

## **FluoGuide A/S submits Clinical Trial Application for phase II trial in head and neck cancer**

**Copenhagen, Denmark - FluoGuide A/S (“FluoGuide” or the “Company”), a biotech company specializing in precision cancer surgery, today announced the submission of the Clinical Trial Application (CTA) for phase II trial in head and neck cancer (oral squamous cell carcinoma cancer). Redeye will host a live streaming event regarding the head and neck trial on 18 October 2024, at 10:00 am CET.**

The CTA submission follows strong clinical topline data for FG001 tested in a proof-of-concept phase II clinical trial in patients with head and neck cancer and is a step on the path to the patients and commercialization.

Feedback from and discussions with key opinion leaders around the globe, has confirmed the ample needs patients with head and neck cancers have and led to a detailed understanding of the clinical trial design. Additionally, the Company obtained feedback on how to optimize the positioning of FG001 from a regulatory, partnering and commercial perspective to fully utilize the opportunities, condensed in the design of the trial (CT-005).

Regulatory and clinical evaluation and discussions with Principal Investigator, Prof. Dr. Max Witjes, has led to the submitted trial design. The phase II trial (CT-005) is designed as a single center trial to:

- Evaluate multiple end-points with clinical applications of FG001 in patients undergoing surgery for head and neck cancer
- Prepare utilization of different kind of surgical equipment
- Enroll 25-30 patients, with first patient planned to be enrolled in Q1 2025, and last patient expected enrolled in H2 2026

First interim data are expected in H2 2025. Depending on data from the trial and feedback from regulatory authorities, the Company is planning to do a multisite registration trial as the next step supporting approval and subsequent commercialization.

FluoGuide will review the trial and its outlook at a live streaming event hosted by Redeye on 18 October 2024, at 10:00 am CET, where Redeye analyst Christian Binder will interview CEO Morten Albrechtsen and CSO Andreas Kjær.

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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](http://www.fluoguide.com)

**About head and neck cancer**

Head and neck cancer includes cancers in the head and neck region of the body. Head and neck cancers are frequently not completely removed or removed with insufficient margins to the surrounding normal tissue and requires follow up treatment with chemoradiotherapy. Chemoradiotherapy causes both short- and long-term side effects that can be avoided if the surgical removal of the cancer is complete the first time. Head and neck cancers are often occurring in close anatomical proximity to small vital structures such as blood vessels supplying the brain and many important nerves. Further, cosmetic considerations are important for most locations of head and neck cancers. Surgical precision is therefore essential for surgical removal of head and neck cancers. Most head and neck cancers arise from squamous cells and are called squamous cell carcinomas.

It is the 6th most common cancer. Worldwide, head and neck cancer accounts for approximately 950,000 newly diagnosed patients (incidence) annually and approximately 450,000 patients die annually due to head and neck cancer. In USA and EU head and neck cancer accounts for approximately 63,000 and 136,000 newly diagnosed patients annually, respectively. Head neck cancer in rest of the world accounts for approximately 750,000 cases annually.

Sources: World Health Organization (International Agency for Research on Cancer), [Global Cancer Observatory \(iarc.fr\)](http://GlobalCancerObservatory(iarc.fr)), Gal TJ et al. Treatment trends in oropharyngeal carcinoma: Surgical technology meets the epidemic. Oral Oncology, Vol 97, 2019, p 62-68 (2) Cramer JD et al. The changing therapeutic landscape of head and neck cancer. Nat. Rev. Clin. Oncol. 16, 669–683 (2019);

For more information on the Company, its uPAR technology platform and pipeline, please visit [www.fluoguide.com](http://www.fluoguide.com)

## Attachments

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