

Press release 2022-02-17

AcuCort announces that the company signs an agreement with consulting company in pharmacovigilance before the upcoming commercialization of ISICORT®

AcuCort AB (publ) (Spotlight Stock Market: ACUC) announced today that the company has signed an agreement with the consulting company TFS (TFS Trial Form Support AB) regarding pharmacovigilance which includes follow-up of side effects and safety regarding ISICORT®. The agreement is a regulatory milestone prior to the upcoming commercialization of ISICORT®.

Under the terms of this agreement, AcuCort ensures that resources and processes are in place, and that the company meets the regulatory requirements regarding pharmacovigilance prior to the upcoming commercialization of the company's approved pharmaceutical product ISICORT®. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. For an increased patient safety, it is a legal obligation for a pharmaceutical company to monitor the drug effects of its product and any side effects.

AcuCort identifies, develops, and commercializes smart products that meet the patient's medical needs for fast and efficient treatment as well as simplicity in administration. That is, the way the drug is delivered into the body. ISICORT® is a thin, small fast-dissolving oral film that is placed on the tongue where the active substance, dexamethasone, dissolves quickly and provides effective relief. ISICORT® is approved in Sweden and intensive work is underway with registration applications for other priority markets.

“It is gratifying that we have now signed an agreement with TFS Trial Form Support. TFS is a well-established consulting company in pharmacovigilance, and TFS meets AcuCort's requirements. It is always important to follow up a pharmaceutical product even after the product has undergone clinical trials and been approved. The purpose is to gain further knowledge about the drug for increased patient safety,” says Jonas Jönmark, CEO of AcuCort.

The information was submitted for publication, through the agency of the contact person below, on February 17, 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.