



**Press release 2020-07-15**

## **AcuCort confirms good progress in ISICORT® national application process**

**AcuCort AB (Spotlight Stock Market: ACUC) received the Second Round Assessment Report from the Swedish MPA as planned in July. Thanks to the ambitious work answering the authority's questions in the previous round, the Second Round Assessment Report is less extensive and no major issues can be foreseen.**

AcuCort received the Second Round Assessment Report from the Swedish Medical Products Agency (MPA), for the ISICORT® national approval process, as per the application timeline. Now having made an assessment of the remaining questions, with regulatory support and further evaluation by the AcuCort Board of Directors, the company can conclude that a large proportion of topics have been nicely completed and the outstanding topics should be manageable. The Second Round Reply will be submitted by AcuCort on August 11<sup>th</sup>, 2020.

“As previously communicated, we worked together with our manufacturing and regulatory partners to give good and complete answers to the First Round Assessment. Now we see that a lot of the topics are nicely completed. A smaller proportion of topics needs some further clarification, and we have some updates to the phrasing of product information to complete now in the second round. Altogether, this makes us confident about the planning ahead,” says Ann Gidner, CEO of AcuCort AB.

### **For more information, please contact:**

Ann Gidner, interim CEO, AcuCort AB

Phone: +46 (0)72 315 1414

Email: [ann.gidner@acucort.se](mailto:ann.gidner@acucort.se)

### **About AcuCort AB (publ)**

AcuCort develops 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). 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. 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](http://www.acucort.com).