FluoGuide announces positive top line result from the first part of the ongoing clinical phase I/II trial testing the safety and performance of FG001 in lightening up aggressive brain cancer

Copenhagen, Denmark, 01.04.2022 – FluoGuide A/S ("FluoGuide" or the "Company") is pleased to announce that FG001 has been shown safe and well tolerated in 40 patients. The early evidence of efficacy has been demonstrated by strong illumination of brain tumors and histology data has now confirmed that the tissue lighted up is cancer. The optimal dose and time of FG001 administration has been decided to be 36 mg administered the evening before surgery.

In total, 40 patients have been administered and FG001 has been shown safe and well tolerated (please see table). No serious drug related adverse events have been reported. Only a few drug-related adverse events were reported as grades 1 or 2 and no pattern or dose relation was observed.

Overview of part 1 of phase I/II clinical trial						
Cohort	**Dosing**	**Dose (mg/pt)**	**Patients (#)**	**HGG *) (#)**	**Non-HGG/not completed (#)**	**Ligth in HGG (%)**
1	morning	1	3	3	0	67%
2	morning	2	3	3	0	100%
3	morning	4	3	3	0	67%
4	morning	8	4	3	1	100%
5	morning	16	3	3	0	100%
5a	evening	16	5	4	1	100%
6	morning	24	3	3	0	100%
7	morning	36	3	3	0	100%
7a	evening	36	5	4	1	100%
8	morning	48	4	2	2	100%
8a	evening	48	4	4	0	100%
Total			**40**	**35**	**5**	**NA**

*) High Grade Glioma

Four patients had other diagnoses than aggressive brain cancer (high grade glioma ('HGG')): One patient had a lung cancer metastasis (adenocarcinoma metastasis) in the brain, one patient had meningioma, and two patients had malignant melanoma metastases in the brain. Intriguingly, the patients with lung cancer metastasis and meningioma demonstrated good illumination of the cancers. One patient with HGG received FG001 but did not undergo surgery, and only safety was monitored.

The pharmacokinetic (PK) profile for FG001 was assessed for the eight dose levels. FG001 showed dose-dependent increases in exposure across dose levels in a linear manner.

Tumor-to-background ratio (TBR) is a measure of the contrast. At the optimal dose and time, 36 mg administered the evening before, all patients revealed a clinically relevant TBR value.

The histology samples from dose cohort 7a (36 mg, evening) and dose cohort 8a (48 mg, evening) have been unblinded and analyzed. The histology results confirm that FG001 lights up aggressive brain cancer.

"Presenting good safety data for FG001 is universal for all indications and at the same time presenting the early evidence of efficacy in aggressive brain cancer is really encouraging for the patients, investors and our team" says Morten Albrechtsen and continues *"We are very excited and are looking very much forward to evaluating FG001 in other cancer indications".*

A more detailed presentation of the clinical data will be presented orally at the 68th Scandinavian Neurosurgical Society (SNS) Congress to be held 14-16 May 2022 in Bergen, Norway.

The Company is currently elaborating the design of part 2 of the ongoing phase I/II trial together with clinicians from EU and US.

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 01-04-2022 12:29 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 and a phase II trial in lung cancer 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".

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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