

## Shareholders Letter January 2015



### *From 2014 to 2015 / Significant achievements to prepare the future*

Dear Shareholders,

2014 marked a turning point in the history of our group.

The merger, completed a little more than six months ago, was a key step to position Onxeo as a strong player in **orphan oncology**.

Today, Onxeo conceives and develops innovative treatments for rare cancer patients, highly promising in terms of therapeutic value and market potential.

2015 will bring exciting news on our major programs at an advanced clinical stage, Livatag®, Validive® and Beleodaq®. This letter will tell you more about it.

Our ambition for the future is to strengthen the growth momentum initiated these past months through the development of our programs and our partnering activities. This growth should be enhanced by the orphan oncology market dynamism, one of the fastest growing market in health industry.

We would like to thank you for your continued trust and, through this letter, reaffirm the commitment of our international and experienced teams to build Onxeo's future success and bring innovative therapeutics for rare cancers to patients. We sincerely hope that you will keep supporting us in this exciting adventure.

With my very best regards.



#### **FEBRUARY 2014**

- Validive® granted with Fast Track status by US regulatory agency (FDA) allowing accelerated review procedure

#### **APRIL 2014**

- 4th DSMB positive recommendation re. Livatag® safety profile in ReLive phase III trial

#### **MAY 2014**

- Livatag® granted fast track designation by FDA

#### **JUNE 2014**

- Merger between BioAlliance Pharma and Topotarget to create Onxeo

#### **JULY 2014**

- Beleodaq® US market approval (PTCL) & commercialization started in the US

#### **OCTOBER 2014**

- Positive preliminary top-line results Phase II for Validive® (severe oral mucositis)

#### **NOVEMBER 2014**

- 5th DSMB positive recommendation re. Livatag® safety profile

#### **DECEMBER 2014**

- Successful rights issue completed for a total of €40.7m

**Judith Greciet** - CEO of Onxeo

## Orphan oncology market: Highly dynamic

- ✔ **7,000 rare or orphan diseases identified** with few (or no) treatments
- ✔ **The largest & Fastest growing group of Orphan Diseases:** estimated to reach about \$81bn in 2018
- ✔ **Market Access optimized with favorable regulatory measures**
  - Faster development pathways & shorter review / approval cycles
  - Commercial exclusivities (US: 7 y. / EU: 10 y.)



## Onxeo key programs: From 2014 to 2015 perspectives

- ✔ **Beleodaq®: HDAC inhibitor already approved and launched in the US** in August for **rare blood cancer PTCL\*** in 2<sup>nd</sup> line.
  - Preparation of **indication extension** in PTCL 1st line jointly with Spectrum pharmaceuticals => **trial initiation early 2016.**
- ✔ **Livatag®:** chemotherapy acting like a **Trojan horse** for the treatment of liver cancer, bypassing tumor cell resistance thanks to **innovative nanoparticle technology.**
  - Positive data safety reviews by international board of experts (DSMB) twice yearly since study initiation => **next DSMB Q2 2015.**
  - **Phase III study enrolment ongoing** in 8 European countries and the US. 35 active centers => 10 to 15 additional centers planned to be opened.
- ✔ **Validive®: Mucoadhesive tablet to prevent severe oral inflammation** induced by radiation therapy in H&N cancer treatment.
  - **Phase II final report under preparation** (positive results announced October 2014) => **phase III initiation end 2015.**
  - Evaluation of **partnering opportunities.**

\* T-Cell Peripheral Lymphoma

## NEWS & EVENTS



### Back from San Francisco

As in previous years, Onxeo was present in San Francisco early January for the 33rd JP Morgan Healthcare conference. This major event gathers more than 25,000 executives from the biotech and finance industries.

Judith Greciet, CEO and Nicolas Fellmann, CFO have met with many US investors which have shown a growing interest for Onxeo and its promising assets.

In parallel, Judith and Aude Michel, Head of Corporate Business Development, had several meetings with potential partners. A corporate presentation has been given at the Biotech Showcase™, the meeting point of all partnering activities this week.

All these contacts are key for our future developments and the international attractiveness of Onxeo.



### 2015 - Financial agenda

- **Full-year Financial Results for 2014**  
*Wednesday, 4<sup>th</sup> March (Analysts' meeting 5<sup>th</sup> March)*
- **Annual Shareholders Meeting**  
at the Company's Headquarters  
*Wednesday, 15<sup>th</sup> April*
- **Quarterly Information as of March 31, 2015**  
*Wednesday, 15<sup>th</sup> April*
- **Consolidated Accounts for H1 2015**  
*Thursday, 30<sup>th</sup> July*
- **Quarterly Information as of September 30, 2015**  
*Tuesday, 27<sup>th</sup> October*

FOR MORE INFORMATION:  
visit our website [www.onxeo.com](http://www.onxeo.com)  
or [contact@onxeo.com](mailto:contact@onxeo.com)



THE ORPHAN ONCOLOGY INNOVATOR