PRESS RELEASE
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FluoGuide provides update on strong clinical trial progress

FluoGuide A/S ("FluoGuide" or the "Company"), a Danish biotech company that pioneers precision cancer surgery, is pleased to provide an update on the status of the Company's three ongoing clinical trials with FG001, which aims to assist surgeons in accurately locating and removing cancerous tissue. Interim results from the phase IIa trial in lung cancer demonstrate consistent activity of FG001 with light detected in 6 out of 8 patients. Encouraging data from the head & neck cancer trial merits a cohort expansion and the phase IIb trial in brain cancer remains on track.

"Clinical data have shown that FG001 has the potential to significantly improve the results of surgery for cancer patients. The last patient has been enrolled into the phase IIa lung trial with positive interim results from the second cohort, the status of the head & neck cancer trial is encouraging, confirming the previous positive interim result. We are pleased with this clinical progress and are looking forward to the final readouts of the three ongoing studies. The next steps of clinical development for FG001 will be prepared over the coming months, based on additional data from the ongoing trials. We remain committed to advancing FG001 towards commercialization with the aim to improve surgery outcomes for patients with cancer," says CEO Morten Albrechtsen.

FluoGuide is conducting three clinical trials with FG001 to guide surgery in cancer patients:

- Phase IIb trial in aggressive brain cancer (high grade glioma)
- Phase IIa (explorative) trial in aggressive lung cancer (non-small cell lung cancer)
- Phase IIa (explorative) trial in aggressive head & neck cancer (squamous cell carcinomas)

Phase IIb trial in aggressive brain cancer

Recruitment of patients remains on track, as previously communicated, with the last patient expected to be enrolled during the summer of 2023 and the topline result approximately 2 months after that, when the analysis of biopsies and MRI scans has been completed. These analyses are blinded and can therefore only be initiated after the last patient has been enrolled.

The trial compares FG001 with the currently approved product 5-ALA for guiding surgery in aggressive brain cancer and the results will be used to support the design of the phase III trial. The ongoing phase IIb trial is not designed to show significant difference or non-inferiority to 5-ALA.

Phase IIa (explorative) trial in lung cancer

An interim evaluation of the second cohort in the phase IIa non-small cell lung cancer (NSCLC) trial showed that FG001 illuminates cancer in 6 out of 8 patients. The last patient has been enrolled (15 patients in total).

The Company expects the topline results to demonstrate that FG001 lights up in the majority of the patients, supporting further clinical development in this indication. The topline result continues to be expected in H1 2023.

Phase IIa (explorative) trial in head & neck cancer

Following encouraging results, Fluoguide has decided to extend the second cohort from 4 to 8 patients to generate a larger data set. FG001 illuminating cancer in all 11 patients enrolled so far. The last patient of the second cohort is expected to be enrolled in June, and communication of the interim results is expected in H1 2023.

It has been decided to expand the trial with 1-2 additional cohorts of 4 patients in order to obtain data from a lower dose, to demonstrate the robustness of FG001's effect across a broad dose range. The topline results for the expanded and amended trial are thus expected to be released in H2 2023.

Clinical Trial Application (CTA) for low grade glioma, high grade glioma and meningioma

FluoGuide has received permission to start a clinical trial of FG001 in low grade glioma, high grade glioma and meningioma from the Danish Medicines Agency and ethical committee. Further details on timelines, design and possible outcomes are expected to be communicated in H2 2023.

For further information, please contact:

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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 aggressive brain cancer (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 trial in meningioma and low-grade glioma is commencing. FluoGuide is listed on Nasdaq First North Growth Market, Stockholm under the ticker “FLUO”.

For more information on the Company, please visit **www.fluoguide.com**

This information is information that FluoGuide A/S is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-05-24 09:52 CEST.

Attachments
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