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FDA approval of Beleodaq™ (belinostat) for Injection

-- Accelerated Approval of Beleodaq™ for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma –

-- Early Action before PDUFA date of August 9, 2014 follows Priority Review --

-- Trigger milestone payment of USD 25 million to Topotarget --

-- Beleodaq is expected to be available to patients in July 2014 and will be launched through Spectrum Pharmaceutical's existing oncology sales force --

Topotarget today announced that the U.S. Food and Drug Administration (FDA) has granted our partner, Spectrum Pharmaceuticals, Inc., Accelerated Approval of Beleodaq for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (R/R PTCL). This follows a Priority Review of the Beleodaq New Drug Application (NDA) and was an Early Approval action prior to the August 9 PDUFA (Prescription Drug User Fee Act) date.

Beleodaq was granted marketing authorization under the FDA's accelerated approval program, which allows conditional approval of a medicine for a life-threatening disease based on early evidence suggesting clinical benefit. The approval is based on results from the BELIEF study, which enrolled 129 PTCL patients refractory to or who had failed at least one prior systemic therapy.

> *"With the FDA's Accelerated Approval of Beleodaq, we have succeeded in developing a new treatment option for patients with PTCL. We are very pleased with the validation of our compound and find that it truly underlines the rationale behind Topotarget's merger with BioAlliance Pharma in providing an even stronger orphan oncology pipeline for the combined entity, Onxeo", says Anders Vadsholt, CEO of Topotarget.*

USD 25 million milestone payment
A milestone cash payment of USD 25 million from Spectrum Pharmaceuticals is triggered by the NDA approval. Moreover, Topotarget is eligible to receive double-digit royalties as well as sales milestones of the aggregated net sales.

Outlook for 2014
Given the merger with BioAlliance Pharma, the Board of Directors does, as previously announced, not find it prudent to provide an earnings outlook for 2014.

Merger with BioAlliance Pharma
On June 27 and 30, 2014, respectively, the shareholders of Topotarget and BioAlliance Pharma adopted the merger between Topotarget and BioAlliance Pharma to create Onxeo. The completion of the merger is now subject to registration by the relevant French and Danish authorities, which is expected to occur in the course of July 2014.

Topotarget A/S

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About Topotarget
Topotarget (NASDAQ OMX: TOPO) is a Danish-based biopharmaceutical company headquartered in Copenhagen, Denmark, dedicated to clinical development and registration of oncology products. In collaboration with Spectrum Pharmaceuticals, Inc., Topotarget focuses on the development of its lead drug candidate, belinostat, which has shown positive results in the treatment of hematological malignancies and solid tumors, obtained by both mono- and combination therapy. For more information, please refer to www.topotarget.com.

About Peripheral T-Cell Lymphoma
According to the Lymphoma Research Foundation (www.lymphoma.org), lymphoma is the most common blood cancer. Hodgkin's lymphoma and non-Hodgkin's lymphoma (NHL) are the two main forms of lymphoma. Lymphoma occurs when lymphocytes, a type of white blood cell, grow abnormally and accumulate in one or more lymph nodes or lymphoid tissues. The body has two main types of lymphocytes that can develop into lymphomas: B-lymphocytes (B-cells) and T-lymphocytes (T-cells). PTCL comprises a group of rare and aggressive NHLs that develop from mature T-cells. PTCL accounts for approximately 10 to 15% of all NHL cases in the United States.

About Beleodaq
Beleodaq is an HDAC inhibitor being studied in multiple clinical trials as a single agent or in combination with chemotherapeutic agents for the treatment of various hematological and solid cancers. Its anticancer effect is thought to be mediated through multiple mechanisms of action, including the inhibition of cell proliferation, induction of apoptosis (programmed cell death), inhibition of angiogenesis, and the induction of differentiation. Beleodaq has been shown to have activity in tumors that had become resistant to anticancer agents such as the platinums, taxanes, and topoisomerase II inhibitors.

About the BELIEF study
The BELIEF study was an open-label, single-arm, non-randomized international trial conducted at 62 centers that enrolled 129 patients with relapsed or refractory PTCL; 120 patients had histologically confirmed PTCL by central review and were evaluable for efficacy. Patients received treatment with Beleodaq (1,000 mg/m2), administered over 30 minutes via IV infusion, once daily on Days 1-5 of a 21-day cycle. Treatment cycles were repeated every three weeks until disease progression or unacceptable toxicity.

The primary efficacy endpoint of the BELIEF study was response rate (complete and partial responses) as assessed by an Independent Review Committee (IRC) using the International Workshop Criteria (IWC) (Cheson 2007). The key secondary efficacy endpoint was Duration of Response. In all evaluable patients (N = 120) treated with Beleodaq, the overall response rate per central review using IWC was 25.8% (n = 31) with rates of 23.4% for PTCL, NOS and 45.5% for AITL, the two largest subtypes enrolled. The median Duration of Response based on the first date of response to disease progression or death was 8.4 months (95% CI: 4.5 - 29.4).

Data from the BELIEF study demonstrated that the most common adverse events (AEs) reported with Beleodaq (>25%) were nausea, fatigue, pyrexia, anemia, and vomiting. Low rates of myelosuppression were observed with an overall rate of thrombocytopenia of 16.3% and neutropenia of 9.3%; these AEs were largely mild to moderate in severity with only 7.0% and 6.2% of patients reporting Grade 3/4 events, respectively. The most common serious adverse reactions (>2%) were pneumonia, pyrexia, infection, anemia, increased creatinine, thrombocytopenia, and multi-organ failure.

Topotarget Safe Harbor Statement
This announcement may contain forward-looking statements, including statements about Topotarget A/S' expectations to the progression of Topotarget A/S' clinical pipeline and with respect to cash burn guidance. Such statements are subject to risks and uncertainties of which many are outside the control of Topotarget A/S, and which could cause actual results to differ materially from those described. Topotarget A/S disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, unless required by Danish law.