

# OncoZenge Receives Conditional Acceptance for the Clinical Phase III Trial ('BEAM-Pain') of BupiZenge™ from European Authorities

***OncoZenge AB (publ) ("OncoZenge" or "the Company"), a clinical-stage company developing an innovative treatment for oral pain in cancer supportive care, today announces that it has received conditional acceptance of its Clinical Trial Application (CTA) for the pivotal Phase III trial of BupiZenge™ in Europe. Denmark has acted as Reference Member State (RMS) in the assessment procedure, with Sweden, Norway, and Germany as Concerned Member States (CMS). The Company remains on track to enroll its first patient in Q2 2026.***

OncoZenge submitted its CTA dossier in December 2025 and subsequently responded to Requests for Information (RFIs) raised by the national competent authorities in Norway, Sweden, Denmark and Germany, coordinated through the RMS. All four countries have since approved the Company's responses to these RFIs which concludes 'Part 2' of the application assessment.

Furthermore, the Company has received confirmation by the RMS that the proposed trial has a positive benefit-risk balance, granting conditional acceptance on the centrally evaluated 'Part 1' in the trial application. The single condition relates to a service provider certificate that needs amendment or update by the Swedish Medical Products Agency (MPA). No issues are outstanding on the trial design or other parts of the application.

The Company has previously guided for a final decision by European authorities by 'late April or early May at the latest'. Considering lead-time in coordinating with the relevant authorities and the supplier, as well as amending the application and lead-time for review, the Company now expects a full approval around mid-May.

There is no impact to the ongoing preparatory activities for initiating the trial, and the Company's objective remains to enrol the first patient in Q2 2026.

The BupiZenge™ Phase III trial, study code BZ003 or 'BEAM-Pain' (*Bupizenge Efficacy Assessment in Mucositis-Pain*) is a multi-center, randomized, registrational trial designed to evaluate the efficacy and safety of BupiZenge™ compared with lidocaine in patients experiencing oral pain due to mucositis induced by radiotherapy, with or without concomitant chemotherapy, in head and neck cancer. The trial will enroll 150 patients across up to 12 clinical sites in Norway, Sweden, Denmark and Germany, with LINK Medical acting as clinical Contract Research Organization (CRO).

**BupiZenge™ - Potential to be the leading treatment for oral pain.**

## Contact

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## About

OncoZenge AB (publ) is a clinical-stage pharmaceutical company developing an innovative, effective, and well-tolerated treatment for oral pain in conditions where current options are insufficient, such as oral mucositis from cancer therapy. Its lead candidate, BupiZenge™, represents a novel formulation of bupivacaine in a lozenge form, aimed at providing rapid and sustained local pain relief without the risks associated with systemic opioids. OncoZenge is headquartered in Stockholm, Sweden, and is publicly traded on Nasdaq First North Growth Market under the ticker ONCOZ. For more information, please visit [www.oncozenge.se](http://www.oncozenge.se).

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## Certified Adviser

Redeye Nordic Growth AB is the company's Certified Adviser.