



Vivoryon Therapeutics Provides Update on US and EU Alzheimer's Clinical Trial Program with PQ912

- **Vivoryon and the Alzheimer's Disease Cooperative Study (ADCS) have developed a new trial design for Phase 2a Alzheimer's trial in the US; as a stage gate to Phase 2b**
- **EU Alzheimer's trial VIVIAD is expected to start in the second half of 2020 due to coronavirus pandemic-related delay**
- **PQ912 receives International Nonproprietary Name (INN), varoglutamstat**

HALLE (SAALE) / Munich, Germany, 26 June 2020 – Vivoryon Therapeutics AG (Euronext Amsterdam: VVY, ISIN DE0007921835) today announced updates to the Company's Alzheimer's Disease clinical development program in the United States and the European Union. In addition, Vivoryon's lead candidate, PQ912, received the approval of the International Nonproprietary Name (INN), varoglutamstat.

The University of California, San Diego Campus, which houses the ADCS, is submitting a modified proposal to the National Institutes of Health for the Phase 2a portion of the US clinical trial program for PQ912 in Alzheimer's Disease. The Phase 2a trial is planned to start in the course of 2021 and end in the course of 2023 and is proposed to include 180 patients who either receive PQ912 or a placebo orally over the course of six months. The trial will include a drug-titration phase, an early cognitive efficacy read-out, an assessment of parallel dose responses to three different, pharmacologically active doses of PQ912 and a composite Neuropsychological Test Battery (NTB) score for assessing cognitive efficacy. Data on electroencephalography (EEG) and cerebrospinal fluid (CSF) biomarkers will be complementary to the Phase 2b EU trial, VIVIAD, and the current safety database will be broadened by the increased patient population. The Phase 2a trial is designed to allow a seamless progression into Phase 2b which will also be run by the ADCS and Vivoryon Therapeutics.

The Phase 2a trial is supported by the National Institute on Aging (NIA), a division of the NIH, through a grant awarded in March 2019 for the project, *A Seamless Phase 2A-B Randomized Double-Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of PQ912 in Patients with Early Alzheimer's Disease*. The funding is listed under award number R01AG061146 to the University of California, San Diego, USA. Vivoryon Therapeutics will cover the remaining financial needs as well as manufacturing costs and drug supply chain management of PQ912 and placebo, including distribution of the study drug. Moreover, central EEG reading at VU Medical Center in Amsterdam, and PK, PD analyses will be covered by Vivoryon Therapeutics.

Howard Feldman MD, Professor of Neurosciences and Director of the ADCS, based at University of California, San Diego School of Medicine, commented, "Our new design of the Phase 2a Alzheimer's trial will be a stage gate to a Phase 2b study. The medication with PQ912 will allow us to target several disease mechanisms, as the modulation of the neuroinflammatory process that occurs in the disease. We are excited to have been given the opportunity to provide important data for our therapeutic concept."



In order to ensure the safety of trial participants and staff in accordance with current health guidelines and regulations surrounding the coronavirus pandemic, Vivoryon's EU Phase 2b trial, VIVIAD, is now expected to start during the second half of 2020 and expected to end in 2023.

As Vivoryon received the approval of an International Nonproprietary Name (INN) for PQ912 from the World Health Organization (WHO) the Company will refer to the compound's nonproprietary and generic name - varoglutamstat - in the future. The name is subject to a four-month objection period, after which the INN is published if no formal objections are raised.

Commenting on the trial updates and INN appointment, **Ulrich Dauer, CEO of Vivoryon Therapeutics, said**, "The importance of study design, particularly in a disease like Alzheimer's, cannot be underestimated. As such, the opportunity to update the US clinical trial protocol will enable us to further expand the framework in which we evaluate and gather information on PQ912. These results ultimately add to the growing body of data on this compound's potential in patients with Alzheimer's. In the meantime, receiving the INN stands as an external recognition of our drug candidate from the World Health Organization and we look forward to watching PQ912 develop as varoglutamstat."

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About Vivoryon Therapeutics AG

With 20+ years of unmatched understanding in identifying post-translational modifying enzymes that play critical roles in disease initiation and progression, Vivoryon's scientific expertise has facilitated the creation of a discovery and development engine for small molecule therapeutics. This platform has demonstrated success by developing a novel therapeutic in type 2 diabetes. In its current programs Vivoryon Therapeutics is advancing its lead product, PQ912, in Alzheimer's disease and its entire portfolio of QPCT and QPCTL inhibitors in oncology and other indications.

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Forward Looking Statements

Information set forth in this press release contains forward-looking statements, which involve a number of risks and uncertainties. The forward-looking statements contained herein represent the judgment of Vivoryon Therapeutics AG as of the date of this press release. Such forward-looking statements are neither promises nor guarantees but are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to



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