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Topotarget A/S
Fruebjergvej 3
DK 2100 Copenhagen
Denmark
Tel: +45 39 17 83 92
Fax: +45 39 17 94 92
Comp. reg.: 25695771
www.topotarget.com

Final data from BELIEF study for ASCO 2013 confirms objective response rate of 26%

Topotarget announces that an abstract containing positive final data from the registrational BELIEF study with belinostat in peripheral T-cell lymphoma (PTCL) has been released for presentation on ASCO (American Society of Clinical Oncology) 2013 on May 31-June 4, 2013. The abstract concludes that the BELIEF study has an objective response rate (ORR) of 26%.

Final results from the CLN-19 BELIEF study on belinostat in patients with relapsed or refractory (R/R) PTCL show that belinostat is well-tolerated with a favorable safety profile and an objective response rate (ORR) of 26%, cf. the protocol definition of the primary endpoint. Moreover, the data show an ORR of 28% in a subset of the patient group with baseline platelets of ≥100,000/µl, which is the commonly used inclusion criterion for this population. The BELIEF study was designed to enroll R/R PTCL (including difficult-to-treat) patients with a platelet count greater than or equal to 50,000/µl. The median duration of response (DoR) was 8.3 months and the longest DoR was 29.4 months.

The study results suggest that belinostat may have the potential to fulfill an unmet medical need, even for difficult-to-treat patients, with relapsed or refractory disease and hence the results reinforces the potential for belinostat to become a meaningful addition to the treatment landscape for PTCL.

"We continue to be extremely encouraged by the results from this study of belinostat in patients with PTCL and find that the positive final data fully supports the intended submission of a New Drug Application with the US Food and Drug Administration by our partner Spectrum Pharmaceuticals," says Anders Vadsholt, CEO of Topotarget.

Spectrum Pharmaceuticals expects to file the New Drug Application for belinostat in PTCL in the summer of 2013.

Below please find the abstract that is now available on ASCO's website (www.asco.org).

Belinostat a novel pan-histone deacetylase inhibitor (HDACi) in relapsed or refractory peripheral T-cell lymphoma (R/R PTCL): Results from the BELIEF trial

O. O'Connor, T. Masszi, K. Savage , L. Pinter-Brown, F. Foss, L. Popplewell, A. Cashen, J.K. Doorduijn, S. Chawla, P. Knoblauch, N. Azarnia, A. Zizani, Brown, G. Hess, Van Hoof, S. Horwitz, A. Shustov.

Background: Therapies approved in US for R/R PTCL have overall response rates (ORR) of 25%-27%. The need for new therapies persists. BELIEF is a pivotal, single-arm study of belinostat in patients with R/R PTCL after failure of ≥1 prior systemic therapies.

Methods: Entry criteria were measurable PTCL, platelets ≥50,000/µL, no prior HDACi therapy, and adequate organ function. PTCL diagnosis was confirmed by central pathology review (CPRG). Belinostat 30 min IV infusion

at 1000 mg/m^2 was administered on days 1–5 of a 3 week cycle until disease progression or unacceptable toxicity. Tumor response was assessed by Cheson 2007 criteria. The primary endpoint was the ORR.

Results: Patients with R/R PTCL (N=129, 53% male, median age 63 y) received belinostat for a median of 2 cycles (range 1–33). The median number of prior therapies was 2 (1-8) including CHOP/CHOP-like (96%) and stem cell transplant (23%). The median administered dose intensity was 98%. One and two dose reductions of 25% occurred in 12% and 1% of patients, respectively, due to various adverse events (AEs). For patients with a CPRG confirmed diagnosis of PTCL (N=120), the ORR was 26% (n=31; 10% CR; 16% PR). The median time to response was 5.6 weeks (range 4.3-50.4). The median duration of response (DoR) was 8.3 months; longest DoR was 29.4 months. For the subgroup of patients with CPRG confirmed PTCL and baseline platelets ≥100,000/µL (N=100) ORR was 28% (CR 11%; PR 17%). The most frequent (≥ 5%) Grade 3-4 treatment emergent AEs were thrombocytopenia (13%), neutropenia (13%), anemia (10%), dyspnea (6%), pneumonia (6%), and fatigue (5%). Patients with platelets <100K tolerated belinostat, with 98% dose intensity. Belinostat was well tolerated with a low incidence of myelosuppression. Discontinuations were due to PD (64%), death (11%), AEs (7%), patient request (8%), and other (4%).

Conclusions: Belinostat demonstrated a 26%-28% ORR in BELIEF and was well tolerated with a favorable safety profile in patients with R/R PTCL including those with low platelets. The low incidence of myelosuppression observed warrants further investigation of belinostat combination therapy to develop new treatment paradigms for R/R PTCL.

Topotarget A/S

For further information, please contact:

Anders Vadsholt, CEO: Direct: +45 39178345; Cell: +45 28989055

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.

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