PRESS RELEASE
16 September 2025 11:01:00 CEST

FluoGuide receives positive FDA feedback on FG001 in high-grade glioma

Copenhagen, Denmark, 16 September 2025 – FluoGuide A/S ("FluoGuide" or the "Company") received positive feedback and alignment with the FDA at a pre-IND consultation on its U.S. clinical study design. This supports both the upcoming IND submission and a future NDA filing for FG001, an intraoperative imaging agent for high-grade glioma (HGG).

FluoGuide has achieved several important milestones in 2025. Our comprehensive pre-IND package included detailed information on completed development activities to support the upcoming IND (Investigational New Drug) and outlined proposed plans for continued studies. Our development plan includes one Phase 2 and one Phase 3 clinical trial in the U.S. to support a New Drug Application (NDA), the formal submission to the FDA required for approval before a drug can be marketed in the U.S.

Importantly, FluoGuide received FDA alignment on its U.S. high-grade glioma (HGG) Phase 2 clinical trial design and key elements of its future Phase 3 clinical program. This regulatory alignment provides a strong foundation for the IND submission, supports long-term development planning, and in our view, de-risks the overall regulatory strategy toward NDA submission. This positions the company to advance its clinical programs with greater confidence and long-term clarity.

Therefore, we also maintain our milestone to submit an IND application for the U.S. Phase 2 clinical registration trial in HGG in Q4 2025. FluoGuide will provide additional information on the development program following submission of the IND application.

Morten Albrechtsen, CEO of FluoGuide said: *“FluoGuide has made substantial progress during 2025. With the constructive feedback from FDA, we believe we have further de-risked the path towards approval, while maintaining our overall plan to submit the IND before year end.”*

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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 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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