PRESS RELEASE
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FluoGuide announces positive results from Phase 2 oral head and neck cancer trial

Copenhagen, Denmark, 29 June 2026 – FluoGuide A/S ("FluoGuide" or the "Company"), a biotech company maximizing surgical outcomes in oncology by lighting up cancer, today announced positive results from the first part of its ongoing FG001-CT-005 Phase 2 trial evaluating FG001 for surgical guidance in patients with oral head and neck cancer.

Key data:

- 19 patients screened, 15 patients enrolled and completed surgery, completing the first part of the trial and allowing release of the primary endpoint results
- The primary endpoint for the first part of the trial was achieved identifying the optimal FG001 dose (0.30 mg/kg)
- FG001 was very well tolerated consistent with prior clinical experience
- All near infrared imaging systems evaluated in the study could detect FG001 in all patients

The positive result will be discussed with Filip Lindkvist, Analyst at Redeye and Morten Albrechtsen, CEO FluoGuide on Wednesday 1 July 2026 with planned release end of the day. All questions are welcome on **ir@fluoguide.com** with a deadline Wednesday noon CET for being addressed in the interview.

FG001 is FluoGuide's most advanced development program. It is designed to bind selectively to cancerous tissue and light it up, helping surgeons remove more cancer with greater precision while sparing healthy tissue. FG001 is being developed as a surgical guidance adjuvant across multiple cancer indications, with a focus on high-grade glioma and oral head and neck cancers. In the United States, FG001 has received Orphan Drug designation and FDA Fast Track designation for high-grade glioma. FluoGuide has also completed a successful IND submission, with FDA authorization to initiate a U.S. high-grade glioma Phase 2 clinical trial expected to support registration.

Head and neck cancer affects approximately 900,000 people worldwide each year and is associated with more than 400,000 deaths annually. In oral head and neck cancer, surgeons aim to remove the tumor with a margin of at least 5 mm of healthy tissue, known as a "clear margin." Achieving a clear margin diminishes the need for additional post-operative adjuvant therapies, such as repeat surgery or radiotherapy, and thereby spares patients the potential side effects and reduced quality of life associated with such additional treatment. Today, final margin status is confirmed after surgery by a pathologist evaluating the removed tissue, which typically takes 7–14 days.

FG001-CT-005 is an open-label, single-dose, dose-finding exploratory Phase 2 trial evaluating FG001, an optical imaging agent, in patients with oral squamous cell carcinoma. The trial is designed to support intraoperative visualization of inadequate surgical margins, with the goal of helping surgeons assess and address inadequate margins while the patient is still in the operating room, rather than waiting for postoperative pathology results.

The primary endpoint of FG001-CT-005 is assessment of the optimal FG001 dose and administration timing. FG001-CT-005 is divided into two parts: Part 1, a dose-finding phase involving 15 patients, and Part 2, a dose-timing phase involving an additional 10 patients. The results reported herein are from Part 1, the dose-finding phase.

The results are from the 15 evaluable patients in the dose-finding part of the trial, in which FG001 doses of 0.15, 0.30, and 0.45 mg/kg were administered 14–18 hours prior to surgery. Based on this analysis, FluoGuide identified 0.30 mg/kg as the optimal FG001 dose, meeting the trial's primary endpoint.

FG001 was confirmed to be very well tolerated, consistent with the safety profile observed in more than 125 patients treated with FG001 across clinical studies to date.

"We are very pleased by these interim findings and the identification of the optimal FG001 dose," said Donna Haire, Chief Operating Officer at FluoGuide*. "Our collaboration with Professor Dr. Max Witjes, a leading international expert in fluorescence-guided margin assessment in head and neck cancer surgery, and his clinical team is bringing us closer to our goal of giving surgeons real-time margin information to guide decisions during surgery."*

Plan and next steps
Additional data from FG001-CT-005 related to margin assessment across the surgical and pathology workflow are still being analyzed. These analyses are designed to further evaluate FG001's role in timely margin assessment, with particular focus on providing surgeons with information about inadequate margins early enough to guide further surgical resection before the surgery is completed.

Part 2 of the FG001-CT-005 trial will further evaluate:

- The remaining 10 patients will receive FG001 prior to surgery to evaluate additional administration timing windows for the selected 0.30 mg/kg dose that would provide greater flexibility for surgical planning.
- Further integration of FG001 into the surgical workflow for assessing margins of resected tumor tissue, with the goal of timely identification of incomplete margins in the operating room rather than waiting for post-surgical pathology evaluation.

Based on the Part 1 results, an amendment to the trial protocol is being prepared to allow evaluation of a more flexible FG001 dosing-to-surgery window in the second part of the trial. In the remaining ten patients, this timing window is intended to further evaluate the selected dose and its imaging performance in oral head and neck cancer, while also supporting clinical workflow integration.

Enrollment of the remaining ten patients is planned to start during Q4 2026 with the topline result to be expected in H1 of 2027.
Discussions with near-infrared imaging system manufacturers involved in the trial are progressing as planned to support the continued development of FG001.

"The positive Part 1 results strengthen our vision that FG001, in collaboration with surgeons and imaging system manufacturers, has the potential to support an integrated surgical workflow that bring timely margin assessment into the operating room for oral head and neck cancer surgery, with the goal of providing a major benefit to patients" said Morten Albrechtsen, CEO, *"While additional data remain to be analyzed, we are encouraged that the findings to date support the key clinical objective of providing surgeons with margin information early enough to guide further resection".*

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About FG001
FG001 is FluoGuide's lead product candidate. FG001 binds specifically to cancerous tissue and light it up. It helps guiding the surgeon in removing all cancer while sparing healthy tissue. FG001 is targeting urokinase-type plasminogen activator receptor (uPAR), which is a cancer specific target expressed extensively in most solid cancers. It consists of a uPAR-targeting peptide linked to a fluorescent molecule with similar spectral specifications to indocyanine green (ICG) and therefore compatible with the current standard of surgical systems visualizing near infrared (NIR) light. The product is administered into a patient's vein (intravenously) prior to surgery and is designed to provide intraoperative NIR fluorescence signal from malignant tissue. FG001 is being developed as a surgical guidance adjuvant across multiple cancer indications, with a focus on high-grade glioma and oral head and neck cancers. In the United States, FG001 has received Orphan Drug designation and FDA Fast Track designation for high-grade glioma. FluoGuide has also completed a successful IND submission, with FDA authorization to initiate a U.S. high-grade glioma Phase 2 clinical trial expected to support registration.

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About FluoGuide
FluoGuide lights up cancer to maximize surgical outcomes in oncology. FluoGuide's lead product, FG001, is designed to improve surgical precision by lighting up cancer intraoperatively. The improved precision has a dual benefit – it reduces both the frequency of local recurrence post-surgery and lessens surgical sequelae. Ultimately, the improved precision enhances the likelihood of complete cure and lower healthcare costs. FluoGuide has demonstrated that FG001 is both effective and well tolerated. FluoGuide has entered partnerships with leading MedTech companies with the aim of accelerating development and commercialization. FluoGuide is listed on Nasdaq First North Sweden under the ticker "FLUO".
For more information on FG001 or FluoGuide's uPAR technology platform, please visit our home page www.fluoguide.com

About head and neck cancer
Head and neck cancer affects approximately 900,000 people worldwide each year and is associated with more than 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. Head and neck cancer includes cancers in the lining of the lips, tongue, mouth, or upper throat. Head and neck cancers are 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.
In oral head and neck cancer, surgeons aim to remove the tumor with a margin of at least 5 mm of healthy tissue, known as a "clear margin." Achieving a clear margin diminishes the need for additional post-operative treatment, such as repeat surgery or radiotherapy, and thereby spare patients potential side effects associated with such additional treatment. Today, final margin is confirmed after surgery by a pathologist evaluating the removed tissue, which typically take 7–14 days.
Determine of the margin can be done in different ways in several precaudal steps from the in vivo removal of the cancer to the post surgery delayed pathologist assessment. Margin assessment is important across surgeries removal of several types of cancer, eg. breast, colorectal and skin. The margin determination technology applied in this trial has the potential to be amplified to all other cancer surgeries where this technique is important.

Attachments
FluoGuide announces positive results from Phase 2 oral head and neck cancer trial