Press release
April 16, 2024

Curasight announces approval of clinical trial application (CTA) for phase 2 trial with uTRACE® in prostate cancer patients

- Dosing of first patient expected 2Q 2024
- CTA approval marks progress in development of uTRACE® in prostate cancer under the collaboration between Curasight and Curium Inc.
- Phase 2 trial is part of Curasight's efforts to build a pipeline of products using radiopharmaceuticals for improved diagnosis and more targeted treatment of different cancer types

Copenhagen, April 16, 2024 - Curasight A/S ("Curasight" or "the Company" – TICKER: CURAS), a clinical stage radiopharmaceuticals company, today announced approval of clinical trial application (CTA) from 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 phase 2 trial is part of Curasight's collaboration with Curium for uTRACE® in prostate cancer, announced in May 2023 and the first patient is expected to be dosed in Q2 2024. The trial is aimed at providing clinical insight into the use of uTRACE® as a non-invasive way of providing more accurate diagnosing and grading of prostate cancer, an area with a recognized high unmet medical need.

"The acceptance of the CTA illustrates the strong progress being made in developing uTRACE® as a potential solution providing better diagnosis and categorization of tumors for prostate cancer patients. Today's news is also testament to the positive collaboration we have with Curium" said Curasight's CEO Ulrich Krasilnikoff. "We look forward to dosing the first patient in this phase 2 trial with Copper-64 uPAR-PET and to continuing momentum in our efforts to bring uTRACE® as a 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 radiopharmaceutical theranostic solution, made up of its uTRACE® diagnostic technology and its uTREAT® radioligand therapy 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 several solid cancers.

PROVIDING ANSWERS FOR CANCER PATIENTS

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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.