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Positive data with belinostat and 5-FU for colorectal cancer presented at ASCO GI 17 January 2009

- ***This study indicates that the treatment can be targeted to a selected group of patients who can benefit from the treatment with belinostat and 5-FU (BelFU) -***

Copenhagen, Denmark, 19 January 2008 – TopoTarget A/S (OMX: TOPO) announces that at the ASCO GI conference (American Society of Clinical Oncology – Gastro Intestinal conference) 15-17 January 2009 positive data from a phase Ib/II study with belinostat and 5-fluorouracil (FU) for patients with colorectal cancer were presented. The study has established that belinostat and 5-FU can be safely given together in full doses . 35 previously heavily treated patients with progressed solid tumors, whereof most suffered from colorectal cancer, have been treated. Of these heavily treated patients 9 (26%) obtained stabilisation of their disease. Preclinical studies indicate synergy between belinostat and 5-FU and this clinical study supports this assumption in patients' blood and cancer tissue.

"It is very promising that 5-FU can be administered in full dose in combination with full dose belinostat. 5-FU is one of the most used anticancer agents for the treatment of colorectal and breast cancer. In this study we see belinostat affecting the biochemistry in the patient's cancer cells, in the same way as we see it in the laboratory. If these data hold, we should be able target those patients with the largest potential for gaining effect of the treatment." said Professor Peter Buhl Jensen, MD, CEO of TopoTarget. *"These patients were very heavily pre-treated with 5-FU why and in several cases a long stabilisation period of the cancer was observed. Combinations of belinostat and 5-FU should be further evaluated in patients with less advanced pre-treatment, where one would normally observe a higher number of patients with objective response".* Peter Buhl Jensen further commented.

The study:
Phase Ib/II- study with belinostat (PXD101) in combination with 5-fluorouracil (FU) for progressed solid tumors
The Phase Ib portion of this study was aiming to find the MTD of intravenous administered belinostat in combination with 5-FU in patients with progressed solid tumors for whom there is no standard treatment. It was shown that 1000mg/m^2/day administered 5 days every 3 weeks in combination with continuous 96 hours infusion of 5-FU 750 mg/m^2/day starting day 2 was safe and with no unexpected adverse events.

An extensive central evaluated investigation of BelFU's effect on the heart was performed and no cardiac side effects were seen.

Despite the extensive pre-treatment (median of 3 prior regimens; majority of patients treated with 2 or more FU-based regimens): – 26% of patients on BelFU achieved stabilization of disease, including 6 patients with time to progression of 12 to 41 weeks.

In pre-clinical studies it has been demonstrated that belinostat down regulate the expression of thymidylate synthase (TS), a main target for 5-FU,. A reduced TS increases the effect of 5-FU. Furthermore belinostat treatment effects are linked to a downregulation of dihydropyrimidine dehydrogenase (DPD) and up-regulation of p21, indicating cell cycle arrest in the G1 phase.
This clinical study confirmed the down regulation of TS in tumor tissue during belinostat monotherapy in 4 out of 4 patients and in 3 out of 4 patients an up-regulation of p21 was seen. In peripheral blood TS, DPD and p21 exhibited a potential pattern of treatment-effect: TS down, DPD down and p21 up. By using these markers as a tool for selection of patients with a "2 out of 3" pattern this may form the basis for finding exactly those patients with the largest likelihood of effect by the treatment of BelFU.

The conclusion of the study was that the BelFU combination should be further evaluated, preferably in patients with less extensive prior treatment, including further assessments of the potential for patient selection based on a favourable expression pattern for TS, DPD, and p21.

Today's announcement does not change TopoTarget's full-year financial guidance for 2008.

TopoTarget A/S

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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, 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, or programmed cell death; promote differentiation; inhibit angiogenesis; and sensitize cancer cells to overcome drug resistance when used in combination with other anti-cancer agents.
Intravenous belinostat is in phase III in peripheral T-cell lymphoma (PTCL) and is currently being evaluated in multiple clinical trials as a potential treatment for cutaneous and peripheral T-cell lymphomas, B-cell lymphomas, AML, mesothelioma, soft tissue sarcoma, Myelodysplastic Syndrome (MDS), and liver, colorectal, and ovarian cancers, either alone or in combination with other anti-cancer therapies. 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. Several trials in the belinostat program are conducted under a Clinical Trials Agreement (CTA) under which the NCI sponsors clinical trials to investigate belinostat for the treatment of various cancers, both as a single-agent and in combination chemotherapy regimens. 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 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. 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 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 expo-sure; 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.