PRESS RELEASE
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FluoGuide A/S receives approval for phase II trial in head and neck cancer

Copenhagen, Denmark – FluoGuide A/S ("FluoGuide" or the "Company"), a biotech company specializing in precision cancer surgery, announces approval of its phase II Clinical Trial Application for FG001 in head and neck cancer (oral squamous cell carcinoma cancer).

The Phase II Clinical Trial Application (CTA) for FG001 in head and neck cancer, announced on October 7, 2024, has been granted approval under the new European process by the Dutch Central Committee on Research Involving Human Subjects and the Medical Ethical Committee of the University Medical Center Groningen.

The CTA submission followed strong clinical topline data from a proof-of-concept Phase II clinical trial of FG001 in patients with head and neck cancer. The trial evaluated surgical precision using various surgical equipment and advanced FG001 to help patients with head and neck cancer."

Morten Albrechtsen, CEO at FluoGuide states: "The approval is a significant milestone to advance FG001 helping patients with head and neck cancer. We are on track to enroll first patient in first quarter of 2025 and the key data trigger point is expected in the second half of 2025 with the interim data."

FluoGuide and Principal Investigator Prof. Dr. Max Witjes are now preparing to initiate the Phase II trial (CT-005) in head and neck cancer, which will be conduct a single center trial to:

- Evaluate multiple endpoints for measuring surgical completeness with FG001 in patients with head and neck cancer
- Explore different benefits of FG001 in assisting these patients
- Access the use of various surgical equipment types
- Enroll 25-30 patients, with enrollment starting in Q1 2025
- The interim data is expected in the second half of 2025 being the data trigger point
- The trial completing in H2 2026

Depending on trial data and regulatory feedback, the FluoGuide plans to conduct a multisite registration trial as the next step toward approval and commercialization.

For further information, please contact:
Morten Albrechtsen, CEO
FluoGuide A/S
Phone: +45 24 25 62 66
E-mail: ma@fluoguide.com

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Certified Adviser:
Svensk Kapitalmarknadsgransking AB
Website: www.skmg.se

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. This improved precision will increase a patient's chance of achieving a complete cure and will lower system-wide healthcare costs. FG001 binds to the receptor uPAR being extensively expressed on most solid cancer types. The photothermal potential of FG001 could add a direct treatment effect of FG001 to further benefit for patients with cancer undergoing surgery.

The Company has published strong results from phase II trials demonstrating the efficacy of FG001 as well as showing it was well tolerated and safe from clinical trials in patients undergoing surgery to remove aggressive brain (high-grade glioma), head & neck and lung cancers. Based on this strong foundation, FluoGuide expands the scope of application of FG001 and advances the development toward approval in aggressive brain cancer.

FluoGuide is listed on Nasdaq First North Growth Market, Stockholm under the ticker "FLUO". Read more about FluoGuide's pipeline, technology, and upcoming events on www.fluoguide.com

Attachments
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