

FluoGuide reports further positive interim data from phase IIa trial of FG001 in head & neck cancer

- All patients now enrolled; interim results show cancer lit up in all 16 patients
- Data from latest 4 patients show cancer lit up in all 4, even at a low dose
- Topline results anticipated during H2 2023

Copenhagen, Denmark – FluoGuide A/S (“FluoGuide” or the “Company”), a pioneer in the cutting-edge field of precision cancer surgery, is pleased to announce the successful completion of patient enrollment in its phase IIa trial with FG001 in patients with head & neck cancer. Data show that cancer lit up in all 16 patients treated in the trial so far, including those receiving a low dose of FG001.

“These new data further confirm the potential of FG001 in guiding surgeons towards removing cancer while leaving healthy tissue. We will now carefully analyze these results, which we expect to be confirmed in the topline data due later this year, as we work to define FG001’s optimal route towards market and making a significant difference to cancer patients. We expect to provide further details on FG001’s development in head & neck cancer later this year,” says Anne Poulsen, Senior Clinical Project Manager at FluoGuide.

FG001 is a fluorophore targeting uPAR, which is a cancer specific target expressed extensively in most solid cancers. The fluorophore has the same spectral specifications as indocyanine green, which is already approved, and this means FG001 can be used on current imaging equipment without adaptation. It is administered into a patient’s vein prior to surgery and lights up the cancer during surgery, helping to guide the surgeon in removing all cancer while sparing healthy tissue.

The open-label, single-center non-randomized explorative phase IIa trial investigating the effect of FG001 in guiding surgery of patients with head & neck cancer (oral oropharyngeal squamous cell carcinomas cancer - OPSCC). Further, the purpose is to obtain proof-of-concept in this indication for the uPAR platform technology used to guide surgical removal of cancer. Data from the trial will provide valuable data needed to guide further development of FG001 in head & neck cancer.

New interim results with a low dose of FG001 (4mg) showed that all 4 patients’ cancer lighted up. This means that cancer lit up in all 16 patients treated in the head & neck cancer trial. Preliminary data suggest FG001 was well tolerated in all patients. Topline results, which will give further detail on tumor-to-background ratio, safety, pharmacokinetics and histology are expected in H2 2023 and after topline data from the phase IIb trial of FG001 in brain cancer, due to prioritization of resources.

"The data underline FluoGuide's very strong progress in 2023. We have strong clinical data on FG001 in three indications, which is supporting development of plans for late-stage clinical development and defining the optimal path to market and commercialization," says Morten Albrechtsen, CEO of FluoGuide.

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About FluoGuide

FluoGuide takes precision surgery to the next level improving the outcome for cancer patients. The Company's lead product, FG001, is designed to improve surgical precision by illuminating cancer cells intraoperatively. This improved precision enabled by FluoGuide's products is expected to have a dual benefit – it reduces both the frequency of local recurrence post-surgery and lessens surgical sequelae. Ultimately, this improved precision will improve a patient's chance of achieving a complete cure and will lower system-wide healthcare costs. The Company has published key results on the efficacy of FG001 as well as showing it was well tolerated and safe from a proof-of-concept clinical study (phase I/IIa) in patients with aggressive brain cancer (high grade glioma) that undergo surgery. A phase IIb trial in aggressive brain cancer is ongoing to obtain valuable information to design the phase III trial. This IIb trial has completed patient enrollment and treatment, and data complication is ongoing. In addition, FluoGuide has demonstrated effect of FG001 in lung and head & neck cancer, topline and positive interim result, respectively. A trial in meningioma and glioma is commencing.

About head and neck cancer

Head and neck cancer includes cancers in the lining of the lips, tongue, mouth, or upper throat. Head and neck cancers is 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.

Worldwide, head and neck cancer accounts for approximately 900,000 cases and over 400,000 deaths annually. It is the 6th most common cancer. In USA and EU head and neck cancer accounts for approximately 66,000 cases annually and 15,000 deaths, and 250,000 cases and 63,500 deaths, respectively. (Source: (1) Global Cancer Observatory. International Agency for Research on Cancer. World Health Organization. Available at: <https://gco.iarc.fr/> (Accessed on June 06, 2021); (2) Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer statistics, 2022; (3) CA

Cancer J Clin 2022; 72:7. Gatta G, Botta L, Sánchez MJ, et al. Prognoses and improvement for head and neck cancers diagnosed in Europe in early 2000s: The EURO CARE-5 population-based study. Eur J Cancer 2015; 51:2130.)

FluoGuide is listed on Nasdaq First North Growth Market, Stockholm under the ticker "FLUO".

Read more about FluoGuides pipeline, technology and upcoming events on www.fluoguide.com

This information is information that FluoGuide A/S is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-08-29 09:32 CEST.

Attachments

[FluoGuide reports further positive interim data from phase IIa trial of FG001 in head & neck cancer](#)