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AcuCort – CEO's Christmas Letter

AcuCort is entering a new and exciting phase, where the commercialization of our innovative and patient-friendly oral film Zeqmelit™, for the treatment of acute and severe allergic reactions, among other things, is in focus. It is gratifying that our questionnaire survey shows that an overwhelming majority, 72 percent, of the patients responding in the survey would prefer an oral film over tablets in the event of a severe allergic reaction.

During the year, we have reached many positive milestones. In November we signed the first commercial agreement for Zeqmelit™ through the distributor agreement with Kamada Ltd. for the Israeli market. Further discussions are ongoing with several potential partners for other selected markets. We have set high standards, which means that our partner of choice should be reputable and have experience in the allergy business area. Our strategy is to attract partners with regional or global market presence and the ability to effectively launch Zeqmelit™.

The U.S. is one of the world's largest and most important markets and we have a regulatory strategy for the U.S. in place. The goal is to submit a registration application to the FDA, the U.S. Food and Drug Administration, during next year. We have high hopes for approval. Our overarching goal is to commercialize Zeqmelit™ globally, i.e., in the EU, the US and in selected key markets.

Other important milestones achieved are, of course, that Zeqmelit™ was approved in Denmark and Norway. This means that the drug is now approved throughout Scandinavia, which is important in our discussions with potential partners and regulatory processes for other markets. In addition, the Swedish Medical Products Agency approved the name change to Zeqmelit™ in Sweden where the drug is already approved, but then under the name ISICORT. The name change is a consequence of the fact that the brand name Zeqmelit™ has proven to be best suited for most of the markets that we have prioritized and for which registration processes are underway. The next step for the Swedish market is to apply for subsidized price for Zeqmelit™ to the Swedish price authority TLV, the Dental and Pharmaceutical Benefits Agency.

At the beginning of the year, we were pleased to announce two positive news. AcuCort received the decision that the company had been exempted from the application fee from the FDA, which would otherwise have cost the company over SEK 15 million. The company was also granted SME status (micro, small or medium-sized enterprise) by EMA, the European Medicines Agency. SME status entails certain administrative and financial advantages when applying for market approval within the EU.

In preparation for commercialization, we have entered into an agreement with Adhex Pharma for commercial and large-scale production of Zeqmelit™. Adhex Pharma is a French pharmaceutical manufacturer specializing in technologies to produce medical patches and thin mouth films and is thus an excellent partner for the manufacture of Zeqmelit™. We have also signed an agreement with the consulting company TFS (TFS Trial Form Support AB) on pharmacovigilance (drug control) that includes follow-up of side effects and safety of Zeqmelit™. It is a legal obligation for a pharmaceutical company to follow up on its product's drug effects and possible side effects for increased patient safety.

I am proud of the AcuCort team and all the many preparations we have made with our sights set on the successful commercialization of Zeqmelit™ in the global market. I am optimistic about next year and I would like to thank all long-term shareholders and our partners who make our growth journey possible.

Merry Christmas and Happy New Year!

Jonas Jönmark
Chief Executive Officer, AcuCort

The information was submitted for publication, through the agency of the contact person below, on December 21, 2022.

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About AcuCort AB (publ)
AcuCort has developed and commercializes Zeqmelit™, a new fast-dissolving oral film to put 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 dosage form primarily for the treatment of severe and acute allergic reactions, croup in children and chemotherapy-induced nausea and vomiting (CINV) and for the treatment of patients with COVID-19 who need supplemental oxygen therapy. Zeqmelit™ is approved in Sweden, Denmark, and Norway. Altogether, this strengthens the company's assessment that the time to commercialization may be relatively short. AcuCort (ticker: ACUC) is listed on the Spotlight Stock Market in Sweden. Please visit www.acucort.se.