Press Release
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OncoZenge Receives European Regulatory Approval to Start Pivotal Phase III Trial of BupiZenge™

OncoZenge AB (publ) ("OncoZenge" or "the Company"), a clinical-stage company developing an innovative treatment for oral pain in cancer supportive care, today announced that it has received regulatory approval to initiate its pivotal Phase III 'BEAM-Pain' trial of BupiZenge™ (BZ003) in Europe.

Denmark acted as Reference Member State (RMS) in the procedure, with Sweden, Norway, and Germany as Concerned Member States (CMS). The Clinical Trial Application (CTA) was submitted in December 2025. Following responses to Requests for Information from all four countries, full approval has now been granted. The company expects to enroll the first patient in Q2 2026.

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

The CTA approval triggers two committed payments under existing agreements: MSEK 15.1 from strategic investor Sichuan Yangtian Bio-Pharmaceutical Co. Ltd ('Tranche 4') and an accelerated €550,000 milestone from European commercialization partner Molteni Farmaceutici S.p.A. Together these milestone receipts will further strengthen the Company's financial position ahead of trial execution.

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

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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**.

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

This information is information that OncoZenge is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2026-05-26 11:20 CEST.