

Press release

June 18 2025

Curasight A/S submits Clinical Trial Application for Phase 1 trial with uTREAT® in brain cancer patients

- Clinical Trial Application (CTA) submission marks progress in development of uTREAT® in aggressive brain cancer (Glioblastoma)
- Glioblastoma is the leading cause of brain cancer deaths in adults
- First patient to be dosed in H2 2025
- uTREAT represents a potential new treatment option in an area of high unmet medical need

Copenhagen, June 18, 2025 - Curasight A/S (“Curasight” or “the Company” – TICKER: CURAS) today announced submission of clinical trial application (CTA) to the European Medicines Agency (EMA) for the phase 1 trial of uTREAT® as a treatment for glioblastoma.

The CTA was submitted under the application pathway Clinical Trials Information System (CTIS) and paves the way for patients to be recruited into a phase 1 trial of uTREAT in brain cancer patients diagnosed with glioblastoma.

“Today’s news marks important progress in our efforts to develop uTREAT for treatment of patients with aggressive brain cancer,” said Curasight’s CEO Ulrich Krasilnikoff, and continues “The recently published investigator-initiated Phase II uPAR-PET data highlights the potential of uTRACE and uTREAT in diagnosing and treating brain cancer, in particularly glioblastoma. The study revealed that 94% of Grade 4 gliomas - including glioblastomas - were uPAR-positive, strongly supporting the potential of uTREAT as a therapy for this cancer type. This is important as the cancer has a poor prognosis, with essentially no improvement in outcome over the last decades. Accordingly, there is a significant unmet medical need, and we hope that uTREAT will prove to be a game-changer for patients with this aggressive cancer”.

About the Phase 1 trial with uTREAT in brain cancer

The trial is aimed at investigating Curasight’s uTREAT as a new type of targeted radiation therapy in glioblastoma patients. The trial will also characterize the safety of this approach.

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 treatment 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.