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## **Positive data from the BELIEF trial presented at the 2013 American Society of Clinical Oncology (ASCO) Annual Meeting**

**Topotarget today announced positive results from the BELIEF trial, a pivotal, single-arm study of belinostat in patients with relapsed or refractory peripheral T-cell lymphoma (R/R PTCL) after failure of  $\geq 1$  prior systemic therapies.**

Data presented on June 1, 2013 at an oral session at ASCO demonstrated the clinical activity of belinostat, a novel pan-histone deacetylase inhibitor, in treating patients (N=129) with R/R PTCL with:

- Objective response rate (ORR) of 26% in heavily pretreated patients
- Median duration of response (DoR) of 13.6 months by International Working Group (IWG) criteria
- Anti-tumor activity demonstrated in poor prognosis PTCL subtypes including AITL with an ORR of 46%, patients with poor marrow reserves and low platelet counts (<100,000 per mL), and patients with previous stem cell transplants
- Well tolerated with an acceptable safety profile and >98% dose intensity that could potentially allow for novel combination chemotherapies

"We are very encouraged by the promising results from the PTCL BELIEF study which underlines belinostat's potential as monotherapy to benefit the treatment of the approximately 70% of patients with R/R PTCL failing current therapies" says Anders Vadsholt, CEO of Topotarget, and continues: "We are likewise excited that our US partner Spectrum Pharmaceuticals are on track to file an NDA for belinostat for this indication during 2013".

The BELIEF study enrolled 129 PTCL patients refractory to or who had failed at least one prior systemic therapy; diagnosis was confirmed by Central Pathology Review. Patients received belinostat at 1000 mg/m<sup>2</sup> as a 30-minute intravenous infusion on days 1 thru 5 every 21 days. The primary study endpoint was the rate of objective response as assessed by an Independent Review Committee.

Single-agent belinostat was shown to induce complete and partial responses even in poor prognosis R/R PTCL subtypes, e.g. angioimmunoblastic T-cell lymphoma (AITL) and anaplastic large-cell lymphoma (ALK). Overall, belinostat was well tolerated, requiring minimal dose reductions or dose delays leading to the successful delivery of high dose intensity treatment to heavily pretreated patients.

The full abstract on the results from the CLN-19 BELIEF study in PTCL was released for presentation at ASCO 2013 on May 15, 2013. For more information, please refer to Topotarget's company announcement no. 15-13, which is available on [www.topotarget.com](http://www.topotarget.com).

### **About belinostat**

Belinostat is a novel pan-HDAC inhibitor in late-stage clinical development with more than 1,000 patients treated. Belinostat has a promising safety profile which allows combination with traditional chemotherapy. Preclinical experiments demonstrated belinostat to be effective against multiple cancers by inhibiting cell proliferation and inducing programmed cell death (apoptosis) in tumor cells. Belinostat has been tested in a number of phase I/II

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clinical trials in hematological cancers and solid tumors both in mono- and combination therapy. Data from these trials have provided evidence of the anti-tumor effect of belinostat, including as monotherapy in PTCL and cutaneous T-cell lymphoma (CTCL), liver cancer, and thymoma.

### **Topotarget A/S**

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### **Background information**

#### **About Topotarget**

Topotarget (NASDAQ OMX: TOPO) is a Scandinavian-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](http://www.topotarget.com).

#### **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.