



## bitop AG AND ACTIVAERO COLLABORATE ON CLINICAL STUDY OF INHALABLE ECTOIN®-SOLUTION

*Witten/Gemünden (Wohra), Germany; June 17, 2009* – bitop AG and Activaero GmbH today announced the start of a clinical study on bitop AG's medical device Ectoin® inhalation solution using Activaero's leading controlled breathing technology, the AKITA<sup>2</sup> inhalation system. Ectoin® inhalation solution is based on Ectoin®, an extremolyte, a natural substance developed by bitop AG and currently available in topical skin creams and nasal sprays for the treatment of dry and irritated tissue.

The present clinical study is a single-center dose-finding, safety and feasibility study involving patients with mild bronchial asthma in Germany. Ectoin® inhalation solution has already shown marked therapeutic efficacy in animal models of allergen induced asthma and the purpose of the study is to investigate the safety and tolerability of Ectoin® inhalation solution in the treatment of asthma.

The AKITA<sup>2</sup>® inhalation system allows for homogeneous drug deposition of aerosolized Ectoin® within the periphery of the lungs in a consistent and reproducible manner. The system also has a smart card technology meaning that data on compliance and dosing can be recorded automatically for each patient.

"We believe that Ectoin® inhalation solution shows tremendous potential as a treatment for mild to moderate bronchial asthma and may also be effective in other lung affecting diseases, e.g. COPD", said Dr. Georg Lentzen, CSO of bitop AG, "and we look forward to be progressing this clinical study using the world-leading technology for the study of inhaled medications."

Dr. Gerhard Scheuch, founder and CEO of Activaero, commented: "The AKITA<sup>2</sup> is the ideal system for the clinical evaluation of inhaled therapeutics, allowing highly precise deposition as well as automatic recording of dosing and compliance. We are delighted that bitop AG will be using AKITA<sup>2</sup> in this clinical evaluation of Ectoin® inhalation solution."

## About bitop

**bitop AG** develops and markets its products on the basis of extremolytes, a group of natural substances, which is responsible for the stress resistance of extremophilic microorganisms. Based on the unique cell protective mechanisms, extremolytes build an innovative therapy approach. The aim is the development of highly effective, well tolerable and also preventively effective therapeutics. For the production of extremolytes bitop AG has developed proprietary biotechnological processes, allowing the worldwide exclusive production of ectoines and other extremolytes. The Company is privately held and located in Witten (Germany).

## About Activaero

**Activaero** is the world leader in controlled breathing technologies for inhaled therapeutic agents. With stand alone inhalation products and inhalation systems available for clinical trials and marketing partnerships, Activaero's technologies allow for the most precise and efficient patient-tailored pulmonary delivery. Activaero currently has two products on the market, AKITA JET<sup>®</sup>, a patient-tailored controlled breathing system with a Smart Card that contains the patient dosing parameters and records the compliance, and Watchhaler<sup>™</sup>, a hand held delivery system tailored specifically to children. The company also has available a range of technologies ideal for the controlled delivery of inhaled therapeutics in the clinical trial setting (AKITA<sup>2</sup><sup>®</sup>, LimiX) and tailored to specific partnerships. Activaero's technological approach has been validated repeatedly in the clinical setting. The company is privately held and located in Gemünden (Wohra) and Munich in Germany and Dublin, Ohio in the USA.

## Further information

*Axel Fischer*  
Marketing  
Activaero GmbH  
t: +49 (0) 6453 64818-0  
e: [fischer@activaero.de](mailto:fischer@activaero.de)

*Dr. Douglas Pretsell*  
Senior Account Director  
College Hill  
t: +49 (0) 89 5700 1806  
e: [douglas.pretsell@collegehill.com](mailto:douglas.pretsell@collegehill.com)

*William C. Zimlich*  
Activaero America, Inc.  
t: +1 (614) 761 3555  
e: [zimlich@activaero.com](mailto:zimlich@activaero.com)

*Dr. Georg Lentzen*  
bitop AG  
t: +49 (0) 2302 914400  
e: [lentzen@bitop.de](mailto:lentzen@bitop.de)

**Notes for editors:**

**AKITA<sup>2</sup>® nebulizer**

AKITA<sup>2</sup> is a world-wide protected intelligent nebulizer control unit that controls the breathing pattern of the patient during inspiration. With AKITA, the inhalation treatment can be tailored individually to each patient through Smart Card technology to improve reproducible dosage in the human lungs. The AKITA<sup>2</sup> system is available for license and marketing for use with specific drug compounds and formulations only.

**Extremolytes**

Extremolytes are low-molecule protective agents of extremophilic microorganisms. They stabilize biological structures such as membranes, proteins or nucleic acids thusly shielding the extremophiles from environmental stress, e.g. strong fluctuations in temperature, high UV radiation and dehydration. The chemical structure of the extremolytes can vary widely. Known are amino acids, betaine, suga- and heteroside derivatives. Extremophilic microorganisms are unique adaptation artists and belong to the oldest life forms on earth. They live where actually no life is to be expected: e.g. in the boiling water of hot springs and geysers, underneath the kilometer thick ice of the Antarctica and in salt lakes. Extremophiles even master living conditions, which for a long time were regarded as sterile and absolutely hostile. This only occurs by means of singular survival strategies on the basis of the formation of extremolytes.