

BupiZenge™ nine-month stability data within specifications

OncoZenge AB (publ) ("OncoZenge" or "the Company"), a pharmaceutical company developing treatments for oral pain management, today announced that nine-month stability data for its investigational lozenge BupiZenge™ are within specifications, under both standard long-term storage conditions and Zone IVb long-term conditions for hot, humid climates, as well as under accelerated conditions.

The batch was manufactured at Meribel Pharma Solutions in Solna, Sweden in Q4 2025 following a technology transfer process. The results validate the development decisions made in this process to ensure a successful scale-up, and quality manufacturing of the product.

BupiZenge is OncoZenge's lead product candidate, designed to provide targeted, long-lasting pain relief for patients with cancer suffering from oral mucositis. It is currently supplied to patients in the Phase III trial BEAM-Pain, evaluating the safety and efficacy of BupiZenge in head and neck cancer patients suffering oral mucositis while receiving radiotherapy, with or without chemotherapy.

The stability data show that the product remains within specifications at standard long-term storage conditions (25°C / 60% RH), accelerated conditions (40°C / 75% RH), and Zone IVb long-term conditions (30°C / 75% RH) — relevant for potential commercial partners in regions with hot and humid climates. Additional data is expected in December 2026, anticipated to support an extension of shelf life to 24 months.

"We are pleased the nine-month data confirm the quality and consistency of our product", said Tuulikki Lindmark, Head of CMC at OncoZenge. "This gives us confidence in reliable supply, and supports our discussions with potential commercial partners in markets where Zone IVb is a requirement."

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. The Company recently received European regulatory approval to initiate its pivotal Phase III study 'BEAM-Pain'. The first patient has been enrolled in the trial and site activations are currently ongoing. 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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