

OncoZenge AB Announces Enrollment of First Patient in Pivotal Phase III BEAM-Pain 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 announces that the first patient has been enrolled in the pivotal Phase III ‘BEAM-Pain’ trial (BZ003) of BupiZenge™.

BupiZenge™ is a novel bupivacaine-based lozenge designed to provide long-acting, non-opioid local pain relief directly at the site of pain for patients suffering from oral mucositis. Oral mucositis is a severe and debilitating side effect of radiotherapy and chemotherapy in cancer patients, often leading to significant pain, difficulty eating/swallowing, weight loss, and increased reliance on opioids.

The randomized, multi-center, open-label Phase III BEAM-Pain trial will evaluate the efficacy and safety of BupiZenge™ compared to standard-of-care lidocaine in patients experiencing oral pain due to cancer therapy-induced mucositis. The study plans to enroll approximately 150 head and neck cancer patients across up to 12 sites in Norway, Sweden, Denmark, and Germany.

“The initiation of BZ003 with the enrollment of the first patient is a meaningful achievement for our development program. Pain associated with oral mucositis remains a very challenging complication of cancer therapy. Through this study, we aim to generate important data on the potential of BupiZenge to improve symptom management and the overall treatment experience for patients.” - Marie-Louise Fjällskog, M.D., Chief Medical Officer of OncoZenge.

The Phase III study is designed as a registrational trial to support a future Marketing Authorization Application (MAA) in Europe. MAA planning together with the Company’s European commercialization partner, Molteni Farmaceutici, will continue in parallel with trial execution to enable a robust and timely MAA submission. The Company continues to engage with potential licensees in other global markets that can seek local approvals based on the European data and approval, for an efficient and co-ordinated global launch.

Stian Kildal, CEO of OncoZenge, commented: “The enrollment of the first patient in our pivotal Phase III BEAM-Pain trial is a major milestone for OncoZenge and brings us closer to delivering a much-needed non-opioid treatment in cancer supportive care. We look forward to collaborating with our CRO and investigators for a successful execution of this trial, and we will provide recruitment updates later this year once reliable recruitment metrics are available.”

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'. 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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