Press release 2023-02-20

The FDA is requesting additional information prior to AcuCort's registration application in the United States

The American agency FDA (U.S. Food and Drug Administration) has announced that AcuCort needs to submit additional information prior to the company's registration application in the United States. This also extends the time for the exemption from registration fee that was previously communicated.

AcuCort has been informed by the American authority FDA that additional documentation is required by the company for its registration application in the United States regarding the drug Zeqmelit®. The company does not see that it would change a positive outcome of the application.

With the extended processing time that the supplement entails, AcuCort has also had the date for the last submission under the Small Business Waiver brought forward. This also extends the time for exemption from the registration fee of USD 1.6 million, approximately SEK 16.7 million.

A new Small Business Waiver application deadline has not yet been provided to AcuCort. AcuCort will notify the market as soon as additional information is approved by the FDA and a new registration deadline has been communicated by the authority.

For further information, please contact:

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This disclosure contains information that AcuCort AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on February 20, 2023, 09:00 CET.

About AcuCort AB (publ)
AcuCort has developed and commercializes Zeqmelit®, a new fast-dissolving oral film to be placed on the tongue, based on the well-known cortisone substance dexamethasone. The drug is a smart product in a new, innovative, patented and user-friendly administration form primarily for the treatment of severe and acute allergic reactions, croup in children, nausea and vomiting during chemotherapy and for the treatment of patients with covid-19 who need 2 supplemental oxygen therapy . Zeqmelit® is approved in Sweden, Denmark, Norway and Finland. All in all, it strengthens the company's assessment that the time until commercialization can be relatively short. AcuCort (short name: ACUC) is listed on the Spotlight Stock Market. Please visit www.acucort.se.