



To NASDAQ OMX Copenhagen A/S
Announcement No. 38-09 / Copenhagen, 17 August 2009

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Initiation of NCI-sponsored Phase 1 study of Belinostat in combination with Cisplatin and Etoposide for Small Cell Lung Cancer and Other Advanced Cancers

Copenhagen, Denmark – August 17, 2009 – TopoTarget A/S (OMX: TOPO) announced today the initiation of patient dosing in a Phase 1 study for the combination of 48 hours continuous intravenous (IV) infusion of belinostat with standard doses of cisplatin and etoposide in a three week cycle for the treatment of patients with small cell lung carcinoma (SCLC) and other advanced cancers. The study is sponsored by the Cancer Therapy Evaluation Program at the National Cancer Institute (NCI, US) under a Clinical Trials Agreement with TopoTarget for the development of belinostat.

The Phase 1 clinical trial is being led by Susan Bates, M.D. and Richard Piekarz, M.D., at the Medical Oncology Branch/CCR/NCI in Bethesda, MD. The protocol is open to all patients with recurrent or advanced cancer for whom standard chemotherapy offers no curative potential. The trial will initially enroll up to 36 patients in order to establish the maximum tolerated dose (MTD) and then an additional cohort of SCLC patients will be treated at the defined MTD.

"We are very happy for the strong continued support from the NCI for the belinostat programme" said Professor Peter Buhl Jensen, CEO of TopoTarget. "This new trial builds on the preclinical data generated by the NCI and TopoTarget that demonstrates synergy in experiments with belinostat in combination with cisplatin and etoposide in SCLC cell lines. This study may provide the basis for a new rational therapeutic opportunity to offer SCLC patients."

The study is designed to escalate the dose of belinostat administered as a 48 hour continuous intravenous (IV) infusion on days 1 and 2, combined with IV infusion of cisplatin on day 2 and etoposide IV daily x 3 on days 2-4 given every 3 weeks for no more than 6 cycles.

The primary objective of the study is to determine a safe and tolerable phase 2 dose for the combination of belinostat with cisplatin and etoposide. Secondary objectives will include an analysis of biomarkers involved in histone deacetylase inhibition and evaluation of tumor response in SCLC patients.

Today's news does not change TopoTarget's full-year financial guidance.

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Background information

About belinostat

Belinostat is a promising small molecule HDAC inhibitor being investigated for its role in the treatment of a wide range of solid tumors and hematologic malignancies either as a single-agent, or in combination with other active anti-cancer agents, including carboplatin, paclitaxel, doxorubicin, idarubicin, cis-retinoic acid, azacytidine and Velcade[®] (bortezomib) for injection. HDAC inhibitors represent a new mechanistic class of anti-cancer therapeutics that target HDAC enzymes, and have been shown to: arrest growth of cancer cells (including drug resistant subtypes); induce apoptosis, (programmed cell death); promote differentiation; inhibit angiogenesis; and sensitize cancer cells to overcome drug resistance when used in combination with other anti-cancer agents. Company-sponsored trials of IV-administered belinostat include a pivotal trial in peripheral T-cell lymphoma (PTCL), a randomized controlled Phase II trial in cancer of unknown primary (CUP), and studies in ovarian, colorectal and soft tissue sarcoma patients. NCI-sponsored trials (single agent and in combination with anti-cancer therapeutics) with IV-administered belinostat include studies in hepatocellular, thymoma, Myelodysplastic Syndrome (MDS), and other solid and hematologic cancers. Continuous intravenous administration (CIV) is being evaluated in clinical trials in solid tumours as well as in AML. An oral formulation of belinostat is also being evaluated in a Phase I clinical trial for patients with advanced solid tumors and lymphomas. Furthermore TopoTarget has a Cooperative Research and Development Agreement (CRADA) with the NCI to conduct preclinical and nonclinical studies on belinostat in order to better understand its anti-tumor activity and to provide supporting information for clinical trials.

About Small Cell Lung Cancer

Lung cancer is the leading cause of death worldwide, causing more than a million deaths annually. In 2008, the estimated number of new lung cancers in the US will be approximately 215,020, with roughly 12-13% of the cases being small cell lung cancer (SCLC) SCLC are commonly associated with smoking. SCLC shows exquisite initial sensitivity to many chemotherapies and radiation therapy but despite that have an aggressive clinical course. Nearly all patients develop resistance to anticancer agents and relapse locally or more commonly systemically. Untreated SCLC has a median survival of 2-4 months after the diagnosis. Reports of expanded survival between 7 and 18 months have been published for these patients when treated. For patients with extensive disease the standard care is 80-100mg/m² cisplatin on day 1 and 80-120mg/m² etoposide on days 1,2 and 3.

About TopoTarget

TopoTarget (OMX: TOPO) is an international biotech company headquartered in Denmark, dedicated to finding "Answers for Cancer" and developing improved cancer therapies. The company was founded and is run by clinical cancer specialists and combines years of hands-on clinical experience with in-depth understanding of the molecular mechanisms of cancer.

TopoTarget has a broad clinical pipeline but is currently focusing on the development of belinostat, which has shown proof of concept as monotherapy in treating haematological malignancies and positive results in solid tumours where it can be used in combination with full doses of chemotherapy, and is in a pivotal trial in PTCL. TopoTarget's expertise in translational research is utilizing its highly predictive in vivo and in vitro cancer models. TopoTarget is directing its efforts on key cancer targets including HDACi, NAD⁺, mTOR, FasLigand and topoisomerase II inhibitors. The company's first marketed product Savene[®]/Totect[®] was approved by EMEA in 2006 and the FDA in 2007 and is marketed by TopoTarget's own sales force in Europe and the US. For more information, please refer to www.topotarget.com.

TopoTarget Safe Harbour 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

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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 enrolment 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.