PRESS RELEASE
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OncoZenge initiates toxicity study and announces modification to the clinical plan

OncoZenge AB (OMX: ONCOZ) has today commenced dosing in a toxicity study for its product candidate BupiZenge®. The study design is based on an advisory meeting with the Swedish Medical Agency and aims to document the safety of repeated oral topical administration of bupivacaine.

Bupivacaine, which is the active pharmaceutical ingredient in BupiZenge®, is the most widely used anesthetic for epidural anesthesia during childbirth, as well as for post-operative pain treatment. The compound and its safety profile has been extensively studied since it was first discovered more than sixty years ago. BupiZenge® has a new and patented formulation which is administered via lozenges for prolonged pain relief in the mouth and pharynx. The study aims to generate supplemental safety data for bupivacaine regarding local and systemic toxicity upon repeated oral topical administration over a longer time period.

The study will comprise six weeks of dosing, followed by laboratory- and data analysis. The start of OncoZenge's planned pharmacokinetic study in cancer patients with oral mucositis, which forms part of the remaining clinical program, is not dependent on the conclusion of the toxicity study.

OncoZenge's strategy has been and remains to conduct a development program for product approval in Europe. At the same time, the company wishes to ensure that investments made in clinical development generate data that will support regulatory approvals in both Europe and the US. Also, in conjunction with negotiations with potential commercial partners or buyers, it is necessary to have a documented understanding of the regulatory requirements to reach the US market.

As previously communicated, OncoZenge has initiated formal correspondence with the American Food & Drug agency FDA in order to fully understand the agency's requirements regarding study design and patient population. The FDA has announced delays on two occasions due to a shortage in resources and their response is now expected at the end of March. OncoZenge's previous plan was to conduct the remaining clinical development program under a combined study protocol that started with a pharmacokinetic study in H1 2022 and subsequently proceeded with a phase III study. In order to both start the pharmacokinetic study according to schedule, while retaining the possibility to potentially modify the phase III protocol based on FDA's requirements, the pharmacokinetic study will be conducted under a separate study protocol. In parallel, OncoZenge will decide on design, geographic scope and final study protocol for the phase III study based on the outcome from the company's interactions with the FDA. The company's target to have topline data from the European phase III study end of 2023 remains unchanged.

OncoZenge is developing BupiZenge® as a novel treatment for pain relief in patients suffering from oral pain caused by oral mucositis, induced by radiation therapy and chemotherapy for cancer. In phase 2 patient studies, BupiZenge® has shown significantly better local pain relief compared with today's standard therapy. Five million people worldwide suffer from oral mucositis caused by cancer therapy. After radiotherapy in the head and neck region, ninety percent of patients develop oral mucositis and of the patients treated with chemotherapy, about thirty percent are affected. Oral mucositis causes severe pain, interruption of cancer treatment and may significantly increase healthcare costs.

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About OncoZenge
OncoZenge is a Swedish pharmaceutical company developing a novel treatment for pain relief in patients suffering from oral pain caused by radiation- and chemotherapy for cancer. The company's product candidate BupiZenge® has in phase 2 patient studies shown significantly greater pain relief compared with today's standard therapy. OncoZenge plans to carry out a phase 3 development program as a basis for regulatory approvals and product launch. OncoZenge has its head office in Stockholm and the company's share is listed on Nasdaq First North Growth Market (OMX: ONCOZ).