PRESS RELEASE 4 October 2018

FDA confirms AcuCort's study design for the United States

AcuCort AB (Spotlight Stock Market: ACUC) today announces that the company has received a positive response from the US Food and Drug Administration (FDA) to the questions asked concerning the design of the bioequivalence studies that will be the basis for a registration application for the company's innovative allergy drug Dexa ODF in the US.

Before starting clinical studies that will be the basis for a registration application in the US, it is customary to have a pre-meeting, a so-called pre-IND meeting, with the FDA to ensure that a planned study meets the authority's requirements on a later application for marketing approval. The FDA has now confirmed AcuCort's suggested study design but wishes that two separate studies are performed, with fasting and non-fasting participants.

Based on the FDA's comments, AcuCort and our CRO partner Quinta-Analytica will now finalize applications to the Czech State Institute for Drug Control, SUKL, for approval to carry out the two bioequivalence studies in the Czech Republic in preparation for a later registration application in the US.

"The positive news from the FDA means that the planning of the US studies with Dexa ODF can continue according to the previously communicated schedule," 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 to be placed on the tongue, based on a well-known variant of cortisone – 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.

This information is information that AcuCort AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, on October 05, 2018.