

FluoGuide receives FDA Fast Track Designation for FG001 in high-grade glioma

Copenhagen, Denmark, 18 March 2026 – FluoGuide A/S (“FluoGuide” or the “Company”), a biotech company maximizing surgical outcomes in oncology by lighting up cancer, announces that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to FG001 as an intraoperative imaging agent to guide surgical resection of high-grade glioma.

U.S. FDA Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to patients earlier.

FluoGuide’s Fast Track designation reflects FDA’s recognition of the serious and life-threatening nature of high-grade glioma, as well as compelling data supporting FG001’s potential to address an unmet medical need through improved intraoperative tumor detection. The designation also provides the company with potential regulatory advantages that may help accelerate FG001’s development and regulatory review.

“Fast Track designation for FG001 is a meaningful recognition by FDA of the significant unmet need in high-grade glioma and the potential of our program to improve intraoperative tumor detection,” said Donna Haire, COO of FluoGuide *“We greatly value the opportunity to work closely with the FDA and deeply appreciate their engagement as we continue to advance FG001 for patients facing this devastating cancer.”*

For FluoGuide, this designation enables earlier and more frequent interactions with FDA, including meetings and written communications to align key aspects of development such as trial design, endpoints, and the evidence needed to support approval. The frequent engagement with the FDA can help identify and resolve issues sooner, increase FluoGuide’s confidence in the development pathway, enhance development predictability, and support a more efficient path through clinical development.

Fast Track designation may also make FG001 eligible for Rolling Review, allowing sections of the future NDA to be submitted and reviewed as they are completed rather than waiting for the full application, which can shorten overall review timelines. In addition, if applicable criteria are met, FG001 could also qualify for Accelerated Approval and Priority Review, which could create the potential for a faster approval and review process, further strengthening the opportunity to advance a potentially differentiated imaging agent that may address persistent unmet need beyond current available approaches for patients with high-grade glioma, a devastating cancer with extremely poor outcomes.

Following the FDA green light on FluoGuide's IND in January, the Company is in preparation to initiate the planned U.S. Phase 2 registration trial of FG001 in high-grade glioma with first patient planned to be enrolled in Q2 this year. FluoGuide anticipates that two U.S. clinical trials will be required to support U.S. regulatory approval of FG001 for HGG.

"We are very pleased achieving this important milestone in our endeavor to help patients with high-grade glioma" said Morten Albrechtsen, CEO of FluoGuide.

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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. The improved precision has a dual benefit – it reduces both the frequency of local recurrence post-surgery and lessens surgical sequelae. Ultimately, the improved precision enhances the likelihood of complete cure and lower healthcare costs. FluoGuide has demonstrated that FG001 is both effective and well tolerated in several phase II clinical trials. The lead indications of FG001 are aggressive brain cancer (glioblastoma) and oral head and neck cancer. FluoGuide has entered partnerships with leading MedTech companies with the aim of accelerating development and commercialization. FluoGuide is listed on Nasdaq First North Sweden under the ticker "FLUO".

For more information on FG001 or FluoGuide's uPAR technology platform, please visit our home page www.fluoguide.com

This information is information that FluoGuide A/S is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2026-03-18 21:19 CET.

Attachments

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