PRESS RELEASE
07 June 2023 09:00:00 CEST

FluoGuide announces positive topline results from phase IIa trial of FG001 in lung cancer

FluoGuide A/S ("FluoGuide" or the "Company"), a Danish biotech company that pioneers precision cancer surgery, is pleased to announce positive topline results from a phase IIa trial of its lead product FG001 in lung cancer. FG001 was shown to illuminate the majority of the patients' lung tumors and was well tolerated in all patients. These results support further clinical development in this indication.

- FG001 was shown to light up lung cancer in 73% of the patients and was safe and well tolerated
- This marks the third cancer indication for which FG001 shows efficacy, underscoring its potential for broad applicability
- Further data in brain and head & neck cancers are expected in H2-2023
- CEO and CSO to host presentation on results on lung cancer results on Thursday 8 June at 09.00 AM CEST, distributed by Redeye

FG001 is a fluorophore targeting uPAR, which is a cancer specific target expressed extensively in most solid types of 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 injected into a patient's vein prior to surgery and lights up the cancer during surgery, helping to guide the surgeon in removing all cancer while sparing healthy tissue.

A total of 15 patients with non-small cell lung cancer (NSCLC), undergoing lung surgery (lobectomy), completed the trial, with a gender distribution of 9 females and 6 males a weight range of 50-92 kg and age range of 50-83 years. The primary objective was to evaluate FG001 for the detection of NSCLC.

The efficacy of FG001 (as a tumor imaging agent) was examined by sensitivity verified by the contrast expressed as tumor-to-background ratio (TBR) showing that 11/15 (73%) patients had a clinically relevant TBR value. The TBR values were measured under conditions with varying amounts of lung tissue covering the tumors, thus attenuating the signal from FG001. If the tumors had been uncovered, the proportion lightening up would likely have been even higher.

The first lung cancer cohort (7 patients) received 36 mg administered in the evening before surgery. The second cohort (8 patients) received 36 mg administered 2 days prior to surgery. The ability of FG001 to illuminate the tumors was similar in the two cohorts, indicating a broad time window for administration of FG001.

FG001 was shown to be safe and well tolerated in all patients. The pharmacokinetic (PK) profile for FG001 was determined in lung cancer patients and the half-life (t1/2) was found to be comparable with that of aggressive brain cancer (high grade glioma).

"We are excited that FG001 has been shown to light up tumors in lung cancer and that we have data showing its efficacy in three cancer indications, underscoring the broad applicability of our lead product. These results are encouraging for the continuation of clinical development in lung cancer and we are looking forward to further data from our FG001 trials in head-and-neck and aggressive brain cancer in the near future. We will prepare next steps for development of FG001, considering data from all these studies and potential partner interest, over the coming months. We look forward to bringing our promising product towards market, with the aim of improving surgery outcomes for cancer patients," says Morten Albrechtsen, CEO of FluoGuide.

"*It is great to see that FG001 lighted up tumors, which is encouraging for its further development into a clinically useful tool to improve surgery and outcome for the lung cancer patients,"* says René Horsleben Petersen, Professor and Chief Thoracic Surgeon at Rigshospitalet and Principal Investigator of the lung cancer study.

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, 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.

"I am pleased to see that the Ministry of Health has approved a pilot project in lung cancer screening in Denmark. The earlier the lung cancer is diagnosed, the better is the prognosis for patients" says René Horsleben Petersen, Professor and Chief Thoracic Surgeon at Rigshospitalet and Principal Investigator of the lung cancer study, and continues: *"Early identification of lung cancer promotes precision surgery as an important factor in lung cancer treatment,"*

FluoGuide expects enrollment of the last patient in its phase IIb trial of FG001 in aggressive brain cancer (high grade glioma) during the summer of 2023 and the topline result approximately 2 months after that. Interim results from the phase IIa trial of FG001 in head & neck cancer are expected in H1 2023.

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FluoGuide CEO Morten Albrechtsen and CSO Andreas Kjaer will present the lung cancer results on Thursday 8 June at 09.00 AM CEST, distributed by Redeye. Questions are welcome at **ir@fluoguide.com** or to Christian Binder, analyst at Redeye.

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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. The 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, 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 being well tolerated and safe in the completed proof-of-concept clinical study (phase I/IIa) in patients with aggressive brain cancer (high grade glioma) undergoing surgery. A phase IIb trial in aggressive brain cancer is ongoing to obtain valuable information to design the phase III trial. In addition, FluoGuide currently explores FG001 lung and head & neck cancer, and a trial in meningioma and low grade glioma is commencing. FluoGuide is listed on Nasdaq First North Growth Market, Stockholm 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**

Attachments
FluoGuide announces positive topline results from phase IIa trial of FG001 in lung cancer