Selected as best IPO in 2019

Press release

FluoGuide gets green light to proceed to second dose level with FG001 in the ongoing clinical phase I/II trial in patients with high grade glioma

Copenhagen, Denmark, 17 December 2020 – FluoGuide A/S ("FluoGuide" or the "Company") is pleased to announce that the dose escalation committee has approved that administration of the second dose level can now be initiated in the ongoing trial evaluating safety and effcicacy of FG001 in patients with high grade glioma undergoing neurosurgery.

Evaluation of the results from the first dose level of FG001, including data from three patients, has been finalized and reported to the dose escalation committee. The dose escalation committee has earlier today been given green light to proceed and enroll the first patient on the second dose level.

The first dose was chosen substantially below the expected optimal dose as a safety precaution when dosing a new product to humans for the first time. It is nevertheless encouraging that no safety issues were identified, which is in line with the result of the pre-clinical program. It is important to underline that the first phase of the trial (up to 24 patients) must be completed and analyzed before any conclusions on tolerability and safety profile can be drawn.

Despite the very low dose tested in this first dose group of patients, light was detected in two out of the three patients. Although this is encouraging, it is important to state that it is not yet possible to conclude anything on the effect of FG001 on the basis of these findings. Additional results from patients dosed with higher levels of FG001 are needed to evaluate the robustness and further analysis is thereafter needed to confirm that the tissue that lights up is actually cancer and tissue that does not light up is free of cancer, which is determined by the patologist at the end of the first phase of the trial.

The clinical phase I/II trial initiation has taken slightly longer than anticipated. However, the set-up is now fully implemented and the following dose groups are expected to be completed faster assuming no impact from the ongoing COVID-19 pandemic takes place. The following timeline is anticipated by FluoGuide: (i) Middle of 2021: Result of first phase (safety and selection of optimal dose); and (ii) Second half of 2021: Efficacy result from the second phase, including estimation of the potential magnitude of benefit of FG001 in guiding surgery of patients with high grade glioma.

"*We are very pleased to see the trial advancing so well, which has only been possible due to hard work delivered by the team at Rigshospitalet, FluoGuide and many others"*, says Morten Albrechtsen, CEO, and continues *"We need to interpret the initial results with caution, but it is encouraging".*

For further information, please contact:
Morten Albrechtsen, CEO
FluoGuide A/S
+45 24 25 62 66
ma@fluoguide.com

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 17 December 2020.

Press release

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 US. 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 due 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, with up to 8 dose groups in total resulting in up to 24 patients in total for the first phase. The second phase will based on the optimal dose selected in the first phase of the trial evaluate the efficacy of FG001 in guiding neurosurgery. The second phase includes 12 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.

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.

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