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# TopoTarget announces next Phase II clinical placebo controlled trial with Avugane™ in acne vulgaris

Copenhagen, Denmark – 24 April 2007 – TopoTarget A/S (CSE: TOPO) announced today that a Phase II clinical trial has been initiated, testing Avugane™, a topical valproic acid – an HDAC inhibitor drug – in the treatment of acne vulgaris. This double-blind, randomised Phase II study comprises four trial arms, testing three different dose strengths of Avugane™ compared to a placebo control group. The trial follows the positive results with Avugane™ as previously announced.

This new Phase II study will investigate the efficacy and safety in a four-armed trial with three different dose strengths of topically applied  $\mathsf{Avugane}^\mathsf{TM}$  in the treatment of mild to moderate acne vulgaris in comparison with a placebo controlled study arm. Patients in this study will be treated over 12 weeks, and the clinical end points include the evaluation of therapeutic efficacy based on counts of facial acne lesions as well as safety and tolerability measurements.

Prof. Dr. Hans Christian Wulf, the coordinating investigator of this new Phase II trial at Bispebjerg Hospital, Copenhagen, commented:

"Avugane" comprises a novel mechanism-of-action in the treatment of acne vulgaris. The results obtained in the completed Phase II study show that Avugane" may represent a new and interesting therapeutic option for patients who do not respond effectively to current standard medications. It will be very interesting to define the optimal dose strengths which may subsequently be used in advanced clinical development."

In a previous Phase II clinical trial, topical monotherapy with Avugane $^{\text{TM}}$  and treatment with the marketed standard product, isotretinoin, a vitamin A analogue, resulted in a comparable reduction in total counts of facial acne lesions. However, Avugane $^{\text{TM}}$  showed indications of an accelerated clinical response, and induced a reduction of inflammatory as well as non-inflammatory types of acne lesions. Furthermore, Avugane $^{\text{TM}}$  was predominantly assessed by the patients to be "well" tolerated, indicating a better local tolerability of Avugane $^{\text{TM}}$  compared with isotretinoin.

"We will continue the promising development of Avugane<sup>™</sup> to further validate its therapeutic efficacy, while in parallel seeking an out-licencing partner with expertise in the field of dermatology. Avugane<sup>™</sup> targets acne vulgaris which represents a significant unmet medical need and we are very encouraged by the therapeutic results obtained in our previous trial. Accordingly, we look forward to investigating the further potential of the drug", said Peter Buhl Jensen, CEO of TopoTarget.





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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. The global sales of topical therapies for acne are estimated at USD 1.65 billion in 2005 and are expected to grow to annual sales of USD 1.83 billion in 2008 (Source: Fox Analytics; Business Insight, The Dermatology Market Outlook to 2011). 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 is used.

#### **About Avugane™**

Avugane $^{\text{TM}}$  comprises a novel and proprietary gel-based formulation of the moderate strength HDAC inhibitor, valproic acid, 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 $^{\text{TM}}$ . Avugane $^{\text{TM}}$  is a repurpose of the marketed drug, valproic acid, used in the treatment of epilepsy. This means that a large part of the work involved in demonstrating the safety of the drug has already been performed.

## About TopoTarget

TopoTarget (OMX – The Nordic Exchange: TOPO) is a biopharmaceutical company, headquartered in Denmark and with subsidiaries in the UK, Germany and the USA, dedicated to finding "Answers for Cancer" and developing improved cancer therapies. TopoTarget is founded and run by clinical cancer specialists and combines years of handson clinical experience with in-depth understanding of the molecular mechanisms of cancer. Focus lies on highly predictive cancer models and key cancer enzyme regula-tors (mainly HDAC, mTOR, and topoisomerase II inhibitors) and a strong development foundation has been built. TopoTarget has a broad portfolio of small molecule preclini-cal drug candidates and seven drugs are in clinical development, including both novel anticancer therapeutics and new cancer indications for existing drugs. Savene™ is TopoTarget's first product on the market. In addition to organic growth, TopoTarget consistently looks for opportunities to strengthen and expand its activities through acquisitions and in-licensing. 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



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on new information from nonclinical 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.

