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## **First patient dosed in part one confirmatory BelCHOP study in PTCL**

**Topotarget announces that the first patient has been dosed in the dose-finding study of belinostat in combination with CHOP for the treatment of peripheral T-cell lymphoma (PTCL).**

The study with BelCHOP\* (belinostat plus Cyclophosphamide, Hydroxydaunorubicin (doxorubicin), Oncovin (vincristine), and Prednisone) is designed to determine what dose of belinostat combined with CHOP can be safely administered together for first-line treatment of patients with PTCL. The purpose is furthermore to establish the recommended dose for a phase III confirmatory study in the indication. The BelCHOP study is a precondition for a phase III confirmatory study with belinostat in PTCL. The BelCHOP study is expected to recruit up to 28 patients.

### **Potential pathway**

The dosage of the first patient in the BelCHOP study is by FDA agreed to be a sufficient activity on the confirmatory study to support a filing with the FDA later this year. This study followed by the phase III study could potentially pave the way for getting belinostat on the European market as this study type has often proven to be a prerequisite from the European Medicines Agency (EMA) for other compounds trying to enter Europe within this indication. Topotarget plan to be seeking scientific advice by EMA on this.

"We believe belinostat has the potential to be an effective, safe treatment in combination with CHOP. Thus, by exploring belinostat in both first- and second-line treatment for patients with PTCL, we might expand belinostat's market potential and treatment range. In addition, the BelCHOP study may support a potential entry for belinostat into the European market", says Anders Vadsholt, CEO of Topotarget.

\*Study number: SPI-BEL-12-104

### **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.