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FDA grants acceptance to file and Priority Review for Beleodaq™ (belinostat) NDA in PTCL

Topotarget A/S announces that the FDA has granted acceptance to file and Priority Review for the Beleodaq™ NDA for the treatment of relapsed or refractory PTCL. The FDA decision date based on PDUFA is set for August 9, 2014. The acceptance to file entails a milestone payment of USD 10 million and 1 million shares in Spectrum Pharmaceuticals, Inc. to Topotarget.

In December 2013, Topotarget's US partner, Spectrum Pharmaceuticals, submitted a New Drug Application (NDA) for Beleodaq™ in relapsed or refractory (R/R) peripheral T-cell lymphoma (PTCL) to the US Food and Drug Administration (FDA). This NDA has now been granted acceptance to file and Priority Review. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) action date of August 9, 2014.

The acceptance to file triggers the first of two expected milestone payments related to the study of Beleodaq™ in R/R PTCL patients in the USA: Spectrum Pharmaceuticals is to pay Topotarget USD 10 million and 1 million Spectrum Pharmaceuticals shares.

> "We are very pleased with this news. This is a significant milestone for Beleodaq™ for the treatment of R/R PTCL patients. Also, the Priority Review designation underlines our drug's potential compared to available treatments. Upon the receipt of the related milestone payment, we will look forward to presenting our new corporate strategy within the near-term future", says Anders Vadsholt, CEO of Topotarget.

As previously disclosed, an additional milestone cash payment from Spectrum Pharmaceuticals is triggered upon an NDA approval. Upon an approval, Topotarget will moreover be eligible to receive potential royalty payments and sales milestones.

Financial outlook 2014
Topotarget expects an estimated pre-tax profit in the range of DKK 55-65 million for the full-year financial result for 2014. The expected net cash and cash equivalents are expected to be around DKK 78-88 million at year-end 2014. The second milestone payment related to an NDA approval is not included in this financial outlook. The shares in Spectrum Pharmaceuticals have an estimated value of USD 7.8 million based on the share price as of February 5, 2014.

Approval process
Within 60 days from the receipt of an NDA, the FDA decides if an application is acceptable for filing and if it is eligible for either Priority Review or Standard Review. Within 74 days from the receipt date, the FDA communicates timelines for the NDA reviewing process including information on meetings during the NDA evaluation. Priority Review can lead to approval within 6 months from the acceptance to file date, while the duration of Standard Review is expected to be 10 months from the acceptance to file date.

An approval will inherit a post-approval commitment to complete a randomized confirmatory phase III study. A dose-finding study of BelCHOP (Beleodaq™ plus cyclophosphamide,

hydroxydaunorubicin, oncovin, and prednisone), which must be conducted prior to the initiation of the phase III study, was initiated in August 2013 and recruitment is expected to be completed in Q4 2014.

A US approval may leverage potential approvals in other territories which accept an FDA file.

About the BELIEF study
The pivotal study of Beleodaq™ 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 (ASCO) annual meeting in 2013 showed an objective response rate (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 angioimmunoblastic T-cell lymphoma (AITL). Safety data presented at the T-Cell Lymphoma Forum in 2013 showed a favorable safety profile of Beleodaq™ when compared to the approved treatments for patients with PTCL and it was emphasized that combining Beleodaq™ with cytotoxic regimens is likely feasible. Beleodaq™ appears to have low myelosuppression and even patients with a poor bone marrow reserve tolerated Beleodaq™.

About the BelCHOP study
The dose-finding BelCHOP study is designed to determine what dose of Beleodaq™ 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 dose-finding study of BelCHOP is expected to recruit up to 28 patients by Q4 2014. The confirmatory phase III study is expected to be initiated in H1 2015.

About Beleodaq™
Beleodaq™ is a novel pan-HDAC (histone deacetylase) inhibitor with more than 1,100 patients treated. Beleodaq™ has a favorable safety profile which may allow combination with traditional chemotherapy. Preclinical experiments showed that Beleodaq™ may be effective against multiple cancers by inhibiting cell proliferation and inducing programed cell death (apoptosis) in tumor cells. Beleodaq™ 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 Beleodaq™, including as monotherapy in PTCL, cutaneous T-cell lymphoma (CTCL), and liver cancer, and as combination therapy in soft tissue sarcoma (STS) 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, Beleodaq™, 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.