To NASDAQ OMX Copenhagen A/S
Announcement no. 28-13 / Copenhagen, December 10, 2013

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New Drug Application for belinostat in relapsed or refractory PTCL submitted to the FDA in the USA

Topotarget announces the submission of a New Drug Application (NDA) for belinostat for the treatment of relapsed or refractory (R/R) peripheral T-cell lymphoma (PTCL) to the US Food and Drug Administration (FDA). The NDA has been filed for Accelerated Approval with a request for Priority Review. Response from the FDA regarding acceptance to file is expected within 60 days from the FDA receipt date.

The NDA for belinostat for the treatment of R/R PTCL in the USA has been submitted to the FDA by our US partner Spectrum Pharmaceuticals, Inc. The application is filed for Accelerated Approval with a request for Priority Review. Potential acceptance to file and decision of Priority Review grant from the FDA is expected within 60 days from the FDA receipt date. If the FDA grants acceptance to file the NDA for belinostat in this indication, a potential Accelerated Approval of the NDA can take place within 8-12 months from the FDA receipt date. The application is based on the CLN-19 BELIEF study and potentially entails two significant milestones (see below) during 2014.

> "The submission of the belinostat NDA is a great step forward for the patients with relapsed or refractory PTCL in desperate need of new treatment options. We are very pleased with this development and now look forward to receiving feedback from the FDA in Q1 2014", says CEO Anders Vadsholt.

Related milestone payments
The first milestone relates to the acceptance to file from the FDA: Upon acceptance, Topotarget is entitled to receive a cash payment of USD 10 million from Spectrum Pharmaceuticals as well as 1 million Spectrum Pharmaceuticals shares (equal to approximately USD 9.4 million). The second milestone matures upon FDA approval of the NDA upon which Spectrum Pharmaceuticals will make a cash payment of USD 25 million to Topotarget.

This company announcement does not change the company's financial outlook for the year 2013.

About the approval process
Within 60 days from the FDA receipt date, the FDA will decide if the application is acceptable for filing and if the application is eligible for either Priority Review or Standard Review. On day 74 from the FDA receipt date, the FDA will communicate timelines for the NDA reviewing process including meetings during the NDA evaluation. Priority Review can lead to approval within 8 months from the FDA receipt date, while the duration of Standard Review is expected to be 12 months.

Belinostat has been filed for Accelerated Approval. It is anticipated that the completion of a randomized confirmatory trial (the BelCHOP study) will be required as a condition to obtain full approval for belinostat in PTCL, while the initiation of this study is a pre-requisite to get

acceptance to file by the FDA. The first part of the confirmatory trial (the BelCHOP study) was initiated in August this year and is on-going.

A potential market authorization application in the European territory requires a completion of the confirmatory randomized trial with BelCHOP, but a US approval may leverage a potential approval in other territories.

About the BELIEF study
The pivotal study of belinostat for the treatment of R/R PTCL was closed for recruitment in September 2011 after the inclusion of 129 patients. Final data presented at the American Society for Clinical Oncology annual meeting in 2013 showed an ORR of 26% in all PTCL patients, 28% in PTCL patients with platelet counts above 100,000/µL, and 45.5% in patients with the PTCL subtype AITL (angioimmunoblastic T-cell lymphoma). Safety data presented at the T-Cell Lymphoma Forum in 2013 showed a favorable safety profile of belinostat when compared to the approved treatments for patients with PTCL and it was emphasized that combining belinostat with cytotoxic regimens is feasible. Belinostat appears to have low myelosuppression and even patients with a poor bone marrow reserve tolerated belinostat.

About the BelCHOP study
The first part of the confirmatory study with BelCHOP (belinostat plus cyclophosphamide, hydroxydaunorubicin (doxorubicin), oncovin (vincristine), and prednisone) is designed to determine what dose of belinostat combined with CHOP can be safely administered together for first-line treatment of patients with PTCL. The purpose is furthermore to establish the recommended dose for the immediate following phase III confirmatory study. The first part of the BelCHOP study is thus a precondition for a phase III confirmatory study with belinostat in PTCL. The first part of the BelCHOP study is expected to recruit up to 28 patients by Q4 2014. The second part of the confirmatory trial is expected to be initiated in H1 2015.

About belinostat
Belinostat is a novel pan-HDAC inhibitor with more than 1,100 patients treated. Belinostat has a favorable safety profile which may allow combination with traditional chemotherapy. Preclinical experiments showed that belinostat may be effective against multiple cancers by inhibiting cell proliferation and inducing programed cell death (apoptosis) in tumor cells. Belinostat has been tested in a number of phase I/II clinical trials in hematological cancers and solid tumors both in mono- and combination therapy. Data from these trials have provided evidence of the anti-tumor effect of belinostat, including as monotherapy in peripheral T-cell lymphoma (PTCL) and cutaneous T-cell lymphoma (CTCL), liver cancer, and combination therapy in soft tissue sarcoma and thymoma.

Topotarget A/S

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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.