



Press release, June 12, 2018

AcuCort's allergy treatment Dexa ODF is ready to be manufactured according to GMP (Good Manufacturing Practice) for clinical use

AcuCort AB (AktieTorget: ACUC) today announces that the company has finalized the scaling-up of the manufacturing process for its drug candidate, the fast-dissolving oral film Dexa ODF to be placed on the tongue for the treatment of acute allergic reactions, and thereby is ready for manufacturing according to GMP (Good Manufacturing Practice) for clinical use in preparation of planned registration applications.

Since May 2017, AcuCort has collaborated with the manufacturing partner Adhex Pharma with the goal to establish a manufacturing process for Dexa ODF that meets the requirements for clinical studies, for registration applications and commercial production. Today's announcement means that the manufacturing process on an industrial scale is defined, that the process parameters are determined and that Dexa ODF has been produced in a series of manufacturing batches that have been analyzed according to current standards.

"It is satisfying that we have achieved yet another important milestone and have shown that we can produce commercial volumes. This year's allergy season has further clarified the need for drugs that effectively, quickly and safely relieve the problems that so many allergics suffer from. Dexa ODF is now another step closer to a registration application," says Mats Lindfors, CEO of AcuCort.

The next step is to manufacture a number of batches on industrial scale according to GMP to be used for example in the bioequivalence studies in which Dexa ODF will be compared with already approved reference drugs containing the same active substance - dexamethasone. The bioequivalence studies will then form the basis for the planned registration applications in the EU and the US.

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.