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Belinostat gets EU Orphan Drug Designation for the treatment of peripheral T-cell lymphoma

On October 15, 2012, the European Commission granted Topotarget A/S an Orphan Drug Designation for belinostat, its novel histone deacetylase (HDAC) inhibitor, for the treatment of peripheral T-cell lymphoma (PTCL). PTCL is a rare form of non-Hodgkin's lymphoma.

"Obtaining Orphan Drug Designation for belinostat in PTCL in the European Union is an important milestone on the path to filing a registration dossier of belinostat in this region. This is positive news for Topotarget and potentially likewise for the rare disease patients with PTCL in need of new treatment options", said Anders Fink Vadsholt, CEO of Topotarget.

Orphan Drug Designation
The EU regulation on orphan medicinal products is intended to encourage the development of drugs that may provide a significant benefit to patients suffering from rare (affecting fewer than five out of 10,000 people) and life-threatening or chronic debilitating conditions for which there is no effective therapies available. The orphan drug designation offers important incentives such as free protocol assistance (to optimize drug development) at the European Medicines Agency, fee reductions for various regulatory activities and following drug approval, and a grant of 10 years' market exclusivity in the EU.

Belinostat was in September 2009 granted Orphan Drug Designation in the US by the U.S. Food and Drug Administration (FDA) for the treatment of PTCL.

Belinostat has clinical effect in the treatment of PTCL
Topotarget has recently announced that the primary efficacy endpoint for the belinostat pivotal BELIEF trial for patients with PTCL has been met in accordance with the Special Protocol Assessment with the FDA which requires the BELIEF trial to reach an objective response rate of at least 20%.

BELIEF is a pivotal, open-label, multi-center, single-arm efficacy and safety trial of i.v. belinostat in patients with relapsed or refractory PTCL. Data from the trial are being further analyzed and are expected to be communicated during Q4 2012. The trial was initiated in December 2008 and recruitment was completed with 129 patients in September 2011.

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 programed cell death (apoptosis) in tumor cells. Belinostat has been tested in a number of phase I/II 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 combination therapy in soft tissue sarcoma, ovarian cancer, and thymoma.

About PTCL
PTCL is a hematological disease including a heterogeneous group of malignancies of T-cell origin that represents approximately 10-15% of all cases of non-Hodgkin's lymphoma. PTCL is an aggressive, high-grade type of cancer with a poor prognosis of expected average survival of approximately two years from diagnosis without treatment. The projections for annual cancer incidences point to 15,500 new cases of PTCL in the US, Japan, and five largest EU countries.

Outlook for the year
This announcement does not change the previously announced outlook statement published on August 29, 2012.

Topotarget A/S

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Background information

About Topotarget
Topotarget (NASDAQ OMX: TOPO) is an international 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.

Topotarget Safe Harbor Statement
This announcement may contain forward-looking statements, including statements about our expectations of the progression of our preclinical and clinical pipeline including the timing for commencement and completion of clinical trials and with respect to cash burn guidance. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Topotarget cautions investors that there can be no assurance that actual results or business conditions will not differ materially from those projected or suggested in such forward-looking statements as a result of various factors, including, but not limited to, the following: The risk that any one or more of the drug development programs of Topotarget will not proceed as planned for technical, scientific, or commercial reasons or due to patient enrollment issues or based on new information from non-clinical or clinical studies or from other sources; the success of competing products and technologies; technological uncertainty and product development risks; uncertainty of additional funding; Topotarget's history of incurring losses and the uncertainty of achieving profitability; Topotarget's stage of development as a biopharmaceutical company; government regulation; patent infringement claims against Topotarget's products, processes, and technologies; the ability to protect Topotarget's patents and proprietary rights; uncertainties relating to commercialization rights; and product liability exposure. We disclaim 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 law.