Onxeo Announces Data Demonstrating High Patient Compliance and Acceptability of Validive® for Treatment of Severe Oral Mucositis

Results Presented in Oral ePoster Presentation at ASTRO Annual Meeting 2015

Paris (France), Copenhagen (Denmark), October 22, 2015 – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, announced compliance and patient acceptability results from a global Phase 2 clinical trial demonstrating daily treatment application of Validive® (Clonidine Lauriad®), a mucoadhesive buccal tablet for the prevention and treatment of chemo-radiation therapy-induced severe oral mucositis (SOM) in patients with head and neck cancer, is well-accepted and well-tolerated by patients, with high compliance, before and throughout chemoradiotherapy treatment.

Results of the study, "Compliance and Patient Acceptability of Clonidine Mucoadhesive Buccal Tablet (Clonidine Lauriad) to Prevent Severe Radiomucositis in Head and Neck Cancer Patients" (Presentation # 1139), were presented by investigator Dr. Jordi Giralt, M.D., Ph.D., Head of the Radiation Oncology Service at Vall d'Hebron University Hospital in Barcelona, Spain, during the ePoster 16 Discussion Session "Head and Neck V" at the 57th American Society for Radiation Oncology (ASTRO) Annual Meeting, being held October 18-21, 2015 in San Antonio, TX.

Judith Greciet, Chief Executive Officer of Onxeo, commented, "These results establish that patient treatment compliance with Validive® is high and consistent between investigator and patient assessment. Compliance is key in the treatment of a lasting condition such as severe oral mucositis, about 5 to 8 weeks, as patients' acceptability is critical to ensure optimal efficacy."

The compliance and acceptability portion of the study found the mean overall patient compliance, calculated as the number of tablets taken as an expression for treatment duration in days, to be 95% (95% confidence interval), with median of 98%. The median duration of tablet adherence was 9 hours. Incidence of detachment of the tablet within the 6 hours was 17.1% and replacement of detached tablets with a new tablet was 41.5%. Tablet detachment and replacement rates were higher during the first weeks of the study, suggesting a learning curve. Overall compliance according to the patient diaries was similar in all treatment groups and consistent with the compliance according to the investigator's evaluation (mean of 89% [95%CI], with median of 98%). Overall mean values, at 95% confidence interval, of comfort, pain-burning and taste according to the daily patient scale from 0 to 10, were respectively 1.36, 1.18 and 1.16 and were not different between treatment groups.

These findings follow efficacy and safety results from the global Phase 2 randomized double-blind, placebo-controlled trial, which were presented at the 2015 ASCO Annual Meeting in May, that confirmed Validive® reduced the incidence and delayed the time to chemo-radiation therapy-induced SOM, with

minimal toxicity, compared to placebo in 183 patients with head and neck cancer patients undergoing chemoradiotherapy.

About Validive® (Clonidine Lauriad®)

Validive® is a therapeutic application of clonidine based on the mucoadhesive technology Lauriad®. Onxeo's proprietary Lauriad® technology significantly increases the mucous and salivary concentrations of the active ingredient it contains, with decreased systemic absorption.

As an agonist of the alpha-2 adrenergic receptors, Validive® exhibits anti-inflammatory properties, and was developed for the prevention and treatment of chemoradioation therapy-induced severe oral mucositis in patients with head and neck cancer. Preclinical studies and a Phase II trial have confirmed Validive's mechanism of action and demonstrated that the therapy significantly reduces incidence of severe mucositis, improves oral mucositis-related symptoms and decreases radiotherapy-related adverse events, and exhibits a favorable safety profile and strong adherence to treatment. Based on these results, the trial Advisory Board approved a Phase III trial, which Onxeo plans to initiate by end 2015

Validive® was granted orphan drug status in Europe in November 2011 and also received Fast-Track status from the U.S. Food and Drug Administration (FDA) in January 2014.

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

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).

Contacts :

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

Caroline Carmagnol / Florence Portejoie – Alize RP (France)
onxeo@alizerp.com
+33 6 64 18 99 59 / +33 1 44 54 36 64

Kirsten Thomas / Lee Roth – The Ruth Group (U.S.)
kthomas@theruthgroup.com /
lroth@theruthgroup.com
+1 508 280 6592 / +1 646 536 7012