PRESS RELEASE
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FluoGuide provides strategic update and outlines development plans towards commercialization of FG001

- **Strong phase II data on FG001 in three indications: brain, head & neck, lung cancers**
- **Assessing potential of photothermal therapy in aggressive brain cancer**
- **Clinical trial to be used for registration of FG001 in fluorescent guided surgery of aggressive brain cancer expected to start in 2025**
- **Phase II trial in head & neck cancer, which offers a range of opportunities with significant value each, in planning**
- **Pursuing multiple partnering opportunities to accelerate commercialization**
- **Focus on development in brain and head & neck cancers**
- **Presentation with Redeye on Wednesday, January 10**

Copenhagen, Denmark – FluoGuide A/S ("FluoGuide" or the "Company"), a pioneer in the cutting-edge field of precision cancer surgery, is pleased to provide an update on its corporate strategy and plans for further clinical development and commercialization of its lead product FG001.

FluoGuide has obtained clinical proof of concept of FG001, a fluorescent molecule targeting the cancer specific uPAR receptor, which lights up cancer cells to improve outcomes of surgery. This includes positive phase II data across three indications: aggressive brain cancer (high grade glioma), head & neck cancer, and lung cancer. FG001 has been granted U.S. Orphan Drug Designation in aggressive brain cancer (high grade glioma).

Based on this strong foundation, FluoGuide plans to expand the scope of application of FG001 and advance its development toward approval in aggressive brain cancer.

Photothermal therapy (PTT) using FG001 has the potential to selectively eliminate cancer cells with a notable sparing of surrounding normal tissue and represents a significant commercial opportunity. FluoGuide has decided to evaluate FG001's potential in PTT in aggressive brain cancer.

FluoGuide plans to advance FG001 into the first clinical trial for registration of FG001 in fluorescence guided surgery (FGS) of aggressive brain cancer, based on feedback from the U.S. Food and Drug Administration (FDA). The benefit of potentially including a treatment effect from PTT in the development of FG001 in this indication will offer considerable potential additional value, significantly reducing the combined development costs for FGS and PTT, which will more than outweigh a delay to the start of regulatory trial.

FluoGuide also aims to initiate a phase II trial in head & neck cancer as it offers several valuable positionings of FG001 for patients as well as several partnering opportunities. Hence FluoGuide will explore partnering options across indications with manufacturers of imaging systems, with the aim of accelerating and expanding the commercial opportunities while retaining the maximum value for its shareholders.

"FluoGuide made excellent progress in 2023 and now we are setting out our plans to improve outcomes of surgery for cancer patients. We will expand the scope of our lead product FG001 through increasing both the number of patients we assist and the benefits they experience, while improving the probability of success by mitigating risks, and thereby enhancing shareholder value," says Morten Albrechtsen, CEO of FluoGuide.

"Specifically, we are examining the possibility of expanding the development trials of FG001 in brain cancer to include photothermal treatment of cancer, as well as guiding surgery. This could bring considerable benefit to patients and is a considerable potential market, and we engage in dialogue with regulators on the design of this trial, which is expected to start in 2025. In parallel, we are preparing a phase II trial in head & neck cancer, which provides a wide range of opportunities to generate value. These plans build on a position of strength, with robust clinical data in hand from three indications and a comfortable financial position with a low fixed rate of cash burn, which allows us to optimize funding and partnerships."

FluoGuide is also advancing the development of CMC (Chemistry, Manufacturing, and Controls) and non-clinical development to allow a timely regulatory package for submission of the New Drug Application (NDA) for FG001.

Brain cancer
Regulatory clinical documentation for the NDA in the first indication, aggressive brain cancer, is expected to include 300 patients to provide evidence of safety. As this total number can be pooled from across different trials and as pivotal trial in aggressive brain cancer would likely require fewer patients, it gives flexibility in the design of the trials. Including PTT in the regulatory trial is anticipated to require a slight increase in terms of number of patients and duration compared to the clinical program necessary for supporting FGS only. FluoGuide is discussing the design of the trial with regulators and is also examining ways to increase support for reimbursement and coverage by insurers and providing more flexibility in timing of FG001 administration in this indication. The potential upside of assessing PTT means that development in fluorescent guided surgery is deferred by approximately half a year, with the first regulatory trial anticipated to start in 2025. A delay that is more than set off by the potential added value of PTT.

Head & neck cancer
FluoGuide intends to initiate a phase II trial with FG001 in head & neck cancer, to explore various regulatory endpoints, imaging systems and partnerships, providing the basis for future regulatory clinical trials. This indication offers a wide variety of value propositions for FG001, while significantly reducing risk for FluoGuide, as it brings exposure to all remaining types of imaging

systems. It thereby complements development in brain cancer and paves the way for potential expansion into other indications, as well as significantly broadening partnership opportunities.

Other indications
FluoGuide intends to focus resources on development of FG001 in brain and head & neck cancers. It will continue to evaluate the commercial opportunity in lung cancer and other indications but has no present plans for clinical trials in these indications.

Presentation
In relation to the strategic update, Morten Albrechtsen, CEO, and Andreas Kjær, CSO, will be participating in an interview with Redeye on Wednesday 10 of January. Questions are welcome before end of Tuesday 9 of January to either Christian Binder (**christian.binder@redeye.se**) or **ir@fluoguide.com**. The presentation will afterwards be published on **https://fluoguide.com/investor/presentations/**.

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About photothermal therapy
The effect of combining light and heat is typically named photothermal therapy. If combined with immunotherapy, it is termed photoimmunotherapy.

Indocyanine green (ICG) emits heat when being excited with high power light. It is possible to adjust the power of the light, so it does not heat up tissue without ICG being present. When targeting ICG to cancer within FG001, it becomes possible to destroy cancer with high precision. This can be applied in brain cancer to help the surgeon “cleaning” brain tissue from invaded by cancer cells and thereby saving critical functions (e.g. speech or movement). The result is destroying the cancer cells while preserving the normal tissue and its critical functions.

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 intraoperatively. This 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, this improved precision will improve a patient’s chance of achieving a complete cure and will lower system-wide healthcare costs. FG001 binds to the receptor uPAR being extensively expressed on most solid cancer types. The photothermal potential of FG001 could add a direct treatment effect of FG001 to further benefit for patients with cancer undergoing surgery.

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The Company has published strong results from phase II trials demonstrating the efficacy of FG001 as well as showing it was well tolerated and safe from clinical trials in patients undergoing surgery to remove aggressive brain (high-grade glioma), head & neck and lung cancers.

Based on this strong foundation, FluoGuide expands the scope of application of FG001 and advance the development toward approval in aggressive brain cancer.

FluoGuide is listed on Nasdaq First North Growth Market, Stockholm under the ticker “FLUO”. Read more about FluoGuide’s pipeline, technology, and upcoming events on **www.fluoguide.com**

Attachments
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