



Vivoryon Therapeutics Announces Enrollment of First Patient in VIVIAD, European Phase 2b Alzheimer’s Disease Study with Varoglutamstat (PQ912)

HALLE (SAALE) / Munich, Germany, 15 July 2020 – Vivoryon Therapeutics AG (Euronext Amsterdam: VVY, ISIN DE0007921835) today announced that the first patient has been enrolled in VIVIAD, a Phase 2b, randomized and multi-center clinical study in Europe. The study will evaluate the safety and efficacy of Vivoryon’s lead candidate, varoglutamstat (PQ912), in patients with Alzheimer’s disease (AD).

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.

VIVIAD will aim to enroll approximately 250 patients with mild-cognitive impairment and early-stage Alzheimer’s disease. The trial will be led by internationally renowned experts at 10 clinical sites in Denmark, Germany and the Netherlands.

The primary endpoints of the trial include the assessment of safety, tolerability and efficacy of varoglutamstat (PQ912) compared to placebo over 48 to 96 weeks of treatment. A composite Neuropsychological Test Battery (NTB) score will be administered throughout the study in order to assess cognitive efficacy. Additionally, a set of exploratory read-outs including cognitive tests, functional electroencephalogram (EEG), magnetic resonance imaging (MRI) assessments and the analysis of new molecular biomarkers in the cerebrospinal fluid (CSF) will be used to evaluate the compound's effect on disease pathology.

Secondary endpoints include long-term safety and tolerability of varoglutamstat (PQ912) and its efficacy on brain activity, cognition and activities of daily living.

The data read-out of the VIVIAD study is expected to be available in 2023.

“The start of patient enrollment for the VIVIAD Phase 2b trial marks an essential milestone for Vivoryon as we continue to bring varoglutamstat (PQ912) one step closer to registration. The initiation of VIVIAD is the result of the significant efforts put forth by our team in preparing the



study and the active collaboration and commitment from the clinical sites,” **commented Ulrich Dauer, Chief Executive Officer at Vivoryon Therapeutics.**

Michael Schaeffer, Chief Business Officer at Vivoryon Therapeutics, added: “The VIVIAD trial design is based on our collaboration with medical expert, Professor Philip Scheltens, Director of the Alzheimer Center at the VU University Medical Center in Amsterdam and his team. Together with the top-level operational performance of our CRO, Nordic Bioscience, we feel very well prepared to further validate the therapeutic potential of varoglutamstat (PQ912) in Alzheimer’s disease.”

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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, varoglutamstat (PQ912), in Alzheimer’s disease and its entire portfolio of QC 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.