FluoGuide proceeds to sixth dose level with FG001 in the ongoing clinical phase I/II trial following strong data from the concluded evening dosing

Copenhagen, Denmark, 17 August 2021 – FluoGuide A/S ("FluoGuide" or the "Company") is pleased to report that FG001 was well tolerated, and light was detected in all patients, as anticipated, in the fifth cohort (16 mg) administered the evening before surgery. The Company will initiate the safety testing of the sixth dose level (24mg) in the ongoing clinical phase I/II trial evaluating safety and efficacy of FG001 in patients with aggressive brain cancer (high grade glioma) undergoing neurosurgery. The safety reporting is anticipated to be in Q3-2021, and the optimal dose selection and top-line efficacy from part 1 is expected in Q1-2022.

FG001 was well tolerated, and light was detected in all patients at the fifth dose level (16mg) administered in the evening before surgery

FG001 is anticipated to be well tolerated and selection of the dose for use in the part 2 of the trial will therefore be based on optimal illumination of the tumor. The Company has now narrowed it down to one of two dose levels (16mg and 24mg). Consolidated safety data will therefore be communicated in Q3 following conclusion of the now initiated 24mg morning dosing at the day of surgery.

The Company has decided, based on the strong data seen from the completed evening-dose testing, that it will generate additional dose-selection data by testing the selected two doses (16mg and 24 mg) with a morning or evening administration the day before surgery. The optimal dose selection and top-line efficacy from part I is therefore expected in Q1-2022. Efficacy results from the second phase enrolling 12 patients from both Denmark and Sweden are anticipated mid-2022.

Five patients were included at the fifth dose level administered in the evening the day before surgery as one patient turned out to have another cancer type than high-grade glioma. This is not uncommon as it can be difficult to diagnose patients based on the pre-surgery images. Light was also detected in this patient, which underlines the potential of using uPAR targeted fluorescence to guide surgery of multiple types of cancer.

"We are excited about the strong result in the first evening administration" says Morten Albrechtsen, CEO and continues "*It is reassuring to see yet another cancer type being illuminated using the uPAR targeted guidance of surgery*".

This disclosure contains information that Fluoguide is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on 17-08-2021 12:26 CET.

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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 is conducting a proof-of-concept clinical study (phase I/II) to demonstrate the effect of FG001 in patients with high grade glioma. 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.

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