Press release 2022-03-01

AcuCort is exempted from the application fee by the U.S. Food and Drug Administration

AcuCort AB (publ) (Spotlight Stock Market: ACUC) announces today that the U.S. Food and Drug Administration, FDA, grants the company's waiver request under the small business waiver provision regarding the application fee for the new drug application of ISICORT®. The positive decision means that AcuCort is exempted from paying an application fee of USD 1.6 million provided that the application is submitted no later than the last day of February 2023.

AcuCort identifies, develops, and commercializes smart drugs that meet the patient's medical needs for a quick and effective treatment as well as simplicity of administration. ISICORT® is approved in Sweden for the treatment of mainly acute and severe allergic reactions. The United States is the world's largest pharmaceutical market and the application to the FDA is strategically important for the company's global commercialization and expansion. AcuCort has previously made the assessment that the company would meet the criteria set by the FDA to qualify for exemption from the application fee. In the fall of 2021, AcuCort filed an application for a fee waiver, which the FDA has now granted. A dialogue with the FDA is ongoing to maximize the probability of a quick and positive processing of the registration application once it has been submitted.

" It is very gratifying that the FDA has granted AcuCort an exemption from paying the registration application fee for ISICORT® in the U.S. The application fee is a large cost for a company like AcuCort and FDA's decision is therefore an important and extremely positive news. The interactions with the FDA continue and our goal is to submit the registration application within the time frame," says Jonas Jönmark, CEO of AcuCort.

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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 March 1, 2022, at 18:25 CET.

About AcuCort AB (publ)
AcuCort has developed 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). A national application was approved by the Swedish Medical Products Agency (MPA) in October 2020. In February 2021, ISICORT® was granted an additional indication – the treatment of COVID-19 patients who need supplemental oxygen treatment. 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.