



# Publication of a case report showing first promising clinical data on FG001s use in treatment of meningioma brain tumor

**Copenhagen, Denmark, 9 November 2021. FluoGuide A/S ("FluoGuide" or the "Company") is pleased to announce the publication of a clinical case report for FG001 in meningioma. The case report indicates that FG001 may be used in other types of brain tumors than High Grade Glioma and thereby opens new opportunities for the realization of clinical and commercial potential of FG001**

FG001 is currently in clinical investigation at Rigshospitalet, Denmark in a phase I/II trial in patients with High Grade Glioma undergoing surgery. This case report describes the result of FG001 from surgery of one patient diagnosed with meningioma post-surgery but was enrolled in the trial suspected to have High Grade Glioma.

The tumor in the patient lightened up with FG001. The surgeon delineated the tumor on the surface and in addition in the cavity. This result has now been published in *Acta Neurochirurgica* as a case report concluding that FG001 is a new promising tool for surgical guidance beyond High Grade Glioma, provided that a prospective validation in a consecutive meningioma cohort confirms the results.

The patient participated in the dose escalation part of the phase I/II trial, which FluoGuide reported in September and where FG001 was found to be well tolerated in all 27 patients from 1 mg up to 36 mg and there was seen light in 25 of the patients. The patient was administered 8 mg of FG001 and although FG001 lightened up already from the first dose (1 mg), doses from around 8 mg is where FG001 appeared most useful for surgical guidance. The image quality has further improved in higher doses and the optimal dose is expected to be 3-4 times higher.

Meningioma accounts for approx. 35% of primary brain tumors worldwide. Approx. 7 per 100,000 are diagnosed with meningioma annually. Approx. 20-30% patients will have cancer recur locally within 10 years after their first surgery. FluoGuide estimates that around 60,000 meningioma patients will annually undergo surgery. This is more patients that undergo surgery for high grade gliomas.

A new clinical trial to investigate the usefulness of FG001 in a larger scale, in patients with meningiomas is planned to be initiated during 2022.

*"This case clearly shows FG001's potential to benefit not only High Grade Glioma patients but more broadly in brain tumor patients including those with meningioma. This is a first piece of evidence published from our clinical trials with FG001 and we plan to publish ongoing when we get more clinical data with FG001 in different cancer types" says Morten Albrechtsen, CEO of FluoGuide A/S, and continues. "Our strategy is to develop a comprehensive product portfolio with different features and benefits that together can reduce costs for the health care system by helping surgeons with intelligent surgical targeting. The published case report is substantiating our strategy."*

The article has the title "A new uPAR-targeting fluorescent probe for optical guided intracranial surgery in resection of a meningioma – a case report." (<https://link.springer.com/article/10.1007/s00701-021-05051-3>)

The first author of the article, Jane Skjøth-Rasmussen\*, MD, PhD, is the primary investigator on FluoGuide's ongoing clinical trial in High Grade Glioma.

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**About Meningioma Cancer**

A meningioma is a tumor that arises from the meninges — the membranes that surround the brain and spinal cord. Although not technically a brain tumor, it is included in this category because it may compress or squeeze the adjacent brain, nerves and vessels. Meningioma is the most common type of tumor that forms in the head. Most meningiomas grow very slowly, often over many years without causing symptoms. But sometimes, their effects on nearby brain tissue, nerves or vessels may cause serious disability. An estimated more than 60.000 people is diagnosed with meningioma in 2021 globally. Incidence rates of meningioma increase with age, with a large increase in diagnosis rates in adults age 65 and older.

**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 early evidence of efficacy of F001 as well as it to be well tolerated and safe in the ongoing proof-of-concept clinical study (phase I/II) in patients with high grade glioma undergoing surgery. FluoGuide is listed on Nasdaq First North Sweden under the ticker "FLUO".