Vivoryon Receives IND Approval for Varoglutamstat's (PQ912) Phase 2 Study in Alzheimer's Disease

HALLE (SAALE) / Munich, Germany, 04 August 2020 – Vivoryon Therapeutics AG (Euronext Amsterdam: VVY, ISIN DE0007921835) today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for varoglutamstat (PQ912). FDA clearance of the IND will enable Vivoryon to initiate its U.S. Phase 2 clinical trial program for varoglutamstat (PQ912) in Alzheimer's disease as planned. All preparations at Vivoryon and its cooperation partner the Alzheimer's Disease Corporate Study (ADCS) at the University of California, San Diego, are in line with the project plan which aims for a study start around mid-2021 and a final data readout in 2023. The trial design will allow a seamless progression into Phase 2b.

The Phase 2a clinical trial will include 180 patients with mild Alzheimer's disease who will either receive varoglutamstat (PQ912) or a placebo orally over the course of six months. The trial design includes a drug-titration phase 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 already active Phase 2b EU trial, VIVIAD.

"The IND clearance represents the completion of the next milestone on our way to soon having two active Phase 2 studies assessing the efficacy of varoglutamstat. This step transforms our lead candidate into a frontrunner of novel therapeutic approaches beyond standard Abeta and Tau targeting drugs in development," **commented Dr. Michael Schaeffer, Chief Business Officer of Vivoryon Therapeutics.** "Varoglutamstat has already shown initial signs of cognitive efficacy in a three months Phase 2a trial in Europe, therefore, we are look forward to reviewing the efficacy results from both Phase 2 trials in Europe and the U.S.," he added.

Varoglutamstat (PQ912) is a novel drug candidate with disease-modifying potential for AD. The small molecule compound targets glutaminyl cyclase (QC), an enzyme which catalyzes the conversion of Abeta into pyroglutamate-Abeta (pGlu-Abeta). This highly toxic modification triggers the formation of toxic soluble Abeta oligomers, key culprits in AD pathology. The Vivoryon team was the first to discover and describe the relevance of the QC enzyme in human diseases in detail and has developed a broad intellectual property portfolio around QC inhibitors and assays.

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About Varoglutamstat (PQ912) in Alzheimer's Disease
Varoglutamstat (PQ912) is a first-in-class, highly specific and potent small molecule inhibitor of Glutaminyl cyclase (QC, QPCT). In a Phase 1 study in healthy young and elderly volunteers, varoglutamstat showed a good safety and tolerability profile up to the highest dose. A subsequent Phase 2a study (SAPHIR) revealed significant improvements in a cognition parameter after only three months of treatment. Based on these findings, Vivoryon initiated a Phase 2b trial (VIVIAD) in Europe in early stage Alzheimer's disease. A second Phase 2a trial is planned in the US and is supported by a significant grant from the NIH.

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. In addition, the company pursues a development program for Meprin protease inhibitors with potential therapeutic use in fibrotic diseases, cancer and acute kidney injury.
www.vivoryon.com

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.