

FG001 clinical data in High-Grade Glioma is now published in Neurosurgery

Copenhagen, Denmark – FluoGuide A/S ("FluoGuide" or the "Company"), a clinical-stage biotech company focused on precision cancer surgery, is pleased to announce its compelling phase I clinical data with FG001 has been published in **Neurosurgery**. The data is the first-in-human result of its proprietary near-infrared (NIR) optical imaging agent, FG001, in patients with malignant glioma undergoing surgery.

The article, published in the prestigious journal *Neurosurgery*, which targets neurosurgeons, is entitled "Novel uPAR-targeting optical imaging agent ICG-Glu-Glu-AE105 (FG001) for visualization of malignant glioma during surgery: First-in-human study in 35 brain cancer patients" and identified with doi:10.1227/neu.0000000000003542, available here: [link](#).

"We are very pleased with the publication of the results from this first-in-human study that shows FG001 not only enables safe and targeted tumor identification including in the transition zone, being the tissue between the cancer and normal tissue which constitutes the biggest challenge for the surgeon treating high-grade glioma - where the agent continued to produce visible fluorescence." said Morten Albrechtsen, CEO of FluoGuide; "FG001 has the potential to redefine how surgeons approach brain tumor resection"

Next clinical step and regulatory path

Following the successful completion of this phase I study, FluoGuide is obtaining FDA regulatory advice prior to initiate the U.S. clinical trial supporting approval of FG001 guiding surgery of patients with High Grade Glioma. FluoGuide anticipates feedback from ongoing regulatory interactions over the summer.

"I am pleased to see the first result of FG001 in patients with malignant glioma published" says Jane Skjøth-Rasmussen, MD, PhD, Chief Physician in the Department of Neurosurgery at Rigshospitalet, Copenhagen, Denmark and Principal Investigator of the trial and the author of the publication, and continues: "The data demonstrates FG001 to be well tolerated and shows a promise for guiding surgery of malignant glioma."

In an editorial comment published together with the article Professor Pierre A. Robe, Chair of Neurosurgical Oncology at the University Medical Center (UMC) concludes: *"Altogether, the results reported here are a welcome and exciting addition to the brain tumor neurosurgical community."* Please refer to the published article for the full commentary.

Glioblastoma is among the most aggressive and lethal forms of brain cancer, with a crucial need for tools that enable maximal tumor resection while preserving healthy brain tissue. FG001 lights up cancer, enabling surgeons to perform more precise surgeries. It is a novel imaging agent that targets the urokinase-type plasminogen activator receptor (uPAR), a protein highly expressed in tumor tissue but largely absent from normal brain cells.

Key results from the phase I study

The result is from the first clinical trial with FG001 in patients with High Grade Glioma and is an open-label, single-center phase I trial involving 35 patients, and FG001 was administered intravenously prior to brain surgery. A dose of 36 mg administered 12-19 hours before surgery provided optimal tumor visualization. The tumor-to-background fluorescence ratio (TBR) was relevant for all image system tested (>1.5) and up to 2.7 (TBR mean) and 3.6 (TBR max). Notably, FG001 achieved a sensitivity of 79% and a specificity of 100% in identifying malignant tissue confirmed by histopathology.

Compared with the imaging agent 5-ALA, FG001 was observed to provide clearer delineation in deeper tissue layers due to its NIR fluorescence properties, with no observed false positives. FG001's safety profile was equally promising, with only few (4) mild drug-related adverse events linked to the drug. It was observed that unlike 5-ALA, no FG001-related nausea or vomiting was reported in patients receiving evening doses, underscoring FG001's favorable tolerability.

High precision in the transition zone

The transition zone, being the tissue between the tumor and the normal tissue, is of special attention to neurosurgeons as it is where they must make the difficult decisions between removing tissue that may be cancer and risking disabling patients by removing more brain tissue than necessary. FG001 worked well in the transition zone where all 7 samples were correctly classified by FG001 whereas 5-ALA had 2 false negative. When the efficacy was calculated for transition zone only, then specificity, sensitivity, positive predictive value (PPV), and negative predictive value (NPV) were all 100% for FG001, whereas the numbers were 100%, 60%, 100%, and 50% for 5-ALA, respectively.

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About FluoGuide

FluoGuide is a biotech company specializing in precision cancer surgery improving the outcome for cancer patients. The Company's lead product, FG001, a novel optical imaging agent that light up cancerous tissue to improve surgical precision in patients undergoing surgery. FluoGuide's products are expected to have a dual benefit – reducing both the frequency of local recurrence after surgery and reducing surgical complications. The improved precision will potentially increase the patients' chance of achieving a complete cure and lower healthcare costs. FG001 binds to the urokinase plasminogen activator receptor (uPAR) being extensively expressed by solid cancer. The photosensitizer therapy potential of FG001 could add a direct treatment effect of FG001 to further benefit for patients with cancer undergoing surgery.

The Company has published strong results from phase II trials demonstrating the efficacy of FG001 in patients undergoing surgery to remove aggressive brain (high-grade glioma), head & neck (oral squamous cell carcinoma) and lung cancers (non-small cell lung cancer). FG001 has also been demonstrated very well tolerated across all patients. Based on this strong foundation, FluoGuide advances the development toward approval in aggressive brain cancer and head & neck cancer.

FluoGuide is listed on Nasdaq First North Growth Market, Stockholm under the ticker "FLUO". Read more about FluoGuide and upcoming events on www.fluoguide.com

Attachments

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