Telitacicept Achieved Primary Endpoint in Phase 3 Clinical Study for IgA Nephropathy

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Results reinforce telitacicept's potential across multiple autoimmune diseases

Data anticipated to be presented at an upcoming medical conference

CAMBRIDGE, Mass., Aug. 27, 2025 (GLOBE NEWSWIRE) -- Vor Bio (Nasdaq: VOR), a clinical-stage biotechnology company transforming the treatment of autoimmune diseases, today announced that its collaborator, RemeGen Co., Ltd (HKEX: 9995, SHA: 688331), achieved the primary endpoint in Stage A of a Phase 3 clinical study in China evaluating telitacicept in adults with IgA nephropathy (IgAN). Details of the study results are planned to be presented at an upcoming medical conference.

"Telitacicept continues to demonstrate consistent, disease-modifying activity across autoimmune conditions, from myasthenia gravis to Sjögren's disease and now IgA nephropathy," said Jean-Paul Kress, M.D., Chief Executive Officer and Chairman of the Board. "In IgAN, where UPCR is a well-established, objective endpoint for regulatory approval, these results underscore the strength of the telitacicept dataset and its comparability to global benchmarks. By directly targeting the upstream drivers of IgAN and stopping the downstream signaling that fuels disease progression, telitacicept has the potential to modify the disease at its core, potentially leading to deeper, more durable responses and long-term kidney preservation for patients. Taken together, these data reinforce our conviction that telitacicept is a pipeline-in-a-product with the potential to deliver a best-in-class profile across multiple autoimmune diseases."

This study is a multicenter, randomized, double-blind, placebo-controlled clinical trial in China that enrolled 318 adult IgAN patients who had received standard therapy. In Stage A of the Phase 3 study, telitacicept achieved the primary endpoint of reducing proteinuria, demonstrating a 55% reduction in 24-hour urine protein-to-creatinine ratio (UPCR) at 39 weeks compared with placebo ($p<0.0001$). UPCR is an objective and globally recognized regulatory marker of disease activity in IgAN. Telitacicept demonstrated a favorable safety profile.

RemeGen announced that it plans to submit a Biologics License Application (BLA) to the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) in China for IgAN, which if approved would become telitacicept's fifth approved indication in China.

About Vor Bio
Vor Bio is a clinical-stage biotechnology company transforming the treatment of autoimmune diseases. The Company is focused on rapidly advancing telitacicept, a novel dual-target fusion protein, through Phase 3 clinical development and commercialization to address serious autoantibody-driven conditions worldwide. For more information visit www.vorbio.com.

About Telitacicept
Telitacicept is a novel, investigational recombinant fusion protein designed to treat autoimmune diseases by selectively inhibiting BLyS (BAFF) and APRIL - two cytokines essential to B cell and plasma cell survival. This dual-target mechanism reduces autoreactive B cells and autoantibody production, key drivers of autoimmune pathology. In a Phase 3 clinical trial in generalized myasthenia gravis in China, telitacicept demonstrated a placebo adjusted 4.83-point improvement in MG-ADL (Myasthenia Gravis Activities of Daily Living scale) at 24 weeks, the primary endpoint of the trial.

Telitacicept is approved in China for systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), and generalized myasthenia gravis (gMG). A global Phase 3 clinical trial in gMG is currently underway across the United States, Europe, South America, and Asia-Pacific to support potential approval in the United States, Europe, and Japan.

About IgA Nephropathy
IgA nephropathy (IgAN) is one of the most common primary glomerular diseases worldwide and a leading cause of chronic kidney disease (CKD) and end-stage renal disease (ESRD). It is characterized by IgA-containing immune complex deposition in the kidney, leading to inflammation, proteinuria, hypertension, and progressive loss of renal function. Up to 40% of patients progress to ESRD within 20 years of diagnosis, underscoring the significant unmet need for effective therapies. Current treatment approaches, including optimized blood pressure control, renin-angiotensin system blockade, and SGLT2 inhibitors, primarily slow disease progression but do not address the underlying immunopathology.

The prevailing scientific consensus is that overproduction of galactose-deficient IgA1 (Gd-IgA1) is a central driver of IgAN. BAFF and APRIL, two cytokines critical to B-cell survival and function, promote the production of Gd-IgA1 and its pathogenic antibodies.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The words “aim,” “anticipate,” “can,” “continue,” “could,” “design,” “enable,” “expect,” “initiate,” “intend,” “may,” “on-track,” “ongoing,” “plan,” “potential,” “should,” “target,” “update,” “will,” “would,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements in this press release include Vor Bio’s statements regarding the potential of telitacicept’s safety profile in IgAN, telitacicept to be a disease-modifying treatment for IgAN and other autoimmune diseases, the potential for telitacicept to lead to deeper, more durable responses in IgAN, the potential for telitacicept to deliver a best-in-class profile across multiple autoimmune disease, potential regulatory approval of telitacicept in IgAN, the timing of presentation of clinical data and submissions to regulatory authorities, the potential of telitacicept to treat indications, Vor Bio’s development and commercialization plans for telitacicept, its ability to change the treatment landscape for patients with autoimmune conditions and other statements that are not historical fact. Vor Bio may not actually achieve the plans, intentions, or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various factors. The results of the clinical trial described in this press release are based on information reported by RemeGen; Vor Bio has not independently verified this data. These and other risks are described in greater detail under the caption “Risk Factors” included in Vor Bio’s most recent annual or quarterly report and in other reports it has filed or may file with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Vor Bio expressly disclaims any obligation to update any forward-looking statements, whether because of new information, future events or otherwise, except as may be required by law.

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