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Initiation of the phase 2 portion of a NCI sponsored study where belinostat is given at higher than usual monotherapy doses in the treatment of patients with liver cancer

Copenhagen, Denmark, 8 January 2008 – TopoTarget A/S (OMX: TOPO) announces that belinostat can be safely administered at higher doses than previously applied in the standard belinostat day 1-5 schedule. A phase 1 study including patients with previously untreated hepatocellular (liver) cancer being conducted by the Cancer Therapeutic Research Group (CTRG) and sponsored by the Division of Cancer Treatment and Diagnosis, National Cancer Institute (NCI, US) has been completed. The phase 2 portion using belinostat as a single agent to be given in doses of 1400 mg/m²/day, days 1-5 every 3 weeks has started. The most frequent dose previously used in the day 1-5 schedule is 1000mg/m²/day – this is the regime where belinostat has proven effect in cancer patients suffering both from solid- and haematological diseases.

The NCI has now confirmed that the phase 2 portion of the trial has been initiated at sites in Hong Kong, Korea, Australia and the US.

"We are excited about the fact that belinostat can be given in escalated doses in the treatment of patients with liver cancer - as higher doses in our pre-clinical models increases efficacy in cancer" said Professor Peter Buhl Jensen, MD, CEO of TopoTarget "We look very much forward to see the data from next step of this study."

The patients in the study suffer from Hepatocellular carcinoma (HCC) which is a common cause of cancer morbidity and mortality. It is a highly aggressive tumor with 90% presenting with unresectable disease, resulting in a median survival of 3-6 months. Inhibitors of histone deacetylase (HDAC) have been demonstrated in HCC cell lines and xenografts to induce apoptosis and tumor regression, and have anti-proliferative, anti-metastatic and anti-invasive effects.

The study:

A phase 1/2 study of PXD101 (belinostat) in patients with unresectable hepatocellular carcinoma with pharmacokinetic and pharmacodynamic evaluation.



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The Cancer Therapeutic Research Group (CTRG) is conducting a phase 1/2 study of PXD101 as first line therapy for patients with unresectable HCC under the Clinical Trials Agreement between TopoTarget and NCI for the development of belinostat. The phase 1 study aimed to determine dose limiting toxicity (DLT) and maximum tolerated dose (MTD).

In the phase 2 portion, up to 37 patients will be treated on the dose level of 1400 mg/m²/day given over 30 min, day 1-5 every 3 weeks. Primary endpoint will be tumour response according to the Response Evaluation Criteria In Solid Tumors (RECIST) and secondary endpoints are: safety, acetylation changes in the histone proteins, induction of cell-cycle arrest or apoptosis, activation of certain cellular genes. Further more the epigenetic changes of peripheral blood of the patients will be measured.

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



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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.

