



FluoGuide enters agreement with Swedish university hospital for the second phase of the ongoing FG001 clinical trial (correction)

Correction: The subject line in e-mail recipients contained a wrong text. No other corrections.

Copenhagen, Denmark, 30 June 2021 – FluoGuide A/S (“FluoGuide” or the “Company”) is pleased to announce that the Company has entered into an agreement with the Department of Neurosurgery, Linköping University Hospital, Sweden to become the second site investigating FG001’s effect in guiding surgical removal of aggressive brain cancer. Linköping University Hospital is added to the second phase of the ongoing clinical phase I/II trial.

The ongoing clinical phase I/II trial with FG001 is designed as a two-phase trial, where the first phase aims to identify the optimal dose and investigate safety and tolerability. The second phase 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. Several of the design elements needed in the pivotal phase III trial is included in the ongoing clinical phase I/II trial of FG001 for use in guiding surgery of glioblastoma.

In collaboration with Copenhagen University Hospital (“Rigshospitalet”) in Denmark, FG001 is currently in the first phase of the clinical trial. For the second phase of the clinical trial, Linköping University Hospital will be included to provide diversity to the trial by working with different centers in different counties. Peter Milos (MD) will be the principal investigator at Linköping University Hospital. The Swedish site is expected to start recruiting patients during H2 2021.

“The neurosurgery department of the University Hospital in Linköping, Sweden is well known for its innovative research in the field of neurosurgery and involvement in numerous clinical trials in brain cancer”, says Morten Albrechtsen, CEO and continues “I am also delighted that Peter Milos, who is an experienced and well reputed neurosurgeon, will be the one to lead the trial in Linköping”.

“There is large need for improving the treatment of patients with high grade glioma and I am looking forward to investigate FG001 in guiding surgery of these patients”, says Peter Milos, MD

For further information, please contact:

Morten Albrechtsen, CEO
Telephone: +45 24 25 62 66
E-mail: 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”.

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.

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