

FluoGuide enrolls first patient in U.S. Phase 2 trial of FG001 in high-grade glioma

Copenhagen, Denmark, 5 October 2026 – FluoGuide A/S ("FluoGuide" or the "Company"), a clinical-stage biotechnology company focused on precision cancer surgery, today announced that the first patient has been enrolled in FG001-CT-006, the Company's U.S. Phase 2 clinical trial of FG001 in patients with newly diagnosed high-grade glioma.

Enrollment of the first patient marks the initiation of FluoGuide's first clinical trial conducted under FluoGuide's U.S. Investigational New Drug (IND) application with the intention to support the future registration of FG001. It represents an important milestone in the Company's advancement of FG001 toward registration in the United States. FG001 has received FDA Fast Track designation as an optical imaging agent for use during surgery in patients with suspected high-grade glioma (WHO Grade 3 or 4).

"The enrollment of the first patient is an important milestone for FluoGuide and reflects our continued progress in executing the U.S. clinical and regulatory development plan for FG001. This study is designed to build the clinical evidence required to support the future registration of FG001 and brings us another step closer to our goal of improving precision and outcomes in cancer surgery," said Morten Albrechtsen, CEO of FluoGuide.

We will provide more information about the trial on an ongoing basis.

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About the FG001-CT-006 trial

FG001-CT-006 is a prospective, multicenter, open-label Phase 2 trial evaluating FG001 as an investigational near-infrared fluorescence imaging agent during surgery in patients with newly diagnosed high-grade glioma. Patients receive a single intravenous dose of FG001 12–19 hours before planned tumor resection, enabling surgeons to use near-infrared imaging during surgery to help visualize tumor tissue and distinguish it from surrounding healthy brain tissue.

The trial will assess the imaging performance of the selected FG001 dose of 0.45 mg/kg and its use in fluorescence-guided neurosurgical tumor resection. Assessments include tumor-to-background tissue contrast during surgery, extent of tumor removal evaluated by MRI within 48 hours after surgery, and central review of imaging and tissue samples. Patients will be followed for six months, including safety monitoring and neurological, functional and quality-of-life assessments.

About FG001

FG001 is FluoGuide's lead product candidate and is designed to bind selectively to uPAR, a target extensively expressed on most solid cancer types. FG001 lights up cancer tissue during surgery and is being developed as a surgical guidance solution across multiple cancer indications, with high-grade glioma and oral head and neck cancer as lead indications. By helping surgeons identify malignant tissue in real time, FG001 has the potential to improve surgical precision and support more complete tumor removal while preserving healthy tissue.

FG001 has received FDA Fast Track designation as an optical imaging agent for use in patients with suspected WHO Grade 3 or 4 high-grade glioma, as an adjunct to visualize malignant tissue during neurosurgery.

About FluoGuide

FluoGuide lights up cancer to maximize surgical outcomes in oncology. FluoGuide's lead product, FG001, is designed to improve surgical precision by lighting up cancer intraoperatively. Improved surgical precision has the potential to reduce local recurrence and surgical complications, improve outcomes for patients and lower healthcare costs. FluoGuide has demonstrated that FG001 is effective and well tolerated and has entered partnerships with leading MedTech companies to accelerate development and commercialization. FluoGuide is listed on Nasdaq First North Sweden under the ticker "FLUO".

Attachments

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