance to Sorafenib.

The Data Safety and Monitoring Board meets every 6 months to review the safety data of the ReLive trial and consequently makes recommendations on the conduct of the study. As in previous safety evaluations since trial’s initiation, the DSMB unanimously recommended to continue the study without modification, based on its positive assessment of the safety data of Livatag®. This fully positive recommendation confirms once more the good safety profile of the product.

About HepatoCellular carcinoma

Hepatocellular carcinoma (HCC), or hepatocarcinoma, is the most common of the primary liver cancers (85% to 90%). It is an aggressive cancer which is resistant to chemotherapy. It is the 2nd highest cause of death from cancer worldwide. It is commonly diagnosed at an advanced stage at which time few therapeutic alternatives exist, presenting a strong therapeutic need. The risk factors are well known: infection by hepatitis viruses (B and C), overconsumption of alcohol (another major cause of cirrhosis) and metabolic diseases, especially obesity, a growing cause of cirrhosis and HCC.

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 to “make the difference”. The Onxeo teams are determined to develop innovative medicines to provide patients with hope and significantly improve their lives.

Key products at 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

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 2013 Reference Document filed with the AMF on April 7, 2014, which is available on the AMF website (<http://www.amf-france.org>) or on the company's website (www.onxeo.com).

Contacts :

Judith Greciet, CEO
j.greciet@onxeo.com
Nicolas Fellmann, CFO
n.fellmann@onxeo.com
+33 1 45 58 76 00

Caroline Carmagnol / Sophie Colin – Alize RP
caroline@alizerp.com / scolin@alizerp.com
+33 6 64 18 99 59 / +33 1 44 54 36 62