Press release 2026-11-16

AcuCort submits NDA for Zeqmelit® to the FDA

AcuCort has today submitted its New Drug Application (NDA) for Zeqmelit® to the US Food and Drug Administration (FDA), thereby applying for marketing authorisation in the United States. The application was submitted via the 505(b)(2) regulatory pathway. The submission marks a key milestone in AcuCort's international expansion and means that the company is now moving into the next phase of its efforts to enter the US market. CEO Jonas Jönmark will take part in a live presentation today at 13:00 CET. A link to the live webcast is provided further down in this press release.

During 2026, AcuCort has achieved two important regulatory milestones ahead of its NDA submission. In April, the company reached agreement with the FDA on its Initial Pediatric Study Plan (iPSP). In July, the FDA also granted AcuCort a renewed Small Business Waiver, exempting the company from the application fee of approximately SEK 22 million.

"Submitting our NDA is one of the most important milestones AcuCort has reached to date. We have worked purposefully on the regulatory preparations for the US over a long period. We are now moving into the next phase. Our focus is on the FDA process and preparing for the commercial introduction of Zeqmelit® in the US market. Our strategy is to do so together with a strong commercial partner," says Jonas Jönmark, CEO of AcuCort.

The US is a central part of AcuCort's international strategy. The company's business model is based on commercialising Zeqmelit® through established pharmaceutical and distribution partners. In November, AcuCort signed a licence and distribution agreement with Kye Pharmaceuticals for Canada, giving the company its first strategic foothold in North America. For the US market, AcuCort intends to enter into a licence agreement with a partner that meets AcuCort's criteria.

AcuCort aims to obtain FDA approval in the second half of 2027. In parallel, the company is continuing its work to identify and enter into an agreement with a commercial partner for the US, as well as preparing for market introduction. The aim is to achieve a full commercial launch of Zeqmelit® in the US during the first half of 2028.

Live presentation

AcuCort CEO Jonas Jönmark will give a live presentation today at 13:00 CET (in Swedish). Viewers will have the opportunity to submit questions during the webcast.

Link: https://youtube.com/live/DFEzYIwf744?feature=share

For further information:

Jonas Jönmark, CEO, AcuCort AB
Phone: 070 365 5400
E-mail: jonas.jonmark@acucort.com

About AcuCort AB (publ)

AcuCort has developed and is commercialising Zeqmelit®, a new rapidly dissolving oral film placed on the tongue, based on the well-established corticosteroid dexamethasone. The medicine has a new, patented and user-friendly dosage form and is intended for, among other uses, the treatment of severe and acute allergic reactions, croup in children, nausea and vomiting associated with chemotherapy, and patients with COVID-19 who require supplemental oxygen therapy. Zeqmelit® is approved in Sweden, Denmark, Norway and Finland, where it is also marketed. AcuCort (ticker: ACUC) is listed on Spotlight Stock Market. For more information, visit www.acucort.se.