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Belinostat in its first pivotal trial in PTCL

- TopoTarget now initiates recruitment of patients in its pivotal trial of belinostat in Peripheral T-Cell Lymphoma (PTCL) -

Copenhagen, Denmark, 17 December 2008 – TopoTarget A/S (OMX: TOPO) announces the opening of patient recruitment in the pivotal study intended for registration of belinostat as monotherapy in the treatment of patients with Peripheral T-Cell Lymphoma (PTCL), a haematological malignancy associated with poor prognosis. The trial will enrol approximately 120 patients. TopoTarget has a Special Protocol Assessment (SPA) agreement with the Food and Drug Administration (FDA) where the design of the study has been agreed. Furthermore a Fast Track designation has been granted by the FDA for the development of belinostat in this indication which supports TopoTarget's rapid market entry strategy. There is currently no standard therapy approved specifically for PTCL.

"We are proud to be able to announce the initiation of this first pivotal study for belinostat. PTCL is a disease with a poor prognosis for which there is no therapy specifically approved." said Peter Buhl Jensen, Professor, MD, CEO of TopoTarget. *"This is the first step in accordance with our clinical development plan to bring belinostat to the market as fast as possible. At the same time we are pursuing the steps necessary to bring belinostat to the market in larger indications like solid tumors in combination therapy to fully exploit the clinical and commercial potential of belinostat."*

The study:

A Pivotal, Multicenter, Single Arm, Open Label Trial of Belinostat (PXD101) in patients with Relapsed or Refractory Peripheral T-Cell Lymphoma.

Approximately 120 patients with PTCL who have failed at least one prior systemic therapy will be enrolled. Patients will be treated with 1000 mg/m2 belinostat administered as a daily 30 minute IV infusion on days 1-5 of 3 week cycles until there is disease progression or unmanageable treatment-related toxicities. The study is designed to establish the efficacy and safety of belinostat.

The trial will be conducted mainly at clinical centres in North America and Europe.

Objectives and methods of evaluation:

The primary study endpoint will be objective response rate (ORR). Objective response is complete response (CR) or partial response (PR) based on independent radiology review.

Secondary objectives of the study are to determine: safety of belinostat monotherapy, time to response, duration of response, time to progression (TTP), progression-free survival (PFS), one-year progression-free rate, one-year survival rate and overall survival (OS).

Rational

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.
Clinical activity of belinostat has been observed in a Phase II trial of belinostat monotherapy in patients with recurrent or refractory cutaneous (CTCL) or peripheral T-cell lymphoma (PTCL). Efficacy is being analyzed separately in PTCL and CTCL patients. In 11 patients evaluable for response in the PTCL arm, 2 durable complete responses (CR; still ongoing at 10 and 16 months, respectively) and 4 Stable Diseases (SD; median duration of 3 months, with 3 still ongoing at 2.6 to 5.3 months) have been observed.

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, 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 Peripheral T-Cell Lymphomas (PTCL)
PTCL represent approximately 10% of all non-Hodgkin's lymphomas (NHL) in Western populations and are associated with a poor prognosis. Most patients with PTCL relapse after initial treatment with cytotoxic agents, and 5-year survival is less than 30%.
T-cell Non Hod g kins Lymphomas, to which PTCL belongs, are associated with a poorer outcome and survival compared to the B-cell lymphomas. The primary response rate for all PTCL subtypes remains at less than 60%, with nearly all patients relapsing. Median survival of all PTCL patients (excluding a few subtypes) is approximately 3-4 years, with a 5-year survival of less than 30%.
There are currently no therapies approved specifically for PTCL. Primary treatment for most subtypes of PTCL remains anthracycline-based regimens, predominantly the combination of cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP). With the exception of ALK-positive ALCL, PTCL subtypes respond poorly to these regimens. The use of radiotherapy, with or without chemotherapy, is preferred as front line treatment of extranodal NK/T-cell lymphoma. The majority of patients with PTCL will relapse after primary therapy. A number of chemotherapy regimens are used for salvage therapy. However, there is currently no consensus regarding the optimal treatment approach for PTCL salvage therapy.

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.