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Positive results in AML with belinostat and idarubicin

-Data were presented at American Society of Hematology (ASH) meeting in San Francisco Dec 6-9, 2008-

Copenhagen, Denmark – December 8, 2008– TopoTarget A/S (OMX: TOPO) announces that belinostat monotherapy and belinostat in combination with idarubicin shows promising effect in acute leukemia in an ongoing Phase I/II international study.

"These are remarkable results obtained in a very difficult to treat population of elderly patients who usually do not tolerate intensive chemotherapy." Said professor Peter Buhl Jensen, MD and CEO of TopoTarget. *"In our labs we have seen surprisingly good effect of prolonged belinostat administration and one of the promising results of this study is a complete response obtained in a patient treated with belinostat monotherapy as a 48 hours continuous infusion (CIV). It is a completely new way of administering this drug type. We have patented the invention and it is very promising that we already in phase I can see a clear anticancer effect.* Peter Buhl Jensen continues: *"Belinostat is the only compound in its class that can be given as a capsule, intravenous (IV) and now also as continuous infusion (CIV).This additional new way of administering belinostat could be clinically and commercially advantageous in certain cancers."*

A Phase I/ II, open-label, non-randomised multi-center study of the histone deacetylase inhibitor belinostat either given as monotherapy or in combination with idarubicin (BeI-Ida) for the treatment of patients with advanced acute myeloid leukemia (AML) has been presented at the ASH conference december 6-9 in San Francisco, USA by the principal investigator, dr. Richard Schlenk.

The study examines two modes of administration of belinostat, a 5-day regimen of daily 30-min infusions given with 3-week intervals and a regimen of continuous intravenous infusion (CIV) for 48 hours given with two week intervals. Both regimens are examined in a dose escalation form in a combination with the established anti-leukemic drug idarubicin with which belinostat showed a high degree of synergy in pre-clinical experiments.
Preliminary results in 34 elderly patients (median age 69), equally divided between the two regimens, showed a good tolerance from both regimens in the dose escalation, which now has reached full belinostat dose. Complete remission has so far been noted in 5 patients including one treated with belinostat CIV alone, one treated with CIV combination and three in the 5-day regimen of belinostat in combination with small doses of idarubicin. It is noteworthy that these remissions are seen among the relative few patients in the highest dose escalation steps.

"This study confirms a pre-clinical finding of anti-leukemic effect of belinostat since in several patients the leukemic blasts on monotherapy with belinostat cleared from blood and in one also from bone marrow. Furthermore the study supports the pre-clinical finding of a synergy between belinostat and the anthracycline class, since four remissions were obtained with small doses of idarubicin in the combination." Peter Buhl Jensen further commented.

Today's news 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, azacitidine 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 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.