Vivoryon Therapeutics N.V. Shares Highlights from Virtual Kidney Disease KOL Event

Halle (Saale) / Munich, Germany, October 1, 2024 – 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 key takeaways from its virtual Kidney Disease Key Opinion Leader (KOL) Event held September 30, 2024. The event focused on the standard of care and existing medical need, market development and dynamics in kidney disorders, as well as on key statistical considerations in kidney disease drug development, with special emphasis on diabetic kidney disease (DKD).

The event, which was hosted by Frank Weber, MD, CEO of Vivoryon, featured presentations from Tobias B. Huber, MD, Chair of the Center of Internal Medicine and Director of the III. Department of Medicine, University Medical Center Hamburg-Eppendorf (UKE), Florian Jehle, renal pharmaceutical industry expert and Kevin Carroll, PhD, CEO, KJC Statistics.

“Our KOL event has shed light on the profound existing medical need of halting disease progression in kidney disease. It clearly outlined that, despite a number of treatments available and scientific advances made in this field over the past years, novel medicines are needed with mechanisms of action suitable to addressing the key inflammatory and fibrotic pathways underlying this disease,” said Frank Weber, MD, CEO of Vivoryon. “I would like to thank all speakers for participating and sharing their knowledge and unique perspectives shaped by their core expertise in key aspects of drug development in kidney disease. Building on the strong body of evidence of varoglutamstat’s ability to protect and improve kidney function, observed in particular in patients with diabetes, we now look forward to keeping the market updated on our progress in fully realizing the potential of Vivoryon’s lead asset varoglutamstat in kidney disease.”

Highlights from Dr. Huber’s presentation include:

- Chronic Kidney Disease (CKD) is a rising global health problem and is set to become the fifth leading cause of years of life lost by 2040.
- Treatments for CKD have advanced in recent years but still do not halt or reverse kidney function decline which will likely increase as the population ages.
- CKD manifests as a progressive decline in kidney function and can lead to significant disability and/or premature death and diabetes is a major risk factor for CKD.
- Inflammation is a key underlying pathway in driving progression of diabetic kidney disease (DKD) and other kidney disorders and targeting inflammatory pathways could represent an approach to address the unmet needs across both the broader CKD population as well as in the rare disease space.

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- Observations from the VIVIAD Phase 2b study have shown that varoglutamstat, with its novel mode of action targeting inflammatory and fibrotic pathways and promising efficacy and safety profile to date, could become an interesting treatment option for patients, if proven successful in double blinded, randomized prospective clinical studies.

Highlights from Mr. Jehle's presentation include:

- Late-stage CKD patients are at greatest risk of kidney failure requiring kidney replacement therapy (dialysis or transplant).
- End-stage renal disease and kidney failure is a major concern for not only patients and physicians, but also health care providers and payors, with costs escalating significantly with later stages of the disease.
- Rate of cardio-metabolic risk factors such as diabetes and hypertension as well as age are key dynamics in the CKD market.
- Current therapies such as SGLT2s and GLP1s only delay disease progression, but are no cure, consequently, a high unmet need remains for the majority of CKD and DKD patients.
- There is a significant market potential for oral varoglutamstat, in particular in the stage 4 and fast progressing stage 3b CKD and DKD patient populations, as well as certain rare diseases such as Alport syndrome and Fabry disease.
- Increasing interest from big pharma in kidney diseases has been demonstrated by recent deals with high valuations.

Highlights from Dr. Carroll's presentation include:

- Analysis of the estimated glomerular filtration rate (eGFR) in CKD studies have evolved over the past 40 years and novel methods for statistical analysis are being applied, with the Random Coefficients (RC) Analysis emerging as preferred method.
- Measuring the eGFR slope via RC analysis was the primary efficacy endpoint in recent FDA approvals in CKD, as well as in many ongoing Phase 3 studies.
- Analysis of data from the VIVIAD study employing this method has yielded consistent findings for eGFR with varoglutamstat, with a substantial treatment effect on the eGFR slope seen for varoglutamstat compared to placebo in the overall population driven by an even larger effect in patients with type 2 diabetes.
- Available results from VIVIAD together with good statistical planning enables an efficient design of a Phase 2 study in patients with DKD stage 3/4 with an interim futility analysis after 62 patients treated for at least 24 weeks.

A replay of the webcast of the virtual R&D Event will be available via the Presentations & Webcasts page in the Investor Relations section on the Company's website at www.vivoryon.com.

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Varoglutamstat in Kidney Disease

Varoglutamstat (PQ912) is a proprietary, potent and selective inhibitor of human glutaminyl cyclases QPCT and QPCTL with therapeutic potential in indications including inflammatory and fibrotic diseases, neurodegenerative diseases, cancer and others. Initially advancing development aiming to treat Alzheimer's disease (AD), varoglutamstat has been investigated in a number of different clinical studies, all of which have consistently demonstrated a favorable safety and tolerability profile both in healthy volunteers and patients with AD. Based on the known anti-inflammatory activity of varoglutamstat, the protocol for the Phase 2 VIVIAD study in AD, which was completed in the first half of 2024, included the investigation of kidney function and measurement of biomarkers of kidney inflammation and fibrosis to explore the role of QPCT/L inhibition on kidney function. Although patients in VIVIAD were selected for their AD status and not for their kidney function level, many of them had reduced kidney function due to age and/or comorbidities. Analysis showed a statistically significant benefit of varoglutamstat on a prospectively defined key kidney function endpoint (eGFR) and a significant reduction of the pro-inflammatory cytokine pE-CCL2. A substantially higher treatment benefit of varoglutamstat on eGFR was observed in a post-hoc diabetes subgroup, triggering plans to advance varoglutamstat into Phase 2 study in DKD, which is currently in planning.

About Vivoryon Therapeutics N.V.

Vivoryon is a clinical stage biotechnology company focused on developing innovative small molecule-based medicines. Driven by its passion for ground-breaking science and innovation, the Company strives to change the lives of patients in need suffering from severe diseases. The Company leverages its 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. The Company has established a pipeline of orally available small molecule inhibitors for various indications including Alzheimer's disease, inflammatory and fibrotic disorders, including of the kidney, and cancer. 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 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

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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. The Company's results of operations, cash needs, financial condition, liquidity, prospects, future transactions, strategies 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.

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