



FluoGuide reaches milestone with FG001 for phase III clinical supply

Copenhagen, Denmark, 8 November 2022 – FluoGuide A/S (“FluoGuide” or the “Company”) is pleased to inform that the first large scale batch for its lead product FG001 has been successfully manufactured in preparation for phase III clinical development.

FluoGuide has successfully collaborated with its supplier PolyPeptide since the very first synthesis of the FG001 API (Active Pharmaceutical Ingredient). FG001 is a clinical development project that was started in 2020 for the novel treatment of aggressive brain cancer. A first large scale batch has now been successfully manufactured by PolyPeptide in preparation for phase III clinical development.

For the pivotal phase III clinical trials, FluoGuide with the support of PolyPeptide has scaled up the manufacturing of FG001 to commercial scale. As part of the clinical process, FluoGuide now plans for three validation batches in commercial scale to be documented and included in the registration package for commercial approval.

Obtaining success with the first Phase III batch is therefore an important milestone for the preparation of any phase III trials and commercialization of FG001.

Morten Albrechtsen, CEO FluoGuide says *“The completion of the first large scale GMP batch is a milestone for our lead product FG001, as it paves the way towards the next clinical steps and bringing us closer to commercialization”*.

Neil Thompson, Director Global Sales and Marketing, Polypeptide says: *“We are thankful for the opportunity to work with FluoGuide on the highly innovative FG001 project and congratulate the whole team for reaching this milestone.”*

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About PolyPeptide

PolyPeptide is a focused Contract Development & Manufacturing Organization (CDMO) for peptide- and oligonucleotide-based active pharmaceutical ingredients. By supporting its customers mainly in pharma and biotech, it contributes to the health of millions of patients across the world. PolyPeptide offers products and services from pre-clinical through to commercial stages, including generics. Its active custom projects pipeline reflects the opportunities from novel drug therapies in development to fight both widespread and rare diseases. Dating back to 1952, PolyPeptide today runs a global network of six GMP-certified facilities in Europe, the U.S. and India with around 1,200 employees as per the middle of 2022. PolyPeptide's shares (SIX: PPGN) are listed on SIX Swiss Exchange. For more information, please visit [polypeptide.com](https://www.polypeptide.com).

About FluoGuide

FluoGuide's primary focus is to maximize surgical outcomes in oncology. 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 has 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 is has demonstrated efficacy of F001 as well as it to be well tolerated and safe in the ongoing proof-of-concept clinical study (phase I/II) in patients with high grade glioma undergoing surgery. FluoGuide has decided to explore FG001 in three other severe cancer indications, namely lung, head & neck, meningioma and low grade glioma. FluoGuide is listed on Nasdaq First North Sweden under the ticker "FLUO".

For more information on the Company's uPAR technology platform and our pipeline please visit our home page www.fluoguide.com

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