



# FluoGuide has received approval from the Danish Medicines Agency to initiate phase II trial with FG001 in head and neck cancer

**Copenhagen, Denmark, 6 September 2022 – FluoGuide A/S (“FluoGuide” or the “Company”) is delighted to announce that the company has received approvals to initiate the phase II trial in head and neck cancer. The trial is expected to enrol first patient in Q4 2022.**

Following the approval from the Danish Medicines Agency, FluoGuide is initiating the phase II trial in collaboration with Department of Otolaryngology, Head & Neck Surgery and Audiology at the University Hospital, Rigshospitalet, in Denmark. Principal investigator is Anders Christensen, MD, Ph.D.

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 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 1H 2023.

FluoGuide has selected head and neck cancer due to a high unmet need, and evidence of uPAR being overexpressed in these cancers. (Please see latest article in ONCOLOGY REPORTS 48: 147, 2022).

Christian von Buchwald, MD, DMSc, Professor, Department of Otolaryngology, Head & Neck Surgery and Audiology says “FG001 has a very promising profile in lighting up cancer” and continues “although you as a surgeon get a CT or MRI scan for pre-operative planning in order to help pinpoint areas of cancerous tissue, it is never easy to assess how much to remove during the operation, and we are therefore very focused on using new tools to help us performing precise surgery”.

Principal investigator Anders Christensen, MD, Ph.D. says “uPAR has been shown to be strongly expressed in head and neck cancer. Therefore, FG001 targeting uPAR is a very interesting technology to allow visualization of tumours in this type of cancer. I am very excited to be the first surgeon to test FG001 in patients with head and neck cancer.”

## **For further information, please contact:**

Morten Albrechtsen, CEO  
FluoGuide A/S  
+45 24 25 62 66  
ma@fluoguide.com

## **Certified Adviser:**

Svensk Kapitalmarknadsgransking AB  
Phone: +46 70 755 95 51  
E-mail: ca@skmg.se

## **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 has demonstrated efficacy of F001 as well as it to be well tolerated and safe in the ongoing proof-of-concept clinical study (phase I/II) in patients with high grade glioma undergoing surgery. FluoGuide has decided to explore FG001 in three other severe cancer

indications, namely lung, head & neck, meningioma and low grade glioma. FluoGuide is listed on Nasdaq First North Sweden under the ticker "FLUO".

For more information on the Company's uPAR technology platform and our pipeline please visit our home page [www.fluoguide.com](http://www.fluoguide.com)

### **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. 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.)

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 954904.

For more information on the Company's uPAR technology platform and our pipeline please visit our home page [www.fluoguide.com](http://www.fluoguide.com)