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Positive subtype data from the BELIEF trial presented at the 12th International Conference on Malignant Lymphoma

Topotarget announces that positive subtype data on angioimmunoblastic T-cell lymphoma (AITL) from the BELIEF trial with belinostat in relapsed or refractory peripheral T-cell lymphoma (R/R PTCL) will be presented at the 12th International Conference on Malignant Lymphoma (ICML) in Lugano, Switzerland, on June 19-22, 2013.

The belinostat abstract, which will be presented orally at the ICML conference, puts special emphasis to the BELIEF trial's subtype AITL, which has shown an objective response rate (ORR) of 45.5%. The abstract further concludes that the favorable safety profile observed warrants further investigation of belinostat-based regimens to optimize outcomes for AITL.

"The PTCL subtype, AITL, represents 15-20% of all PTCL cases and we are hence very thrilled that belinostat shows a response rate of an astounding 45.5%, which places our compound at the top of available treatments in the indication", says Anders Vadsholt, CEO of Topotarget A/S.

Below is the full-length abstract, which will be presented on June 22, 2013.

Belinostat in relapsed or refractory peripheral T-cell lymphoma (R/R PTCL) subtype angioimmunoblastic T-cell lymphoma (AITL): Results from the pivotal BELIEF trial.

S. Horwitz; O. O'Connor, W. Jurczak; A.Van Hoof; G. Hess; Z. Gasztonyl; J.K. Doorduijn; J. Walewski; P. Brown; A.Vranovsky; Sissolak; I. Auer; A. Duletic-Nacinovic; A. Shustov; S. Chawla; P. Knoblauch; G. Wulf; O. Visser; P. L. Zinzani; T. Masszi.

Introduction: PTCL is a heterogeneous, aggressive disease with poor prognosis. AITL is a subtype representing 15–20% of PTCL. AITL treatment is similar to other forms of PTCL with 5-year OS rates of 10–32%.

Methods: BELIEF was a single-arm study of belinostat in patients with R/R PTCL after failure of ≥1 prior systemic therapies. Entry criteria were measurable disease, platelets≥50,000/ml, no prior histone deacetylase inhibitor (HDACi) therapy, and adequate organ function. PTCL was confirmed by central pathology review group (CPRG). Belinostat (1000mg/m, 2 IV_5 days) was given as a 3week cycle until progression or unacceptable toxicity. Tumor response was assessed by Cheson 2007 criteria. The primary endpoint was ORR. Subgroup analysis examined response by PTCL subtype.

Results: Of 129 patients enrolled with R/R PTCL, data presented here are from22 patients with CRPG confirmed AITL, including 5 with baseline platelets <100,000/ml, a median age of 70 (range 48–78) years, 64% female, a median of 2 (range 1–5) prior therapies (21 CHOP/CHOP-like; 4 stem cell transplant), and 8 had bone marrow involvement. Belinostat was administered for a median of 4 cycles (1–29) with a median dose intensity of 94%. Dose reductions in 3 patients

were due to grade 2 and 3 QTC prolongation in 1 patient, immune hemolytic anaemia, and hypokalemia/dyspnea/fever. Response rate for AITL was 45% (4 CR, 6 PR) with a median duration of response of 7.5 (1.6–29.4) months. Of the responders, 2 had baseline platelets of 78,000 and 79,000; with one patient achieving CR. Data is reported as of 31AUG2012, with 3 patients remaining on treatment at 55, 105, and 135 weeks* and 19 discontinued. Discontinuations were due to PD in 14 patients, AEs in 2 and other reasons for 3. Sixteen patients have died, 5 were alive, and 1was lost to follow-up. Median PFS and OS for patients with AITL were 5.8 and 9.2 mos, respectively.

Conclusions: Belinostat treatment resulted in a 45% response rate among patients with R/R AITL. The favorable safety profile observed warrants further investigation of belinostat-based regimens to optimize outcomes for AITL.

*Please note that there is a typo in the abstract made public on http://onlinelibrary.wiley.com/doi/10.1002/hon.2057/abstract; months should read weeks.

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Background information

About Topotarget
Topotarget (NASDAQ OMX: TOPO) is a Scandinavian-based biopharmaceutical company headquartered in Copenhagen, Denmark, dedicated to 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.

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