

Publication of positive phase II clinical data for FG001 in patients with head and neck cancer

Copenhagen, Denmark, 19 November 2024 – FluoGuide A/S (“FluoGuide” or the “Company”) is pleased to announce publication of the first clinical data on FG001, a novel imaging agent tested in patients undergoing surgery for head and neck cancer.

The data has been published in *Theranostics*, a prestigious journal with a high impact factor of 12.4. The article is entitled “*Optical molecular imaging in oral- and oropharyngeal squamous cell carcinoma using a novel uPAR-targeting near-infrared imaging agent FG001 (ICG-Glu-Glu-AE105): An explorative phase II clinical trial*” and identified with doi:10.7150/thno.100042. FG001, is designed to enhance surgical accuracy by illuminating cancer cells intraoperatively using fluorescent light. It selectively binds to the uPAR receptor, widely expressed in most solid cancer types. The use of FG001 is expected to reduce the incidence of local recurrence after surgery and surgical complications, ultimately improving treatment outcomes for patients while also reducing healthcare costs.

Key findings from the study

- **Patient Enrollment:** The trial included 16 patients diagnosed with oral or oropharyngeal squamous cell carcinoma undergoing surgery
- **Efficacy:** FG001 successfully illuminated cancerous tissues in all enrolled patients, achieving a 100% sensitivity rate, the primary endpoint of the study
- **Dosage Variability:** Consistent results were observed across a broad range of doses (4, 16 and 36 mg per patient)
- **Imaging Contrast:** The tumor-to-background ratio exceeded 2.0 in all patients with an average of 2.99, significantly above the threshold for usefulness (1.5 – 2.0)
- **Tolerability:** FG001 demonstrated excellent tolerability, with no drug related adverse events reported
- **Time Frame for Use:** The agent remained effective within the relevant time window, detectable from 2 hours up to at least 19 hours post-administration, based on the longitudinal data
- **Specificity:** FG001 was shown to be specific to cancer, as confirmed by the colocalization of FG001 fluorescence and histology
- **Clinical Applications:** The trial identified several relevant applications in the surgical workflow for head and neck cancer surgery, including guiding surgery, evaluating surgery (margin detection), and real time evaluation of lymph node spread

Morten Albrechtsen, CEO at FluoGuide says: *“The publication of these promising results of FG001 in head and neck cancer is a significant milestone for FG001”* and continues: *“The high-rank publication of these interesting clinical data lays out a good foundation for the forthcoming clinical trial planned for start in Q1 next year providing a new and promising help for patients with head and neck cancer.”*

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About FluoGuide

FluoGuide is a biotech company specializing in precision cancer surgery. FluoGuide's lead product, FG001, is designed to enhance surgical accuracy by illuminating cancer cells intraoperatively using fluorescent light, which binds to the uPAR receptor, widely expressed in most solid cancer types. It is anticipated that FG001 will decrease both the incidence of local recurrence after surgery and surgical complications, improving cancer treatment and outcomes for patients, while also reducing healthcare costs. Moreover, FluoGuide's technology platform may also be utilized for photothermal therapy (PTT), which kills cancer cells through heating them with the use of near-infrared light. A technique that spares healthy surrounding tissue from damage, offering a direct therapeutic effect of FG001, further benefiting patients undergoing cancer surgery.

FluoGuide is listed on the Nasdaq First North Growth Market in Stockholm under the ticker symbol "FLUO". For more information about FluoGuide's pipeline, technology, and upcoming events, visit www.fluoguide.com

Attachments

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