Press release

FluoGuide releases positive interim result of FG001 in head and neck cancer

Copenhagen, Denmark, 9 January 2023 - FluoGuide A/S ("FluoGuide" or the "Company") is pleased to announce the positive interim result of FG001 in head and neck cancer that FG001 lights up in 4 out of 4 patients following the interim evaluation of the first four patients dosed in the ongoing explorative phase IIa trial in patients with head and neck squamous cell carcinomas (HNSCC) undergoing surgery.

Detection of light was made from the tissue identified macroscopically as cancer by the surgeon. At the end of the trial, the pathologists will histologically examine the tissue that lights up to determine if the tissue samples contain cancer or normal tissue. Although this is an encouraging interim result, it is important to state that a final conclusion regarding the effect of FG001 cannot be reached until after the histology examinations have been completed at the end of the trial. The optimal dose in patients with head and neck squamous cell carcinomas (HNSCCs) undergoing surgery has not yet been established. FluoGuide has selected head and neck cancer, the 6th most common cancer, due to a high unmet need and evidence of uPAR overexpression. The ongoing trial is conducted in cooperation with the Department of Otorhinolaryngology, Head and Neck Surgery & Audiology at the Copenhagen University Hospital - Rigshospitalet, in Denmark.

The phase IIa trial is designed to obtain proof-of-concept in head and neck cancer for our uPAR platform technology used to guide surgical removal of cancer. The plan is to enrol up to 16 patients. The primary endpoint is sensitivity for detection of cancer defined as the relative number of patients, where FG001 lights up the cancer confirmed by histopathology. FluoGuide expects top line results to be available in H1 2023. FluoGuide has selected head and neck cancer due to the high prevalence, a high unmet need, and strong evidence of uPAR being overexpressed in these cancers.

"We are very pleased to see FG001 also lighting up in head and neck cancer, which further supports FG001 as a relevant product for guiding surgery beyond aggressive brain cancer" says Morten Albrechtsen, CEO of FluoGuide.

This disclosure contains information that Fluoguide is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on 09-01-2023 10:30 CET.

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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. The 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, the improved precision will improve a patient's chance of achieving a complete cure and will lower system-wide healthcare costs. The Company has demonstrated efficacy of F001 as well as it being well tolerated and safe in the completed proof-of-concept clinical study (phase I/IIa) in patients with high grade glioma undergoing surgery. A phase IIb trial in aggressive brain cancer is ongoing to obtain valuable information to design the phase III trial. In addition, FluoGuide currently explores FG001 lung and head & neck cancer,

and a trail in in meningioma and low grade glioma is commencing. FluoGuide is listed on Nasdaq First North Growth Market, Stockholm under the ticker “FLUO”.

About head and neck cancer

Head and neck cancer includes cancers in the lining of the lips, tung, 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 EUROCARE-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