Belinostat resumé på ASCO Gastrointestinal Cancers Symposium 2012


Nedenfor er det videnskabelige kliniske resumé, der nu er tilgængeligt på ASCO’s hjemmeside (www.asco.org).

Efficacy of belinostat in advanced hepatocellular carcinoma (HCC): Phase I and II multicentered study of the Mayo Phase 2 Consortium (P2C) and the Cancer Therapeutics Research Group (CTRG).

Abstract No.: 259

Session: General Poster Session B: Cancers of the Pancreas, Small Bowel, and Hepatobiliary Tract

Background:
Belinostat is a novel histone deactylase inhibitor which demonstrates preclinical activity in HCC. We report the results of a phase I/II study in belinostat in patients (pts) with unresectable HCC.

Methods:
Major eligibility criteria included histologically confirmed HCC not amenable to curative treatment; PS ≤ 2; adequate organ function; prior systemic therapy was allowed. In the phase I portion, belinostat was given i.v. on D1-5 every 3 weeks with dose levels of 600, 900, 1200, and 1400 mg/m²/day. In the phase II portion, belinostat was tested at the MTD. Primary endpoint was PFS and secondary endpoints were RR according to RECIST and OS. CT assessment was done every 8 weeks.

Results:
Phase I portion: a total of 18 pts were accrued; no DLTs were observed at 1400mg/m²/day for 5 days, and this dose was selected for phase II development. Phase II portion: 42 pts were accrued; Median age = 57.5 years; 41 had Child’s A function, and 24 pt had ECOG 0. Sixteen (38%) had previous systemic therapy, and 21 (50%) had previous transarterial therapy. Median follow-up was 20.0 months. The PR and SD rate was 2.4% (1/42) and 45.2% (19/42). Median PFS was 2.64 months (95%CI. 1.55-3.17) and OS was 6.60 months (95%CI. 4.53-11.60). Grade 3 or higher toxicities (>5% rate) were abdominal pain (9.5%), hyperbilirubinemia (9.5%), raised ALT (9.5%); anemia (7.1%) and vomiting (7.1%).

Conclusions:
Belinostat demonstrates disease stabilization in a predominantly pretreated population of pts with unresectable HCC with an acceptable safety profile. Further randomized studies are warranted. Supported in part by N01-CM-62205.
Topotarget A/S

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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 tumors 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 A/S
Topotarget (NASDAQ-OMX: TOPO.CO) is an international biopharmaceutical company headquartered in Copenhagen, Denmark, dedicated to clinical development and registration of oncology products. Topotarget focuses, in collaboration with Spectrum Pharmaceuticals, Inc., on the development in pivotal studies of its lead drug candidate, belinostat, which has shown positive results as a monotherapy treating hematological malignancies and positive results in solid tumors. Belinostat may be used in combination with full doses of chemotherapy, and is in a pivotal trial within PTCL (peripheral T-cell lymphoma). For more information, please refer to www.topotarget.com.

Topotarget A/S Safe Harbor 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 A/S 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 A/S 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 A/S’ history of incurring losses and the uncertainty of achieving profitability; Topotarget A/S’ stage of development as a biopharmaceutical company; government regulation; patent infringement claims against Topotarget A/S’ products, processes and technologies; the ability to protect Topotarget A/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.