



THE ORPHAN ONCOLOGY INNOVATOR

## ***Key milestones and consolidated accounts***

### ***First six months 2014***

- ***Major evolution of the Company, renamed Onxeo, resulting from the merger between BioAlliance Pharma and Topotarget***
- ***Good progress of the major portfolio products***
- ***Financial resources strengthened and expenses controlled***

**Paris (France), Copenhagen (Denmark), August 1, 2014** – Onxeo SA (Euronext Paris, NASDAQ OMX Copenhagen - ONXEO), an innovative company specialized in the development of drugs for orphan oncology diseases, today publishes its consolidated half-year accounts as of June 30, 2014, and the major key milestones achieved during the first six months.

The first six months were marked by a major and particularly outstanding event in the European biotech environment, the merger between BioAlliance Pharma and Topotarget. This transforming and ambitious transaction, approved by more than 99% of both companies' shareholders, has given birth to Onxeo, a major player in the rare and/or orphan oncology diseases area. The company has an enlarged portfolio of advanced programs and a highly skilled team of experts in the development and registration of drugs. Thanks to this transaction, completed on July 22, 2014, Onxeo has acquired an international dimension with teams in France and Denmark, a dual listing on Euronext Paris and Nasdaq OMX Copenhagen, an enlarged shareholder base and a strategic partnership with Spectrum Pharmaceuticals, who have the responsibility of the co-development and commercialization of Beleodaq® (belinostat) in the U.S. market.

The first six months of 2014 were also marked by significant achievements in the development of the key programs:

#### **Livatag® (doxorubicin Transdrug™)**

- Active European expansion of the phase III trial ReLive in primary liver cancer, and for the fourth time, the Data Safety Monitoring Board (DSMB), in charge of reviewing trial safety data, has issued a positive recommendation, confirming Livatag®'s good safety profile.
- « Fast Track » designation obtained from the Food and Drug Administration (FDA) allowing enhanced interaction between Onxeo and the FDA to optimize review process from development phase to registration.

### Validive® (clonidine Lauriad®)

- In May, completed recruitment of the 183 patients planned in the international phase II clinical trial, therefore remaining on track for the announcement of the preliminary trial results in Q4 2014.
- « Fast Track » designation obtained from the FDA in the prevention and treatment of oral mucositis induced by radiotherapy and/or chemotherapy in cancer patients. This status shows FDA recognition of oral mucositis severity and medical needs that Validive® could address.

### Beleodaq® (belinostat):

- Grant of U.S. marketing authorization of Beleodaq® for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). This approval triggered a \$25 million payment from the American partner, Spectrum Pharmaceuticals. Beleodaq® has been available to patients since July 2014 and is promoted in the U.S. by Spectrum's oncology sales team.

During the first six months, Onxeo enhanced value of its non-strategic and already registered products through partnership agreements, notably with Sitavig® with a licensing agreement signed with U.S. company Innocutis (Charleston, SC) who launched the product on the U.S. market in July.

### Analysis of the H1 2014 accounts

Consolidated accounts (IFRS-compliant) <i>In thousands Euros</i>	30/06/2014 (6 months)	30/06/2013 (6 months)
Revenues	653	845
Operating expenses	(9 188)	(8 430)
<i>R&amp;D investments</i>	(5 662)	(5 213)
Operating profit/loss	(8 535)	(7 585)
Non-recurring charges linked to the merger	(4 397)	0
Net profit/loss	(12 951)	(7 488)

*The above summarized consolidated accounts of Onxeo only includes BioAlliance Pharma's activity for the 1<sup>st</sup> six months, Topotarget being in the scope from June 30, 2014, date of merger with BioAlliance Pharma, according to the IFRS standard.*

The first six months accounts reflect the control of operating expenses in the context of a strong acceleration of company's clinical programs.

Indeed, although the company has reached many significant achievements during the period, it has succeeded in controlling R&D expenses, the major part of operating expenses, with a 9% increase compared to the first six months of 2013. Including the other expense lines, whose increase also

remained limited in the first half, the operating income, excluding non-recurring expenses related to the merger, is in line with the previous year.

The cash usage was also limited (- €6.4 million) and Onxeo strengthened its overall cash level with the contribution of €14.2 million from Topotarget on June 30, 2014. This amount includes milestones received from Spectrum Pharmaceuticals early this year, upon acceptance for filing of Beleodaq®'s New Drug Application from the FDA. These milestones amounted to \$10 million and 1 million Spectrum shares. Accordingly, the consolidated cash position of Onxeo has increased from €11.3 million as of December 31, 2013 to €19.1 million as of June 30, 2014. During the second half of 2014, a loan of €10 million has been granted by Financière de la Montagne, the company's largest shareholder, and a \$25 million milestone related to Beleodaq®'s registration will be received before year end.

*"The merger with Topotarget and the creation of Onxeo represent a key strategic step for the company, which will accelerate value creation based on its new assets in the orphan oncology therapeutic area, a sector with increasing value. I am particularly proud of this achievement, supported by the company's teams, by our Board of directors and by our shareholders. This merger gives us a real critical mass and places Onxeo as a major player in Europe",* comments Judith Greciet, CEO of Onxeo.

The half-year financial report including half-year accounts as of June 30, 2014 has been approved by the Board of directors on August 1, 2014. This report, as well as Onxeo half-year activity report, are available on the company's website: [www.onxeo.com](http://www.onxeo.com).

#### **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 to "make the difference". The Onxeo teams are determined to develop innovative medicines to provide patients with hope and significantly improve their lives.

#### **Key products at advanced development stage are:**

Livatag® (Doxorubicin Transdrug™): Phase III in hepatocellular carcinoma

Validive® (Clonidine Lauriad®): Phase II in severe oral mucositis

Beleodaq® (belinostat): registered in the US in peripheral T-cell lymphoma

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

#### **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 2013 Reference Document filed with the AMF on April 7, 2014, 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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