Press release

FluoGuide gets green light to proceed to third dose level with FG001 in the ongoing clinical phase I/II trial in patients with high grade glioma

Copenhagen, Denmark, 13 January 2021 – FluoGuide A/S ("FluoGuide" or the "Company") is pleased to announce that the dose escalation committee has approved initiation of the third dose levelin the ongoing clinical phase I/II trial evaluating safety and efficacy of FG001 in patients with high grade glioma undergoing neurosurgery.

Evaluation of the results from the second dose level of FG001, including data from three patients, has been finalized and reported to the dose escalation committee. The dose escalation committee has today given their approval to proceed and enroll patients at the third dose level.

The results from the second dose level are in line with data from the first three patients at the first dose level, in respect to safety and tolerability. Light was detected in all three patients at the second dose level. It is important to underline that the trial still is at an early stage, and that the first phase of the trial (up to 24 patients) must be completed and analyzed before any conclusions on tolerability and safety profile can be made. It is also important to state that it is not yet possible to establish the efficacy of FG001 on the basis of findings from these first two dose levels, as further analysis is needed to confirm that the tissue that lights up is actually cancer and tissue that does not light up is free of cancer.

The recruitment of patients over the next months may be slowed down due to the ongoing COVID-19 pandemic. However, as of now FluoGuide still expects to meet the following overall timeline remains as earlier communicated: (i) Middle of 2021: Result of first phase (safety and selection of optimal dose), subject to number of cohorts; and (ii) Second half of 2021: Efficacy result from the second phase, including estimation of the potential magnitude of benefit of FG001 in guiding surgery of patients with high grade glioma.

"We need to interpret the initial results with caution, but it is encouraging to see the study advance as planned" says Morten Albrechtsen, CEO.

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This information is information that FluoGuide A/S is obliged to publish in accordance with the EU Market Abuse Regulation. The information was provided by the contact person set out above for publication on 13 January 2021.

About (see next page).

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About FluoGuide
FluoGuide's primary focus is to maximize surgical outcomes in oncology. The Company's first 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.

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.

About the clinical trial
The ongoing first phase of the clinical phase I/II trial with the objective to test the safety and determine the optimal dose of FG001 in patients with high grade glioma undergoing neurosurgery, is designed with three patients in each dose group ('cohorts'), with up to 8 dose groups in total resulting in up to 24 patients in total for the first phase. The second phase will be based on the optimal dose selected in the first phase of the trial. It is expected that the optimal dose is found after the 5th to 8th cohort. The second phase includes 12 patients resulting in the total number of patients in the entire trial of up to 36 patients in total.

The dose escalation committee's role is to evaluate the result after each dose level and only if the dose escalation committee identifies no issues they will give clearance to proceed to the next dose level. The commitee consists of three people, the Principle Investigator, an independent anesthesiologist and a medical doctor from FluoGuide.

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