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Belinostat abstract for American Association for Cancer Research 2014

Clinical data on belinostat will be presented at the 2014 American Association for Cancer Research (AACR) Annual Meeting, April 5-9, 2014.

Shown below is the abstract that is now available on AACR’s website (http://www.aacr.org/).

Abstract number: CT207. Presentation time: Monday, April 07, 2014, 8:00 AM -12:00 PM. Location: Hall A-E, Poster Section 38. Poster board number: 7.

Pharmacokinetic analysis of the HDAC inhibitor belinostat (PXD-101) and metabolites in patients with hepatic dysfunction

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Introduction: Histone deacetylases (HDAC) are frequently deregulated in human cancers and their inhibition allows re-expression of silenced genes. Belinostat is an HDAC inhibitor with in vitro and in vivo activity in multiple malignancies, currently in phase II trials. We report the pharmacokinetics of belinostat and metabolites in patients enrolled in a phase I liver dysfunction trial currently being conducted and led by the NCI.

Methods: Patients enrolled into the study were assigned to varying cohorts depending on their level of hepatic dysfunction (normal=N, mild=H1, moderate=H2, and severe=H3). All patients were given a 30-minute infusion at 400 mg/m2 on cycle 1 day -7. Heparinized plasma samples were collected prior to infusion, 15 and 25 min after start, and 5, 10, 15, 30, 60, 90, 120, 240, 360, 480, and 1440 minutes after infusion. Patients from the NCIIDTC had samples collected and these were quantitated by a previously validated assay for belinostat, belinostat-glucuronide, methyl-belinostat, M21, M24, and M26. Pharmacokinetic parameters were derived non-compartmentally with PK Solutions. Metabolic ratios were calculated as a measure of metabolic fate.

Results: 15 patients (N=2, H1=10, H2=2, H3=1) had useable pharmacokinetic data. Observed belinostat Cmax (N=21.1±4.9, H1=55.8±78.0, H2=23.0±7.2, H3=23.1 µg/mL) and belinostat AUC0-inf (N=806±294, H1=1308±996, H2=702±82, H3=780 µg/mL•min) did not reveal any trends with dysfunction cohort. Metabolic AUCinf ratios of belinostat to the various metabolites also did not appear to change with dysfunction cohort.

Conclusion: Liver function does not appear to affect the pharmacokinetics or metabolic fate of belinostat. Analysis of additional subjects is on-going. The results of this study will facilitate optimal dosing for patients with liver dysfunction.
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Background information

About Topotarget
Topotarget (NASDAQ OMX: TOPO) is a Scandinavian-based biopharmaceutical company headquartered in Copenhagen, Denmark, dedicated to the clinical development and registration of oncology products. In collaboration with Spectrum Pharmaceuticals, Inc., Topotarget focuses on the development of its lead drug candidate, belinostat, which has shown positive results in the treatment of hematological malignancies and solid tumors, obtained by both mono- and combination therapy. For more information, please refer to www.topotarget.com.

Topotarget Safe Harbor Statement
This announcement may contain forward-looking statements, including statements about Topotarget A/S’ expectations to the progression of Topotarget A/S’ clinical pipeline and with respect to cash burn guidance. Such statements are subject to risks and uncertainties of which many are outside the control of Topotarget A/S, and which could cause actual results to differ materially from those described. Topotarget A/S disclaims 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 Danish law.