

Press release 2022-06-27

AcuCort is granted SME status by the European Medicines Agency, EMA

AcuCort AB (publ) (Spotlight Stock Market: ACUC) announces that the European Medicines Agency, EMA, has decided that the company meets the requirements for SME status in accordance with current EU regulations. The positive decision entails certain administrative and financial benefits for AcuCort in future applications for market approval for the company's pharmaceutical product ISICORT® within the EU.

During the spring, AcuCort applied to EMA aiming to qualify the company in the category micro, small or medium-sized enterprise (SME) laid down in Regulation (EC) No 2049/2005. EMA's positive decision confirms AcuCort's eligibility to benefit from the provisions for administrative and financial assistance for SMEs when applying for market approval within the EU. The achieved SME status is valid until December 31, 2023.

ISICORT® is a thin and small fast-soluble mouth film, containing the glucocorticoid dexamethasone, to put on the tongue where the active anti-inflammatory substance dexamethasone dissolves quickly and provides effective relief. ISICORT® is an approved drug in Sweden for the treatment of, among other things, acute and severe allergic reactions. Intensive work is underway with registration applications for other priority markets such as the EU and the United States.

"It is very gratifying that the European Medicines Agency has granted AcuCort SME status in the EU. Fees for market registrations are large costs for a company like AcuCort. Therefore, we truly welcome EMA's positive decision," says Jonas Jönmark, CEO of AcuCort.

Earlier this year, the U.S. Food and Drug Administration, FDA, granted AcuCort's application for exemption from the application fee via a so-called Small Business Waiver for the registration process of ISICORT® in the U.S.

The information was submitted for publication, through the agency of the contact person below, on June 27, 2022.

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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.