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TopoTarget A/S

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# APO866 shows clinical activity in CTCL and B-CLL. APO866 hits the NAD+ target selected via TopoTarget's discovery technology

Copenhagen, Denmark, 22 December 2008 – TopoTarget A/S (OMX: TOPO) announces an update on phase II data with APO866 in three clinical studies. APO866 has demonstrated a confirmed partial response (PR) in Cutaneous T-Cell Lymphoma (CTCL) and transient reductions in white blood cells in patients with B-cell Chronic Lymphocytic Leukaemia (B-CLL) whereas there was no clinical effect in melanoma. APO866 -a specific inhibitor of the key enzyme involved in the synthesis of NAD+ is administered by continuous infusion at 0.126 mg/m<sup>2</sup>/hr for 96 hours in a 28 day schedule and is reasonably well tolerated. While this ongoing CTCL study has shown encouraging signs of clinical activity, five more patients are required for the interim analysis.

"APO0866 rights came to TopoTarget through the acquisition of Apoxis in 2007 and we have evaluated the drug in three phase II studies. I am happy to announce that we now have evidence activity in cancer patients. APO866 has demonstrated a confirmed PR in cutaneous T-Cell lymphoma and transient reductions in white blood cells in patients with B-CLL", said Peter Buhl Jensen, Professor, MD, CEO of TopoTarget.

"From our laboratory investigations we believed that the NAD+ target could be very important in cancer treatment and this confirms our beliefs. It is very difficult to find anticancer drugs with new mechanisms of action and activity beyond models. We still have a long way to go but now we know that this target and mechanism works also in cancer patients", Peter Buhl Jensen further commented.

Today's announcement does not change TopoTarget's full-year financial guidance for 2008.

**TopoTarget A/S** 



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## **Background information**

### About APO866

APO866 is tested in three clinical trials as monotherapy: Melanoma, B-CLL ant CTCL APO866 is a first-in-class, potent and specific inhibitor of nicotinamide phosphoribosyl transferase ("NMPRT"), a key enzyme involved in the synthesis of nicotinamide adenine dinucleotide ("NAD"). APO866 exhibits broad antineoplastic activity in pre-clinical models of tumours, and is in pre-clinical development in combination with chemotherapeutic compounds and radiotherapy. APO866 has a novel mechanism of action and therefore represents a new therapeutic approach to cancer.

### 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 handson 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.

