Press release

FluoGuide selects lung cancer as the next indication for FG001 and will initiate phase II trial in the beginning of 2022

Copenhagen, Denmark, 10 November 2021 – FluoGuide A/S ("FluoGuide" or the "Company") is delighted to announce that the company has selected lung cancer as the second clinical indication for FG001.The clinical trial will be conducted at Rigshospitalet in Denmark during 2022.

FluoGuide now broadens the clinical potential for fluorescence-guided cancer surgery with FG001 to include the first prevalent indication – lung cancer. FluoGuide will initiate the phase II trial in collaboration with Department of Cardiothoracic at Rigshospitalet in Denmark. As announced in October 2021, FG001 was safe and well tolerated in 27 patients with high grade glioma enabling the expansion into other cancer indications.

The phase II trial is designed to enrol up to 24 patients. The primary endpoint is sensitivity defined as the 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.

FluoGuide has selected the lung indication mainly due to: A high unmet need, evidence of a high concentration of uPAR expression in the lungs and that surgeons are familiar with using endoscopes during surgery.

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.

"The selection of the lung as the second indication for FG001 is a very important step for us" says Morten Albrechtsen, CEO and continues *"We have seen early positive data in our brain cancer trial, and by starting in a more prevalent indication, as lung cancer, we are adding significant value to our clinical potential. Furthermore, in the ongoing trial we saw a lung cancer metastasis lighting up just as well as the glioma cancers. This is very encouraging"*

For further information, please contact:

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References

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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 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 FG001

FluoGuide’s lead product, FG001, is designed to allow surgeons to clearly differentiate cancer from normal tissue during surgery through a novel uPAR-targeted luminescent technology. The increased precision enabled by FG001 decreases the risk of leaving malignant cells behind, reducing the risk of local recurrence, and maximizing outcomes. FG001 is currently in Phase I/II for aggressive brain cancer. The phase I part has been concluded with satisfactory safety and tolerability, and FG001 has also shown early evidence of efficacy.

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