Positive Phase II preliminary results of Validive for the prevention of Severe Oral Mucositis in Head and Neck cancer patients

Improved oral mucositis related symptoms and decreased adverse events related to radiotherapy

03.11.2014 - Onxeo S.A. announced positive preliminary top-line results from its Phase II clinical trial of Validive® (mucoadhesive buccal tablet MBT clonidine Lauriad®) for prevention of severe oral mucositis (OM).

Oral mucositis is a radio/chemotherapy related condition occurring very frequently in patients undergoing head and neck cancer treatment. Based on the well-established WHO scale, OM is considered as "non severe" for grades 0 to 2, based on level of pain and burden for the patients. From grade 3 to 4, OM is rated severe, based on symptoms such as pain and mouth dryness which prevents patients from drinking and eating and induces increased hospitalization and treatment breaks. With no curative or preventive treatment currently, OM represents a serious unmet medical need for the patients.

Onxeo has performed a large international randomized, double-blind, placebo-controlled Phase II trial comparing the efficacy and safety of Validive® 50 µg and 100 µg applied once daily to those of placebo in the prevention and treatment of chemoradiation therapy-induced severe oral mucositis in 183 patients with head and neck cancer.

All patients received a postoperative radiochemotherapy with a mean cumulative dose of 61 Gray in combination with cisplatin-based chemotherapy in most of the cases. Endpoints were to compare the incidence, severity, time to onset and duration of severe OM as well as use of opioids and other adverse events related to cancer radiation treatment between the Validive® pooled groups and placebo. They were evaluated twice a week during the whole radiotherapy treatment.

The key results of the Phase II study showed:

- Significant decrease in the incidence of severe oral mucositis (grades 3 and 4) in the Validive® pooled arms versus placebo. Overall incidence of severe OM was 45% in the Validive® groups, with a maximum absolute decrease of 16% compared to placebo.
- Occurrence of severe OM has been delayed in the Validive® groups compared to placebo.
- Higher doses of radiation have been received by the Validive® treated patients before severe OM occurred.
Improvement of critical conditions related to severe oral mucositis and radiation therapy, especially dysphagia, nausea and vomiting in both Validive® groups.

No significant difference in efficacy observed between Validive® 50 µg and 100 µg groups.

In terms of safety, Validive® showed a good safety profile with no major difference in the nature, incidence and severity of adverse events in the placebo and the Validive® groups.

Based on these preliminary data the Board has recommended pursuing the development of Validive® with the initiation of a Phase III trial in the same patient population. The company plans to initiate this trial in 2015.