

AcuCort.®

AcuCort confirms response from the Swedish MPA regarding ISICORT® market application

AcuCort AB (Spotlight Stock Market: ACUC) has received the Primary Round Assessment Report from the Swedish Medical Products Agency (MPA), in response to the national Market Authorization Application (MAA) for ISICORT® in September 2019. The company is currently reviewing the report and preparing answers. No significant obstacles have been identified. No major objections towards an approval have been raised by the MPA.

As reported on September 30th 2019, AcuCort AB has submitted a national hybrid application for approval of the company's drug candidate ISICORT® to the Swedish Medical Products Agency (MPA) in September 2019. The agency now has reverted as expected after 110 days of assessment, with the Primary Round Assessment Report including an overview and question list.

There were no major objections in the assessment, and the initial analysis of the report and the question list has not revealed any significant obstacles.

"It is obviously of great importance to carefully review the Swedish Medical Products Agency assessment of our application and prepare our formal reply. We are reviewing the report together with our regulatory experts and preparing input and activities. I am very pleased to proceed to this stage, and I foresee the work with great confidence," says Ann Gidner, interim CEO at AcuCort.

For more information, please contact

Ann Gidner, interim CEO, AcuCort AB

Phone +46 (0) 723 151414

Email ann.gidner@acucort.se

About AcuCort AB (publ)

AcuCort develops and commercializes ISICORT®, a new fast-dissolving oral film to put on the tongue, based on a well-known cortisone substance – 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 was carried out with positive results and a national hybrid application has been submitted to the Swedish Medical Products Agency. Altogether, this strengthens the company's assessment that the time to commercialization of ISICORT® may be relatively short. AcuCort (ticker: ACUC) is listed on the Spotlight Stock Market in Sweden. Please visit www.acucort.com.