



Vivoryon Therapeutics N.V. Reports Positive Independent Data Safety Monitoring Board Recommendation for Phase 2b Study of Varoglutamstat in AD

- *Parallel group, dose-finding part of the study completed*
- *DSMB recommends that the study should proceed with a maximum dose of 600 mg BID varoglutamstat or placebo*
- *All subjects randomized to the treatment arm will now receive selected dose*
- *Decision based on safety data from 181 patients*
- *Detailed study results to be presented at an upcoming medical conference*

HALLE (SAALE) / MUNICH, GERMANY, June 23, 2022 – [Vivoryon Therapeutics N.V.](#) (Euronext Amsterdam: VVY; NL00150002Q7) (Vivoryon), a clinical stage company focused on the discovery and development of small molecule medicines to modulate the activity and stability of pathologically altered proteins, today announced that it has completed the parallel group, dose-finding part of its European Phase 2b study VIVIAD ([NCT04498650](#)) and that the independent Data Safety Monitoring Board (DSMB) has selected the highest dose investigated, 600 mg twice daily (BID), as the final dose to be administered in the second part of the study. VIVIAD is a state-of-the-art Phase 2b study designed to evaluate the safety, tolerability and efficacy of varoglutamstat in 250 subjects with mild cognitive impairment (MCI) and mild Alzheimer's disease (AD). The DSMB decision is based on safety data from 181 patients, 90 of which had completed the week 24 treatment visit at the May 17 cut-off date. All subjects randomized to the treatment arm will be treated at the selected dose of 600 mg BID moving forward and will continue treatment for up to 48-96 weeks dependent on study entry date.

Detailed results of the study will be presented at an upcoming medical conference.

“We are encouraged by the DSMB’s decision to continue the study with the highest dose tested in our treatment arm, which is key to the next steps of clinical development in Europe, the U.S. and also in China led by our partner Simcere,” said Dr. Ulrich Dauer, CEO of Vivoryon. “We look forward to announcing the detailed VIVIAD interim safety results later this quarter.”

VIVIAD is actively enrolling patients and will continue to evaluate its primary and secondary outcome measures, which include multiple cognitive, safety and biomarker endpoints. Vivoryon remains on target to report final data for the study in the second half of 2023.

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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

Vivoryon 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.

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

Tel: +49 175 8041816

Email: vivoryon@trophic.eu