

Press release October 16, 2019

AcuCort reports that bioequivalence was not achieved in the second study for US registration

This is an English version of the press release published in Swedish on October 15, at 15:59 (SE time). AcuCort AB (Spotlight Stock Market: ACUC) reports that the results from the last of the two planned bioequivalence studies for registration of the company's drug candidate ISICORT® in the US did not meet the requirements for bioequivalence with the reference product. In the current study ISICORT® met the criteria for bioequivalence concerning two of the three criteria. AcuCort has previously reported positive results from the first of the two studies for registration in the US, and from the bioequivalence study on which the company's submitted application for market approval in Sweden is based.

The current study is performed on non-fasting participants, comparing ISICORT® 6 mg fast-dissolving oral film with an already approved reference product, West-Ward Pharmaceuticals' Dexamethasone 6mg tablets USP. The criteria for bioequivalence mean that the tested product should be within a certain range of the reference product's value for three criteria.

"We will now analyze the results in order to identify the measures needed to meet the US criteria for bioequivalence in the case of non-fasting participants. We continue working towards the unchanged goal to register and commercialize ISICORT®," says Mats Lindfors, CEO of AcuCort.

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About AcuCort AB

AcuCort develops and commercializes ISICORT®, a new fast-dissolving oral film to put on the tongue, based on a well-known cortisone substance containing – 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. Taken together, this strengthens the company's 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.