



***Oral presentation of Phase II trial results of Validive®***

***at the MASCC/ISOO International Symposium***

***Copenhagen, Denmark – 25-27 June 2015***

**Paris (France), Copenhagen (Denmark), May 6, 2015** – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, today announced that Validive® (clonidine Lauriad®) phase II clinical trial results have been accepted for an oral presentation at the MASCC/ISOO International Symposium taking place in Copenhagen from June 25 to June 27, 2015.

The MASCC/ISOO Annual meeting is dedicated to supportive care in cancer and particularly to therapeutic options to minimize symptoms and complications associated with cancer as well as therapy-induced side effects. Its international and multidisciplinary approach dedicated to research and education positions MASCC/ISOO as a reference organization in this growing field.

Late October 2014, Onxeo reported positive preliminary top-line results of the large international Phase II clinical trial with Validive® in the prevention of oral mucositis in patients undergoing head and neck cancer treatment. The study showed a reduction in the incidence of severe oral mucositis with a very good safety. Based on these data and upon Onxeo's Board of experts opinion, the company intends to initiate a Phase III trial to confirm product's efficacy and safety profile end 2015.

*"After a poster presentation of its Phase II results at a major event in the field of oncology, the ASCO 2015 annual meeting, Validive® is now distinguished by the oncology supportive Care international specialists forum. Both selections highlight the quality of the trial and the data obtained as well as the interest of the product in the prevention of severe oral mucositis. These distinctions reinforce our conviction that Validive® is a key asset of our pipeline",* comments Judith Greciet, CEO of Onxeo.

Severe oral mucositis is a particularly invalidating pathology occurring in more than 60% of patients treated with radio/chemotherapy for head and neck cancer and has currently no validated curative or preventive treatment. It may induce intense oral pain and eating disability requiring enteral or parenteral nutritional support. Thirty percent of patients need to be hospitalized as a result and symptoms can force patients to stop treatment for an undefined period thus reducing treatment efficacy.

### **About MASCC/ISOO**

« Multinational Association of Supportive Care in Cancer » (MASCC) is an international, multidisciplinary organization dedicated to supportive care for patients with cancer. In 1998 MASCC joined forces with the « International Society of Oral Oncology » (ISOO), an organization that addresses the management of complications arising in oral tissues secondary to cancer and its treatments.

The MASCC/ISOO Annual Meeting on Supportive Care in Cancer is designed to educate and inform an international audience of healthcare professionals on ways to minimize symptoms and complications associated with cancer as well as therapy-induced side effects. This meeting is intended for physicians, nurses, dentists, oral surgeons, dental hygienists, pharmacists, social workers, nutritionists, and other healthcare providers involved in the care of cancer patients.

### **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](http://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](http://www.onxeo.com)).*

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