



**PRESS RELEASE September 7, 2018**

## **AcuCort's allergy medicine Dexa ODF has been manufactured and released according to Good Manufacturing Practice, GMP**

**AcuCort AB (Spotlight Stock Market: ACUC) today announces that the company's manufacturing partner Adhex Pharma has manufactured and released three batches of AcuCort's allergy medicine, the fast-dissolving oral film Dexa ODF, according to Good Manufacturing Practice, GMP. Production according to GMP is an important milestone in the development plan. The batches will be used in the planned bioequivalence studies that later will form the basis for the application for product registration of Dexa ODF firstly in the EU.**

Since May 2017 AcuCort has collaborated with its manufacturing partner Adhex Pharma. The objective has been to establish a manufacturing process for Dexa ODF that meets the requirements for production of pharmaceuticals for commercial use or clinical studies, according to Good Manufacturing Practice. Products manufactured according to GMP is a condition for obtaining approval to conduct the studies that later will form the basis for registration applications.

"Producing Dexa ODF according to defined quality requirements on a commercial scale according to Good Manufacturing Practice is the most important milestone so far in the development of AcuCort's innovative allergy medicine. We look forward to the next important step in the development plan, which is approval from the Czech regulatory authority SUKL to start the bioequivalence study in the EU," says Mats Lindfors, CEO of AcuCort.

### **For more information, please contact**

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### **About glucocorticoids**

Every year millions of patients across the world use medicines containing glucocorticoids, for example against allergy and viral croup. Also, cancer patients suffering from nausea and vomiting in connection with chemotherapy (CINV) use this type of drug. One big disadvantage is that these drugs are not perceived to be user-friendly or require medical staff. First having to dissolve the tablets in water can be very awkward in an acute situation, for the sufferers as well as for other persons helping them. The sufferer may have difficulties swallowing, and thus a fast-dissolving film to be placed on the tongue, with the same effect as the tablet, may have a wide application area.



### **About AcuCort**

AcuCort develops and commercializes Dexa ODF, a new fast-dissolving oral film containing the glucocorticoid dexamethasone. Dexa ODF is a smart product in a new, innovative, patented and user-friendly dosage form, primarily for the treatment of acute allergic reactions, viral croup in children and chemotherapy-induced nausea and vomiting (CINV). Dexa ODF is estimated to have a short time to market as the company only has to repeat a previously successful bioequivalence study before applying for market approval in Europe. Please visit [www.acucort.com](http://www.acucort.com).