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# TopoTarget reports Phase II trial results with Avugane™ in acne vulgaris

***- New Avugane™ data in the two groups of patients receiving 3% and 6% doses support further clinical development -***

**Copenhagen, Denmark – 13 March 2009 – TopoTarget A/S (OMX: TOPO) has announced that treatment with topical Avugane™ gel (valproic acid) 3% and 6% gave encouraging results in patients with acne vulgaris. Although the changes in the counts of the acne lesions did not reach statistically significant differences between the three treatment groups (0.5%, 3%, and 6%) in this small study, the overall assessment both by the investigators and the patients did demonstrate a trend towards more favourable effect in the 3% group.**
**The original protocol had the 6% Avugane™ treatment as the target treatment and it was unfortunate that stability problems prevented a study of this probably optimal concentration. However the short treatment provided to six patients with the 6% Avugane™ did show promising results particularly of the inflammatory lesions. All three grades of the Avugane™ gels were very well tolerated.**
**The trend in the efficacy assessment report supports a trial of a new and more stable formulation of 6% Avugane™.**
**TopoTarget intends to outlicense the drug to a partner with expertise in the dermatological field.**

*"Although this study supports our previous positive valproic acid results in acne there are still a formulation tasks to solve with this product. We are focusing on belinostat and have stopped our dermatology activities and we hope to outlisence the use of valproic acid for skin diseases,"* says professor Peter Buhl Jensen, CEO of TopoTarget. *"In addition to the opportunity of using valproic acid in dermatology it is exciting to see that there are 17 investigators initiatiated clinical trials ongoing in cancer using valproic acid. These trials are not sponsored by TopoTarget but we do have a strong patent protection in the use of valproic acid in cancer and we look forward to seeing the results of these studies",* Peter Buhl Jensen further comments.


The Study:
A double-blind, randomised, parallel group, placebo-controlled dose finding Phase II study to compare the efficacy and safety of topically applied Avugane™ of different concentrations in subjects with mild to moderate acne vulgaris.

Conclusion:
7o patients with facial acne were randomly allocated to a 12-week topical treatment with Avugane 0.5%, Avugane 3%, Avugane 6% gel or a placebo gel. Early in the trial the 6% gel unfortunately showed stability problems and this arm of the study was discontinued, and the treatment of 6 patients already allocated was stopped after 18-37 days of treatment. Patients had from 21 to 118 counted acne lesions (median 45) of which about half were of the inflammatory type.
The number of lesions (including subtypes) and the investigators and the patients overall impression of the treatment benefit was assessed after 4 weeks (d28), 8 weeks (d56) and 12 weeks (d85).
The treatment induced a significant improvement over time both in the total number of acne lesions and in the subsets inflammatory or non-inflammatory lesions, an improvement which at d85 reached a 33-40% reduction. This was also born out by the investigator overall assessment at the time points (table 5) and the corresponding patient assessments (table 6).
Allthough the changes in the counts of the acne lesions did not reach statistically significant differences between the three small treatment groups, the overall assessment both by the investigators and the patients did demonstrate a trend towards more favourable effect in the 3% group.
The original protocol had the 6% Avugane treatment as the target treatment and it was unfortunate that stability problems prevented a study of this probably optimal concentration. However the short treatment provided to six patients with the 6% Avugane did show promising results particularly of the inflammatory lesions. All three grades of the 3% Avugane gels were very well tolerated.
The trend in the efficacy assessment does support a further trial of a new and more stable 6% Avugane.

The results do not change TopoTarget's financial expectations for 2009.

**TopoTarget A/S**

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**Background information**

**About Acne Vulgaris**
Acne vulgaris is the most common inflammatory skin disorder among adolescents. Approximately 80% of all adolescents show signs of acne in various degrees and 15% of adolescents suffer from acne so severely that they need clinical treatment. The more severe forms of acne typically have a significant effect on patients' physical and psychological well-being. Furthermore, many patients fail to respond adequately to available treatments or suffer from adverse effects associated with such treatments. Current topical therapies for all forms of acne are estimated to generate $1.5 billion in annual sales in the United States alone (Source: IMS, June 2004). Traditional treatments for mild to moderate facial inflammatory acne include over-the-counter topical medications for mild cases, and prescription topical medications or oral antibiotics for mild to moderate cases. For more severe forms of acne, oral treatment with the retinoid product isotretinoin (Roaccutan, F. Hoffman-La Roche Ltd) is one of the commonly used approaches.


**About Avugane™**
Avugane™ comprises a novel and proprietary gel-based formulation of a moderate strength HDAC inhibitor for topical therapy of inflammatory skin diseases including indications such as acne vulgaris, psoriasis and atopic dermatitis. The pathogenesis of Acne vulgaris is

multifactorial, being influenced by hormonal, microbiological, and immunological factors as well as proliferative cellular mechanisms which are targeted specifically by the HDAC inhibitory activity of Avugane™.

**About TopoTarget**
TopoTarget (OMX: TOPO) is an international biotech company headquartered in Denmark, dedicated to finding ''Answers for Cancer'' and developing improved cancer therapies. The company was founded and is run by clinical cancer specialists and combines years of hands-on clinical experience with in-depth understanding of the molecular mechanisms of cancer.
TopoTarget has a broad clinical pipeline but is currently focusing on the development of belinostat, which has shown proof of concept as monotherapy in treating haematological malignancies and positive results in solid tumours where it can be used in combination with full doses of chemotherapy, and is in phase II in PTCL. TopoTarget's expertise in translational research is utilizing its highly predictive in vivo and in vitro cancer models. TopoTarget is directing its efforts on key cancer targets including HDACi, NAD+, mTOR, FasLigand and topoisomerase II inhibitors. The company's first marketed product Savene®/Totect® was approved by EMEA in 2006 and the FDA in 2007 and is marketed by TopoTarget's own sales force in Europe and the US. For more information, please refer to www.topotarget.com.

**TopoTarget Safe Harbour Statement**
This announcement may contain forward-looking statements, including statements about our expectations of the progression of our preclinical and clinical pipeline including the timing for commencement and completion of clinical trials and with respect to cash burn guidance. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. TopoTarget cautions investors that there can be no assurance that actual results or business conditions will not differ materially from those projected or suggested in such forward-looking statements as a result of various factors, including, but not limited to, the following: The risk that any one or more of the drug development programs of TopoTarget will not proceed as planned for technical, scientific or commercial reasons or due to patient enrolment issues or based on new information from non-clinical or clinical studies or from other sources; the success of competing products and technologies; technological uncertainty and product development risks; uncertainty of additional funding; TopoTarget's history of incurring losses and the uncertainty of achieving profitability; TopoTarget's stage of development as a biopharmaceutical company; government regulation; patent infringement claims against TopoTarget's products, processes and technologies; the ability to protect TopoTarget's patents and proprietary rights; uncertainties relating to commercialization rights; and product liability expo-sure; We disclaim 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 law.