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Belinostat gets European orphan drug designation for the treatment of malignant thymomas

On July 17, 2013, the European Commission granted Topotarget an orphan drug designation for belinostat for the treatment of malignant thymomas.

The EU regulation on orphan medicinal products is intended to encourage the development of drugs that may provide a significant benefit to patients suffering from rare (affecting fewer than five out of 10,000 people) and life-threatening or chronic debilitating conditions for which there is no effective therapies available. The orphan drug designation offers important incentives such as free protocol assistance (to optimize drug development) at the European Medicines Agency (EMA), fee reductions for various regulatory activities and, following drug approval, a grant of 10 years' market exclusivity in the EU.

> "Belinostat has potential to benefit many patients struck by different forms of cancer and we are very happy that we have achieved yet another orphan drug designation for belinostat – this time in the indication malignant thymomas. This progress is very encouraging and will hopefully come to fulfill the true unmet medical need for those affected by this rare and severe disease", says Anders Vadsholt, CEO of Topotarget A/S.

About malignant thymomas
Malignant thymomas are very rare tumors with prevalence in the range of 0.13 to 0.25 per 100,000. There is no product authorized in EU for the treatment of malignant thymomas.

Treatment with belinostat monotherapy in a group of 41 heavily pretreated patients with malignant thymomas did, in an NCI study (NCI8174), show intriguing duration of response and disease stabilization. Data from another NCI-sponsored study (NCI8602), where belinostat is combined with the cytotoxic regimens cisplatin, doxorubicin, and cyclophosphamide for first-line treatment of malignant thymomas, which was presented at ASCO (American Society for Clinical Oncology) 2012 reported a response of 75% in thymoma patients receiving the combination. The full abstract is available on www.topotarget.com.

About belinostat
Belinostat is a novel pan-HDAC inhibitor in late-stage clinical development with more than 1,100 patients treated. Belinostat has a promising safety profile which allows combination with traditional chemotherapy. Preclinical experiments demonstrated belinostat to 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.