

To NASDAQ OMX Copenhagen A/S  
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**TopoTarget A/S**

Symbion  
Fruebjergvej 3  
DK 2100 Copenhagen  
Denmark  
Tel: +45 39 17 83 92  
Fax: +45 39 17 94 92  
CVR-nr: 25695771

**Positive BelCaP data in bladder cancer patients in Phase II study presented at the AACR/NCI/EORTC "Molecular Targets and Cancer Therapeutics" conference 2008**

**- TopoTarget announces that belinostat shows promising effect in bladder cancer in the Phase II study of the BelCaP combination. Furthermore, tomorrow, 23 October, data will be announced from a study of belinostat in combination with doxorubicin; belinostat administered orally as a capsule and intravenous belinostat treatment over 3 or 6 hours –**

[www.topotarget.com](http://www.topotarget.com)

A conference call will be hosted tomorrow, 23 October 2008 at 2.00 pm (CET)

**Copenhagen, Denmark, 22 October 2008 – TopoTarget A/S (OMX: TOPO) has presented promising data in bladder cancer using the BelCaP regimen with 1 complete response (CR), 3 partial responses (PR) and 10 patients out of 15 experiencing stable disease (SD). The data was presented at the AACR/NCI/EORTC "Molecular Targets and Cancer Therapeutics" conference 2008. BelCaP (belinostat in combination with standard doses of carboplatin and paclitaxel) was administered to patients with bladder cancer, who had previously relapsed from treatment with carboplatin/cisplatin.**

The study:

**A Phase II, open-label, non-randomised multi-center study of the histone deacetylase inhibitor belinostat in combination with carboplatin and paclitaxel (BelCaP) for the treatment of patients with urothelial carcinoma of the bladder (transitional cell carcinoma, or TCC).**

The study shows data from 15 bladder cancer patients, who had all received prior platinum-based treatment, 14 of which were evaluable. 4 responses have been observed to date (1 CR and 3 PR): A complete response was observed in a patient with bladder cancer, who received the BelCaP regimen as 2<sup>nd</sup> line treatment; CR was observed following the second cycle of BelCaP treatment, and the result was confirmed after cycle 4, after which the patient received consolidation radiotherapy. A partial response (PR) was observed in a patient who received the BelCaP regimen as 2<sup>nd</sup> line treatment; PR was observed following the second cycle and was increased to a non-confirmed complete response (CR) following cycle 4; after discontinuing the BelCaP treatment, the patient received radiotherapy. A partial response was observed in a patient receiving the BelCaP combination as 2<sup>nd</sup> line treatment; PR was confirmed following cycle 4, and the patient discontinued the treatment after cycle 5 due to an allergic reaction. A partial response was observed in a patient receiving BelCaP as 3<sup>rd</sup> line treatment; PR was observed following cycle 2 and confirmed

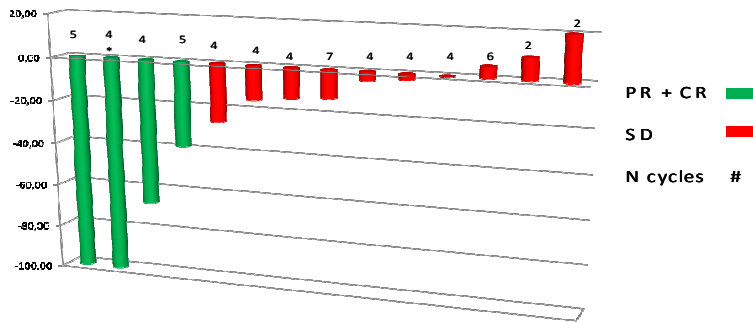


**Positive clinical data for belinostat from four studies presented at the AACR/NCI/EORTC "Molecular Targets and Cancer Therapeutics" conference 2008**

after cycle 3. The patient went off the study after cycle 4 due to relapse.

In addition, 10 patients experienced disease stabilisation (SD) with the longest stabilisation period being 6 and 7 treatment cycles of 3 weeks. Both these patients received BelCaP as 2<sup>nd</sup> line treatment. One patient continues on therapy (ongoing).

**Best response waterfall plot**



Conclusion:

The BelCaP regimen, which is a combination of belinostat (an HDACi) and carboplatin and paclitaxel, has a safety profile comparable to that of carboplatin and paclitaxel administered alone. With 4 responses (1 CR and 3 PR) out of 14 evaluable patients, this regimen shows promising activity in patients with pre-treated bladder cancer.

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

**Conference call**

A conference call to provide an update on the clinical development of belinostat will be hosted by Peter Buhl, CEO and Jan Fagerberg Medical Director, Belinostat Project Leader and will be followed by a question and answering session. The conference call takes place on October 23 at 2.00 pm (CET).

A presentation will be available at [www.Topotarget.com](http://www.Topotarget.com) before the teleconference

To participate in the conference call please dial:

From Denmark: 70 26 50 40

Outside Denmark: +45 70 26 50 40 or +44 208 817 9301

A replay of the conference call will be available approximately two hours after the conference call and until October 30, 2008 at 5.00 pm (CET) at the following number: +353 1 436 4267 pin code 1445475#.

**TopoTarget A/S**

For further information, please contact:

Ulla Hald Buhl  
Director IR & Communications

Telephone +45 39 17 83 92  
Mobile +45 21 70 10 49



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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, azacitidine 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 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, MDS, and liver, colorectal, and ovarian cancers, either alone or in combination with anti-cancer therapies. 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 Trial 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. In May 2005, TopoTarget announced the signing of 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 is founded and run by clinical cancer specialists and combines years of hands-on clinical experience with in-depth understanding of the molecular mechanisms of cancer. Focus lies on highly predictive cancer models and key cancer targets (including HDACi, NAD+, mTOR, FasLigand and topoisomerase II inhibitors). TopoTarget has a broad clinical pipeline with 9 products in development, including 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. 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](http://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 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.

