

## FluoGuide announces positive interim results from phase IIa trial of FG001 in head & neck cancer

FluoGuide A/S (“FluoGuide” or the “Company”), a Danish biotech company that pioneers precision cancer surgery, is pleased to announce positive interim results from the phase IIa trial of its lead product FG001 in head & neck cancer. FG001 was shown to illuminate tumors in all of the patients.

- FG001 was shown to light up tumors in 100% of the patients
- In line with the efficacy data in brain and lung cancers, underscoring FG001’s potential for broad applicability
- Topline results from the trials in brain and head & neck cancers expected in H2 2023

Data show all 12 patients in the first two cohorts, undergoing surgery for head & neck squamous cell carcinomas (HNSCC), had their tumors lit up with FG001.

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 third cohort of a further 4 patients has been initiated on a low dose of FG001 to enable investigation of a broad dose range, which will inform dose selection for a future phase IIb trial. It is therefore expected that some cancers in the third cohort of patients will not light up.

*“We are pleased to report another positive set of results with FG001, our imaging agent for guiding cancer surgery. We are building up a broad data set showing FG001 is effective across a range of cancers and this, combined with its compatibility with different types of imaging equipment, means it has the potential to significantly improve the outcome of surgery for these patients, with tumors removed more precisely while leaving healthy tissue undamaged,”* says Morten Albrechtsen, CEO of FluoGuide.

*“We will now prepare the next steps for development of FG001 over the coming months, considering data from all three indications – lung, head & neck and aggressive brain cancers – and potential partner interest.”*

FluoGuide expects enrollment of the last patient in its phase IIb trial of FG001 in aggressive brain cancer (high grade glioma) during the summer of 2023 and the topline result approximately 2 months after that. The topline result from the phase IIa trial of FG001 in head & neck cancer is expected in H2 2023.

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**About FluoGuide**

FluoGuide's primary focus is to maximize surgical outcomes in oncology. The Company's lead product, FG001, is designed to improve surgical precision by illuminating cancer cells intraoperatively. The improved precision enabled by FluoGuide's products has a dual benefit – it reduces both the frequency of local recurrence post-surgery and lessens surgical sequelae. Ultimately, the improved precision will improve a patient's chance of achieving a complete cure and will lower system-wide healthcare costs. The Company is conducting a proof-of-concept clinical study (phase I/II) to demonstrate the effect of FG001 in patients with high grade glioma and a phase II trial in lung cancer to demonstrate the effect of FG001 in guiding cancer surgery in patients with lung cancer. FluoGuide is listed on Nasdaq First North Sweden under the ticker "FLUO".

**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.)

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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