

To OMX Nordic Exchange Copenhagen
Announcement No. 23-08 / Copenhagen, June 6, 2008

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TopoTarget announces positive data from a phase II study of belinostat monotherapy in patients with recurrent or refractory peripheral or cutaneous T-Cell lymphoma (PTCL and CTCL) and the granting of a Fast Track designation from FDA for belinostat in PTCL

Copenhagen, Denmark – June 6, 2008 – TopoTarget A/S (OMX: TOPO) announces that positive belinostat data were presented at the 10th International Conference On Malignant Lymphoma in Lugano, Switzerland, June 04-07, 2008 from a phase II trial in patients with recurrent or refractory peripheral or cutaneous T-Cell lymphoma (PTCL and CTCL). Two durable and still ongoing complete responses with belinostat monotherapy were demonstrated in 11 evaluable patients with PTCL. Furthermore 4 objective responses, 1 CR (Complete Response) and 3 PR (Partial Response) in 20 heavily pre-treated evaluable patients with CTCL, were evident. Time to response in CTCL was median 15.5 days and is a promising finding. In addition a substantial number of patients with stable disease (SD) were observed in both diseases. Intravenous belinostat was shown to be safe and well tolerated and the objective response rate in both arms has met the pre-defined criteria for advancement to the second stage of the Simon two-stage design. Enrolment is ongoing in the CTCL and PTCL arms of the study to a total of 34 patients per arm. Additional new centres have been initiated to accelerate recruitment. Based on the activity in the presented study and a defined development program FDA has granted a Fast Track designation for the development of belinostat monotherapy in patients with relapsed or refractory PTCL after at least one prior systemic therapy.



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"These data are even more promising than those presented at the ASH meeting in December 2007, especially the durability of the complete remissions in patients with PTCL are important for the further development in this indication. The challenge is now to increase patient inclusion in the ongoing study and to initiate a pivotal study in PTCL. Data presented in Lugano included 36 patients for both T-cell indications with information on the database as of May 08, currently we have 42 out of a total 68 patients recruited. New centers have recently been opened which brought us to more than 20 open sites, our goal for this study is approximately 30 active sites." Said MD Professor Peter Buhl Jensen, CEO of TopoTarget. "Fast recruitment to this trial is a focus area for TopoTarget which now, as a sole owner, is concentrating its efforts on the development of belinostat. In addition, the fast track designation for the PTCL development from the FDA is an important step for the market advancement of belinostat" Peter Buhl Jensen further commented.

The study:

Phase II open-label trial of belinostat (PXD101) in patients with recurrent or refractory Peripheral or Cutaneous T-Cell Lymphoma.

Background: Belinostat is a small molecule class I and II histone deacetylase inhibitor (HDACi). HDACi's modulate gene expression within tumor cells, including tumor suppressor genes, leading to G1 and G2/M cell cycle arrest, induction of apoptosis (programmed cell death), inhibition of angiogenesis, immune modulation, and promotion of cellular differentiation. Belinostat monotherapy at 1000 mg/m²/daily for 5 days in a 3-weekly cycle is well-tolerated.

Methods: Primary study objective is objective response rate for belinostat therapy in CTCL and in PTCL. Main eligibility criteria are patients who have failed at least one prior line of systemic therapy and who have a Karnofsky performance status $\geq 70\%$. Patients were treated with belinostat administered at 1000 mg/m², as a 30 min IV infusion once daily on days 1-5 of a 21-day cycle. For patients with CTCL the assessment of efficacy was evaluated by SWAT (Severity Weighted Assessment Tool) performed every cycle to assess cutaneous lesions. For PTCL patients assessment of efficacy was measured by CT scans every 2 cycles according to standard lymphoma criteria.

Results: 14 patients with PTCL are included, 11 of which were evaluable for response. Patients received median of 2 prior therapies and 79% had Stage III or IV disease. Objective responses were observed in 2 patients (2 CR) and stable disease (SD) was demonstrated in 4 patients.

In the CTCL indication 22 patients are included, 20 of which were evaluable for response. The patients had received a median of 3 prior regimens (17/22 prior retinoids) and 68% had Stage IV disease. Objective responses were observed in 4 patients (1 CR + 3 PR); stable disease (SD) in 9 patients. Time to response was median 15.5 days (range 14-113 days) and is a promising finding. In addition significant pruritus relief was seen in 6 of 11 patients.

Duration of responses for PTCL CR's was 40-42 weeks and ongoing. Duration of response in CTCL, CR is 67 weeks and ongoing.

Fast track designation: Fast track designation was granted by FDA for the development program for belinostat (PXD101) IV for relapsed or refractory PTCL after at least one prior systemic therapy.



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The poster presentation will be available on TopoTarget's homepage at www.topotarget.com

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, MDS, and liver, colorectal, and ovarian cancers, either alone or in combination with anti-cancer therapies. An oral formulation of belinostat is also being evaluated in a Phase I clinical trial for patients with advanced solid tumors. In August 2004, CuraGen signed a Clinical Trials Agreement with the NCI under which the NCI will sponsor several clinical trials to investigate belinostat for the treatment of various cancers, both as a single-agent and in combination chemotherapy regimens. In May 2005, TopoTarget announced the signing of 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 is founded and run by clinical cancer specialists and combines years of hands-on clinical experience with in-depth understanding of the molecular mechanisms of cancer. Focus lies on highly predictive cancer models and key cancer targets (including HDACi, NAD+, mTOR, FasLigand and topoisomerase II inhibitors). TopoTarget has a broad clinical pipeline with 9 products in development, including 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. 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



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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 exposure; 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.

