



***Validive® at the MASCC/ISOO International Symposium:
Oral presentation of Phase II trial results and
meeting with its International Advisory Board***

Paris (France), Copenhagen (Denmark), June 30, 2015 – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, has presented Validive® (clonidine Lauriad®) Phase II clinical trial results at the MASCC/ISOO International Symposium which took place in Copenhagen from June 25 to June 27, 2015 and on this occasion, held a meeting of its Advisory Board to discuss design of the Phase III clinical trial.

The annual MASCC/ISOO 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. Validive® was distinguished to be part of this oncology supportive care forum with an oral presentation of the positive final results of its Phase II clinical trial. These final data confirm the product's favorable safety profile and efficacy in reducing severe oral mucositis in patients with head and neck cancer receiving chemoradiation therapy. These positive results provide the basis for a Phase III trial to further evaluate the efficacy of Validive®, which Onxeo plans to initiate by end 2015/early 2016.

This event was therefore the designated opportunity for Onxeo to bring together some members of its international Advisory Board* dedicated to oral mucositis and to the associated clinical development program with Validive®. At this point in the product's development stage, the discussion was focused on the Board's recommendations on the Phase III trial design, especially in terms of indication, dosage, population and clinical endpoints, based on the phase II final results.

"We were very happy to share these positive results with the medical community, and in particular with those who need to provide their patients with a new, attractive therapeutic option to prevent severe oral mucositis, a severe condition induced by chemoradiation therapy for which no preventive treatment is currently available. Clonidine Lauriad represents a very promising product and its mucoadhesive formulation makes it especially well adapted to treat oral mucositis", comments Pr René-Jean Bensadoun, principal investigator of the Phase II clinical trial.

"The MASCC conference has been a great opportunity for us to meet with our key advisors to discuss further plans for the development of Validive® further. The board has shown again great enthusiasm around Validive® as a potential treatment of severe oral mucositis and we would like to thank them for their support and accurate advice as international experts of Oral Mucositis, regarding our phase III plan.", added Graham Dixon, CSO Head of R&D of Onxeo.

**This multidisciplinary Advisory Board is composed of internationally recognized European and American experts, in the fields of oral mucositis and oral medicine, oncology and radiotherapy: Drs René-Jean Bensadoun (Nice, France), Paolo Bossi (Milan, Italy), Joel Epstein (Los Angeles, US), Jorge Giralto Lopez del Segredo (Barcelona, Spain), Michael Henke (Freiburg, Germany), Rajesh Lalla (Farmington, US), Stephen Sonis (Boston, US) and Yungan Tao (Villejuif, France). Its purpose is to provide advice and input on development strategy and medical positioning of Validive® in oral mucositis.*

About severe oral mucositis

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 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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