FluoGuide proceeds to seventh dose level (36 mg) with FG001 in the ongoing clinical phase I/II trial following continued improvement of tumor illumination with increasing doses

Copenhagen, Denmark, 14 September 2021 – FluoGuide A/S ("FluoGuide" or the "Company") is pleased to announce that FG001 was well tolerated, and light was detected in all patients in the sixth cohort (24 mg), administered in the morning before surgery. The data from the sixth dose (24 mg) showed a continued improvement and clear illumination of the tumors in all three patients. The dose escalation committee has therefore recommended to initiate the seventh dose level (36 mg) in the ongoing clinical phase I/II trial.

FluoGuide is conducting a clinical phase I/II trial evaluating safety and efficacy of its lead asset, FG001, in patients with aggressive brain cancer (high grade glioma) undergoing neurosurgery. The Company is pleased to announce that FG001 was well tolerated, and an increased illumination of the tumors were detected in all three patients at the sixth dose level (24 mg), administered in the morning before surgery. Based on the strong data, the Company has decided to generate additional safety and dose-selection data by testing 36 mg the morning before surgery, which has been approved by the dose escalation committee. Regarding the illumination, the protocol is designed to continue dose escalation as long as illuminations improve. As this has continuously been observed including with the latest dose of 24 mg, the dose escalation will continue to the next dose level of 36 mg.

"Also, with the latest dose of 24 mg FG001 we observed a further improvement in tumor illumination" says Morten Albrechtsen, CEO and continues: "*Based on this, we therefore continue to the next dose level of 36 mg in order to establish the optimal dose to be used in the second part of the ongoing trial as well as in the upcoming pivotal trials. Only by a thorough dose escalation and study of the optimal dose, we can be sure to fully unfold the potential of FG001 as a tool to improve cancer 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 14-09-2021 08:02 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 the clinical phase I/II trial with FG001

The ongoing phase I/II clinical trial in patients with high grade glioma has two phases: (1) a phase to establish safety and tolerability and select the optimal dose; and (2) an efficacy assessment phase. The dose escalation phase (part 1) includes cohorts of three patients with high grade glioma receiving FG001 in the morning before surgery. The safety is evaluated following completion of each cohort. Estimation of the magnitude of benefit of FG001 (efficacy) is done in the second phase of the trial and will include 12 patients to be recruited in both Denmark and Sweden. Importantly, this data will used to calculate the number of patients needed (power calculation) for the pivotal phase III trial required for registration. Efficacy data will also be used to help inform pricing for FG001.

The evidence of FG001's effect is coming in steps with increasing validity: (1) An image where the cancer can be seen different from the normal tissue; (2) The neurosurgeon's positive feedback, (3) Histology of selected tumors (removed), (4) The randomized reading of the samples of all patients (incl. low dose), and (5) then finally the part 2. result. The first steps are now realized and the remaining will come subsequently until final completion of part 2.

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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