FluoGuide releases positive interim result of FG001-CT002, a phase IIa trial evaluating FG001 in patients with non-small cell lung cancer (NSCLC) undergoing surgery

Copenhagen, Denmark, 6 November 2022 – FluoGuide A/S ("FluoGuide" or the "Company") is pleased to announce that FG001 lights up in 5 out of 7 patients in an interim evaluation in the ongoing phase IIa trial in non-small cell lung cancer (NSCLC)

FluoGuide has evaluated data from 8 patients in the exploratory phase IIa trial in patients with non-small cell lung cancer (NSCLC) undergoing surgery. FG001 was well tolerated in all 8 patients.

One patient was not diagnosed with non-small cell lung cancer (NSCLC) but lung metastases from bladder cancer. In 5 of the 7 patients with NSCLC, FG001 lighted up the cancer. FG001 did also light up in the patient diagnosed with metastases from bladder cancer, however, this patient was excluded from the analysis as the patient did not have NSCLC.

Detection of light was made from the tissue identified macroscopically as cancer by the surgeon. At the end of the trial, the pathologists will histologically examinate the tissue that lights up to determine if the tissue samples contain cancer or normal tissue. Although this is an encouraging interim result, it is important to state that the final conclusion regarding the effect of FG001 will not be reached until after the histology examinations have been completed at end of the trial. The optimal dose in patients with NSCLC undergoing surgery is not yet established, which also means that the result in the optimal dose is anticipated to be similar or better.

Moving forward, the time of administration of FG001 prior to surgery will be investigated to select the optimal dosing in patient with lung cancer (NSCLC) undergoing surgery. The primary endpoint is sensitivity defined as the relative number of patients, whose cancer is illuminated by FG001. The trial is conducted at the Department of Cardiothoracic Surgery at the University Hospital, Rigshospitalet, in Denmark. The top line result is expected in H1 2023.

FluoGuide has selected lung cancer due to a high unmet need, evidence of uPAR overexpression and surgeon familiarity with using optical endoscopes during surgery.

"We are very pleased to see light with FG001 in lung cancer, supporting FG001 as a relevant product for guiding surgery beyond aggressive brain cancer" says Morten Albrechtsen, CEO and continues *"It is important to understand that the trial is exploratory and aims to establish the dose and time of FG001 administration prior to surgery in patients with lung cancer."*

For further information, please contact:

Morten Albrechtsen, CEO
FluoGuide A/S
+45 24 25 62 66
ma@fluoguide.com

Certified Adviser:

Svensk Kapitalmarknadsgransking AB
Phone: +46 70 755 95 51
E-mail: ca@skmg.se

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 shown it to be well tolerated and safe in the ongoing 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, meningioma and low grade glioma. FluoGuide is listed on Nasdaq First North Sweden under the ticker "FLUO".

About Lung cancer

Globally, 2.2 million individuals are diagnosed with lung cancers annually and 1.8 million patients die every year with lung cancer. It is the second most commonly diagnosed type of cancer and the leading cause of cancer death in 2020. Today, lung cancer is typically diagnosed when the cancer already has spread being an important reason for its high mortality. Clinical trials have shown that screening programs increase the survival by identifying patients with lung cancer earlier. These trials have demonstrated that screening leads to increased number of patients diagnosed with early-stage cancer - approx. 80% compared to approx. 40% in non-screened population, and hence improving the survival for patients diagnosed with lung cancer. This is the motivation for implementing screening programs for patients at high risk of lung cancer. Accordingly, implementation of screening programs for lung cancer are underway in major countries like USA.

For patients diagnosed with localized or loco-regional cancer, which means the cancer has not spread outside of the lung, surgery is an essential treatment for intended complete removal of the cancer. Identifying cancer early will therefore increase the number of patients relevant for surgery and the demand for a product that can guide the surgeon is likely to follow.

Ref: Sung et al, "Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries", CA Cancer J Clin 2021;71:209-249; and The National Lung Screening Trial Research Team. (2011). Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening. N Engl J Med, 365(5), 395–409.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 954904.

For more information on the Company's uPAR technology platform and our pipeline please visit our home page www.fluoguide.com