FluoGuide announces regulatory approval from Swedish Authorities (MPA and Ethics committee) to commence Phase II clinical trial with FG001 in guiding surgery of high grade glioma in Sweden

Copenhagen, Denmark, 26 August 2021 – FluoGuide A/S ("FluoGuide" or "the Company") is pleased to announce that the company has received regulatory approval for expanding the ongoing clinical phase I/II trial to Sweden with FG001.

The ongoing clinical phase I/II trial with FG001 is designed as a two-phased trial, where the first phase aims to identify the optimal dose and investigate safety and tolerability. Phase II will provide efficacy data that will be used to design the following pivotal phase III trial intended to support regulatory approval of FG001 in high grade glioma, aggressive brain cancer.

After the approval in Sweden, Linköping University Hospital will be the second site investigating FG001 ´s effect. Sweden and Linköping University Hospital is added to phase II of the clinical phase I/II trial, to provide diversity to the trial by working with different centers in different counties. First patient enrollment is expected after the reporting of phase I of the ongoing I/II clinical trial.

"We look forward to expanding the clinical trial with Peter Milos and his team at Linköping University Hospital" says Morten Albrechtsen, CEO and continues*, "We are happy to see that the regulatory process went so smoothly thanks to a very professional effort from the people involved in FluoGuide and Linköping".*

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

Certified Adviser:
Svensk Kapitalmarknadsgranskning AB
Phone: +46 11 32 30 732
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".

About high grade glioma and glioblastoma
High grade glioma is grade III and IV glioma (WHO) grad IV glioma is also termed glioblastoma. High grade glioma is an aggressive brain cancer. 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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