

Press release 2026-04-13

AcuCort and the FDA agree on iPSP – important step towards US market approval

Pharmaceutical company AcuCort today announces that it has agreed an iPSP (Initial Pediatric Study Plan) with the U.S. Food and Drug Administration (FDA) for its product Zeqmelit®. This constitutes a prerequisite for AcuCort to submit a New Drug Application (NDA) in the United States, which is planned for later this year.

The iPSP process is of central importance ahead of AcuCort's forthcoming NDA submission to the FDA, the world's single largest pharmaceutical market. At the end of March 2026, AcuCort submitted its responses to the FDA's additional questions. The company has now reached agreement with the FDA on the iPSP.

“We are very pleased to have reached another major and important milestone through our agreement with the FDA on our iPSP, a decision that further strengthens our commercial growth trajectory. This has been a prolonged process that has delayed our ability to submit an NDA in the United States. It is therefore particularly gratifying that we have now concluded this process and can proceed with the application,” says Jonas Jönmark, CEO of AcuCort.

“AcuCort has made a strong start to 2026, a year that began with a commercial agreement with Glenmark Pharmaceuticals. This agreement expands our presence from the Nordic market of 20 million inhabitants to a European market of approximately 200 million people. Combined with the outcome from the FDA, AcuCort is well positioned for the internationalisation of our medicinal product Zeqmelit®,” says Jonas Jönmark, CEO of AcuCort.

The next step is for AcuCort to apply for a renewed Small Business Waiver from the FDA, which would exempt the company from the application fee of approximately SEK 16 million. AcuCort was granted such a waiver in 2022. Following approval, the company can proceed with the submission of the NDA in the United States.

This information is information that AcuCort AB is required to disclose in accordance with the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out below, on 13 April 2026.

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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, where the product is also marketed. AcuCort (ticker: ACUC) is listed on the Spotlight Stock Market. Visit www.acucort.se for more information.