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Belinostat abstracts at the European Multidisciplinary Cancer Congress 2011

Copenhagen, Denmark – 13 September, 2011 – Today Topotarget A/S (NASDAQ OMX: TOPO.CO) announced that clinical data on belinostat will be presented at The European Multidisciplinary Cancer Congress in Stockholm, 23-27 September 2011.

Below is a list of the two abstracts accepted at The European Multidisciplinary Cancer Congress http://stockholm2011.ecco-org.eu/Programme;

Abstract 6597, Monday 26 September, time: 8.00-10.00, Hall C

A phase II study of epigenetic therapy using belinostat for patients with unresectable hepatocellular carcinoma: a multicenter study of the Mayo Phase 2 Consortium (P2C) and the Cancer Therapeutics Research Group (CTRG)

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Background: Patients with unresectable hepatocellular carcinoma (HCC) carry a dismal prognosis. Epigenetic aberrations have been reported in HCC. Belinostat is a novel, low molecular weight, histone deacetylase inhibitor. The purpose of this study was to assess the efficacy of epigenetic therapy with belinostat in patients with unresectable HCC.

Patients and methods: Major eligibility criteria included histologically confirmed HCC that is not amenable to curative treatment; ECOG≤2; adequate organs functions. The belinostat dose used was 1400 mg/m^2/day i.v. on day 1-5 every 3 weeks, as defined in a prior phase I study. The primary endpoint was progression-free survival (PFS) and the secondary endpoints were response rate (RR) according to RECIST and overall survival (OS). Adverse events were reported using CTCAE v3.

Results: 42 patients were accrued. Prior therapies included surgery (36%), radiofrequency ablation (7%), transarterial therapy (50%); prior systemic therapies (38%). Median follow-up was 20.0 months. Median cycle no. was 2 (range: 1-12). The PR and SD rate was 2.4% (1/42) and 45.2% (19/42) respectively. Median PFS was 2.64 months (95%C.I. 1.55-3.17) and OS was 6.60 months (95%C.I. 4.53-11.60). Grade ≥3 toxicities that occurred in ≥5% included: 4 (9.5%) abdominal pain, 4 (9.5%) hyperbilirubinemia, 4 (9.5%) raised alanine transaminase, 3 (7.1%) anemia, 3 (7.1%) vomiting, 2 (4.8%) distension, 2 (4.8%) hemorrhage, 2 (4.8%) prolonged QTc and 2 (4.8%) dehydration. One patient developed sudden death but it was determined not likely due to study medication.

Conclusions: With the majority of patients having failed prior therapy, epigenetic therapy with belinostat demonstrates tumor stabilization and is generally well-tolerated. Further studies including combinational study with other agents is warranted.

Acknowledgement: The study was sponsored by the Division of Cancer Treatment and Diagnosis, National Cancer Institute, U.S.A, and its collaborator TopoTarget.

Abstract 7105, Sunday 25 September, time: 11-12, Hall A8

Belinostat in Combination With Carboplatin and Paclitaxel (BelCaP) for Treatment of Bladder Cancer - a Pharmacokinetic Study of Exposure to Belinostat and Its Metabolites

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Background: Belinostat (Bel, PXD101) is a class I and II Histone DeACetylase (HDAC) inhibitor. A single arm Ph II study was conducted to evaluate the safety and activity of Belinostat, Carboplatin and Paclitaxel (BelCaP) in patients (pts) with Transitional Cell Carcinoma of the Bladder (TCCB) (n=15). A part of the study was a pharmacokinetic study of plasma exposure to Bel and its metabolites. The *in vitro* efficacy of belinostat and its metabolites were compared and related to plasma exposure in pts.

Materials and Methods: Pts with TCCB were treated with BelCaP every third week; Bel was given as a 1000mg/m^2 30-min i.v. inf. on days 1–5 with P (175mg/m^2) and subsequently Ca (AUC5) administered 2–3hrs after Bel on day 3. The plasma exposure (AUC) of Bel and its metabolites were determined. The *in vitro* pharmacological effect of Bel and its five major metabolites: belinostat glucuronide (BelGlcU), 3-(Anilinosulfonyl)benzene carboxylic acid (3-ASBA), methylated belinostat (Metbel), belinostat amide (Belam) and belinostat acid (Belac) were examined in a HeLa HDAC enzyme inhibition assay (HDAC-i), in WST proliferation assays and in clonogenic assays (CA). Fold differences in exposure of metabolites and belinostat (10 pts on day 3) and fold differences in *in vitro* efficacy of belinostat and metabolites were compared.

Results: The exposure of each metabolite relative to Bel was evaluated. The increases (molar $AUC_{0-\infty}$) relative to Bel were 16- (BelGlcU), 3- (3-ASBA), 1- (Metbel), 1- (Belam) and 0.5-fold (Belac).

Bel metabolites did not inhibit HDAC-i activity or cell WST proliferation *in vitro*. In the CAs the IC_{50} for Bel were 0.4 to 1.3µM. Three metabolites had weak effect relative to Bel. The fold increase in IC_{50} relative to Bel was: >65 (BelGlcU), >42 (Metbel) and >114 (Belam).

Conclusions: Five major human Bel metabolites (BelGlcU, 3-ASBA, Metbel, Belam and Belac) were identified in a Ph II study of BelCaP in pts with TCCB. Bel metabolites were inactive in HDAC-i assays and in WST assays and had weak activity in CA. The metabolite with highest fold exposure compared to Bel was BelGlcU (16-fold), which was 65 fold less effective *in vitro* than Bel. The present study finds that Bel metabolites do not have significant biological effect at therapeutic relevant plasma exposure in cancer pts.

Today's news does not change Topotarget's full-year financial guidance for 2011.

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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, 5-FU, etoposide 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 (IV) is in pivotal trial 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, and 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. Topotarget has a Clinical Trial Agreement (CTA) with the NCI to clinical studies on belinostat in order to better understand its anti-tumor activity.

About Topotarget
Topotarget (NASDAQ OMX: TOPO.CO) is a Scandinavian-based international biotech company headquartered in Denmark, dedicated to improve cancer therapies. In collaboration with Spectrum

Pharmaceuticals Inc. Topotarget currently focuses on the development in pivotal studies of its lead drug candidate, belinostat, which has demonstrated a clear anti-neoplastic effect in both hematological malignancies and solid tumors. Belinostat can be used in combination with full doses of chemotherapy, and is currently in a pivotal trial within PTCL (peripheral T-cell lymphoma) and phase II in cancer of unknown primary site (CUP). Topotarget's cancer drug target is HDAC. Totect® is a product on the market developed from Topotarget's drug discovery technology. Totect® is marketed by the company's own sales specialists in the US. The European rights to Savene® were divested in March 2010 as a consequence of the focus to develop and commercialize belinostat. 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 enrollment 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.