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AcuCort submits Initial Pediatric Study Plan (iPSP) to the FDA

AcuCort, a pharmaceutical company, has submitted its Initial Pediatric Study Plan (iPSP) to the U.S. Food and Drug Administration (FDA) as part of its regulatory pathway for obtaining FDA approval of Zeqmelit® in 2025.

The submission of the iPSP represents a key milestone in the regulatory process to secure market authorization for Zeqmelit® in the United States. The FDA mandates that all companies seeking approval for new drug applications (NDAs) submit an iPSP as part of the approval process.

"This submission marks an important step forward in our efforts to make Zeqmelit® accessible to patients in the U.S. It is the final preparatory step before we can proceed with submitting our complete NDA to the FDA. The U.S. is a strategic priority market for AcuCort, and we firmly believe that Zeqmelit® addresses a critical medical need, particularly in acute situations requiring rapid, convenient, and effective treatment," says Jonas Jönmark, CEO of AcuCort AB.

The FDA will now review the submitted iPSP, with a response expected within 90 days.

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