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

Copenhagen, Denmark – 29 May 2009 – TopoTarget A/S (OMX: TOPO) has announced positive data from a phase I study of belinostat given as oral monotherapy in three different schedules (A) continuous daily dosing; (B) daily dosing on day 1-14 every 3 weeks; C) daily dosing day 1-5 every 3 weeks) in patients with solid tumors. Oral belinostat can be delivered safely in multiple schedules. Despite a median of 3 prior lines of therapy 48 (64%) of 75 evaluable patients achieved tumor growth control (SD), 15 patients had a treatment duration \geq 3 months. The safety profile and long stabilizations in multiple tumor types makes belinostat an interesting option for further evaluation as a monotherapy and in combination with chemotherapy.

"These new data demonstrate an increased utility of belinostat which now can be administered both as IV and oral allowing maximum flexibility for optimizing the use of this important new drug class", says professor Peter Buhl Jensen, CEO of TopoTarget.

"We look forward to obtain data from the CUP phase II randomized study where this principle is introduced (BelCaP versus carboplatin and paclitaxel, BelCaP = belinostat with carboplatin and paclitaxel) in solid tumors where belinostat is given as IV on the first three days and followed up by oral belinostat the remaining two days in a five days treatment every three weeks" Peter Buhl Jensen further comments.*

*CUP= Cancer of Unknown Primary site

The study:

Phase I dose escalating trial of belinostat in patients with solid tumors. Patients were treated with multiple schedules A) continuous dosing x 1 or 2 daily; B) 1 or 2 daily dosing on day 1-14 every 3 weeks; C) daily dosing day 1-5 every 3 weeks to assess safety, pharmacokinetics (PK) and efficacy.

Results:

92 patients, median age 59 have been included. Major cancer types included colorectal (21%), prostate (16%), bladder (11%). Most frequent related adverse events were fatigue (54%), nausea (52%), anorexia (40%), vomiting (32%), diarrhea (29%) as we know them from other studies of belinostat. Hematological toxicity was mild. The patients had in general been treated with prior multiple lines of therapy median 3 (range 1-11).

Recommended dose for A) continuous dosing was determined as 250 mg once or twice daily, recommended dose for B) was determined as 750 mg daily, with option for intra-pt dose escalation if limited toxicity. For schedule C) the recommended dose was determined as 2000 mg daily, also here with option for intra-pt dose escalation if limited toxicity.

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Tumor growth control (SD) has been reached in 48 patients (64% of the 75 evaluable patients) and the duration was 3 months or more in 15 patients for example 710 days in a patient with adenoid cystic cancer; 510 days in a patients with bladder cancer and 485 days in a patient with renal cancer.

Conclusions:

Oral belinostat can be delivered safely in multiple schedules. Despite a median of 3 prior lines of therapy 48 (64%) of 75 evaluable patients achieved tumor growth control (SD), 15 patients had a treatment duration \geq 3 months.

The safety profile and long stabilizations in multiple tumor types makes belinostat an interesting option for further evaluation as a monotherapy and in combination with chemotherapy.

Oral belinostat should be further evaluated in disease specific solid tumor phase II studies.

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, 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

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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.