FluoGuide has submitted a Clinical Trial Application (CTA) to the Danish Medicines Agency to initiate phase II trial with FG001 in lung cancer

Copenhagen, Denmark, 22 December 2021 – FluoGuide A/S ("FluoGuide" or the "Company") is delighted to announce that the company has submitted a CTA to initiate the phase II trial in lung cancer. The clinical trial will be conducted at Rigshospitalet in Denmark.

Following approval from the Danish Medicines Agency, FluoGuide will initiate the phase II trial in lung cancer in collaboration with Department of Cardiothoracic Surgery at the University Hospital, Rigshospitalet, in Denmark.

The phase II trial is designed to enrol up to 24 patients with non small cell lung cancer (NSCLC). The primary endpoint is sensitivity defined as the relative number of patients, where FG001 lights up the cancer. FluoGuide expects the patients to be enrolled during 2022 and top line results to be available late 2022. The trial includes 2 interim evaluations after 8 and 16 patients, respectively.

FluoGuide has selected lung cancer as the second indication to investigate after malignant glioma. The selection of lung cancer is due to a high unmet need, evidence uPAR being overexpressed in the lung cancer and that the surgeons are familiar with using optical endoscopes during surgery.

"Lung cancer is the second most frequent form of cancer worldwide and the deadliest. Early detection and lung sparring minimal invasive surgery is key for survival and quality of life" says principal investigator and professor René Horsleben Petersen, MD PhD and continues*: "This requires precise surgery, and I have a great expectation of studying the effect of FG001 in guiding future lung cancer surgery."*

Due of the flare up of the ongoing COVID-19 pandemic, it may result in delay of regulatory approval and thus the patient inclusion.

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 is has demonstrated early evidence of efficacy of F001 as well as 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 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