FluoGuide receives permission to start phase IIb trial in aggressive brain cancer

Copenhagen, Denmark, 30 August 2022 – FluoGuide A/S ("FluoGuide" or the "Company") is pleased to announce that the company now has received the permission to start the phase IIb clinical trial with FG001.

FluoGuide has now received approval from the Danish Ethical Committee and the trial can start in Denmark.

FluoGuide announced in April FG001's highly promising results in aggressive brain cancer (high grade glioma) following its phase I/IIa trial. 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) that illuminate contained cancer.

Based on these strong results, FluoGuide has decided to expand the design of the phase IIb trial. FG001 will now be 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 (compared to the originally planned 12 patients), will be randomized 1:1 against Gliolan (5-ALA). The design of the phase IIb trial aims at non-inferiority to 5-ALA on the primary endpoint. The trial is not powered to show significance, and the result will be used to calculate the number of patients needed for the phase III trial.

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

Morten Albrechtsen, CEO says: "*We are very pleased to receive the approval from the Danish Ethical Committee faster than expected to be able to start this important IIb trial in patients with aggressive brain cancer*"

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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 has demonstrated efficacy of F001 as well as it to be well tolerated and safe in the proof-of-concept clinical study (phase I/II) in patients with high grade glioma undergoing surgery. FluoGuide has decided to explore FG001 in three other severe cancer indications, namely lung, head & neck cancer, 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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