

Presentation of data where use of FG001 demonstrates improved surgical outcome in metastatic pancreatic cancer compared to standard surgery using only white light

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 how FG001 for *in vivo* fluorescent guidance improved surgical resection of metastatic pancreatic cancer in comparison with traditional white light surgery.

Pancreatic cancer remains one of the deadliest cancers, and the one and five-year survival rates have been reported as 15% and 3%ⁱ, respectively. Radical surgical tumor resection is critical for improved outcome and better survival rates. However, due to generally late diagnosis only a small portion of patients are eligible for surgery. Even in the small group of patients that undergo surgery with curative intent, relapse is frequent. In addition, the low survival rate for pancreatic cancer is due to lack of other effective treatments. Optical guided surgery could be a solution to obtain better surgical outcome.

The study presented had two objectives; (1) Evaluation of the use of FG001 in resection of the primary tumor and metastases in an orthotopic human xenograft pancreatic cancer model using different types of equipment; and (2) Investigation of whether fluorescent-guided imaging using FG001 could locate additional metastases when following conventional removal of metastasis under white light surgery using the da Vinci[®] Surgical Robotic System operated by a human surgeon.

FG001, a uPAR target fluorescent molecule, was in this study injected intravenously before imaging with two different near-infrared camera systems (Fluobeam800[®] and the da Vinci[®] Surgical Robotic System equipment). The result showed that FG001 was an excellent probe for intraoperative optical imaging with a mean tumor-to-background ratio (TBR) for the primary tumor of 3.5 (95% CI: 3.3; 3.7) and a TBR for the metastases of 3.4 (95% CI: 3.1; 4.0). Further, a benefit using intraoperative fluorescent guidance was shown yielded identification of an additional 14% metastases compared to using normal white light surgery. On a subject basis, in 4 of 8 mice (50%) there were identified additional metastases with FG001 optical imaging compared to white light.

"Translated to humans, this result indicates that half of the patients undergoing traditional white light surgery would have been sent home with a metastasis that could have been detected and removed using FG001." Says Morten Albrechtsen, CEO of FluoGuide, and further comments: "We are very excited to bring this promising product forward with the potential to help improve the surgical outcome for patients with pancreatic cancer"

PhD student Karina Juhl from Rigshospitalet and University of Copenhagen, presenting the data concluded that: "the uPAR-targeted optical probe enables intraoperative optical cancer imaging, including during robotic surgery, and may be a benefit for intended radical resection of disseminated pancreas cancer by finding more metastasis than with traditional white light surgery."

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About FluoGuide

FluoGuide A/S provides solutions for maximizing surgical outcome through intelligent targeting. FluoGuide's first product, FG001, improves precision in cancer surgery by lighting up the cancer and its invasive growth into the surrounding tissue. FG001 is made of a cancer targeting molecule linked to a fluorophore. The FluoGuide products is expected to reduce the suffering of patients and increase the likelihood of cure. They can also reduce costs for the health care system and thus benefit society. FluoGuide focuses on demonstrating the effect of FG001 in patients by conducting a human proof-of-concept clinical trial. The potential of FluoGuide goes beyond FG001 and cancer surgery. FluoGuide is listed on Spotlight Stock Market (ticker: FLUO)

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.

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).

ⁱ Carrato A, Falcone A, Ducreux M, Valle JW, Parnaby A, Djazouli K, Alnwick-Allu K, Hutchings A, Palaska C, Parthenaki I. A Systematic Review of the Burden of Pancreatic Cancer in Europe: Real-World Impact on Survival, Quality of Life and Costs. *J Gastrointest Canc.* Springer US; 2015; 46: 201–11. doi: 10.1007/s12029-015-9724-1.