Onxeo files application for key Livatag® patent

Potential expansion of Livatag IP estate to extend commercial exclusivity through 2036

Paris (France), Copenhagen (Denmark), September 15, 2015 – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative biopharmaceutical company specialized in the development of drugs for orphan oncology diseases, today announced that it has filed an international patent application to protect the overall compound related to its primary liver cancer orphan oncology product Livatag®. The patent application has been filed in the US and Europe and will be expanded to include other regions, including the Asian territories, under the patent review procedure. If granted, this patent would protect Livatag® until 2036.

The new patent application is based on a specific composition of nanoparticles resulting from the selection of a particular type of poloxamer that significantly improves the control over the size of the Transdrug™ nanoparticles in the large scale synthesis process. If granted, this "product patent" would provide the strongest possible protection and would enable the extension of Livatag®'s market exclusivity upon commercialization.

Livatag® is currently being evaluated as a second-line treatment for advanced hepatocellular carcinoma (HCC) in an ongoing, international, randomized Phase III clinical trial (the ReLive study), and targets a large market for which there are no available therapeutic options.

Livatag® (doxorubicin Transdrug™) is based on an innovative technology allowing formulating a chemotherapeutic agent (e.g. doxorubicin) within nanoparticles composed of polyalkylcyanoacrylate, cyclodextrin, and poloxamer (the Transdrug™ nanoparticles). This nanoparticle formulation provides new and promising therapeutic properties, such as overcoming the mechanisms of chemo resistance developed by tumor cells that affect standard chemotherapy agents.

Livatag® is currently protected by two robust patent families, one of which covers the first generation of nanoparticles of doxorubicin until 2019, with the second covering the specific administration scheme until 2031/2032, depending on the territories.

"This patent application represents an important opportunity to strengthen the IP protections related to Livatag®, which is a significant asset for the Company. Moreover, it is a major achievement for our intellectual property and scientific teams as the patent, if granted, will further extend Livatag®'s market exclusivity in key regions including Asia. Already in late stage clinical development, Livatag® targets a large market, with a peak sales potential estimated at €800 million. We believe that the product can generate substantive value for Onxeo and our shareholders, and the ability to retain that potential value through patents and other means is of paramount importance as we continue to move forward", said Judith Greciet, CEO of Onxeo.

About ReLive

ReLive is an international Phase III trial designed to assess Livatag®'s efficacy on survival in 400 patients with advanced hepatocellular carcinoma (HCC) following treatment after failure or intolerance to Sorafenib. The trial is implemented in 11 countries (Europe, US, MENA region). To date, 50% of patients (i.e. about 200 patients) have been randomized, around 65 patients per arm and more than 100 patients have been treated with Livatag® for a total of about 450 infusions. This recruitment rate is in line with expected timelines of issuing preliminary outcomes of the Phase III study by H1 2017.

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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