

ACTIVAERO'S WATCHHALER™ RECEIVES FDA 510(K) CLEARANCE

Gemünden, Germany, July 16, 2008—Activaero GmbH, the world leader in controlled breathing technologies for inhaled therapeutic agents, today announced that the US Food and Drug Administration (FDA) has issued 510(K) clearance for the Company's Watchhaler® spacer, a revolutionary inhalation concept for children. The 510(k) clearance allows Activaero to market the Watchhaler™ device in the US. Watchhaler was previously launched in Europe in April of last year.

Dr Gerhard Scheuch, Founder and CEO of Activaero commented: "Childhood asthma is a growing problem on both sides of the Atlantic and parents need reliable spacers to ensure their children get the right doses of asthmatic medication. The Watchhaler® makes supervision easier for the parent, inhalation more fun for the child and dosing of medication more controlled and accurate. We are delighted to be able to bring this revolutionary spacer to the US Market."

Watchhaler™ is a reservoir system, or 'spacer', controlling the inhalation flow rate and volume to target the aerosol specifically to the lung region, where the drug is needed. This system is particularly tailored to the needs of child patients using asthma medication. The child friendly Watchhaler™ spacer is designed for use with standard metered dose inhalers (MDIs) of the kind often used for inhaled medication.

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®, a patient-tailored controlled breathing system with a smartcard that records the patient dosing parameters, and Watchhaler™, 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 and tailored to specific partnerships (AKITA²®, LimiX™). Finally, Activaero works with partners on a consultancy basis in the development of ideal inhaled delivery systems and the logistics in clinical trials. 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
Activaero GmbH
Phone: +49 (0) 6453 64818-0
E-Mail: fischer@activaero.de

William C. Zimlich
Activaero America, Inc.
Phone: +1 (614) 761 3555
E-Mail: zimlich@activaero.com

Dr. Douglas Pretsell
Account Director, Munich Bureau Chief
College Hill
Phone : +49 (0)89 57 00 18 06
E-Mail: douglas.pretsell@collegehill.com

Notes for editors:

Approximately 20 million Americans have asthma, with 9 million children under the age of 18 suffering from the disease. And yet up to now they have been poorly served by inhalation technologies designed mainly for adults. The use of a Metered Dose Inhaler (MDI) is the prevalent method of asthma drug delivery and to make these suitable for children, asthma experts advocate the use of a holding chamber known as a spacer, into which the aerosol spray is released before it is inhaled by the child.

Watchhaler™ is a spacer developed especially to suit the requirements of children and supervising adults and addresses four key concerns:

- **Child-centric design:** Young children can be intimidated by the typically 'cold' and functional designs of spacers. Watchhaler™ therefore has a more childlike and welcoming look, using vivid colors and a shape like a toy animal.
- **Reduced electrostatic charge:** Many spacers have an inherent problem in that handling of them can introduce a static charge that attracts the drug to the walls of the surface and reduce the time available for inhalation. Watchhaler™ has a protective outer chamber around the aerosol balloon so that the balloon cannot be touched. Only limited static charge is introduced and the drug can now remain airborne within the balloon for a longer time.
- **Controlled efficient delivery:** The face masks currently used with spacers offer no adequate control of either flow rate or volume. With Watchhaler™ the inspiration flow rate is mechanically controlled via a patented valve at the air inlet and the inhalation volume is limited by a balloon inside the device. This reduces inhalation velocity to allow a slow, controlled delivery of the therapeutic aerosol.
- **Supervision of treatment:** With standard spacers it is often not possible for the therapist or parent to gauge how completely or successfully the child has inhaled the drug. With the Watchhaler™ the balloon folds up during inhalation, providing parents and therapists with a clear means of identifying that the process has been successful.

The Watchhaler™ is available through pharmacies in Germany and through an online shop at www.watchhaler.com.