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Belinostat abstracts at ASCO 2011

Copenhagen, Denmark – 19 May 2011 – Topotarget A/S (NASDAQ OMX: TOPO.CO) announced today that clinical data on belinostat will be presented at the 2011 Annual Meeting of the American Society of Clinical Oncology (ASCO) to be held June 3-7, 2011 at the McCormick Place Convention Center in Chicago.

Shown below are the summaries of the abstracts that are now available for viewing on the ASCO.org website (www.asco.org).

A phase I and pharmacodynamic (PD) study of the histone deacetylase (HDAC) inhibitor belinostat (BEL) plus azacitidine (AZC) in advanced myeloid malignancies.

Abstract No: 6521

Session: Leukemia, Myelodysplasia, and Transplantation. Type: Poster Discussion Session, Time: Friday June 3, 2:00 PM to 6:00 PM. Location: McCormick Place E450b
Discussion Time: Friday June 3, 5:00 PM to 6:00 PM. Location: McCormick Place Arie Crown Theater.

Author(s): O. Odenike, L. A. Godley, J. Madzo, T. Karrison, M. Green, A. S. Artz, R. J. Mattison, K. W. L. Yee, M. Bennett, N. Fulton, G. Koval, G. Malnassy, R. A. Larson, M. J. Ratain, W. Stock; The University of Chicago, Chicago, IL; University of Wisconsin, Madison, WI; Princess Margaret Hospital, Toronto, ON, Canada.

Abstract:

Background: We hypothesized that targeting two mechanisms of epigenetic silencing with a potent HDAC inhibitor BEL plus the DNA methyltransferase inhibitor AZC would be additive or synergistic with regard to transcriptional de-repression and up-regulation of specific target genes.

Methods: Part 1 of the study was a dose escalation phase to establish the MTD of BEL in combination with a fixed dose of AZC. 3 to 6 pts were enrolled per dose level in the absence of a DLT or until the 1000mg/m2 dose level of BEL was attained. AZC was given at a dose of 75mg/m2/d SC on days 1-5, with escalating doses of BEL given IV over 30 minutes on the same days in a 28 day cycle. In part 2, pts were randomized during cycle 1 to AZC alone, or BEL/AZC at the established MTD of BEL. Part 2 was designed to evaluate the relative contribution of BEL to the combination, based on change in PD variables analyzed at day 5 of therapy in comparison to baseline, in cycle 1. In subsequent cycles all pts could receive BEL/AZC.

Results: 56 pts were enrolled, part 1 (n=24), part 2 (n=32). Median age 68, range (42-83). AML de novo=53% t- AML/MDS=18%, MDS/CMML=27%, PMF=2%; 68% had primary refractory or relapsed disease, 43% had poor risk cytogenetics. In part 1, dose escalation was feasible up to the 1000mg/m2 dose level of BEL, without first course DLT. In part 2, 18 pts (9 in each arm) had marrow samples at baseline and at day 5 for q-RT-PCR analysis for *p21*, *MDR1* and *HIST1H3H* transcript levels. At day 5, *MDR1* was significantly upregulated in the BEL/AZC arm when compared with AZC alone arm (p=0.0089), in contrast to *p21* and *HIST1H3H* which were not significantly different between the 2 arms. There were18 responses (CR=6, marrow CR =2, PR= 1, HI-P=7, HI-N=2); 13 of these occurred at the 1000mg/m2 dose level of BEL.

Conclusions: The combination of BEL and AZC is feasible, responses have been observed in several pts at the RP2D of 1000mg/m2 of BEL plus 75mg/m2 AZC. A significant upregulation in *MDR1* was observed in the BEL/AZC arm at day 5 compared with the AZC alone arm, suggesting a relative biologic contribution of BEL to the combination. The clinical correlates of these observations require evaluation in the context of a larger trial.

Management of thymic epithelial tumors (TETs) at the National Cancer Institute (NCI).

Abstract No: e17511

Publication-only abstracts (abstract number preceded by an "e"), published in conjunction with the 2011 Annual Meeting but not presented at the Meeting, can be found online only. The publication-only abstracts are not included in the print or USB versions of the *ASCO Annual Meeting Proceedings Part I*, but they are citable to the *Journal of Clinical Oncology.*

Author(s): A. Rajan, R. J. Kelly, A. Lopez-Chavez, C. A. Carter, E. Szabo, B. Scepura, M. J. Manu, A. W. Berman, G. Giaccone; National Cancer Institute, Bethesda, MD.

Abstract:

Background: TETs are very rare anterior mediastinal tumors.

Methods: We performed a retrospective review of patients (pts.) with TETs presenting to the NCI for enrollment in ongoing clinical trials, standard-of-care therapy or a second opinion.

Results: Seventy-three pts. were seen between 12/2007 and 12/2010; 43 males (41%), median age at diagnosis: 48 years (range, 17 - 81). Fifty-four pts. were Caucasian (74%), 7 (10%) African-American, 8 (11%) Asian and 4 (6%) Hispanic. Histology: B1 5 (7%), B2 13 (18%), B2/B3 1 (1%), B3 9 (12%), thymic carcinoma (TC) 35 (48%), atypical carcinoid 2 (3%) and unclassified thymoma 8 (11%). Fifty pts. were enrolled in clinical trials: 28 on a phase II study of the HDAC inhibitor, belinostat (B), 27 on a phase II study of the IGF -1R inhibitor cixutumumab (C) (including 10 previously on B), 3 on a phase I study of chemotherapy (PAC) plus B and 2 on a phase II study of the cyclin-dependant kinase inhibitor PHA-848125AC. Median number of previous systemic therapy regimen that had been administered was 2 (range, 0-10). Forty-three pts. (59%) had extra-thoracic metastases; liver, bone and lymph nodes were the most common sites. Fourteen pts. (19%) had at least one autoimmune disease; myasthenia gravis (10%) was the most common. Three out of six pts. with TC with neuroendocrine features had Cushing's syndrome. Eleven pts. (15%) had opportunistic infections including shingles (8%) and candidiasis (4%). Forty-eight pts. On clinical trials were evaluable for response: B: 2PR, 18SD, 8PD; C: 1PR, 16SD, 8PD; PACB: 1PR, 2SD; PHA: 2SD.

Median survival for all pts. was 117 months (T - not reached; TC - 56 months). Among 28 pts. enrolled on B, the only clinical predictor of response and survival was presence of intra-thoracic disease only. Of 12 tumors (B1-1, B2-2, B3-1, C-7, atypical carcinoid-1) evaluated for overexpression of HER2 by IHC, none was positive. One patient with TC had a c-KIT mutation in exon 11.

Conclusions: Histologic diagnosis of thymoma and the presence of intra-thoracic disease only predicts for longer survival in pts. with TETs. Targeted drugs can induce prolonged disease stabilization and few responses in heavily pretreated patients. Molecular profiling of tumors will be necessary in order to advance the field.

This announcement has no impact on Topotarget's financial 2011 expectations.

Topotarget A/S

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Background information

About belinostat

Topotarget 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 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 an 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 other chemotherapeutic agents, and is currently in a pivotal trial within PTCL (peripheral T-cell lymphoma) and phase II in cancer of other unknown primary site (CUP). Topotarget's cancer drug targets are HDAC, NAD+, and topoisomerase II. 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. 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.