PRESS RELEASE
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FluoGuide confirms positive topline results from phase IIa trial of FG001 in head & neck cancer at International Academy of Oral Oncology conference

- **Oral presentation outlines positive efficacy and safety data**
- **Confirms interim data showing FG001 met primary endpoint, with cancer lit up in 16 /16 (100%) patients, and was very well tolerated**
- **Several applications for potential clinical benefit will be further explored**
- **Topline phase IIb results of FG001 in high-grade glioma expected later in November 2023**

Copenhagen, Denmark – FluoGuide A/S ("FluoGuide" or the "Company"), a pioneer in the cutting-edge field of precision cancer surgery, today announced that topline results from the phase IIa trial of its lead product FG001 in guiding surgery in patients with head & neck cancer, confirming positive efficacy and safety, were presented at the International Academy of Oral Oncology (IAOO) 2023 conference in Incheon, South Korea.

"These encouraging first clinical results, showing that FG001 was able to light up cancer in all head & neck cancer patients in the trial, indicate it could make a significant difference for operating surgeons and their patients. The data suggest several potential applications in head & neck cancer and I look forward to see further results from FG001's clinical development," said Anders Christensen, MD, PhD, Principal Investigator and head and neck surgeon, who presented the data at IAOO.

FG001 is a fluorophore targeting uPAR, which is a cancer specific target expressed extensively in most solid cancers. 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 fluorophore has the same spectral specifications as indocyanine green, which is already approved, and means FG001 is compatible with most imaging equipment.

The open-label, single-center non-randomized explorative phase IIa trial investigated the effect of FG001 in guiding surgery of patients with head & neck cancer (oral and oropharyngeal squamous cell carcinomas – OPSCC). The purpose was 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 be valuable to guide further development of FG001 in head & neck cancer including potential clinical benefits. The topline results were:

- 4 patients were dosed with 4mg, 8 patients were dosed with 16 mg and 4 patients were dosed with 36mg. The cancer lit up in all patients with a relevant Tumor To Background Ratio (TBR).
- Safety: No Serious Adverse Events or drug-related Adverse Events were reported.
- Several applications for potential clinical benefit were hypothesized and will be explored in further trials.

"The result of this first clinical trial of FG001 in head & neck cancer is very promising and reinforces the potential of FluoGuide's unique uPAR-targeting technology platform. uPAR is extensively expressed in solid cancers, so targeting potentially enables precise removal of cancer tissue. We are now analyzing the data to optimize the value of FG001 to help surgeons and for the benefit of patients with head & neck cancer," said Andreas Kjaer, Chief Scientific Officer of FluoGuide.

"We now have phase IIa data showing efficacy and safety of FG001 across three indications and are looking forward to topline results from our phase IIb trial in aggressive brain cancer, which are expected later in November 2023. Overall, our data provide a very solid foundation for late-stage clinical development as we define our plans and move FG001 towards commercialization."

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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 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 late-stage clinical trials. 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.

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.

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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, please visit **www.fluoguide.com**

Attachments

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