PRESS RELEASE
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FluoGuide submits an IND for FG001, to initiate first U.S. registration trial

Copenhagen, Denmark, 21 January 2026 – FluoGuide A/S ("FluoGuide" or the "Company"), a biotech company maximizing surgical outcomes in oncology by lighting up cancer, today announced that it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for FG001. The IND supports the initiation of the Company's first registration trial 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 registration trial remains on track, with enrollment of the first patient expected in Q2 2026.

IND submission – 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.

Prior to submission, FluoGuide held a pre-IND meeting with FDA, during which the agency reviewed a comprehensive development package covering completed work and proposed plans for ongoing studies.

Importantly, 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 the 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.

First registration trial – clear regulatory path

FluoGuide anticipates that two clinical trials will be required to support U.S. 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 - one of the most aggressive forms of cancer.

"The IND submission reflects focused execution across regulatory, clinical and technical disciplines. I am very proud of the FluoGuide team and our collaborating neurosurgeons for delivering a high-quality IND package that reflects the maturity of the FG001 program and supports a clear path toward U.S. registration trials in high-grade glioma – advancing our mission to maximize the outcomes for patients facing this highly aggressive brain cancer," said **Donna Haire**, COO of FluoGuide.

"As we enter 2026, FluoGuide has reached a key inflection point. With the IND now submitted, we have further de-risked our lead program and established a well-defined regulatory path toward U. S. approval. Our mission remains unchanged: to maximizing outcomes in cancer surgery" said **Morten Albrechtsen**, CEO of FluoGuide *and continue "We are now well positioned to advance toward registration".*

Following the IND submission, FluoGuide will continue preparations for the planned U.S. Phase 2 registration trial in high-grade glioma and will provide updates as appropriate, with first patient planned enrolled in Q2.

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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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