OncoZenge Submits Clinical Trial Application for Pivotal Phase III Trial (BZ003) of BupiZenge™

OncoZenge AB (publ) ("OncoZenge" or the "Company"), a clinical-stage pharmaceutical company developing innovative treatments for oral pain in cancer supportive care, today announces that it has submitted the Clinical Trial Application (CTA) for its pivotal Phase III trial (BZ003) of BupiZenge™ to the European Medicines Agency (EMA).

The BupiZenge™ Phase III trial (BZ003) is designed as a multi-center, randomized registrational trial to evaluate the efficacy and safety of BupiZenge™ compared to lidocaine in patients experiencing pain due to oral mucositis induced by radiotherapy with or without concomitant chemotherapy, in head and neck cancer patients. The trial will recruit 150 patients and be conducted across multiple sites in Norway, Sweden, Denmark and Germany. Patient recruitment is expected to commence in Q2 2026, following regulatory approval.

BupiZenge™ is a novel, non-opioid oral lozenge formulation of the well-established local anesthetic bupivacaine. In a previously completed Phase II study, BupiZenge™ demonstrated statistically significant and clinically meaningful pain relief compared to standard of care, together with a favorable safety profile.

Stian Kildal, Chief Executive Officer of OncoZenge, commented: "The submission of our clinical trial application marks a major milestone in OncoZenge's history, and it brings us significantly closer to delivering BupiZenge™ to the millions of cancer patients who suffer from debilitating oral pain with limited effective treatment options today. I extend my sincere gratitude to our entire team for their dedication, professionalism and efforts over the past weeks and months to get us here, on-time."

Marie-Louise Fjällskog, MD, oncologist and clinical development advisor: "Cancer patients undergoing radiation or chemotherapy often experience severe oral mucositis despite today's standard of care. BupiZenge™ has the potential to meaningfully improve their quality of life — helping them eat and drink more comfortably, reducing reliance on opioids, and supporting completion of their treatment regimens. We look forward to the trial next year and to generate the data necessary to advance to the next steps towards market approval."

Christina Junvik, Head of Regulatory adds: "Submission of the CTA for BZ003 is a very important milestone for us. It marks the point where we have brought everything together and are ready to present the study to the authorities. We have worked closely with sites, patients, and external advisors to ensure the Phase III trial is both practical to conduct and aligned with regulatory expectations. We now look forward to interactions with the authorities in the New Year, and continuing the steps needed to eventually offer BupiZenge™ to patients."

Tuulikki Lindmark, Head of CMC comments: "This milestone is a critical step forward in BupiZenge's product development, where our Phase III product and process need to demonstrate readiness for trial, and commercial use, upon future regulatory approval. We have valued the close collaboration with Meribel Pharma Solutions, Galenica and Molteni

Farmaceutici to de-risk our development and secure quality."

Anna Asplind, Phase III Program Manager: "It is very motivating to now have execution plans in place and submitted to the authorities, with line of sight to patients in Europe. We thank our CRO LINK Medical for their efforts in site selection, documentation and CTA submission, and look forward to regulatory approval and a good collaboration with our study sites next year."

About BupiZenge™ BupiZenge™ is an innovative lozenge formulation of bupivacaine, a local anesthetic with decades of documented clinical use. The product candidate is being developed as a safe, effective, non-opioid treatment for oral pain, with oral mucositis in cancer patients as the primary indication. Oral mucositis is a common and severe side effect of cancer therapies that causes painful inflammation and ulceration in the mouth, often impairing patients' ability to eat, drink, and complete their cancer treatment.

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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