Vivoryon Therapeutics Receives FDA Fast Track Designation for Varoglutamstat in Early Alzheimer's Disease

Halle (Saale) / Munich, Germany December 22, 2021 – Vivoryon Therapeutics N.V. (Euronext Amsterdam: VVY; NL00150002Q7) (**Vivoryon**), a clinical stage company focused on discovery and development of small molecule medicines to modulate the activity and stability of pathologically altered proteins, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for varoglutamstat (PQ912), an investigational oral small molecule medicine for the potential treatment of early Alzheimer's disease (AD). Varoglutamstat is Vivoryon's lead product candidate and is designed to block formation of N3pE amyloid, a particularly neurotoxic variant of the Abeta peptide, by inhibiting glutaminyl cyclase (QPCT) and its isoenzyme (QPCTL). Varoglutamstat is currently being investigated in two Phase 2 clinical trials in patients living with early and mild AD: the European Phase 2b VIVIAD study and the recently initiated Phase 2a/b VIVA-MIND study in the U.S.

"Having been granted Fast Track designation for varoglutamstat in early AD is extremely encouraging and we value the opportunity to interact closely with the FDA as we progress varoglutamstat through clinical development in the U.S.," said Dr. Ulrich Dauer, CEO of Vivoryon. "We fully recognize the dire need for safe and widely available therapies to treat this devastating disease and remain dedicated to contributing to the global effort of improving the lives of the millions of patients, families and caregivers affected."

Fast Track is a process designed to facilitate the development, and expedite the review of drugs with the potential to treat serious conditions and fill an unmet medical need, aiming to bring important new drugs to the patient earlier. With Fast Track designation, the development of varoglutamstat can benefit from more frequent engagement with the FDA to discuss varoglutamstat's development plan and ensure collection of the appropriate data needed to successfully advance varoglutamstat through clinical development. A drug that receives Fast Track designation is also potentially eligible for Accelerated Approval and Priority Review, if relevant criteria are met[1].

###

[1] https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track

Vivoryon Therapeutics N.V.
Weinbergweg 22
06120 Halle (Saale)
Germany
www.vivoryon.com
contact@vivoryon.com

For more information, please contact:
Investor Contact
Vivoryon Therapeutics N.V.
Dr. Manuela Bader, Director IR & Communication
Tel: +49 (0)345 555 99 30
Email: IR@vivoryon.com

Media Contact
Trophic Communications
Valeria Fisher / Sophia Hergenhan
Tel: +49 175 8041816
Email: vivoryon@trophic.eu

About Vivoryon Therapeutics N.V.
Vivoryon is a clinical-stage biotechnology company focused on developing innovative small molecule-based medicines. Driven by our passion for ground-breaking science and innovation, we strive to change the lives of patients in need suffering from severe diseases. We leverage our in-depth expertise in understanding post-translational modifications to develop medicines that modulate the activity and stability of proteins which are altered in disease settings. Beyond our lead program, varoglutamstat, which is in Phase 2 clinical development to treat Alzheimer‘s disease, we have established a solid pipeline of orally available small molecule inhibitors for various indications including cancer, inflammatory diseases and fibrosis. www.vivoryon.com

About Varoglutamstat (PQ912)
Vivoryon’s most advanced medicine in development, varoglutamstat, is a differentiated small-molecule inhibitor with a unique dual mechanism of action (MOA) designed to address all hallmarks of AD: Abeta pathology, tau pathology, neuroinflammation and synaptic impairment. Firstly, varoglutamstat blocks the enzyme glutaminyl cyclase (QPCT), which is found in the brains of AD patients in much higher quantities than in healthy individuals and which has been shown to be linked to AD pathology. QPCT catalyzes the formation of N3pE amyloid a particularly neurotoxic variant of Abeta peptides, which is not present in the brains of healthy individuals and only found in AD patients. N3pE amyloid in the brain acts as a seeding element for Abeta aggregation, thus providing a starting point for plaque formation. It and has been described to correlate with the cognitive ability of AD patients. Varoglutamstat acts further upstream of other therapeutics, aiming to prevent the toxic Abeta variant N3pE from forming and seeding plaques, rather than reducing them after they have formed. Secondly, varoglutamstat exploits the fact that the enzymatic activity of glutaminyl cyclases is also required for the stability and full potency of the proinflammatory protein CCL2, with QPCTL, an isoform of QPCT, upregulating CCL2 by converting it into pE-CCL2. Thus, blocking QPCTL holds the potential to reduce neuroinflammation. Moreover, CCL2 is also a promoter of the tau pathology, which, in turn is linked to synaptic impairment, enabling simultaneous

targeting of these pathologies. In contrast to many other drugs in development in AD which are antibodies that have to be injected or infused, varoglutamstat can be very conveniently administered as an oral pill.

Varoglutamstat is not yet authorized by any regulatory authority and the safety and efficacy have not yet been established.

Forward Looking Statements

This press release includes forward-looking statements, including, without limitation, those regarding the business strategy, management plans and objectives for future operations of the Vivoryon Therapeutics N.V. (the "Company"), estimates and projections with respect to the market for the Company's products and forecasts and statements as to when the Company's products may be available. Words such as "anticipate," "believe," "estimate," "expect," "forecast," "intend," "may," "plan," "project," "predict," "should" and "will" and similar expressions as they relate to the Company are intended to identify such forward-looking statements. These forward-looking statements are not guarantees of future performance; rather they are based on the Management's current expectations and assumptions about future events and trends, the economy and other future conditions. The forward-looking statements involve a number of known and unknown risks and uncertainties. These risks and uncertainties and other factors could materially adversely affect the outcome and financial effects of the plans and events described herein. Actual results, performance or events may differ materially from those expressed or implied in such forward-looking statements and from expectations. As a result, no undue reliance should be placed on such forward-looking statements. This press release does not contain risk factors. Certain risk factors that may affect the Company's future financial results are discussed in the published annual financial statements of the Company. This press release, including any forward-looking statements, speaks only as of the date of this press release. The Company does not assume any obligation to update any information or forward-looking statements contained herein, save for any information required to be disclosed by law.

Vivoryon Therapeutics N.V.
Weinbergweg 22
06120 Halle (Saale)
Germany
www.vivoryon.com
contact@vivoryon.com