

## OncoZenge Confirms Submission of Responses to EMA on the BupiZenge™ Phase III Trial (BZ003)

***OncoZenge AB (publ), OncoZenge or "the Company", developing innovative treatments for oral pain management, today announced the complete submission of responses to European authorities' Requests for Information on the planned Phase III trial of BupiZenge™, BZ003. The Company continues to expect a Clinical Trial Application (CTA) approval decision by late April or early May at the latest, consistent with the objective of first patient enrolment in Q2 2026.***

The CTA dossier was submitted in December 2025. Following submission, and in line with the European Medicines Agency (EMA) process, the application was confirmed as complete and accepted for review. As part of the stipulated review process, Requests for Information (RFIs) were issued from authorities in countries participating in the trial – namely Norway, Sweden, Denmark and Germany – as well as from EMA centrally through its designated Reference Member State, Denmark.

The Company today confirms that it has provided responses, clarifications, and minor updates to the submitted documentation, in accordance with the feedback received.

"With these responses we remain on schedule in our interactions with European authorities, and are particularly pleased that none of the queries raised any major concerns about the proposed trial," said Christina Junvik, Head of Regulatory at OncoZenge. "This achievement is a testament to the strong team efforts to submit a robust dossier at the end of last year, and we now look forward to the authorities' feedback on initiation of the trial and with that, the prospect of recruiting our first patients in Q2 2026, following approval."

The Company will provide further updates following receipt of the CTA decision.

The OncoZenge team wishes all shareholders, stakeholders, partners and followers a Happy Easter.

**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](http://www.oncozenge.se).

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## Certified Adviser

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