

Onxeo Reports Third Quarter Financial Information and Provides Business Update

- **AsiDNA™ clinical development progressing to plan**
 - First safety and activity results of the phase I DRIIV-1 study expected in Q4 2018
 - Phase Ib/IIa combination studies of AsiDNA™ to be initiated as early as H1 2019
- **New first-in-class compound from PlatON™, expected before end 2018, will enter preclinical testing in 2019**
- **Cash position of €13 million at September 30, 2018, supports the Company's development in the attractive field of DNA Damage Response into 2020**

Paris, October 25, 2018 – 6:30 pm CEST - Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO FR0010095596), a clinical-stage biotechnology company specializing in the development of innovative drugs in oncology targeting tumor DNA Damage Response (DDR) to fight resistant cancers, today reported its consolidated revenues and cash position at September 30, 2018, and provided a business update.

Judith Greciet, Chief Executive Officer of Onxeo, said: *“The development of AsiDNA™, our strongly differentiated lead product in the compelling field of DNA Damage Response (DDR), has considerably accelerated in the third quarter of 2018, especially on the clinical side with the DRIIV -1 study running at full speed. Given the favorable recruitment pace, we are on track to publish the preliminary activity results before the end of this year. These activity data will be of paramount importance as they should confirm that AsiDNA™ enters tumoral cells and engages with its biological targets. This demonstration that AsiDNA™ is active in man via intravenous administration will represent a significant catalyst in the value of this product. This will open the way to the initiation of phase Ib/IIa combination studies to confirm the interest of combining AsiDNA™ with PARP inhibitors or other tumor-DNA damaging agent, and Onxeo plans to start a first combination study as soon as H1 2019. The optimization of new leads from PlatON™ is also moving forward. We maintain our objective to announce a new drug candidate, with different targets from those of AsiDNA™, by the end of 2018 in order to proceed with preclinical tests in 2019.”*

Q3 2018 financial information

Revenues for the third quarter of 2018 reached €3.3 million and consisted of:

- €0.6 million in recurring revenues, in line with 2017 figure, corresponding to product sales from the European named patient program (NPP) and royalties on sales of partner Spectrum Pharmaceuticals. The latter has no cash impact as a result of the royalty monetization implemented in June 2018 with SWK Holdings Corporation.
- €2.7 million in non-recurring revenues mostly including milestone payments from licensing agreements on historical products divested to Vectans Pharma in July 2017. Indeed, Onxeo has retained the right to most milestones payments attached to the products sold to Vectans.



At September 30, 2018, the Company had a consolidated cash position of €13 million compared with €11 million at June 30, 2018. This cash position includes €2.4 million in gross proceeds from drawdowns of the equity line implemented on June 15, 2018, with Nice & Green SA. Provided full utilization of this financing reserve, cash runway will extend into 2020, allowing the Company to reach planned short-term value-creating milestones resulting from current preclinical and clinical programs.

9-month 2018 corporate highlights, recent events & outlook

• **AsiDNA™**

- New 'composition of matter' patent granted in January 2018 providing European protection until 2031 with a potential extension to 2036. Together with previously granted patents, Onxeo's DNA-targeting technologies, products and combinations are now protected by 10 patent families worldwide.
- Additional preclinical results of AsiDNA™ in combination with PARP inhibitors (PARPi), published in July 2018, demonstrated a strong synergistic effect and a reversion of tumor resistance.
- The DRIIV-1 study of AsiDNA™, conducted at leading oncology centers in France and Belgium since April 2018, is progressing according to plan. The favorable pace of recruitment confirms the Company's expectations of publishing preliminary activity results in Q4 2018 and completing the study in Q1 2019.

The positive preclinical data of AsiDNA™ in combination with PARPi, together with the expected activity results of the DRIIV-1 study, will support the initiation of phase Ib/IIa studies of AsiDNA™ in combination in H1 2019.

• **platON™**

- Onxeo's proprietary chemistry platform enables the Company to generate additional innovative drug candidates with the common feature of targeting tumor DNA functions through a decoy mechanism.
- Onxeo has made significant progress in the optimization of a new compound and expects to announce, by the end of the year, a new first-in-class drug candidate, targeting different tumor cell DNA-binding functions than AsiDNA™.
- The Company intends to initiate preclinical studies and CMC activities for this new compound in 2019.

• **Beleodaq®**

- Onxeo¹ and Spectrum Pharmaceuticals received a Paragraph IV Notice Letter stating that Fresenius Kabi USA, LLC has submitted to the FDA an Abbreviated New Drug Application seeking approval from the FDA to manufacture and market a generic version of Beleodaq® (belinostat) for injection, 500 mg, in the United States.
- Onxeo and Spectrum jointly filed a patent infringement lawsuit² against Fresenius which triggered a stay of FDA approval of Fresenius' ANDA that expires on January 3, 2022. Onxeo and Spectrum have confidence in the validity of the patents covering Beleodaq® in the US. In addition, Beleodaq® is protected from competition in the United States by Orphan Drug Exclusivity until July 3, 2021.

UPCOMING EVENTS

- **BIO-Europe:** November 5-7, 2018, Copenhagen (Denmark)
- **Boursocap / Les Echos – Investir Event:** November 21, 2018, Paris (France)
- **Investor meetings during the JP Morgan Healthcare Conference 2019:** January 7-10, 2019, San Francisco (US)
- **BioMed Event:** January 22, 2019, Paris (France)

¹ Through its fully owned subsidiary, Topotarget UK.

² The case is pending in Delaware, is in the early pleading stages, and is captioned *Spectrum Pharmaceuticals, Inc. et al v. Fresenius Kabi USA, LLC et al*, 18-cv-01533 (CFC)



About Onxeo

Onxeo (Euronext Paris, NASDAQ Copenhagen: ONXEO) is a clinical-stage biotechnology company developing innovative oncology drugs targeting tumor DNA-binding functions through unique mechanisms of action in the sought-after field of DNA Damage Response (DDR). The Company is focused on bringing early-stage first-in-class or disruptive compounds (proprietary, acquired or in-licensed) from translational research to clinical proof-of-concept, a value-creating inflection point appealing to potential partners.

Onxeo is developing **AsiDNA™**, a first-in-class, highly differentiated DNA Damage Response (DDR) inhibitor based on a unique decoy & agonist mechanism acting upstream of multiple DDR pathways. Translational research has highlighted the unique properties of AsiDNA™, notably its ability to oppose and even reverse tumor resistance to PARP inhibitors regardless of the genetic mutation status, and its strong synergy with other tumor DNA-damaging agents such as chemotherapy and PARP inhibitors. AsiDNA™ is currently being evaluated for systemic (IV) administration in advanced solid tumors in the DRIIV-1 phase I study (DNA Repair Inhibitor administered IntraVenously).

AsiDNA™ is the first compound generated from **platON™**, the Company's proprietary chemistry platform of decoy oligonucleotides dedicated to the generation of new innovative leads to broaden Onxeo's pipeline.

Onxeo's portfolio also includes **belinostat**, an HDAC inhibitor (epigenetics). Belinostat is already conditionally FDA-approved as a 2nd line treatment for patients with peripheral T cell lymphoma and marketed in the US by Onxeo's partner, Spectrum Pharmaceuticals, under the name Beleodaq®.

For further information, please visit www.onxeo.com

Forward looking statements

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 section 5.7.1.4 "Risk Factors" ("*Facteurs de Risque*") of the 2017 registration document filed with the *Autorité des marchés financiers* on April 25, 2018 under number D.18-0389, which is available on the *Autorité des marchés financiers* website (www.amf-france.org) or on the Company's website (www.onxeo.com).

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