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

Copenhagen, Denmark, 8 April 2021 – FluoGuide A/S ("FluoGuide" or the "Company") is pleased to announce that the dose escalation committee has approved initiation of the fifth dose level in the ongoing clinical phase I/II trial evaluating safety and efficacy of FG001 in patients with high grade glioma undergoing neurosurgery.

The results from the patients in the fourth dose level show that FG001 was well tolerated, and the light intensity continues to increase with higher dose levels. Light was detected in all patients.

The data from this dose level differed from previous dose levels as the light intensity from the blood also became detectable. This was expected and may indicate that we are close to the optimal dose level.

Four patients (not three) were included at this dose level as one included 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 detected in this patient.

The data suggests that background light intensity can be reduced if FG001 is administered in the evening prior to surgery. This would presumably give an even better image quality and tumor delineation. To ensure that the best possible combination of FG001 dose and time of administration is carried forward into the phase II trial, the company has therefore developed a protocol amendment to explore the evening administration as well. This allows for a comparison of morning and evening administration prior to initiating the second part of the phase I/II trial. The protocol amendment has been submitted to Danish Medicines Agency and Ethical committee and approval is pending while the morning administration of the fifth dose level is being investigated.

The Company does not expect the timelines for the trial to be significantly impacted as the planned two highest dose levels unlikely will be required for safety assessment and furthermore not contribute to an improved image quality. The two highest dose levels are therefore planned to be replaced with evening dosing.

"The initial data from the trial is encouraging, and I look forward to the evening dosing as well as the histology results, which needless to say, are very important for the conclusion of the trial" says Jane Skjøth-Rasmussen, MD, PhD, Consultant Neurosurgeon and Principal Investigator.

"The trial is making really good progress in identifying the boundaries of FG001's performance that will allow us to select the most optimal dose and time of administration for future clinical development" says Grethe Nørskov Rasmussen, CDO.

"The positive result in the patient with the non-glioblastoma cancer more than triple the number of patients FG001 potentially can help" says Morten Albrechtsen, CEO and continue *"Moreover, it hints on what we can expect on cancer derived from other tissues than brain, such as breast and lung derived cancers".*

It is important to underline that the first part of the trial must be completed and analyzed before any final conclusions on tolerability and safety profile can be made. It is also important to state that the pathology examination at the end of the first part is needed to confirm that the tissue that lights up is cancer and tissue that does not light up is free of cancer.

There is still a risk that the recruitment of patients over the next months may be slowed down due to the ongoing COVID-19 pandemic but FluoGuide expects to have data from the first part of the trial available within Q3 2021.

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 08-04-2021 14:39 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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