PRESS RELEASE

Advanced Accelerator Applications Announces First Patients Dosed in Two Clinical Studies with PSMA-R2 for Prostate Cancer

Second Theragnostic Program for Oncology Enters the Clinic

Saint-Genis-Pouilly, France, June 22, 2018 - Advanced Accelerator Applications S.A. (AAA), a Novartis company and leader in nuclear medicine theragnostics, today announced that the first patients have been dosed in two Phase I/II clinical studies of radiolabeled PSMA-R2, a urea-based ligand of Prostate-Specific Membrane Antigen (PSMA), which is commonly expressed on prostate cancer cells.

The PROter study is an open-label, multi-center, dose-escalation/dose-expansion trial evaluating treatment with ^{177}Lu-PSMA-R2 RadioLigand Therapy in patients with PSMA positive progressive, metastatic castration-resistant prostate cancer following previous systemic treatment. Primary objectives for Phase I include characterizing the drug's safety profile and tolerability, as well identifying a recommended Phase II dose. The primary objective for Phase II is assessment of antitumor activity, as measured by radiographic progression-free survival. Other objectives include prostate-specific antigen (PSA) response, time to PSA progression and overall survival. Approximately 96 patients are expected to be enrolled in the PROter trial.

The PROfind study is an open-label, multi-center trial evaluating Positron Emission Tomography (PET) imaging with ^{68}Ga-PSMA-R2 in patients with biochemical relapse and metastatic prostate cancer. The primary objective of the study is to assess the safety and tolerability of a single administration of ^{68}Ga-PSMA-R2. Secondary objectives include evaluation of pharmacokinetics, biodistribution and dosimetry of ^{68}Ga-PSMA-R2, as well as comparison with conventional imaging modalities. Approximately 30 patients are expected to be enrolled in the PROfind trial.

"Advancing PSMA-R2 into clinical studies is a major milestone for AAA," commented Germo Gericke, M.D., Head of Research and Development at Advanced Accelerator Applications. "This is the second theragnostic program in our oncology pipeline and we are eager to explore the full potential of this innovative platform in large patient populations, such as prostate cancer."

Prostate cancer is the second most common type of cancer in men worldwide leading to substantial morbidity and mortality[1]. It represents the second most common cause of cancer death in men in the USA and the third most common cause of death in developed countries[2,3]. Most cases of prostate cancer are curable if diagnosed at an early stage. Nevertheless, up to 40% of the patients with prostate cancer develop biochemical relapse within 10 years after initial local treatment with curative intent[4] and some patients will progress to metastatic prostate cancer. Despite the effectiveness of hormone therapy in the treatment of metastatic prostate cancer, patients who live long enough will ultimately succumb to metastatic castration-resistant prostate cancer.

More information about the PROter study may be found at:
https://www.clinicaltrials.gov/ct2/show/NCT03490838?term=NCT03490838&rank=1

More information about the PROfind study may be found at:
https://www.clinicaltrials.gov/ct2/show/NCT03490032?term=NCT03490032&rank=1

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About Advanced Accelerator Applications S.A.

Advanced Accelerator Applications, a Novartis company, is an innovative radiopharmaceutical company developing, producing and commercializing radioligand theragnostics. AAA is an established leader in radiopharmaceuticals for Positron Emission tomography (PET) and Single-Photon Emission Computed Tomography (SPECT) diagnostic imaging, mainly used in clinical oncology, cardiology and neurology. For more information, please visit: https://www.adacap.com/.

References

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