

Update on 2025 Outlook and Company progress

Copenhagen, Denmark, 3 July 2025 – FluoGuide A/S ("FluoGuide" or the "Company"), a clinical-stage biotech company focused on precision cancer surgery, is pleased to share an update on the 2025 Outlook and ongoing progress. As part of this update, FluoGuide has refined timing of some milestones - some are progressing ahead of schedule, while others are slightly delayed. There are no changes to the overall development.

FluoGuide has made significant progress during the first half of 2025. Beginning with the Q3 2024 report, we began to forecast milestones for the coming year (2025) to enhance transparency and make it easier to track our progress. In keeping with this approach, we now provide a update on our 2025 outlook and we plan to present the 2026 milestones later in the year. We will also organize sessions in the second half of the year to outline the development path and trial design in greater detail.

"FluoGuide has made substantial progress during the first half of 2025. While this may not yet be reflected in a high number of press releases, the groundwork we are laying is critical to our long-term success – and the momentum is building," said Morten Albrechtsen, CEO of FluoGuide.

The 2025 milestones:

Brain cancer:

a) Submission of an Investigational New Drug (IND) application in the U.S. for a clinical trial to support the registration of FG001 as an imaging agent for guiding surgery in aggressive brain cancer (glioblastoma):

The Company remains on track to submit the IND application in H2 2025 to initiate U.S. clinical trial(s) of FG001 as an imaging agent to guide surgery in patients with aggressive brain cancer (glioblastoma). The trial(s) is intended to support a future New Drug Application (NDA) submission to FDA.

b) Continuing discussions with FDA to finalize the design of the upcoming U.S. clinical trial (s) that will support registration of FG001 as an imaging agent to guide surgery in aggressive brain cancer:

Prior to submitting the IND, FluoGuide plans to consult with FDA and expects to submit a pre-IND meeting request in July. Feedback from the FDA is anticipated by the end of Q3 or early Q4. To de-risk the IND process and enable focused FDA feedback, FluoGuide is preparing a robust pre-IND package that includes detailed information on completed development and proposed plans for remaining data generation. This approach is intended to provide the FDA with a strong foundation for evaluating key components of the IND prior to its submission, and de-risking the regulatory process.

c) Preliminary data from an investigator-initiated trial involving 20 patients with meningioma and low-grade glioma:

The trial, initiated and conducted as an investigator-initiated trial, enrolled 10 patients with meningioma and 10 with low-grade glioma. While meningioma and low-grade glioma are considered benign tumors, they both typically recur after surgery and disabilities last lifelong in those younger patients than patients with glioblastoma. The two indications represent distinct brain tumor indications that could support future expansion of FG001's use beyond glioblastoma.

The principal investigator has submitted the first results from the trial as an abstract to scientific conferences scheduled to take place in the second half of 2025. Although FluoGuide cannot share the data prior to its presentation, this study provides valuable insights that can strengthen the design and execution of FluoGuide's upcoming U.S. clinical trial in glioblastoma.

d) Completion of optimization of FG001 in combination with the laser system in pre-clinical models:

The photothermal effect of FG001, which involves heat-mediated killing of cancer cells, has been confirmed using a laser system that is compatible with use throughout clinical development and potential drug approval. In addition, FG001 is expected to demonstrate a photodynamic effect, in which cancer cells are destroyed through a light-activated chemical process, and this is currently under investigation. These two mode-of-actions represent distinct potential in brain tumor indications, each with its own development path. FluoGuide sees this progress as a potential opportunity to advance its glioblastoma program, expand into additional brain cancer indications, and broaden its footprint in the larger brain cancer market. Further updates on timing, development plans, and expected impact will be provided in H2 2025.

Head and neck cancer:

e) Enrollment of first patient and interim data from first 15 patients (CT-005):

Enrollment is ahead of schedule, even though the first patient was enrolled in April. FluoGuide remains on track to present interim data from the first 15 patients in H2 2025. While enrollment has progressed well so far, FluoGuide notes that enrollment timing can vary.

f) Submission for FDA feedback on a U.S. trial in head and neck cancer:

FluoGuide remains on track to submit for U.S. FDA regulatory feedback in H2 2025 on a trial of FG001 in head and neck cancer. This represents yet another potential indication expansion beyond the current glioblastoma program. Further, an indication with profound partner interest.

Partnering:

g) 1-2 additional partnerships expected in H1 2025:

Earlier this year, FluoGuide entered into an agreement with SurgVision, a Bracco-owned company, as noted in the Q1 2025 report. In the clinical trial evaluating FG001 in oral head and neck surgery, five different imaging systems are being investigated. Two of these systems are from Intuitive Surgical and SurgVision, while the remaining three have not yet been disclosed. FluoGuide expects to announce at least one additional partnership in 2025.

For further information, please contact:

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About FluoGuide

FluoGuide's primary focus is to maximize surgical outcomes in oncology. FluoGuide'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, this improved precision enhances the likelihood of achieving a complete cure and helping to lower healthcare costs. FluoGuide has demonstrated that FG001 is both effective and well tolerated in a proof-of-concept phase I/II clinical study in patients with high-grade glioma undergoing surgery. FluoGuide is also exploring FG001 in three other severe cancer indications: lung cancer (phase IIa), head & neck cancer (phase IIa), and both meningioma and low-grade glioma. FluoGuide is listed on Nasdaq First North Sweden under the ticker "FLUO".

For more information on FluoGuide's uPAR technology platform and our pipeline please visit our home page www.fluoguide.com

Attachments

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