PRESS RELEASE
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FluoGuide announces FG001 meets primary endpoint in phase IIb trial in aggressive brain cancer

- **All patients (12/12) receiving FG001 had additional cancer detected by optical guidance**
- **FG001 was safe and well tolerated in all patients**

Copenhagen, Denmark – FluoGuide A/S ("FluoGuide" or the "Company"), a pioneer in the cutting-edge field of precision cancer surgery, today announced positive topline efficacy and safety results in the phase IIb trial with the lead product FG001 for guiding surgery in aggressive brain cancer (high-grade glioma).

"I am pleased with this first result of FG001 efficacy in aggressive brain cancer. Here is a promising drug and we should now define the best use of it for the benefit of our patients" says Jane Skjøth-Rasmussen, MD, PhD, Chief Physician in the Department of Neurosurgery at Rigshospitalet, Copenhagen, Denmark and Principal Investigator of the trial.

The controlled, randomized, multi-center phase IIb trial (FG001-CT-001) investigated the effect of FG001 in guiding surgery of patients with aggressive brain cancer and compared FG001's effect to 5-ALA. The patients were randomized 1:1 to FG001 or 5-ALA. Fluorescence-guided surgery using FG001 or 5-ALA were compared to white light surgery with each patient serving as its own control. The trial was not designed to show statistical difference (superiority, non-inferiority). The results are used to plan further clinical development.

The topline results are:

- All patients receiving FG001 (12/12) or 5-ALA (12/12) had additional cancer detected by optical guidance, showing FG001 was superior to white light
- FG001 was safe and well tolerated with 2 mild (grade 1) related adverse events
- FG001 lit up 12/12 patients' cancer with a tumor to background ratio (TBR) larger than 2
- No statistically significant differences were observed between FG001 and 5-ALA in histopathology (sensitivity, specificity, negative predictive value and positive predictive value) or gross total resection (GTR) measured on MRI
- Pharmacokinetics of FG001: T1/2 was 13 hours and Cmax was 9.35 mg/L

FG001 is a fluorophore targeting uPAR, which is a cancer-specific target expressed extensively in most solid tumors. It is injected 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 fluorophore has the same spectral specifications as indocyanine green (ICG), which is an approved compound used clinically. Accordingly, FG001 can be visualized with ICG compatible imaging systems.

"These results are in line with our expectations of a safe and effective drug and the data generated will be used for the optimal design of the next stage clinical development. We have

positive phase II data on FG001 in three indications – aggressive brain, head & neck and lung cancers – which provide multiple options for routes to market," says Andreas Kjaer, Chief Scientific Officer of FluoGuide.

"FluoGuide has reached a major landmark in its development. The positive completion of this phase IIb trial in brain cancer following the recent U.S. Orphan Drug Designation in the same indication, sets the stage for further clinical development of FG001 and for defining our strategy towards commercialization," says Morten Albrechtsen, Chief Executive Officer of FluoGuide.

Tomorrow, Andreas Kjaer, CSO and Morten Albrechtsen, CEO will present more details of the published data at Redeye. Questions are welcome before end of Monday to either Christian Binder (**christian.binder@redeye.se**) or **ir@fluoguide.com**.

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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 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 clinical trials in patients with aggressive brain cancer (high-grade glioma) that undergo surgery. In addition, FluoGuide has demonstrated the effect of FG001 in lung and head & neck cancers.

For more information on the Company, please visit **www.fluoguide.com**

This information is information that FluoGuide A/S is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-11-13 08:35 CET.

Attachments
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