FluoGuide's update on FG001's clinical development

Copenhagen, Denmark, 24 August 2022 – FluoGuide A/S ("FluoGuide" or the "Company") provides an update on the clinical development of FG001.

FluoGuide announced in April FG001's highly promising results in aggressive brain cancer (high grade glioma) following its phase I/IIa trial. FG001 was demonstrated to be well tolerated with only few patients reporting mild side effects (3 out of 40 patients). Furthermore, 100% of the biopsies from patients in the optimal dose (n=8, with 33 biopsies obtained) had their cancer illuminated. Based on these strong results, FluoGuide has decided to expand the design of the phase IIb trial in aggressive brain cancer with 24 patients instead of 12. Furthermore, FluoGuide has decided to explore FG001 in phase IIa clinical trials in three other severe cancer indications.

Status and plans for the clinical development of FG001:

FG001 – Phase IIb trial in aggressive brain cancer: Based on the positive data, FG001 will be tested in a clinical phase IIb trial as a standalone treatment compared to Gliolan (5-ALA), which is the only approved product for intraoperative guidance during aggressive brain cancer surgery. 24 patients (compared to the originally planned 12 patients), will be randomized 1:1 against Gliolan (5-ALA). The patients will be recruited at two sites: Linköping, Sweden and Copenhagen, Denmark. FluoGuide has received approvals from Swedish Medical Products Agency and Swedish Ethical Committee, and the first patient is planned to be enrolled in the beginning of October. In Denmark, FluoGuide has received approval from Danish Medicines Agency (DMA) and is awaiting approval from the Ethical Committee, which is expected at the latest by November. The first patient in Denmark will be enrolled as soon as the Ethical Committee approval has been granted. The results of the phase IIb trial are expected to be available in H1 2023.

FG001 – Phase IIa trial in lung cancer: The trial is designed to enroll up to 24 patients. First interim analysis following evaluation of 8 patients is anticipated in Q4 2022 and top line data in H1 2023. The trial was approved in March 2022 and initiated in May 2022. Due to slower-than-anticipated patient enrollment, FluoGuide has amended the protocol with broader inclusion criteria, which has now been approved by both the Ethical Committee and the DMA in Denmark.

FG001 – Phase IIa trial in head and neck cancer: The Clinical Trial Application (CTA) in Denmark has been filed. The trial is designed as a phase IIa trial to obtain proof-of-concept for the use of FG001 in head and neck cancer. The plan is to enroll up to 16 patients. The primary endpoint is sensitivity, defined as the relative number of patients where FG001 lights up the cancer, as confirmed by histopathology. Top line results for this trial are anticipated in H1 2023.

FG001 – Phase IIa trial in meningioma and low grade glioma: The trial is designed as a phase IIa trial to obtain proof-of-concept for the use of FG001 in meningioma and low grade glioma. The primary endpoint is expected to be sensitivity, defined as the relative number of patients where FG001 lights up the cancer, as confirmed by histopathology. The Company is finalizing the protocol prior to the CTA submission. The results from this trial are expected in H2 2023.

Online investor presentation on Thursday, August 25, at 4:00 pm CEST

FluoGuide invites investors to attend an online investor conference call on Thursday, August 25, 2022, at 4:00 pm CEST. CEO Morten Albrechtsen and CSO Andreas Kjaer will be presenting the updated clinical development strategy as well as how this positions the Company for future development.

To register for the online presentation, please register at: www.ir.live/fluoguide

To call in via phone, please, use the following details:

Attendee Dial-in Number: +1 (312) 248-9348
Attendee Dial-in ID Number: 395583#
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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 has demonstrated efficacy of F001 as well as it to be well tolerated and safe in the ongoing proof-of-concept clinical study (phase I/II) in patients with high grade glioma undergoing surgery. FluoGuide has also started a phase II trial to demonstrate the effect of FG001 in guiding cancer surgery in patients with lung cancer. FluoGuide is listed on Nasdaq First North Sweden under the ticker "FLUO".

For more information on the Company's uPAR technology platform and our pipeline please visit our home page www.fluoguide.com

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