

Positive interim data from phase IIa trial of FG001 in head & neck cancer presented as a case report at the World Molecular Imaging Congress in Prague

Copenhagen, Denmark, 7 September 2023 – FluoGuide A/S (“FluoGuide” or the “Company”) is pleased to see the first data from FG001 study guiding cancer surgery in patients with head & neck cancer presented at the World Molecular Imaging Congress (WMIC) 2023 in Prague. The presentation contains a patient case.

The poster *“Optical-Guided Surgery in Patients with Oral and Oropharyngeal Squamous Cell Carcinoma (OSCC & OPSCC) Using a Novel uPAR-targeting Near-Infrared Imaging Agent FG001: An Explorative Phase II Clinical Trial – a Case Example”* (presenter: Dr. Amanda Øster Andersen, PI: Dr. Anders Christensen both from Rigshospitalet) presents a case from the phase IIa study for FG001 in patients with head & neck cancer, showcasing the specificity of FluoGuide’s uPAR-targeting optical imaging agent FG001, for detection of oral squamous cell carcinoma (OSCC). The poster further builds on the positive interim data from the phase IIa trial for FG001 in patients with head & neck cancer, on which topline results are expected during H2 2023.

“We are pleased to see positive data being presented and are looking forward to the topline results as well as presentation of the complete results of the trial later this year”, says Andreas Kjær, CSO.

The poster can be found attached to this press release, as well as under our publications:

<https://fluoguide.com/technology/publications/>

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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.)

For more information on the Company, please visit www.fluoguide.com

Attachments

[Positive interim data from phase IIa trial of FG001 in head & neck cancer presented as a case report at the World Molecular Imaging Congress in Prague](#)
[WMIC Poster](#)