Vivoryon Therapeutics and Simcere Announce Strategic Regional Licensing Partnership to Develop and Commercialize N3pE Amyloid-targeting Medicines to Treat Alzheimer's Disease in Greater China

Halle (Saale) / Munich, Germany and Nanjing, China, June 29, 2021 – 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 they have entered into a strategic regional licensing partnership to develop and commercialize medicines targeting the neurotoxic amyloid species N3pE (pGlu-Abeta) to treat Alzheimer's disease (AD) in Greater China.

The agreement grants Simcere a regional license to develop and commercialize varoglutamstat (PQ912), Vivoryon's Phase 2b-stage N3pE amyloid-targeting oral small molecule glutaminyl cyclase (QPCT) inhibitor with disease-modifying potential for AD, as well as the Company's preclinical monoclonal N3pE-antibody PBD-C06 in the Greater China region.

QPCT is an enzyme responsible for the formation of N3pE amyloid, a neurotoxic molecule that is not found in healthy individuals and has been identified as a driver of AD pathology. N3pE amyloid is not only implicated in Abeta peptides aggregating into plaques which are widely observed in AD patients, but also has a negative impact on other pathologies that underly the disease, including tau pathology, neuroinflammation, and impairment of synaptic function. By inhibiting QPCT and thus preventing the formation of toxic N3pE amyloid, varoglutamstat acts very early in disease pathogenesis and thereby has the potential to prevent neuronal damage.

Vivoryon's monoclonal N3pE-antibody PBD-C06 is specifically designed to bind to and remove neurotoxic N3pE amyloid from the brain and has been optimized with respect to low immunogenicity and low potency to induce amyloid-related imaging abnormalities (ARIAs), a major side effect in antibody-based AD therapies.

Under the terms of the agreement, Vivoryon will receive an undisclosed upfront payment and will also be eligible for payments upon achievement of certain development and sales milestones, with all components amounting to a total of over US$565 M. In addition, Vivoryon will receive double-digit royalties on sales. Further financial details were not disclosed.

Pursuant to the agreement, Simcere will be responsible for clinical development of varoglutamstat in patients with early AD in China. The clinical development program in Greater China is intended to be complementary to Vivoryon's efforts in Europe and the US including Vivoryon's ongoing European VIVIAD Phase 2b trial as well as the Company's planned Phase 2a/b study in the US, which is anticipated to start in the second half of this year. Simcere has also acquired an option to advance PBD-C06, an antibody that specifically targets N3pE amyloid, towards clinical development.

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"This regional partnership represents an important milestone on our journey to bringing novel therapeutic options to as many patients suffering from Alzheimer's disease as possible," commented Michael Schaeffer, PhD, Vivoryon's Chief Business Officer. "With prevalence rising in China, AD is already a heavy burden on patients, families and the country's healthcare system. In partnering with Simcere, who is continuously recognized as one of the top innovative pharmaceutical and manufacturing enterprises in China, we hope to be able to make an impact beyond our own focus of developing varoglutamstat towards the markets in Europe and the US."

"We are extremely pleased to have entered into this agreement with Vivoryon to leverage the potential of innovative N3pE amyloid-targeting agents to treat Alzheimer's disease in Greater China," added Kevin Oliver, PhD, Senior Vice President and Head of Global Business Development at Simcere. "Both partners are clearly committed to delivering meaningful therapies to AD patients in need, in line with Simcere's mission of providing today's patients with medicines of the future."

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About varoglutamstat (PQ912)
Varoglutamstat is an orally administered small molecule inhibitor of glutaminyl cyclase (QPCT), an enzyme which catalyzes the formation of N3pE amyloid, a particularly neurotoxic molecule not found in healthy individuals that has been identified as a driver of Alzheimer's disease (AD). N3pE amyloid triggers a number of pathological processes in AD, including the formation of toxic soluble Abeta oligomers, tau pathology, neuroinflammation, and impairment of synaptic function. By preventing formation of this toxic molecule, varoglutamstat acts very early in disease pathogenesis and thus has the potential to prevent neuronal damage. Varoglutamstat is currently in Phase 2 clinical development.

About PBD-C06
PBD-C06 is a preclinical stage humanized and de-immunized IgG1 antibody specifically designed to bind to and remove neurotoxic N3pE amyloid from the brain. The antibody is optimized with respect to low immunogenicity and low potency to induce amyloid-related imaging abnormalities (ARIAs), which represent the major severe side effects of antibody-based AD therapies.

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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 live of medically underserved patients 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 before they cause irreversible damage. Beyond our lead program, varoglutamstat, which is in Phase2 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 Limited
Simcere Pharmaceutical Group Limited 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 has a diversified product portfolio in strategically focused therapeutic areas, including oncology, central nervous system diseases and autoimmune diseases, with leading positions in their respective therapeutic segments and/or established track record. 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 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 N.V. 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.

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.

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