PRESS RELEASE
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FDA clears FluoGuide's IND for FG001 in High-Grade Glioma; U.S. clinical trial remains on track

Copenhagen, Denmark, 20 February 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 informed the Company that it can proceed with the proposed clinical investigation for FG001. The IND supports the initiation of the Company's first trial supporting registration in patients with high-grade glioma (HGG).

The IND submission represents a key regulatory milestone for FluoGuide and marks the transition of FG001 to late-clinical development, advancing the program toward U.S. registration. Initiation of the first U.S. trial supporting registration remains on track, with enrollment of the first patient expected in Q2 2026.

Following the FDA green light on FluoGuide's IND, the Company will continue preparations to initiate the planned U.S. Phase 2 registration trial of FG001 in high-grade glioma. The Company will provide updates as appropriate, with first patient planned to enroll in Q2.

"We are excited to reach this FDA review milestone, keeping our program on track as we advance FG001 into our planned U.S. clinical trial" said Morten Albrechtsen, CEO of FluoGuide.

IND process – foundation for U.S. registration
An Investigational New Drug (IND) application is required to obtain U.S. regulatory authorization to initiate clinical trials of a new drug. FG001 is a well-advanced, clinical-stage product, and significant portions of the submitted IND package, including the preclinical section, are expected to form the basis of the future New Drug Application (NDA) required to obtain approval to market FG001 in the U.S.

Across the pre-IND and IND processes, FluoGuide engaged with the FDA to review a comprehensive development package covering completed work and proposed plans for ongoing studies.
Importantly, through these interactions and the subsequent IND submission, FluoGuide received FDA alignment on the design of its U.S. Phase 2 clinical trial in HGG to support registration, as well as on key elements of the subsequent Phase 3 program.

This regulatory alignment provides a strong foundation for long-term development planning, and in our view, de-risks the regulatory process as we advance toward NDA submission and future U. S. approval of FG001.

Clear regulatory path

FluoGuide anticipates that two U.S. clinical trials will be required to support U.S. regulatory approval of FG001 for HGG.
Both trials are expected to enroll patients over approximately one year, with final timelines and enrollment subject to emerging data and regulatory feedback.

This program establishes a clear, structured and capital-efficient path toward U.S. approval of FG001 in HGG – a devastating brain cancer with poor outcomes and limited effective treatment options.

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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

Attachments
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