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ODAC (FDA's US Oncologic Drugs Advisory Committee) backs T cell lymphoma - PTCL and CTCL compounds

Copenhagen, Denmark – September 4, 2009 – TopoTarget A/S (OMX: TOPO) commented today on the FDA's Oncologic Drugs Advisory Committee (ODAC) Advisory Panel 10-4 vote which stated that pralatrexate would have a reasonable likelihood of benefiting patients with relapsed or refractory peripheral T-cell lymphoma (PTCL) and that this recommendation may lead to an approval for pralatrexate in PTCL patients. Further more the ODAC committee recommended the approval of romidepsin for the treatment of Cutaneous T-cell Lymphoma (CTCL) – if approved by the FDA romidepsin will be the second HDACi drug on market which substantiates the future of this novel drug class in anticancer treatment.

We are pleased that the ODAC panel recognized the need for new therapeutics to treat PTCL, a disease with a poor prognosis for which there is no specifically approved drug and no accepted standard of care. Here as in other cancer diseases, a single agent is not curative and the need for combination therapy of active drugs was emphasized. Belinostat is active in PTCL and belinostat can be safely combined with all tested modern chemotherapeutic drugs. Therefore TopoTarget believes that belinostat offers this opportunity to PTCL patients.

TopoTarget is enrolling PTCL patients in the pivotal BELIEF trial. The BELIEF trial is designed under a Special Protocol Assessment (SPA) already in agreement with the FDA, the US health authorities. This is an agreement on the design of a pivotal trial. TopoTarget also has a Fast Track designation which supports the Company's rapid market entry strategy. TopoTarget plans to file for full approval in December 2010. Accordingly TopoTarget does not anticipate that the September 24 FDA approval decision on pralatrexate will impact the potential approval of belinostat based upon a successful BELIEF trial.

About Advisory Committees

The Food and Drug Administration, to assist in its mission to protect and promote the public health, uses 48 committees and panels to obtain independent expert advice on scientific, technical, and policy matters.

Today's news does not change TopoTarget's full-year financial guidance.

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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 II 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 I clinical trial for patients with advanced solid tumors and lymphomas. 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.