PRESS RELEASE
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FluoGuide receives FDA Orphan Drug Designation for FG001 in high-grade glioma

- **Orphan status applies to visualization of malignant tissue during surgery**
- **Orphan Drug Designation facilitates the development of treatment options for rare disorders**
- **Topline results of phase IIb trial in high-grade glioma expected before end-November**

Copenhagen, Denmark – FluoGuide A/S (OMX: FLUO "FluoGuide" or the "Company"), a pioneer in the cutting-edge field of precision cancer surgery, is pleased to announce its lead asset FG001 has received Orphan Drug Designation from the U. S. Food and Drug Administration (FDA) as an optical imaging agent for the visualization of malignant tissue during surgery for high-grade glioma.

The FDA's Office of Orphan Products Development grants orphan drug designation to FG001 to support the development of this diagnostic agent for the management of malignant glioma as a rare disorder affecting fewer than 200,000 people in the U.S. Orphan Drug designation provides certain benefits, including market exclusivity upon regulatory approval, exemption of FDA application fees, and tax credits for qualified clinical trials. The designation applies for use of FG001 in the most aggressive gliomas, classified as grades III and IV by the World Health Organization (WHO).

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 cancer while sparing healthy tissue.

The granting of orphan designation by the FDA is important and may simplify FG001's path towards market approval and can provide significant benefits in conducting clinical trials, as well as during commercialization. We have completed enrollment and treatment in our phase IIb clinical trial of FG001 and are now looking forward to top line results, which we expect by the end of November. We are now discussing plans for next stage clinical development of FG001 in aggressive brain cancer with regulators, so we can ensure the most effective route to approval, supported by the necessary data," says Morten Albrechtsen, CEO of FluoGuide.

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 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% of the biopsies from patients treated with FG001 illuminated cancer. The trial is not powered to demonstrate statistical significance between any of FG001, white light or 5-ALA.

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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**

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 2023-10-03 10:34 CEST.

Attachments
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