# FluoGuide has enrolled the first patient in the phase IIb trial in aggressive brain cancer

**Copenhagen, Denmark, 20 October 2022 – FluoGuide A/S ("FluoGuide" or the "Company") is pleased to announce that the first patient has now enrolled in the phase IIb clinical trial with FG001 in aggressive brain cancer.**

In the phase IIb trial, FG001 is being tested 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 will be randomized 1:1 against Gliolan (5-ALA). The primary endpoint of the phase IIb trial measures the proportion of patients with relevant change in clinical strategy, which is aligned with regulatory position for pivotal trials in fluorescence guided surgery. The trial aims to demonstrate non-inferiority to 5-ALA, and the result will be used to calculate the number of patients needed for the phase III trial. The trial is not powered to show significance.

The patients are being recruited at two sites: Linköping, Sweden and Copenhagen, Denmark. The results of the phase IIb trial are expected to be available in H1 2023.

The phase IIb trial follows the highly promising phase I/IIa results in aggressive brain cancer (high grade glioma) that FluoGuide announced in April 2022. 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) showed cancer illumination with high sensitivity and specificity.

Morten Albrechtsen, CEO says: "*I am very pleased that the important IIb trial in patients with aggressive brain cancer is progressing as planned*"".

**For further information, please contact:**

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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 has demonstrated efficacy of F001 as well as it to be well tolerated and safe in a proof-of-concept clinical study (phase I/II) in patients with high grade glioma undergoing surgery. FG001 is currently in phase IIb in high grade glioma. FluoGuide is also exploring FG001 in three other severe cancer indications, namely lung (in phase IIa), head & neck cancer (in phase IIa), meningioma and low grade glioma. 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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