Press release

FluoGuide acquires rights to photothermal therapy using FG001

Copenhagen, Denmark, 9 March 2021 – FluoGuide A/S ("FluoGuide" or the "Company") is pleased to announce that the Company has acquired worldwide exclusive rights to use FG001 for photothermal therapy in combination with dedicated light source.

Photothermal therapy is an extension of photodynamic therapy, in which a photosensitizer (e.g. FG001) is excited with light of a specific wave length. This light excitation brings a molecule, such as FG001, to an excitation state where it releases energy in the form of heat. Under optimal conditions, the generated heat will kill cancer cells while sparing normal tissue.

Photothermal therapy with FG001 has already demonstrated a clear effect in preclinical models and shown to be safe to normal tissue in these models.

The combination of FG001 and its binding to uPAR expressing cancer cells potentially gives a very broad use of FG001 for photothermal therapy, including some of the most prevalent cancer types. Near Infered Light (NIR) is used to excite FG001, which has the advantage over visible light of penetrating deeper into the tissue and therefore has potential to precisely destroy cancer tissue 1-2 cm into the tissue while sparing surrounding healthy tissue. In comparison will visible light only penetrates approximately 1-2 mm into the tissue.

With the obtained exclusive rights, FluoGuide can now not only guide surgery through FG001, but potentially also help the surgeon to destroy hidden cancer cells, or superficial cancer that cannot be removed, e.g. because it has invaded a vital stucture in, for instance, the brain.

The exclusive rights has been aquired from Copenhagen University Hospital (Rigshospitalet). The underlying patent application to use FG001 for photothermal therapy was filed by Rigshospitalet and will be published during 2021. It will, if granted, not expire until 2039. The acquisition of the exclusive rights will not affect FluoGuide's cost budget for 2021, during which the photothermal capabilities will be further evaluated in pre-clinical studies and an optimal development path planned. Future payments to Rigshospitalet will be through royalties as a low single digit percentage of sales by FluoGuide. There will be no cash payments in 2021 by FluoGuide to Rigshospitalet, but FluoGuide will take over the patent costs.

"Based on the academic, preclinical studies performed so far, the technology seems promising. It is indeed exciting that FG001, in addition to guiding the surgeon by lightening up the cancer, also can be used in photothermal therapy," says Andreas Kjær, Chief Scientific Officer of FluoGuide.

"*It is potentially a promising technology that we are looking forward to explore further with additional preclinical studies and hopefully later also test in clinical studies,*" says Grethe Nørskov Rasmussen, Chief Development Officer and continues: *"This is a potential add-on benefit of FG001 that will not affect our current focus on the development and approval of FG001 in guiding surgery in patients with glioblastoma as fast as possible.*"

"Although at an early stage, the acquisition of exclusive rights is important in order to increase the value FluoGuide can provide to cancer patients and society at large, while supporting our vision to optimize surgical outcomes," says Morten Albrechtsen, CEO, and continues: "*The value of this concept is potentially very high but it is important to bear in mind that the development is also more complicated compared to what FG001 is currently developed for – guiding oncological surgery by lightning up cancer tissue.*"

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FluoGuide A/S is obliged to publish this information in accordance with the EU Market Abuse Regulation. The information was provided by the contact person set out above for publication on 9 March 2021.

About FluoGuide
FluoGuide's primary focus is to maximize surgical outcomes in oncology. The Company's first 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 conducting a proof-of-concept clinical study (phase I/II) to demonstrate the effect of FG001 in patients with high grade glioma. FluoGuide is listed on Nasdaq First North Growth Market Stockholm under the ticker "FLUO".

About high grade glioma and glioblastoma
The first indication for FG001 is glioblastoma but FG001 has potential in several indications. Almost all patients with glioblastoma have a cancer expressing uPAR. A total of 60,000 patients gets high grade glioma and more than 30,000 patients are diagnosed with glioblastoma annually in the EU and the U.S. Approximately 8-12 % of the patients are children. The prognosis for individuals with glioblastoma is very poor. Approximately 50 % of the patients die within 14 months and only 5 % are alive after five years from diagnosis. Precise removal of glioblastoma tumors is very difficult as the brain contains vital structures often near the cancer. Local reoccurrence of glioblastoma is common and happens in almost 100 % of all patients.

About the clinical trial
The ongoing first phase of the clinical phase I/II trial with the objective to test the safety and determine the optimal dose of FG001 in patients with high grade glioma undergoing neurosurgery, is designed with three patients in each dose group ('cohorts'), with up to eight dose groups in total resulting in up to 24 patients in total for the first phase. The second phase will be based on the optimal dose selected in the first phase of the trial. The second phase includes twelve patients resulting in the total number of patients in the entire trial of up to 36 patients in total.

The dose escalation committee's role is to evaluate the result after each dose level and only if the dose escalation committee identifies no issues they will give clearance to proceed to the next dose level. The commitee consists of three people, the Principle Investigator, an independent anesthesiologist and a medical doctor from FluoGuide.

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