Press release

FluoGuide has received approval to commence with FG001 in evening dosing in the ongoing clinical phase I/II trial in patients with high grade glioma

Copenhagen, Denmark, 12 May 2021 – FluoGuide A/S ("FluoGuide" or the "Company") is pleased to announce that the Danish Medicines Agency and Ethical Committee has approved administration of FG001 in the evening before surgery.

The data from the ongoing dose finding trial suggests that background light intensity might be further 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 in clinical development, the company has therefore made a protocol amendment to explore also evening administration. This allows for a comparison of morning and evening administration during the ongoing phase I/II trial. The protocol amendment has now been approved by the Danish Medicines Agency and Ethical Committee.

"The approval gives us the opportunity to test FG001 in an evening dosing, which will add important information for the subsequent clinical trials" says Morten Albrechtsen, CEO

FG001 is currently being tested at the fifth dose level. The results from the first fourth dose levels showed that FG001 is well tolerated, and the light intensity continues to increase with higher dose levels.

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.

Regarding the timeline, there is still a risk that 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.

For further information, please contact:
Morten Albrechtsen, CEO
FluoGuide A/S
+45 24 25 62 66
ma@fluoguide.com

Certified Adviser:
Svensk Kapitalmarknadsgransking AB
Phone: +46 70 755 95 51
E-mail: ca@skmg.se

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".

Press release

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.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 954904.