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Positive data on oral belinostat in phase I dose escalating study in Lymphoma presented at ASCO

Copenhagen, Denmark – 30 May 2009 – TopoTarget A/S (OMX: TOPO) has announced positive data from a phase I study of belinostat given as oral monotherapy day 1-14 every three weeks in patients with lymphoma presented at the ASCO (American Society of Clinical Oncology) annual conference May 29 - Jun 2. Oral belinostat can be delivered safely to lymphoma patients in doses that are higher than the maximum tolerated dose for patients with solid tumors. Current dose level is 1500 mg daily with 5 patients still ongoing. Despite extensive pre-treatment, 7 of 10 evaluable patients have achieved stabilization of disease for up to nine months. Early onset of tumor shrinkage has been seen in patients with Hodgkin's disease and Mantle cell lymphoma. The acceptable safety profile and early tumor shrinkage noted warrants continued evaluation of belinostat in lymphoma, especially in combination with other active compounds.

"These new positive data demonstrate that the oral form of belinostat can be administered in higher doses than previously reported in solid tumors. Belinostat has already at this stage and despite extensive prior treatments in 7 out of 10 evaluable patients achieved disease control for up to 9 months. These findings and the flexibility in optimizing the dose to the cancer patients is important for this new drug class", says professor Peter Buhl Jensen, CEO of TopoTarget.

The study:

A phase I, open label, dose-escalation, multi-center study. Objectives are to determine safety and dose limiting toxicity (DLTs) for oral belinostat in patients with relapsed/refractory lymphoma and to assess preliminary efficacy.

Belinostat treatment included day 1 to 14, once daily administration every 21 days with doses escalated in steps of 250 mg from 750 mg to current level of 1500 mg.

Results:

15 patients, median age 53 have been treated. Most common lymphoma types are Mantle cell lymphoma (33%), Hodgkin's disease (33%) and Cutaneous T-cell lymphoma (13%). Most frequent related adverse events were anorexia, diarrhea fatigue and vomiting as we know them from other studies of belinostat. Hematological toxicity has been mild. The patients had in general been treated with prior multiple lines of therapy median 4 (range 1-12).

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Stable disease (SD) seen in 7 of 10 extensive pre-treated evaluable patients, including 3/3 patients with Mantle cell lymphoma, 3/4 patients with Hodgkin's disease, and the only evaluable patient with Cutaneous T-cell lymphoma (previously progressing on Vorinostat). Median treatment duration for patients with SD is currently +77 days (range 62 to +282 days; 3 patients in ongoing treatment).

Even though no partial remissions (PRs) have been noted according to the International Working Group criteria (Cheson 2007), tumor shrinkage of 43 to 49% has been observed in 1 patient with Hodgkin's disease and 2 of 3 evaluable patients with Mantle cell lymphoma, after two cycles of therapy (first assessment time point).

Conclusions:

Oral belinostat can be delivered safely with a day 1 to 14, q3 weekly, schedule in patients with lymphoma. This dose is higher than the dose that has been established for patients with solid tumors. No Dose limiting toxicities (DLTs) have been seen at dose levels 750 to 1250 mg daily. At the current dose level of 1500 mg daily 1 patient has experienced a DLT, thus the cohort has been expanded. Most common adverse events have been anorexia, diarrhea, fatigue, and vomiting. Hematological toxicity has been mild. Despite extensive pre-treatment 7 of 10 currently evaluable patients have achieved stabilization of disease for up to nine months. Early onset tumor shrinkage has been seen in patients with Hodgkin's disease and Mantle cell lymphoma. The acceptable safety profile and early tumor shrinkage noted in Mantel cell lymphoma and Hodgkin's disease warrants continued evaluation of belinostat in lymphoma, especially in combination with other active compounds.

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.

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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 phase III 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 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.