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Update on AcuCort's FDA Application ahead of Launch in the USA

The process for AcuCort's application for market approval in the USA for Zeqmelit® is in an intensive phase. The company assesses that the dialogue with the FDA is constructive and that there are conditions to submit the application during the second half of 2024.

AcuCort received the company's first commercial order for the oral film Zeqmelit® at the end of February and plans to start sales in the Nordic region during the summer of 2024. As a result, the company is enhancing preparations for the prioritized potential market in the USA.

The FDA, Food and Drug Administration, process has taken longer than previously estimated, which does not prompt any changes in AcuCort's strategy to launch Zeqmelit® in the USA.

"We perceive the FDA's view of AcuCort as positive. The lengthy process has been about procedural steps and processing times," says Jonas Jönmark, CEO of AcuCort.

To provide AcuCort's stakeholders with a deeper understanding of the process, the company here answers some common questions.

Question: What type of market approval is applicable for Zeqmelit®?
Answer: Zeqmelit® contains dexamethasone, which is a long-standing approved active pharmaceutical ingredient in the USA. This means that companies seeking new approvals for products with the same substance do not necessarily need to conduct large, complicated, and expensive clinical trials to demonstrate efficacy and safety. As the active substance is already on the market, FDA approval can be sought based on bioequivalence.

Question: Will AcuCort seek market approval based on bioequivalence?
Answer: Yes, the FDA confirmed in 2018 that AcuCort can apply for approval based on bioequivalence in a so-called FDA 505(b)(2) process. AcuCort needs to demonstrate that Zeqmelit® behaves similarly in the body as an already approved reference product with the same active substance. Such studies should be conducted on healthy volunteer subjects (not patients), and the FDA requires them to be conducted on both fasting and non-fasting participants. AcuCort has already conducted these studies in 2018 and 2019.

Question: What does market approval based on bioequivalence entail?
Answer: FDA approval based on bioequivalence means that AcuCort can receive the same approved medical indications as the reference product has in its medical documentation. As dexamethasone is approved for a variety of diseases and conditions, this is fundamentally positive as it means that Zeqmelit® can be broadly used in healthcare.

Question: What remains before AcuCort can submit a formal application?
Answer: Before AcuCort can submit its NDA application (New Drug Application), an analysis must be conducted regarding the consequences of pediatric use for new products. Such an analysis is required by law in the USA. This is done within the framework of an iPSP (initial Pediatric Study Plan). In an iPSP, AcuCort must describe how it ensures that the use of Zeqmelit® among children is effective and safe for each approved indication found in the reference product's documentation.

Question: How long does it take to receive a response to an application and what does it cost?
Answer: An NDA application under 505(b)(2) takes approximately 12 months, and the process costs just over 2 million USD in 2024, which is over 20 MSEK. However, AcuCort has received a Small Business Waiver (SBW) approved. An SBW means that AcuCort does not need to pay anything for its NDA application. AcuCort received its SBW approval already in 2022, and since the deadline has expired, it needs to be renewed, which is an administrative formality.

Question: Where is AcuCort in the process?
Answer: AcuCort is working intensively on the iPSP process, where we have had several interaction cycles with the FDA regarding supplements and more information. The iPSP process is challenging for both AcuCort and the FDA for two reasons. Firstly, dexamethasone is an older substance, and secondly, it has a large number of approved indications. Several of the indications are of minor nature with very small patient groups. Both the investigation and compilation of documentation, as well as the FDA's review of the documentation, have taken a long time. The process has also been complicated by the need for different departments within the FDA to coordinate their opinions and responses. After the latest feedback from the FDA, in January, which we deemed as positive, AcuCort submitted what we believe to be the final supplements in February. If the FDA views our iPSP positively, we estimate that an NDA application can be submitted during the second half of 2024.

Question: Does AcuCort hire experts for the FDA application?
Answer: Yes, we work with a regulatory consulting firm in the USA; NSF Health Sciences LLC.

For further information:
Jonas Jönmark, CEO AcuCort AB
Tel: +46 70 3655400
Email: jonas.jonmark@acucort.se

About AcuCort AB (publ)
AcuCort has developed and is commercializing Zeqmelit®, a new rapidly dissolving oral film placed 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 administration form primarily for the treatment of severe and acute allergic reactions, croup in children, nausea and vomiting during chemotherapy, and for the treatment of patients with COVID-19 requiring supplemental oxygen therapy. Zeqmelit® is approved in Sweden, Denmark, Norway, and Finland. AcuCort (ticker: ACUC) is listed on the Spotlight Stock Market. Visit www.acucort.se for more information.