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Belinostat and Velcade® is well tolerated in combination - Encouraging data from a phase 1 study presented at the AACR/NCI/EORTC Molecular Targets and Cancer Therapeutics Conference

Copenhagen, Denmark – November 17, 2009 – TopoTarget A/S (OMX: TOPO) announced today that phase 1 data from a National Cancer Institute (NCI)-sponsored study was presented at the AACR/NCI/EORTC Molecular Targets and Cancer Therapeutics Conference 2009. In the laboratory there is strong synergy when combining belinostat and bortezomib (Velcade®). Drugs supporting each others' activity are eagerly sought for, especially if they can be given safely in full doses. The study was designed to determine the maximum tolerated dose (MTD) and to evaluate the safety and pharmacokinetic (PK) behaviour of the combination of belinostat and bortezomib. It was concluded that belinostat and bortezomib is well tolerated in combination with a tolerable toxicity profile and no evidence of pharmacological interactions. Four patients have maintained stable disease for 4-6 cycles of therapy.

To date, 26 patients have been enrolled in the study. Twenty-two patients were evaluable for toxicity and received a total of 58 treatment cycles; median 2 (range 1-6). At the highest dose level, dose limiting toxicity (DLTs) included grade 4 thrombocytopenia and grade 4 fatigue. Most adverse events (AEs) have been mild to moderate. Grade 1-2 AEs include anorexia, acute infusion reaction, fatigue, nausea, neutropenia (1), pain, phlebitis, thrombocyctopenia, and vomiting. Grade 3 AEs include anorexia, dehydration, fatigue, nausea, vomiting, hypoalbuminemia, and elevation of alkaline phosphatase. Analysis of belinostat pharmacokinetics (PK) demonstrates no statistical differences in the parameters between days 1 (belinostat only) and 2 (belinostat + bortezomib). Doses of belinostat from 600 to 1000 mg/m2 result in dose-proportional increases in drug exposure. Four patients have maintained stable disease for 4-6 cycles of therapy.

Conclusions: Belinostat and bortezomib is well tolerated in combination with a tolerable toxicity profile and no evidence of pharmacological interactions. Accrual is ongoing at the MTD (belinostat: 1000 mg/m2 – bortezomib: 1.3 mg/m2).

"Belinostat and Velcade® are synergistic in all our laboratory models. We now know how that full doses of belinostat can be given with full Velcade® doses. This promising combination can now be tested in larger populations. Without NCI's support and sponsorship we probably would not have had these promising results today," said MD, Professor Peter Buhl Jensen, CEO of TopoTarget. *"Belinostat may become an important treatment alone or may be part of an effective combination treatment as the safety profile of belinostat allows it to be combined in full dose with conventional and novel therapies like Velcade®"*.

Combination therapy with drugs having different mechanisms of action is used in order to attack the cancer cell and potentially increase response rates. In addition to the benefit obtained with the drug

used as a single agent, belinostat has an advantage in that it exhibits little dose limiting bone marrow toxicity which often results in dose reductions in many chemotherapy combinations.
Today's news does not change TopoTarget's full-year financial guidance.

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, doxorubicin, idarubicin, 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, (programmed cell death); promote differentiation; inhibit angiogenesis; and sensitize cancer cells to overcome drug resistance when used in combination with other anti-cancer agents. Company-sponsored trials of IV-administered belinostat include a pivotal trial in peripheral T-cell lymphoma (PTCL), a randomized controlled Phase 2 trial in cancer of unknown primary (CUP), and studies in ovarian, colorectal and soft tissue sarcoma patients. NCI-sponsored trials (single agent and in combination with anti-cancer therapeutics) with IV-administered belinostat include studies in hepatocellular, thymoma, Myelodysplastic Syndrome (MDS), and other solid and hematologic cancers. 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 1 clinical trial for patients with advanced solid tumors and lymphomas. These NCI-sponsored clinical studies are being conducted under a Clinical Trials Agreement with TopoTarget. 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 a pivotal trial 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.