

Press release

New Alzheimer's drug PRI-002 receives EMA approval for Phase II study

Düsseldorf/Leipzig, 20.11.2023 - Priavoid GmbH and PRIInnovation GmbH announce today that the European Medicines Agency (EMA) has granted approval to conduct a Phase II clinical trial for the drug candidate PRI-002 to combat Alzheimer's disease.

The study, which is named PRImus-AD, is being conducted by PRIInnovation as sponsor in close collaboration with Priavoid and is funded by the German Federal Agency for Disruptive Innovation SPRIND with funds from the German Federal Ministry of Education and Research. The objective of the study is to demonstrate the efficacy of PRI-002 in patients with early-stage Alzheimer's disease as well as to further substantiate its safety profile, which was already shown to be convincing and beneficial in three Phase I studies. To this end, PRI-002 is being tested in a placebo-controlled Phase II study in 270 patients across initially six European countries.

The scientific basis for the study is a purely physical mechanism of action by which neurotoxic aggregates ("oligomers") of the Abeta protein are directly broken down into their individual, harmless building blocks ("monomers") and without the intervention of the immune system. PRI-002 thus fundamentally differs from antibody-based drug candidates that are currently applying for drug approval.

There are high hopes for the Phase II trial, which has now been approved, given that there are around 1.1 million Alzheimer's patients in Germany alone for whom no effective, disease-modifying and safe drugs have been approved to date.

Philipp Bürling, CEO of Priavoid GmbH, commented on the approval: "Phase II is groundbreaking for us as a company, but also for millions of people affected worldwide."

Prof. Dr. Dieter Willbold, co-founder of Priavoid adds, "After decades of setbacks in drug development, there has been some positive news recently. We can't wait to get started with the trial."

And PRIInnovation GmbH, which was founded by SPRIND specifically for the purpose of conducting this study, has also reached an important milestone. Dr. Kathrin Thiem, Co-CEO of PRIInnovation, says: "SPRIND's mission is to fund projects with disruptive potential that have a major benefit for humanity - but for which there is no private-sector funding. If we can show the efficacy of PRI-002 in this study, this is without any doubt a disruptive innovation."

Results for this study are expected in 2026. The aim is then to move seamlessly into a corresponding pivotal Phase III study.

About Priavoid Ltd:

Priavoid GmbH is a spin-off of Forschungszentrum Jülich and Heinrich Heine University Düsseldorf, which was founded in 2017 and is based in Düsseldorf. The company develops novel all-D-peptide drug candidates for the treatment of neurodegenerative diseases such as Alzheimer's, Parkinson's, ALS (amyotrophic lateral sclerosis) or Tauopathies. The most advanced of these is PRI-002 for Alzheimer's disease. All drug candidates are designed to have an anti-prionic mechanism of action to break down neurotoxic protein aggregates. The company is privately funded, including by Qiagen co-founder Prof. em. Dr. Dr. h.c. Detlev Riesner.

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About SPRIND:

The Federal Agency for Disruptive Innovations SPRIND was founded on December 16, 2019, with its registered office in Leipzig. The sole shareholder is the Federal Republic of Germany, represented by the Federal Ministry of Education and Research (BMBF) and the Federal Ministry of Economics and Climate Protection (BMWK). SPRIND fills a gap in the German innovation landscape: it finds new, groundbreaking technologies for the major challenges of our time, while ensuring that the value created by the resulting companies and industries remains in Germany and Europe. SPRIND is financed by funds from the federal budget. SPRIND is managed by Rafael Laguna de la Vera and Berit Dannenberg.

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About PRInnovation GmbH:

PRInnovation GmbH, with headquarters in Leipzig and Düsseldorf, was founded in June 2021. It is a 100% subsidiary of the Federal Agency for Disruptive Innovations. PRInnovation GmbH is managed by Dr. Kathrin Thiem and Dr. Alexander Brener. PRInnovation is working on the further clinical development of the therapeutic all-D-peptide PRI-002, a drug candidate against Alzheimer's dementia with an innovative mechanism of action. PRInnovation will assume the responsibilities and duties of the sponsor for the PRImus-AD study, a randomized, double-blind, placebo-controlled Phase II clinical trial to evaluate the safety and efficacy of PRI-002 in patients with Alzheimer's disease.

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