PRESS RELEASE
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FluoGuide completes patient enrollment and treatment in FG001 phase IIb clinical trial in aggressive brain cancer

- **Trial investigates the effect of FG001 in guiding surgery of patients with aggressive brain cancer**
- **The multi-center trial compares FG001 to 5-ALA and white light**
- **Topline results anticipated to be reported in 2-3 months**

Copenhagen, Denmark – FluoGuide A/S ("FluoGuide" or the "Company"), a pioneer in the cutting-edge field of precision cancer surgery, is pleased to announce the successful completion of patient enrollment and treatment in the phase IIb trial with FG001 in patients with aggressive brain cancer. This means the trial is on track to read out topline results in 2-3 months from now.

FG001 is a fluorophore targeting uPAR, which is a cancer specific target expressed extensively in most solid cancers. The fluorophore has the same spectral specifications as indocyanine green, which is already approved, and this means FG001 can be used on current imaging equipment without adaptation. It is administered into a patient's vein prior to surgery and lights up the cancer during surgery, helping to guide the surgeon in removing all cancer while sparing healthy tissue.

The controlled, randomized, multi-center phase IIb trial (FG001-CT-001) investigates the effect of FG001 in guiding surgery of patients with aggressive brain cancer and compares FG001's effect compared to 5-ALA and white light. The patients are randomized in 1:1 between FG001 and 5-ALA. FG001 and 5-ALA are compared to white light in their respective arm with the patients as their own control. The trial was based on the highly promising results from a phase I/IIa trial in the same indication, where 100% **[A1]** of the biopsies from patients treated with FG001 illuminated cancer.

With recruitment completed, the topline results of the phase IIb trial are expected in 2-3 months and will be conducted with analysis of biopsies and MRI scans. These analyses are blinded and initiated after last patient is enrolled and treated.

"Completion of recruitment and treatment in this phase IIb trial of FG001 in brain cancer is an important milestone for FluoGuide. The team has worked with particular dedication in moving our lead product towards market in its first indication and I am excited to see the results, which we expect later this year, and to build this into the design of the phase III trial. This continues FluoGuide's strong clinical progress and we also anticipate topline data from the phase IIa trial of FG001 in head & neck cancer in H2 2023, as we aim to bring a significant improvement to patients undergoing cancer surgery," says Morten Albrechtsen, CEO of FluoGuide.

The main aim of this phase IIb trial is to generate the required data to inform design of a phase III trial of FG001 in aggressive brain cancer, and it is not powered to demonstrate significant superiority or non-inferiority of any of FG001, white light or 5-ALA.

White light means that no product is used to guide the surgeon in removing the aggressive brain cancer. 5-ALA is the only approved imaging agent in the world, including Europe and US, for guiding surgery of aggressive brain cancer (grade III and IV glioma). Hospitals around the world use either white light – ie nothing - 5-ALA, or an off-label product, which has not been approved for guiding brain surgery without clinical documentation for effect and safety accepted by regulatory agencies. FG001 has several technological advantages over 5-ALA, such as being based on near infrared light which gives deeper visibility (1-2 cm versus 1-2 mm) and hence an anticipated higher chance of detecting cancer which is located deeper in tissue.

Patients included in the trial were diagnosed with suspected high-grade glioma where the surgeon expected to be able to make a complete removal of the tumor. The 24 patients were equally randomized between FG001 and 5-ALA. The primary endpoint is the proportion of patients who benefit from the imaging agent, measured by removal of more of the cancer at the end of surgery.

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About FluoGuide
FluoGuide takes precision surgery to the next level improving the outcome for cancer patients. The Company's lead product, FG001, is designed to improve surgical precision by illuminating cancer cells intraoperatively. This improved precision enabled by FluoGuide's products is expected to have a dual benefit – it reduces both the frequency of local recurrence post-surgery and lessens surgical sequelae. Ultimately, this improved precision will improve a patient's chance of achieving a complete cure and will lower system-wide healthcare costs. The Company has published key results on the efficacy of FG001 as well as showing it was well tolerated and safe from a proof-of-concept clinical study (phase I/IIa) in patients with aggressive brain cancer (high grade glioma) that undergo surgery. A phase IIb trial in aggressive brain cancer is ongoing to obtain valuable information to design the phase III trial. This IIb trial has completed patient enrollment and treatment, and data complication is ongoing. In addition, FluoGuide has

demonstrated effect of FG001 in lung and head & neck cancer, topline and positive interim result, respectively. A trial in meningioma and glioma is commencing.

FluoGuide is listed on Nasdaq First North Growth Market, Stockholm under the ticker “FLUO”.

Read more about FluoGuides pipeline, technology, and upcoming events on **www.fluoguide.com**

Attachments
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