

Vivoryon Therapeutics Announces Update on Phase 2b Alzheimer's Clinical Trial, VIVIAD

Vivoryon has extended the trial protocol through the inclusion of exploratory parameters and plans to enroll patients in selected study sites in Denmark, Germany and the Netherlands

HALLE (SAALE)/MUNICH, Germany, 18 March 2020 – Vivoryon Therapeutics AG (Euronext Amsterdam: VVY, ISIN DE0007921835) announced today an update on the Phase 2b clinical trial testing the Company's lead candidate and first-in-class, highly specific and potent small molecule inhibitor of Glutaminyl cyclase, PQ912 in patients with early-stage Alzheimer's Disease.

The clinical trial named VIVIAD, derived from "advancing disease modifying treatment and noninvasive diagnostics of Alzheimer's disease," has been designed to test the efficacy and safety of various doses of PQ912 in 250 early-stage Alzheimer's patients in a randomized, placebo-controlled study over the course of 48 to 96 weeks. Prof. Dr. Scheltens, VU Amsterdam will act as coordinating investigator and VIVIAD intends to use a total of only 10 high-recruiting sites from Denmark, Germany and the Netherlands. The study is scheduled to enroll its first patient in Q2 2020 with the topline results expected towards the end of 2022.

The primary endpoints of the study are designed to assess the safety and tolerability of PQ912 in addition to its efficacy on working memory and attention. The secondary endpoints include long-term safety and tolerability of PQ912 and its efficacy on brain-activity, cognition and activities of daily living.

Vivoryon has also added exploratory parameters selected with the rationale of advancing less invasive diagnostic technologies. This will include the Winterlight Labs speech assessment, the use of EEG to test neuronal network activity and connectivity, as well as a set of blood-based biomarkers run by Nordic Bioscience. The inclusion of these parameters will further strengthen PQ912's data package and introduce more innovative and less demanding diagnostic tools to future patients.

Dr. Michael Schaeffer, CBO of Vivoryon Therapeutics commented:

"We have tailored and prepared this trial strategically and value the support of Prof.Scheltens, one of the world leading Alzheimer experts, as our coordinating investigator. With Nordic Bioscience, Winterlight Labs and VUMC Amsterdam we have excellent and well-trusted partners to provide us with a greater level of detail and information. We look forward to treating the first patient in the next months."

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About PQ912 in Alzheimer's Disease

PQ912 is a first-in-class inhibitor of the QC enzyme that addresses a very distinct disease pathway and provides a dual mode of action in contrast to other available Alzheimer's Disease programs in development. Positive results from a Phase 2a clinical trial published in June 2017 demonstrated a significant improvement in the synaptic function of PQ912-treated Alzheimer's patients versus a control group in addition to measurable improvements in the memory performance of patients treated with PQ912, despite the short treatment time of only twelve weeks.

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.

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 differ materially from those contemplated in these forward-looking statements. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any such statements to reflect any change in our expectations or any change in events, conditions or circumstances on which any such statement is based.

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