PRESS RELEASE 04 October 2018

AcuCort obtains regulatory approval to start bioequivalence study for the EU

AcuCort AB (Spotlight Stock Market: ACUC) today announces that the Czech State Institute for Drug Control, SUKL has approved the company's application to conduct the bioequivalence study that is planned to be the basis for a registration application for the company's innovative allergy drug Dexa ODF in the EU.

In order to conduct clinical studies, AcuCort must gain approval from both the ethical committee and the regulatory authority in the country where the study will be performed. Together with the previously obtained approval from the ethical committee, today's news means that the study that will be the basis for an application for marketing approval in the EU can now be started.

"A further strategic milestone has been achieved with SUKL's approval of our study application. The decision enables us to start this important study 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 04, 2018.