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Belinostat acts synergistically when combined with castration and anti-hormone therapy in hormone refractory prostate cancer models

- Pre-clinical data presented at 2nd Multidisciplinary Meeting on Urological cancers in Barcelona EMUC-ESMO-

Copenhagen, Denmark – November 28, 2009 – TopoTarget A/S (OMX: TOPO) announced today that data from a pre-clinical study in aggressive hormone refractory prostate cancer cell lines and in xenografts demonstrate that prostate cancer cell lines are all sensitive to belinostat inhibition and that belinostat can increase the sensitivity towards anti-hormone therapy and as a result become attractive in the treatment of hormone refractory prostate cancers. Data were presented by Claudio Festuccia et al from the University of L'Aquila, Italy at the 2nd Multidisciplinary Meeting on Urological cancers in Barcelona EMUC-ESMO.

Background:

Prostate cancer is the most frequently diagnosed malignancy and one of the leading causes of cancer death in men accounting for about 10% of male cancers of North America and Western\ Northern Europe. Although androgen ablation therapy (castration) induces remission in 80-90% of men with advanced prostate cancer, the majority of prostate cancer patients develop treatment resistance with a median time of 18-24 months to disease progression. One hypothesis is that some of the mechanisms that are normally under androgen control become constitutively active in androgen-independent tumor cells. Histone modifications acetylation and deacetylation are the major driving force for epigenetic gene regulation. It has been established that Histone deacetylases (HDAC) are up-regulated in most human cancers. HDAC inhibitors (HDACIs) are a novel class of relatively specific anticancer drugs, which were originally identified by their capacity to reverse the transformed phenotype.

Conclusion:

Taken together, the results demonstrate a clear antineoplastic effect of belinostat against the prostate cancer cell lines and that sensitization to the antihormone agent Bicalutamide pointed towards that the combined therapy based on Belinostat and Bicalutamide may offer a new pharmacological tool in the treatment of castration resistant prostate cancer.

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, cancer of unknown primary (CUP), ovarian cancer, small cell lung cancer, thymoma, liver, soft tissue sarcoma, lymphoma, AML, Myelodysplastic Syndrome (MDS), 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 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

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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.