

Press release 2019-09-30

AcuCort applies for market approval of ISICORT® in Sweden

AcuCort AB (Spotlight Stock Market: ACUC) announces that the company has submitted a national hybrid application for approval of the company's drug candidate ISICORT® to the Swedish Medical Products Agency (MPA). A hybrid application is applicable since ISICORT® is a new dosage form and the company intends to introduce changes in its Summary of Product Characteristics (SPC) compared to the selected reference product.

AcuCort develops and commercializes ISICORT®, a new fast-dissolving oral film to be placed on the tongue, primarily for the treatment of severe and acute allergic reactions, croup in children and chemotherapy-induced nausea and vomiting (CINV). ISICORT® offers several patient benefits that also allow for improved patient compliance. Compliance is an expression of the patient having his or her medicine available and taking it according to the doctor's prescription.

In accordance with AcuCort's previously communicated registration strategy regarding ISICORT®, the company first applies for a national approval in Sweden during the third quarter, in order to as soon as possible after approval, extend the application to several EU countries via the so-called Mutual Recognition Process (MRP). The Swedish Medical Products Agency will review the application and will probably return, a number of months into the review process, with questions for AcuCort to answer. Therefore, it is not possible today to predict a date for the Swedish Medical Products Agency's decision on approval.

"It is a major milestone for AcuCort that our innovative drug candidate ISICORT® is now so well developed and documented that it has been submitted for the Swedish Medical Products Agency's approval review. Extensive, high-quality efforts have been put into compiling our application and we are now looking forward with great expectations to the Swedish Medical Product Agency's assessment," comments Mats Lindfors, CEO of AcuCort.

AcuCort recently launched the registered trademark ISICORT®. The drug candidate was previously called Dexa ODF.

For more information, please contact

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About AcuCort AB

AcuCort develops and commercializes ISICORT®, a new fast-dissolving oral film containing the well-known glucocorticoid – dexamethasone. ISICORT® is a smart product in a new, innovative, patented and user-friendly dosage form primarily for the treatment of severe and acute allergic reactions, croup in children and chemotherapy-induced nausea and vomiting (CINV). The bioequivalence study that forms the basis of the application for



marketing approval in Europe is carried out with positive results, which strengthens the assessment that the time until commercialization of ISICORT® may be relatively short. AcuCort (ticker: ACUC) is listed on the Spotlight Stock Market in Sweden. Learn more at www.acucort.com.