



The excellent phase I/IIa clinical data of FG001 in aggressive brain cancer was presented at the World Molecular Imaging Congress

Copenhagen, Denmark, 3 October 2022 – FluoGuide A/S (“FluoGuide” or the “Company”) is pleased to inform of presentation of the outstanding clinical data from the completed phase I/IIa trial with FG001 in patients with aggressive brain cancer undergoing surgery, at the World Molecular Imaging Congress (WMIC) held 28 September – 1 October 2022 in Miami, US. Promising pre-clinical data on FG002 was also presented at the same conference.

Andreas Kjaer, Professor and CSO at FluoGuide presented the excellent phase I/IIa clinical data of FG001 in aggressive brain cancer data at the World Molecular Imaging Congress (WMIC).

In the phase I/IIa trial, which had Chief Surgeon Jane Skjøth-Rasmussen as Principal Investigator, the neurosurgeon collected 31 tissue samples during surgery from the 8 patients dosed with FG001, at 36 and 48 mg in the evening. This included both tissue that lit up and tissue that did not lit up. After surgery, two histopathologists evaluated the samples independently and determined if the tissue samples contained cancer or not. The histopathologists read the samples in a blinded manner, meaning that they did not know where the neurosurgeon had taken the samples or if the samples had lightened up. 100% of the biopsies that lit up during surgery contained cancer.

In the 40 patients FG001 were administered to, FG001 was shown to be safe and well-tolerated. No serious drug related adverse events were reported. Only a few (4) drug-related mild adverse events (grade 1 and 2) were reported in 3 patients out of the 40 included patients.

The presentation took place at the session ‘Curative Intent with Image-Guided Surgery’ on Friday 30 September at WMIC (abstract can be found [here](#)). Please also find the initial press release on the clinical data from 1. April 2022 [here](#)

Based on the excellent clinical data, FG001 is advanced into a phase IIb trial in aggressive brain cancer where the top line result is expected in H1 2023.

Morten Albrechtsen, CEO says: “100% is as good as it gets, and needless to say, essential particularly in brain cancer surgery”.

Furthermore, Dr. Sorel Kurbegovic presented promising pre-clinical data on FG002. The presentation took place at the session ‘Curative Intent with Image-Guided Surgery’ on Friday 30 September at WMIC.

Data on FG002 has also been published in the article entitled “IRDye800CW Labelled uPAR-Targeting Peptide for Fluorescence-Guided Glioblastoma Surgery: Preclinical Studies in Orthotopic Xenografts”. FluoGuide’s founder and CSO Andreas Kjær is senior author of the article ([link to publications](#) – see “3. FG002 in vivo study”)

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About FluoGuide

FluoGuide's primary focus is to maximize surgical outcomes in oncology. The Company's lead product, FG001, is designed to improve surgical precision by illuminating cancer cells intraoperatively. The improved precision enabled by FluoGuide's products has a dual benefit – it reduces both the frequency of local recurrence post-surgery and lessens surgical sequelae. Ultimately, the improved precision will improve a patient's chance of achieving a complete cure and will lower system-wide healthcare costs. The Company has demonstrated efficacy of F001 as well as it is shown to be well tolerated and safe in the proof-of-concept clinical study (phase I/II) in patients with high grade glioma undergoing surgery. FluoGuide is exploring FG001 in three other severe cancer indications, namely lung, head & neck and less aggressive brain cancer (meningioma and low grade glioma). The clinical phase IIa trials is ongoing in lung and head & neck cancer, and a trial in less aggressive brain cancer is commencing. FluoGuide is listed on Nasdaq First North Sweden under the ticker "FLUO".

About high grade glioma and glioblastoma

The first indication for FG001 is glioblastoma but FG001 has potential in several indications. Almost all patients with glioblastoma have a cancer expressing uPAR. A total of 60,000 patients gets high grade glioma and more than 30.000 patients are diagnosed with glioblastoma annually in the EU and US. Approximately 8-12 % of the patients are children. The prognosis for individuals with glioblastoma is very poor. Approximately 50 % of the patients die within 14 months and only 5 % are alive after five years from diagnosis. Precise removal of glioblastoma tumors is very difficult due the brain contains vital structures often near the cancer. Local reoccurrence of glioblastoma is common and happens in almost 100% of all patients.

For more information on the Company's uPAR technology platform and our pipeline please visit our home page www.fluoguide.com

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