



THE ORPHAN ONCOLOGY INNOVATOR

Onxeo receives USPTO Notice of Allowance for key AsiDNA™ patent, extending IP protection in the U.S. until 2031

- **Products, including AsiDNA (signal interfering DNA), protected until 2031 with potential extension to 2036**
- **Onxeo's intellectual property for DNA repair signal interfering technology and products protected by 8 patent families worldwide**

Paris (France), Copenhagen (Denmark), July 4, 2016 – Onxeo S.A. (Euronext Paris, Nasdaq Copenhagen: ONXEO), an innovative company specialized in the development of orphan oncology therapies, today announced it received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) relating to a key patent for its signal interfering DNA product candidate, AsiDNA™.

This new patent significantly strengthens the Company's AsiDNA intellectual property portfolio by protecting several conjugated nucleic acid molecules as well as AsiDNA's pharmaceutical composition and related methods for treating cancer. The patent application was filed in October 2015 as a continuation of a first US application (now Pat. No. 9,205,099, granted in February 2016) and allowed today. This patent's allowance, less than one year after its filing confirms the innovative science behind the technology of Signal Interfering DNA products. Corresponding patent applications have been already granted and/or are currently under examination notably in Europe, Australia, Canada, China, Israel, India and Japan.

The allowed patent has a term expiring in mid-2031, before a possible patent term adjustment (PTA). This term could be further extended to 2036 through the patent term extension (PTE)..

The IP estate related to AsiDNA consists of eight worldwide patent families, covering its technology platform, its products conjugated or not, their therapeutic utilization as a monotherapy or in combination with radiotherapy, hyperthermia or chemotherapy as well as their method of administration and potential biomarkers for predicting the response to a therapy with AsiDNA and/or other related products.

"Strengthening our intellectual property protection is a key element of our ambitious development plan for AsiDNA and our ability to deliver on its full potential in a large number of indications. We are pleased that the USPTO issued this Notice of Allowance so quickly after the initial application was submitted, which we believe speaks to the unique and innovative nature of the technology," commented Judith Greciet, CEO of Onxeo.

"Building a strong patent position in the US is an important part of our value-creation strategy across all of our product and platform candidates. The addition of this patent to the AsiDNA IP portfolio will

significantly strengthen our position in the DNA repair market and protect our ability to continue developing this novel technology,” added Aude Michel, Head of Corporate Development at Onxeo also in charge of IP.

AsiDNA: a first-in-class DNA repair signal interfering product with blockbuster potential

Onxeo’s first-in-class signal-interfering (siDNA) product candidate, AsiDNA, is a short, double-stranded DNA molecule that breaks the cycle of tumor DNA repair by interfering at the core of DNA damage, blocking multiple repair pathways, while sparing healthy cells. AsiDNA and its signal-interfering technology offer potential new treatment options for patients suffering from various types of cancer.

The technology has already demonstrated its ability to increase the efficacy of radiotherapy¹, radiofrequency ablation², and chemotherapy³ in a variety of preclinical animal models, positioning it as a promising candidate for both mono- and combination therapy. A first-in-human Phase I trial⁴ (DRIIM) for metastatic melanoma further demonstrated that AsiDNA therapy showed strong tolerance and safety when administered intra-tumorally and subcutaneously around the tumors, with no evidence of inflammatory reaction. Results presented at ASCO 2015⁵ showed, based on 23 patients, an objective response rate (ORR) of 59% and a complete response (CR) rate of 30% compared to 10% CR with low-dose radiotherapy alone⁶.

About Onxeo

Onxeo is a leading developer of orphan oncology drugs. The Company is focused on developing innovative therapeutics for rare cancers, one of the fastest growing markets in the healthcare industry with high, unmet medical needs. Onxeo’s vision is to become a global leader and pioneer in oncology, with a focus on orphan or rare cancers, by developing advanced, effective, and safe therapeutics designed to improve the lives of patients. Onxeo’s comprehensive portfolio features a broad orphan oncology pipeline, with four independent programs in various stages of clinical development, including Onxeo’s first approved orphan oncology drug, Beleodaq®. The Company is headquartered in Paris, France and has approximately 50 employees. Onxeo is listed on Euronext in Paris, France (Ticker: ONXEO, ISIN Code: FR0010095596) and Nasdaq Copenhagen, Denmark (Ticker: ONXEO).

Onxeo’s orphan oncology products are:

- **Livatag®** (Doxorubicin Transdrug™): Currently being evaluated in a Phase III trial (ReLive) in patients with hepatocellular carcinoma (primary liver cancer); and in combination with other cancer agents in first-line HCC
- **Beleodaq®** (belinostat): FDA-approved in the US in 2014 under the agency’s accelerated approval program as a second-line treatment for patients with peripheral T-cell lymphoma (PTCL) and currently marketed by Onxeo’s partner in the US, Spectrum Pharmaceuticals; belinostat in combination with other cancer agents is currently in development in first-line treatment for patients with PTCL (BelCHOP) and in other solid tumors
- **AsiDNA**: The first-in-class siDNA (signal-interfering DNA) which has successfully undergone a proof-of-concept Phase I trial in metastatic melanoma
- **Validive®** (Clonidine Lauriad®): Positive final results from a Phase II trial in head and neck cancer patients with severe oral mucositis

In addition, Onxeo has successfully developed and registered two non-cancer products which are currently being commercialized in the U.S. and Europe.

Learn more by visiting www.onxeo.com.

To receive our press releases and newsletters, please register on: <http://www.onxeo.com/en/newsletter/>

¹ Quanz et al., 2009, Berthault et al., 2011, Coquery et al., 2012, Biau et al., 2014

² Devun et al., 2014

³ Devun et al. 2011, Herath et al., 2016

⁴ DRIIM Phase 1 trial, “DNA Repair Inhibitor & Irradiation on Melanoma” NCT01469455)

⁵ Abstract available at <http://meetinglibrary.asco.org/content/143029-156>

⁶ Based on literature data.

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