

FluoGuide includes first patient in phase II trial of FG001 for head and neck cancer

Copenhagen, Denmark – FluoGuide A/S ("FluoGuide" or the "Company"), a biotech company specializing in precision cancer surgery, is pleased to announce the inclusion of the first patient in its phase II clinical trial (CT-005) investigating FG001 in head and neck cancer.

The trial is conducted in collaboration with the University Medical Center Groningen and is led by Principal Investigator Prof. Dr. Max Witjes. It aims to evaluate the effectiveness of FG001, a novel optical imaging agent that light up cancerous tissue to improve surgical precision in patients undergoing surgery for oral squamous cell carcinoma, a type of head and neck cancer. By improving tumor visibility, FG001 helps surgeons achieve more complete removal of the cancerous tissue while preserving healthy tissue. The trial will also explore the use of different types of surgical equipment to access FG001' application across a variety of surgical environments.

"Initiation of this trial marks a significant milestone in our mission to enhance surgical outcomes for patients with head and neck cancer, also reflecting the strong collaboration between FluoGuide, leading surgeons, and surgical equipment partners, including Intuitive Surgical to address the challenges posed by cancerous tumors located in anatomically complex areas." says Morten Albrechtsen, CEO of FluoGuide, "We look forward to advance FG001 through this trial and look forward to the interim data, which will be a key step forward in the development of our head and neck program for FG001."

The trial is a single-center trial (FG001-CT-005) designed to:

- Evaluate multiple endpoints for measuring surgical completeness using FG001
- Explore the different benefits of FG001 in assisting head and neck cancer surgery
- Assess the use of different surgical equipment types

The first interim date is anticipated in the second half of 2025 and will serve as a key data trigger point. Upon completion of this phase II trial and guided by data, FluoGuide plans to initiate a multi-site registration trial as the next step toward regulatory approval and commercialization of FG001.

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FluoGuide is a biotech company specializing in precision cancer surgery improving the outcome for cancer patients. The Company's lead product, FG001, a novel optical imaging agent that light up cancerous tissue to improve surgical precision in patients undergoing surgery. FluoGuide's products are expected to have a dual benefit – reducing both the frequency of local recurrence after surgery and reducing surgical complications. The improved precision will potentially increase the patients' chance of achieving a complete cure and lower healthcare costs. FG001 binds to the urokinase plasminogen activator receptor (uPAR) being extensively expressed by solid cancer. The photosensitizer therapy potential of FG001 could add a direct treatment effect of FG001 to further benefit for patients with cancer undergoing surgery.

The Company has published strong results from phase II trials demonstrating the efficacy of FG001 in patients undergoing surgery to remove aggressive brain (high-grade glioma), head & neck (oral squamous cell carcinoma) and lung cancers (non-small cell lung cancer). FG001 has also been demonstrated very well tolerated across all patients. Based on this strong foundation, FluoGuide advances the development toward approval in aggressive brain cancer and head & neck cancer.

FluoGuide is listed on Nasdaq First North Growth Market, Stockholm under the ticker "FLUO". Read more about FluoGuide and upcoming events on 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 \(iarc.fr\)](#), 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);

Attachments

[FluoGuide includes first patient in phase II trial of FG001 for head and neck cancer](#)