Press release
December 18, 2023

Curasight A/S submits clinical trial application (CTA) for phase 2 trial with uTRACE® in prostate cancer patients

- Company on track to dose first patient in 2Q 2024
- CTA marks progress in development of uTRACE® in prostate cancer under the collaboration between Curasight and Curium

Copenhagen, December 18, 2023 - 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 investigation of uTRACE® in a phase 2 trial as a non-invasive alternative or supplement to traditional biopsies in prostate cancer patients in active surveillance.

The CTA was submitted under the new application pathway Clinical Trials Information System (CTIS) and paves the way for patients to be recruited into the phase 2 trial of uTRACE® in prostate cancer which is part of the collaboration with Curium, announced in May 2023.

"Today's news marks important progress in our efforts to develop uTRACE® for use in improving diagnosis for prostate cancer patients," said Curasight's CEO Ulrich Krasilnikoff. "This is an important step in our collaboration with Curium, and the moving towards dosing the first patient in a phase 2 trial with Copper-64 and allowing us to keep momentum in our efforts to bring uTRACE® as a potential new option for patients."

About the Phase 2 trial with uTRACE® in prostate cancer
The primary objective of the phase 2 trial is to investigate Curasight's first-in-class PET tracer, 64Cu-DOTA-AE105 as a non-invasive grading tool of prostate cancer patients that are followed in active surveillance.

Patients in active surveillance are continuously monitored for changes in the aggressiveness of their prostate cancer and can be followed for years without identifying the need for treatment. The trial design is informed from research and earlier studies with uTRACE® as well as protocol discussions with the US Food and Drug Administration (FDA). The phase 2 trial is part of the development framework agreed under the deal with Curium.

About the uPAR diagnostic platform
The uTRACE® platform is part of Curasights uPAR theranostic solution, made up of its uTRACE® diagnostic technology and its uTREAT® targeted treatment technology. In prostate cancer, uTRACE® is presently developed for diagnostic purposes only. Curasight's ambition is to develop both uTREAT® and uTRACE® to improve diagnosis and treatment solutions of certain cancers.

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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.