

Press release

26 August 2025

Curasight announces acceptance of clinical trial application (CTA) for phase 1 trial with uTREAT® in brain cancer patients

- Phase 1 study in aggressive brain cancer (Glioblastoma) is the first clinical trial investigation of uTREAT belonging to Curasight's treatment platform.
- Initiation of the study marks a key milestone with Curasight now in clinical development with both its diagnostic (uTRACE®) and therapeutic (uTREAT®) platforms
- Dosing of first patient expected Q4 2025

Copenhagen, 26 August 2025 - Curasight A/S ("Curasight" or "the Company" - TICKER: CURAS), a clinical stage radiopharmaceuticals company, today announced the European Medicines Agency (EMA) has approved the company's clinical trial application (CTA) for the investigation of uTREAT® in a phase 1 trial.

The phase 1 trial is part of Curasight's theranostic strategy developing more gentle and targeted diagnosis and treatment of certain types of cancer. Dosing the first patient in the trial is expected to occur before the end of the year.

Today's news means Curasight is now in clinical development with both its diagnostic (uTRACE) and therapeutic (uTREAT) platforms.

"The approval of the CTA underlines the strong progress being made in developing uTREAT as a potential more targeted therapeutic solution for patients with aggressive brain cancer, where there is a strong unmet medical need," said Curasight's CEO Ulrich Krasilnikoff and continues, "There has been little progress in treating glioblastoma over the last decades but recently published data from an investigator-initiated Phase II study highlighted the potential of both uTRACE and uTREAT in diagnosing and treating brain cancer where 94% of Grade 4 gliomas -including glioblastomas - were uPAR-positive."

About the Phase 1 trial with uTREAT in brain cancer

The trial aims to investigate Curasight's uTREAT as a new type of targeted radiopharmaceutical therapy in glioblastoma patients. Participants in the trial are patients with newly diagnosed verified or suspected GBM. The trial design is informed from research and earlier studies with uTRACE® as well as protocol discussions with Key Opinion Leaders.

About the uPAR theranostic platform

Curasight's uPAR theranostic platform combines two key technologies - uTRACE and uTREAT both targeting the uPAR receptor. uTRACE is designed to deliver sensitive imaging for diagnosis, while uTREAT offers a targeted radiopharmaceutical solution. Together, they form an integrated approach to improving the diagnosis and treatment of cancers that express uPAR. Curasight's ambition is to develop both uTRACE and uTREAT to improve diagnosis and treatment of uPAR-expressing cancers.

About high grade glioma

Treatment of glioblastoma and other high-grade gliomas (WHO grades 3 or 4) presents a significant unmet medical need, necessitating innovative and effective treatments. A total of approx. 65,000 patients are diagnosed with primary brain tumors and more than 30,000 patients are diagnosed annually with the most aggressive form, glioblastoma, in the US and EU. Approximately 10 % of the patients are children. The prognosis for individuals with glioblastoma is very poor as approximately 50% of the patients die within 14 months and after five years from diagnosis only 5% are still alive. External beam radiation is a cornerstone in the therapy of brain cancers. uTREAT could potentially replace or reduce the use of external beam radiation and thereby lower side effects to the healthy brain due to more specific tumor tissue targeting.

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Curasight is a clinical development company based in Copenhagen, Denmark. The Company is a pioneer in the field of exploiting a novel Positron Emissions Tomography (PET) imaging (uTRACE®) and Radioligand Therapy (uTREAT®) Theranostic Platform targeting the urokinase-type plasminogen activator receptor ("uPAR"). The technology is expected to improve diagnosis and provide more gentle and efficient treatment of multiple cancer types.