

FluoGuide updates IND submission timing for FG001 – trial initiation unaffected

Copenhagen, Denmark, 19 December 2025 – FluoGuide A/S (“FluoGuide” or the “Company”), a biotech company specializing in precision cancer surgery, today announced an update to the submission date for its for its Investigational New Drug (IND) application to mid-January 2026.

The updated timeline relates to the IND application supporting the first of two planned registration trials for FG001 in patients with high-grade glioma (HGG). The Company expects to submit the IND in mid-January 2026, compared to end-December 2025 as previously communicated.

Importantly, this updated submission timing will have no impact on the planned initiation of the first registration trial for FG001.

“I am thankful to our hard-working team and collaborating neurosurgeons for their focused efforts to complete the IND application, which is designed to guide surgery in patients with high-grade glioma,” said Morten Albrechtsen, CEO of FluoGuide.

For further information, please contact:

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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



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Attachments

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