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Positive update of TopoTarget's initial phase II study with belinostat in PTCL and CTCL supports the registration plan in PTCL

Copenhagen, Denmark – 16 March 2009 – TopoTarget A/S (OMX: TOPO) has announced that positive data from a study of belinostat given as monotherapy 1000 mg/m^2/daily for 5 days every 3-weeks for the treatment of Peripheral T-Cell lymphoma (PTCL) and Cutaneous T-Cell lymphoma (CTCL) was presented at an international Lymphoma meeting in Bologna March 16-18. The data included an assessment of all treated patients, albeit preliminary since patients are still on treatment and in follow-up. The study has finalized recruitment with 53 patients treated. Initial data from this study led TopoTarget to initiate its pivotal study in PTCL in December 2008 following a Special protocol Assessment (SPA) procedure and Fast Track agreement with the FDA.

"*Importantly these new data support the company's development plan for PTCL. We have earlier announced that 2 out of 11 patients with PTCL had durable responses with belinostat. PTCL is a very serious disease in which our medicine works and the initial data were the basis for our SPA and Fast Track agreement with the FDA. The now up-dated data show that 5 out of 20 patients have responded. There is a big unmet medical need in this disease and with response rates of 25% for PTCL and with complete remissions belinostat monotherapy can become an important treatment,"* says professor Peter Buhl Jensen, CEO of TopoTarget.

"Combination therapy is used in order to attack the cancer cell from different angels and thereby increase response rates. In addition to the benefit obtained with the drug used as a single agent, belinostat has the big advantage that it exhibits no dose limiting bone marrow toxicity which is the main cause for dose reduction in the most successful chemotherapy combinations. This is why we expect a lot from belinostat in combination therapy as well," Peter Buhl Jensen further comments.

The study:
Phase II open-label trial of belinostat (PXD101) in patients with recurrent or refractory Peripheral or Cutaneous T-Cell Lymphoma
The primary study objective is objective response rate for belinostat monotherapy in CTCL and in PTCL. Included patients should have received at least one prior line of systemic therapy, and the study data showed that they had received significantly more than that, i.e. median of 3 (range 1-10) prior systemic regimes of treatment. Patients were treated with belinostat administered at 1000 mg/m^2, as a 30-min IV infusion once daily on days 1-5 of a 21-day cycle.

Results: The efficacy population for PTCL included 20 patients. These patients had received a median of 3 prior systemic treatment regimens (range 1-10 regimens) and 80% had Stage III or IV disease. Responses (complete/partial responses; CR/PR) were observed in 5 patients and stable disease (SD) was demonstrated in 5 further patients, indicating a response rate of 25% and a disease control rate (CR/PR/SD) rate of 50% based on the current preliminary data. Median duration of response (CR/PR) is currently +5.2 months, and up to +16.5 months. Median duration of stable disease (SD) is currently +3.6 months, and up to +6.1 months. Three patients each with CR/PR and SD, respectively, have not yet experienced progressive disease and thus median durations of CR/PR and SD can increase by longer follow-up time.

The efficacy population for CTCL included 29 patients. These patients had received a median of 3 prior systemic treatment regimens (range 1-9 regimens) and 17 of them had Stage III or IV disease.

Responses (complete/partial responses; CR/PR) were observed in 4 patients and stable disease (SD) was demonstrated in 17 further patients, indicating a response rate of 14% and a disease control rate (CR/PR/SD) rate of 72% based on the current preliminary data. Median duration of response (CR/PR) is 9.0 months, and up to +15.4 months. Median duration of stable disease (SD) is currently +1.4 months, and up to 4.2 months. One patient with CR and five patients with SD have not yet experienced progressive disease and thus median duration of SD can increase by longer follow-up time.

The short time to response noted in patients with CTCL, median 16 days (range 14-35 days), is a promising finding. In addition significant pruritus relief was seen in 7 of 14 evaluable patients (i.e. patients with significant pruritus at baseline). Also the time to significant pruritus relief was short (median 16 days; range 7 to 45 days).

Belinostat monotherapy at 1000 mg/m^2/daily for 5 days in a 3-weekly cycle is safe and well-tolerated in previously treated patients with CTCL and PTCL with the most frequent any grade drug-related adverse event being: nausea (57%), injection site reaction (30%), vomiting (27%) flushing (14%), anorexia (11%) and fatigue (11%). Belinostat had only minor hematological toxicity (no grade 4 shift from baseline anemia, neutropenia or thrombocytopenia, and grade 3 was only 3% for neutropenia, 3% for thrombocytopenia, and 0% for anemia) and a minimal impact on cardiac conductivity (e.g. no grade 3 QTc-prolongation was noted in approximately 700 ECGs analyzed by a central laboratory).

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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 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, 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.