OncoZenge AB Unveils Key Insights from UCLA Patient Engagement Study on Oral Mucositis Pain Management

OncoZenge AB (publ) ("OncoZenge" or "the Company"), a pharmaceutical company developing BupiZenge™, an innovative non-opioid lozenge for localized relief from severe oral pain, today shared key findings from its patient engagement study conducted in collaboration with UCLA Health. The study, completed in December 2025, gathered perspectives from 43 patients undergoing or having completed radiation therapy for head and neck cancer, and a focus group discussion with four participants. These insights highlight unmet needs in managing oral mucositis pain and have directly informed optimizations to the design of OncoZenge's upcoming Phase III clinical trial for BupiZenge™ in Europe.

Scope and Purpose of the Study

The study was initiated to integrate patient voices into the clinical development process, aligning with Good Clinical Practice (GCP) guidelines that emphasize patient perspectives in trial design. Through surveys and a virtual focus group discussion moderated by UCLA Health experts, participants shared their experiences with pain progression, current treatment limitations, and desired attributes for new therapies. The goal was to validate assumptions in the Phase III protocol, reduce risks such as patient drop-outs, and enhance BupiZenge™'s positioning as a patient-friendly solution. Prelmininary results from the study were incorporated into OncoZenge's Clinical Trial Application (CTA) submission to the European Medicines Agency (EMA) in December 2025, with the Phase III trial set to commence immediately upon the anticipated CTA approval.

"The insights from the UCLA study confirm the severe impact of oral mucositis on patients' daily lives and highlight the limitations of current treatments. BupiZenge represents a promising non-opioid alternative that could offer targeted, effective pain relief with fewer side effects, ultimately improving quality of life for cancer patients during treatment," said Marie-Louise Fjällskog, MD, PhD, Chief Medical Officer at OncoZenge.

Summary of Findings

The study revealed consistent themes across patient experiences, underscoring the debilitating impact of oral mucositis and the inadequacies of existing treatments:

- **Early onset of pain persisting beyond treatment**: Typical onset of pain is during week 2-3, with intensified pain during weeks 6–7 of radiation therapy and remaining severe for 1–2 weeks post-treatment, severely impairing swallowing, eating, drinking, and sleep.
- **Patients reported severe pain:** Even with today's best in class pain management where 90% used a combination of lidocaine, opioids and morphine and other solutions, 40% of patients reported OM pain of 9-10 on a 0-10 scale. 74% of patients reported 'worst pain' of 7 or more on a 0-10 scale.

- **Opioids offer relief but at a cost**: Opioids like morphine and oxycodone were somewhat effective for offering relief but caused significant side effects, including severe constipation and concerns over dependence, leading patients to use them sparingly.
- **Current topical therapies fall short**: Lidocaine and similar options often caused stinging, provided only brief relief (lasting minutes), and were limited to the mouth and upper throat, failing to address swallowing-related pain.
- **Patients' Top 3 concerns reveal significant Quality of Life impacts:** Pain eating (84%), Pain drinking (72%), Weight loss (40%), Constant pain (37%), Difficulties sleeping (30%).
- **High demand for non-opioid innovations**: Patients expressed strong interest in a fast-acting, longer-lasting, non-opioid therapy that reliably reduces swallowing pain, enables eating and uninterrupted sleep, and minimizes systemic side effects.

Other important patient feedback

Patient narratives provided vivid examples of the challenges faced, with particular emphasis on pain severity:

- Swallowing pain led to prolonged struggles with nutrition; one participant described staring at a protein shake for an hour before attempting to consume it, while another timed intervals between sips, initially taking 20–25 minutes for pain to subside after each swallow, gradually reducing to 15, 10, and then 5 minutes as recovery progressed.
- Sleep disruption was widespread due to pain and excessive mucus production, requiring frequent spitting and contributing to psychological distress and fatigue, especially in later treatment weeks; patients reported being in a "dark spot" psychologically during weeks 6–7, with general fatigue from treatment exacerbating the severity.
- Among the 43 summarized responses (with 7 from patients in ongoing radiotherapy), altered taste (e.g., food tasting like "dirt/ash") and weight loss were common, exacerbating the reluctance to eat; pain was often described as radiating to the ears, causing ringing, and being more intense than post-surgical pain, with some patients relying on opioids like morphine for 3–4 weeks despite fears of addiction and severe side effects like constipation.
- In the focus group, priorities for a new treatment included efficacy during swallowing to facilitate meals (top priority), long-acting relief for 2–4 hours to allow sleep, fast onset for timing with eating, consistent effects, and fewer side effects than opioids. For a lozenge format, acceptability hinged on reaching deeper throat pain without impairing speech or safe swallowing. Suggested improvements included pleasant flavors (e.g., bubblegum, strawberry, or fruit), a smooth, non-sticky texture, and potential benefits like reduced mucus production. Ideal introduction timing was when pain first emerges (similar to lidocaine) extending into post-treatment recovery.

The study findings prompted adjustments to the Phase III study design, including fewer study visits and simplified reporting requirements to lower patient burden and improve retention. Select study participants also reviewed and offered feedback on the draft study protocol.

"We thank Dr Robert K. Chin, Dr Michelle Ann Eala and the team at UCLA Health for their efforts on this very timely patient engagement study. Findings confirm widely acknowledged deficiencies in today's standard of care and insights from the study has been embedded in our Phase III study

protocol, and in the clinical trial application for BupiZenge submitted to EMA in December," said Stian Kildal, CEO of OncoZenge.

"Oral mucositis remains a debilitating side effect for many cancer patients undergoing treatment. Collaborating with OncoZenge on this patient engagement study allows us to amplify patient voices and explore innovative solutions like BupiZenge™, with an eye toward future clinical advancements also in the US," said Robert K. Chin, MD, PhD, Radiation Oncologist at UCLA Health.

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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