Vivoryon Therapeutics and Simcere Announce CDE Approval of Chinese Clinical Trial Application for Varoglutamstat (SIM0408, PQ912) in Patients with Alzheimer's Disease

Halle (Saale) / Munich, Germany and Nanjing, China, February 28, 2022 – Vivoryon Therapeutics N.V. (Euronext Amsterdam: VVY; NL00150002Q7) (**Vivoryon**) a clinical-stage biotechnology company focused on developing innovative small molecule-based medicines and Simcere Pharmaceutical Group Ltd (HKEX: 2096) (**Simcere**) today announced that China's Center for Drug Evaluation (CDE) of National Medical Products Administration (NMPA) has approved the Clinical Trial Application for varoglutamstat (SIM0408, PQ912), a medicine in development for the treatment of Alzheimer's disease (AD) developed in Greater China by Simcere.

"We are proud to have obtained CDE approval of our Clinical Trial Application of varoglutamstat which represents our strong commitment in the battle against Alzheimer's disease," said Dr. Renhong Tang, Executive Vice President of Simcere. "We will push forward the Phase 1 clinical study of varoglutamstat in China with all our efforts, and prepare to join the active global Phase 2 efforts."

"We are delighted with Simcere's rapid progress towards bringing new treatment options to the millions of patients suffering from Alzheimer's disease in China," said Dr. Michael Schaeffer, Chief Business Officer of Vivoryon. "Varoglutamstat has already demonstrated encouraging clinical results in earlier studies, and we look forward to building on our experience from the completed and ongoing studies in the EU and U.S. to support our partner during this significant phase in development."

Varoglutamstat is a differentiated oral small-molecule inhibitor with a unique mode of action designed to address several key mechanisms underlying AD pathology, including Abeta pathology, tau pathology, neuroinflammation and synaptic impairment. Varoglutamstat is currently in Phase 2 clinical development in Europe (VIVIAD study) and the U.S. (VIVA-MIND study).

On June 29, 2021, Simcere and Vivoryon entered into a strategic regional licensing partnership to develop and commercialize medicines targeting the neurotoxic amyloid species N3pE (pGlu-Abeta) to treat AD in Greater China and comprises Vivoryon's clinical lead product candidate varoglutamstat (SIM0408, PQ912) as well as Vivoryon's preclinical monoclonal N3pE-antibody PBD-C06.

###

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

About Varoglutamstat (PQ912, SIM0408)
Varoglutamstat, is a differentiated small-molecule inhibitor with a unique dual mechanism of action (MOA) designed to address all hallmarks of Alzheimer's disease (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 has not yet been approved by any regulatory authority and the safety and efficacy have not yet been established. Vivoryon has received Fast Track designation for varoglutamstat in early AD by the U.S. Food and Drug Administration (FDA) in December 2021.

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 Simcere Pharmaceutical Group
Simcere Pharmaceutical Group (2096.HK) is rapidly transitioning to an innovation and R&D-driven pharmaceutical company, with a mission of "providing today's patients with medicines of the future." It has established a national key laboratory of translational medicine and innovative pharmaceuticals. Simcere focuses on oncology, central nervous system disease and autoimmune disease therapeutic areas, with a diversified product portfolio and industry-leading capabilities. Its vigorous in-house R&D efforts and extensive R&D collaborations have made it a strategic cooperation partner with world leading pharmaceutical companies and biotechnology companies, in an effort to bring more global life science breakthroughs to China. For more information, please visit www.simcere.com.

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

Simcere Forward Looking Statements
Information set forth in this press release contains forward-looking statements, which involve a number of known and unknown risks, uncertainties and assumptions. The forward-looking statements contained herein reflect the current judgment and views of Simcere Pharmaceutical Group Limited 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, or may not materialize, 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, whether as a result of new information, future events or otherwise, to reflect any change in our expectations or any change in events, conditions or circumstances on which any such statement is based.

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

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

Simcere Pharmaceutical Group Limited
Investor Contact
Dr. Jason Bao, Board Secretary and Executive Director
Tel: +86(25)8556 6366
Email: ir@simcere.com

Media Contact
Jian Hou
Tel: +86(25)8556 6666
Email: simcere.mediarelations@simcere.com