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Presentation of data where FG001 demonstrates dose-depended effectiveness in lightening up glioblastoma in a preclinical model

FluoGuide A/S's ("FluoGuide", ticker FLUO) compound FG001 lights up the cancer and has in preclinically studies demonstrated potential to vastly improve the radicality of surgery in different types of cancer. Today data was presented at World Molecular Imaging Congress 2019 (WMIC) in Montreal, demonstrating dose-dependent FG001 effectiveness in lightening up glioblastoma in a preclinical model.

Despite several decades of effort in improving the standard therapy of Glioblastoma (GBM), an aggressive form of cancer in the brain, the average life expectancy after a GBM diagnosis is only 14 months. Surgery in combination with radiation and adjuvant chemotherapy is standard of care for patient with GBM. High precision is particularly important in GBM surgery to radically remove the GBM without creating unnecessary side-effects for the patients.

FG001, a uPAR target fluorescent molecule, was in this study injected intravenously before imaging. The primary aim of this study was to determine the optimal dose and useful time-window of FG001 in an orthotopic human xenograft GBM model. FG001 has previously been demonstrated to lighten up GBM, however, as a preparation for the forthcoming clinical study in humans, FG001 was in this study tested in different doses to help planning the design of the clinical study.

Doses of 1, 2.5, 5, or 10 nmol of FG001 was administered intravenously prior to removal of the glioblastoma cancer. The mouse was then imaged with a near-infrared (NIR) camera, VisionSense, to determine the tumor-to-background ratio (TBR). After determination of the optimal dose, a new group of mice was included and operated using optical guidance from the fluorescent signal. The highest mean TBR value was 8.7 was found at a dose of 5 nmol with almost the same TBR found at 2.5 nmol. The TBR at 2.5 and 5 nmol were approximately 3-fold higher than at 1 nmol ($p=<0.01$). Compared to 2.5 and 5 nmol, there was no additional improvement of TBR by increasing the dose to 10 nmol.

"FG001 again showed that it lightens up human brain cancer and an optimal dose giving a high visibility and contrast to the background has been now been determined as an important information for designing the forthcoming clinical study" says Morten Albrechtsen, CEO of FluoGuide, and further comments: "Yet another equipment for NIR imaging was used used together with FG001 in this study compared to the data presented yesterday on FG001 guided surgical resection of metastatic pancreatic cancer. This illustrates the important fact that FG001 is compatible with a broad range of types of equipment."

PhD student Karina Juhl from Rigshospitalet and University of Copenhagen, presenting the data concluded that: "Orthotopic xenograft glioblastoma was clearly delineated from healthy tissue by optical imaging using the uPAR targeted optical probe FG001 and the ex vivo fluorescent signal co-localized with uPAR expression. A dose of 2.5 - 5 nmol FG001 was demonstrated to create the optimal TBR and visibility."

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About the World Molecular Imaging Congress (WMIC)

The World Molecular Imaging Congress (WMIC) is organized by the World Molecular Imaging Society (WMIS) widely recognized expertise in molecular imaging. WMIC was established in 2011 by integrating the Academy of Molecular Imaging and the Society for Molecular Imaging into a single streamlined society focused on advancing the field of molecular imaging (MI).

About FluoGuide

FluoGuide A/S (Spotlight Stock Market: FLUO:SS) provides solutions for maximizing surgical outcome through intelligent targeting. FluoGuide's first product FG001 increases precision in cancer surgery by lighting up the cancer and its invasive growth into the surrounding tissue. FG001 is expected to reduce suffering for the patients and increase the likelihood of cure. It can also reduce costs for the health care system for the benefit of society. FluoGuide focuses on demonstrating the effect of FG001 in patients by conducting a human proof-of-concept clinical trial and expects to announce the first result of this study during first half of 2020.

About FG001

FG001, FluoGuide's first product, lights up the cancer and its invasive growth into the surrounding tissue. It helps the surgeon remove the entire tumor during surgery and increases the chance for complete cure of the patient. The task for the surgeon is simply to "turn the lights on and see the entire tumor". The solution helps surgeons remove a minimal amount of normal tissue while also reducing the risk of leaving cancer tissue behind. This reduces the suffering of the patient and increases the likelihood of cure, and also reduces costs for the health care system. FG001 is currently prepared for a proof-of-concept clinical study.