

Press release 2025-09-25

AcuCort granted extended SME status by the European Medicines Agency (EMA)

AcuCort AB has been granted extended SME (Small or Medium-sized Enterprise) status by the European Medicines Agency (EMA).

The extension means that AcuCort will be treated as an SME by the Agency until 31 December 2026. As a result, the company will be exempt, either fully or partially, from fees associated with regulatory applications related to the sale and marketing of pharmaceuticals within the EU and EEA.

- The extension of our SME status is highly valuable. It helps us keep our regulatory costs down and provides access to qualified support in key processes. Maintaining SME status is of central importance now as we take the step into Europe with registrations in additional European countries, says Jonas Jönmark, CEO of AcuCort.

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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.