



## ***Onxeo announces acquisition of DNA Therapeutics and provides update on Validive® development plan***

- *Onxeo acquires first-in-class, signal-interfering DNA molecule based on one of the most promising new approaches in cancer treatment*
- *Acquisition expands Company's R&D pipeline and opens new opportunities in orphan oncology indications*
  - *Further development of Validive® to be conducted in partnership*

**Paris (France), Copenhagen (Denmark), February 29, 2016** – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology therapeutics, today announced that it has reached an agreement to acquire DNA Therapeutics, a privately-held, clinical-stage biopharmaceutical company, for its signal-interfering DNA (siDNA) repair technology, which is directed at overcoming cancer resistance mechanisms, and includes lead product candidate DT01. The acquisition, which is subject to customary closing conditions, is expected to close by the end of March 2016.

The acquisition of DNA Therapeutics continues to demonstrate Onxeo's commitment to developing novel orphan oncology drugs that position the Company at the forefront of scientific research for rare cancers with high, unmet medical needs, and have the potential to generate significant value for the Company and its stakeholders by opening other indications and markets.

Under the terms of the agreement, Onxeo is acquiring DNA Therapeutics for an upfront payment of €1.7 million in common shares at deal closing. Additional payment will come in the form of milestones including €1 million in cash or in ONXEO shares, at ONXEO's sole discretion, upon successful initiation of a Phase II trial in a selected indication as well as royalty payments on future commercial sales, up to €25 million per indication developed and approved.

In conjunction with the transaction, in parallel with the contribution in kind, a large part of DNA Therapeutics' historical shareholders have agreed to invest €1 million in cash in Onxeo shares, showing their full support to Onxeo to take over the development of the siDNA technology.

Interview of Judith Greciet:

<http://www.labourseetlavie.com/videos/entreprises-strategie-et-resultats/judith-greciet-ceo-onxeo-it-s-really-in-our-core-strategy,2292.html>

### **The signal-interfering DNA (siDNA) innovation**

Through DNA Therapeutics, Onxeo is acquiring a first-in-class clinical signal-interfering DNA (siDNA) molecule breaking the cycle of tumor DNA repair while sparing healthy cells. The siDNA technology offers a potential new treatment option for patients suffering from various types of cancer.

A first-in-human Phase 1/2a trial performed in metastatic melanoma demonstrated that siDNA molecules showed good tolerance and safety when administered intra-tumorally and subcutaneously around the tumors. Onxeo now plans to initiate the development of this first-in-class product by the systemic route, and to assess their safety and tolerance in monotherapy and in combination with other DNA-damaging agents in various solid tumors. This clinical development will be implemented after first optimizing the manufacturing process, set to start as soon as the deal closes.

Judith Greciet, CEO of Onxeo, commented: *“The acquisition of DNA Therapeutics and its siDNA technology represents a significant milestone for Onxeo. We are excited about this opportunity, which, based on its differentiated mechanism of action to fight cancer, will be significant in strengthening the level of innovation in our orphan oncology portfolio and instrumental in delivering value for our shareholders. The development of new agents specifically targeting DNA repair while sparing healthy tissues is imperative in the treatment of many solid tumors. Based on preclinical findings, we plan to evaluate the product in orphan oncology indications where a systemic application is suitable and for which there is significant unmet need, for example triple-negative breast cancer and platinum-resistant ovarian cancer”.*

### **Update on Validive® further steps**

Over the course of 2015, Onxeo has continued to advance the clinical development of Validive® and notably its validation by the US and European regulatory agencies. Despite recognition from both agencies of Validive®’s interest and value to patients, these discussions have confirmed that two Phase 3 clinical trials will be required for registration in the US, which makes the further clinical program significantly longer and more costly than expected. Therefore, the Company has decided it is in the best interest of its shareholders to move forward with this Phase 3 program only with the support of a partner. While actively seeking for such collaboration, Onxeo will continue to promote the scientific value of Validive® through presentations at meetings.

*“Validive® remains a key asset in our orphan oncology pipeline. We have successfully developed the product to date and it is ready to enter Phase 3 as soon as we find the appropriate partner,”* commented Judith Greciet. *“We are particularly excited about the acquisition of DNA Therapeutics and its first-in-class product-candidate which largely complements our core expertise and scientific ambitions. We believe it will be a tremendous addition to our pipeline, creating sound opportunity for short-to-long term milestones, adding value for our shareholders and bringing potentially new treatment options to patients with rare cancers.”*

### **About DNA repair**

Biological responses to DNA damage and approaches to prevent the repair mechanisms allowing cancer cells to escape treatments have been identified as one of the most promising new avenues in cancer treatment. Most therapies against cancer induce DNA damage to tumor cells. DNA damage can also occur spontaneously in certain types of genetically unstable cancers. Yet cancer cells have the ability to recognize DNA damage and activate multiple DNA repair pathways or proteins to survive damages. These DNA repair processes contribute to cancer aggressiveness and resistance.

## About the signal-interfering DNA (siDNA) technology

The siDNA technology developed by DNA Therapeutics, and acquired by Onxeo, breaks the cycle of cancer DNA repair activities by interfering at the core of DNA damage and interfering with multiple repair pathways, while sparing healthy cells. The technology, known as Dbait, was invented by Marie Dutreix, Research Director at The French National Centre for Scientific Research (CNRS), and Jian-Sheng Sun, Professor at The French National Museum of Natural History (Museum National d'Histoire Naturelle) in Paris, and further developed in Dr. Dutreix's lab at Institut Curie. DNA Therapeutics was formed as a spin-out of the Institut Curie and three other French academic institutions.

The siDNA molecule is a short double-stranded DNA molecule that acts as a decoy, providing a false DNA break signal to attract DNA repair proteins which prevents the recruitment of repair enzymes to the site of actual DNA damage. Cancer cells do not have the ability to stop division in the face of DNA damage; they will continue dividing with the damaged DNA and therefore die. Healthy cells, on the other hand, will halt cell division until the compound is no longer present and damaged DNA can be repaired.

In a variety of preclinical animal models, the siDNA molecule demonstrated an increase in the efficacy of radiotherapy<sup>1</sup>, radiofrequency ablation<sup>2</sup>, and chemotherapy<sup>3</sup>, and has not lead to toxicity with repeated cycles of treatment, making it a promising candidate for both monotherapy and combination therapy. A first-in-human Phase 1/2a trial, "DNA Repair Inhibitor & Irradiation on Melanoma" (DRIIM; NCT01469455), in patients with metastatic melanoma demonstrated the safety of local administration of the product. Additionally, no maximum-tolerated dose (MTD) was identified and the product showed excellent tumor response correlated with systemic exposure.

## 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 comprehensive portfolio features a broad orphan oncology pipeline, with three independent programs in advanced clinical development, including Onxeo's first approved orphan oncology drug, Beleodaq®. In addition, Onxeo has successfully developed and registered two non-cancer products which are currently being commercialized in the U.S. and Europe. 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. 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 orphan oncology products at the advanced development stage are:

- **Livatag®** (Doxorubicin Transdrug™): Currently being evaluated in a Phase III trial (ReLive) in patients with hepatocellular carcinoma (primary liver cancer);
- **Validive®** (Clonidine Lauriad®): Positive final results from a Phase II trial in head and neck cancer patients with severe oral mucositis;
- **Beleodaq®** (belinostat): FDA-approved in the U.S. 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 U.S., Spectrum Pharmaceuticals; belinostat in combination with CHOP (BelCHOP) is also in development as first-line treatment for patients with PTCL.

For more information, visit the website [www.onxeo.com](http://www.onxeo.com)

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

Follow us on Twitter: @Onxeo\_

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

**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](http://www.onxeo.com)).

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## MAIN TERMS AND CONDITIONS OF THE CONTRIBUTION IN KIND

**Nature of the transaction..** The present transaction is a contribution in kind governed by the common rules applicable to the contributions in kind set forth under Article L. 225-147 of the French Commercial Code.

**Legal Framework of the Issuance.....** The Board of Directors of ONXEO will make use of the delegation granted under the 14<sup>th</sup> resolution approved by the ordinary and extraordinary shareholders' meeting on May 20, 2015 for the ONXEO new shares to be issued in consideration for the contribution referred to in the present press release.

**Reasons for the Offer .....** These ONXEO new shares will be issued in consideration for the contribution of all the securities issued by DNA THERAPEUTICS and contributed by their holders to ONXEO.

**Consideration for the Contribution .....** The transaction will be paid through the issuance of 553,819 ONXEO new shares for an issuance price equal to the weighted average market price of ONXEO on the Euronext Paris market over the thirty trading sessions preceding February 29, 2016, i.e. execution date of the agreement between ONXEO and the holders of DNA THERAPEUTICS' securities.

An additional consideration equal to € 1 million will be payable in cash or in ONXEO shares, at ONXEO's sole discretion, to the contributors subject to product entering into at least one Phase II clinical trial. Additional payments payable in cash will be due to the contributors in case of commercialization of the product on the basis of the sums received in this respect.

**Entitlement to New Shares** The new shares will be ordinary shares of the same class as the existing shares. They will be entitled to dividend rights and be equivalent to the existing shares of the company as from the date of completion of the transfer of ownership of the DNA THERAPEUTICS' securities to ONXEO.

**Listing of the New Shares ..** The new shares issued as a result of the capital increase will be subject to an admission request for trading on compartment B of Euronext Paris and on NASDAQ Copenhagen. Their listing will however occur only upon delivery of the certificate of filing of the custodian. They will be admitted on the same quotation line as the existing shares, will be totally assimilated to them upon admission to trading and will be traded under ISIN code FR0010095596 – mnemonic code: ONXEO.

**Lock-up.....** For a period of 3 to 6 months, depending on the contributors, as from the closing date, the contributors will commit not to sell all or part of the ONXEO shares they shall receive in consideration for their contribution.

**Conditions Precedent**..... The completion of the transaction will be subject to the satisfaction of certain conditions precedent, including notably the issuance by BM & A, who has been appointed as expert appraiser for the contribution in kind by order of the President of the Commercial Court of Paris dated February 3, 2016, of its report as required under the applicable regulations.

**Impact on the Company's**

<b>Shareholders' Equity</b> .....	Portion of the group's shareholders' equity per share	Non-Diluted Basis	Diluted Basis
	Before issuance of the new shares resulting from the capital increase <sup>1</sup> .....	€ 2.45	€ 2.34
	After issuance of the new shares resulting from the capital increase.....	€ 2.41	€ 2.31

<b>Impact on shareholder's equity share</b> .....	Shareholder's equity share	Non-Diluted basis	Diluted Basis
	Before issuance of the new shares resulting from the capital increase <sup>1</sup> .....	1%	0.95%
	After issuance of the new shares resulting from the capital increase.....	0.99%	0.94%

**MAIN TERMS AND CONDITIONS OF THE PRIVATE PLACEMENT**

**Nature of the transaction** ..... Capital increase through the issuance of new ordinary shares, with cancellation of the shareholders' preferential right, through a private placement as provided for under L. 411-2 of the French Monetary and Financial Code.

**Legal Framework of the Issuance**...  
The Board of Directors of ONXEO will make use of the delegation granted under the 10<sup>th</sup> resolution approved by the ordinary and extraordinary shareholders' meeting on 20 May 2015.

**Reasons for the Offer** ..... This capital increase is made in the context of the contribution in kind to ONXEO of all the securities issued by DNA THERAPEUTICS and is designed to enhance ONXEO's financial resources and allow DNA THERAPEUTICS' shareholders to support ONXEO's development.

**Beneficiaries of the Offer** ..... The offer is reserved to a restricted circle of investors, composed of those of the DNA THERAPEUTICS' shareholders willing to support ONXEO, in particular for the development of the assets formerly developed by DNA THERAPEUTICS.

**Maximum Amount of the Offer** .....

<sup>1</sup> On an aggregate number of shares of 40.552.083

One million Euros (€ 1,000,000)

**Number of New Shares /**

**Subscription Price .....** The transaction will be made through the issuance of a number of new shares determined on the completion date by application of an issuance price equal to the weighted average market price of the ONXEO shares on the Euronext Paris market during the five trading sessions immediately preceding the completing date, reduced by a discount of 15%.

**Entitlement to New Shares.....** The new shares will be ordinary shares of the same class as the existing shares. They will be entitled to dividend rights and be equivalent to the existing shares of the company as from the date of completion of the transfer of ownership of the DNA THERAPEUTICS' securities to ONXEO.

**Listing of the New Shares .....** The new shares issued as a result of the capital increase will be subject to an admission request for trading on compartment B of Euronext Paris and on the NASDAQ Copenhagen. Their listing will however occur only upon delivery of the certificate of filing of the custodian. They will be admitted on the same quotation line as the existing shares, will be totally assimilated to them upon admission to trading and will be traded under ISIN code FR0010095596 – mnemonic code: ONXEO.

**Lock-up.....** For a period of 3 months as from the completion date, the investors will commit not to sell all or part of the ONXEO shares they will have subscribed through this private placement. Then, as from the expiration date of this first period, the investors will commit not to sell (i) more than a third of their shares per month and (ii) more than a third of the weighted average of the daily transactions over the preceding thirty trading sessions, during any given trading session.

**Impact on the Company's Shareholders' Equity and on the share of any given shareholder in Shareholder's Equity .....**

The impact on the shareholders' equity and on the share of any given shareholder in the Shareholders' Equity will be determined on the new shares issuance date, based upon the definitive issuance price and the number of issued shares.

**Completion.....** It is contemplated that the present private placement will be completed simultaneously to the contribution in kind of all the DNA THERAPEUTICS' securities to ONXEO.

In accordance with the provisions of article L. 411-2 of the French Monetary and Financial Code and article 211-2 of the General Regulations of the French Financial Market Authority (Autorité des marchés financiers, AMF), this transaction is not subject to a prospectus to be approved by the AMF as the total amount of the transaction is between €100,000 and €5,000,000 and represents less than 50% of Company total share capital.