FluoGuide

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Press release

FluoGuide announces regulatory approval from Danish Medicines Agency to commence Phase I/II clinical trial with FG001 in guiding surgery of high grade glioma (including glioblastoma)

Copenhagen, Denmark, 3 September 2020 – FluoGuide A/S ("FluoGuide" or "the Company") is pleased to announce that the company has received regulatory approval for the first clinical phase I/II trial. It is the first time that our lead uPAR targeting product - FG001 - will be used to guide oncology surgery.

FluoGuide appreciates that the Danish Medicines Agency wants to conduct an audit of the clinical trial site at Rigshospitalet to provide priority to patients safety as the clinical trial is a first-in-man with a new chemical entity. The first patient is therefore expected to be included in the study ultimo October. The outlook of the clinical trial remains, otherwise, as described in the latest quarterly report (page 6).

"This certainly marks an important milestone for FluoGuide and we look forward to start the clinical trial and advance our lead product FG001. The trial has no long-term follow-up as the end-point is FG001's effect in detecting cancer during surgery and we will therefore regularly report on the results of this trial during 2020", says Morten Albrechtsen, CEO of FluoGuide A/S

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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 above for publication on 3 September 2020.

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, these improvements will improve a patient's chance of achieving a complete cure and will lower system-wide healthcare costs. The Company is undertaking a proof-of-concept clinical trial (phase I/II) to demonstrate the effect of FG001 in patients with glioblastoma.

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