

## Safety study initiated with FG001

**FluoGuide A/S ("FluoGuide") hereby announces that the first *in vivo* dosing of FG001 will commence today. This is an important milestone advancing FG001 for clinical evaluation in patients with glioblastoma. FluoGuide has chosen a strategic way forward in species selection with minimal risk.**

FluoGuide's FG001 is designed to be well tolerated and its two main components have both demonstrated excellent tolerability profiles in humans.

The result of the species qualification points FluoGuide to use the species with the longest delivery time and the first results from the clinical study with FG001 in patients with glioblastoma will therefore be presented in Q3 2020 instead of Q2 2020. Despite a temporal shift of one quarter, no other milestones or budget are affected.

The safety of FG001 is to be established in non-clinical toxicity studies to the satisfaction of both FluoGuide and health authorities before it can be tested in humans. uPAR differs between humans and the animal species normally used in safety studies. This species difference in uPAR binding is important to understand and take into consideration when interpreting the findings, or lack of findings, in non-clinical toxicity studies before setting the first human dose.

FluoGuide has chosen to conduct an *in vitro* investigation of these differences in uPAR binding for a number of reasons: (1) to reduce risk for patients when testing FG001 first-in-humans, (2) to reduce the risk of delays of commercial milestones by having to re-do the *in vivo* safety studies at a later stage where a repetition of the *in vivo* safety studies could have caused significant delays and additional costs, and (3) the set-up of uPAR binding assays can significantly accelerate FluoGuide's pipeline of uPAR targeted fluorophores.

### **Morten Albrechtsen, CEO comments:**

*"We are delighted that the safety study is now initiated and look forward to an exciting 2020. We would of course have preferred to deliver the first result from the clinical study in Q2 2020 but prefer to temporal shift three months now to minimise risk of a delay at a later stage that could have seriously affected our commercial milestones and budget".*

### **For further information, please contact:**

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*FluoGuide A/S is obliged to publish this information in accordance with the EU Market Abuse Regulation. The information was provided by the contact person above for publication on the 9th of January 2020.*

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### **About FluoGuide**

FluoGuide A/S 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.