Telitacicept Achieved Primary Endpoint of Reducing Proteinuria in Stage A of a Phase 3 Clinical Study for IgA Nephropathy in China

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Treatment with telitacicept for 39 weeks resulted in a rapid, clinically meaningful, and statistically significant reduction in proteinuria, with a favorable safety profile

Telitacicept demonstrated a 55% reduction in 24-hour urine protein-to-creatinine ratio (24h-UPCR) at 39 weeks compared with placebo; statistically significant benefits also achieved across all key secondary endpoints

Data presented as late-breaking oral presentation at American Society of Nephrology's Kidney Week 2025

BOSTON, Nov. 08, 2025 (GLOBE NEWSWIRE) -- Vor Bio (Nasdaq: VOR), a clinical-stage biotechnology company transforming the treatment of autoimmune diseases, today announced that the primary endpoint was achieved in Stage A of a Phase 3 clinical study in China evaluating telitacicept in adults with IgA nephropathy (IgAN). In addition, statistically significant benefits were achieved across all secondary endpoints in the study, which was conducted by RemeGen Co., Ltd (HKEX: 9995, SHA: 688331), Vor Bio's collaborator.

"Telitacicept delivered statistically significant deep, sustained, and clinically meaningful reductions in proteinuria with stabilization of kidney function and a favorable safety profile. An objective endpoint like 24h-UPCR validates the therapeutic effect of dual BAFF/APRIL inhibition. These findings, alongside the strong pharmacodynamic evidence of telitacicept's dual B-cell pathway inhibition, demonstrate its potential to deliver disease-modifying effects in IgAN," said Jean-Paul Kress, M.D., Chief Executive Officer and Chairman of the Board. "With this Phase 3 success in IgAN, telitacicept has provided additional clinical evidence supporting its mechanism in yet another indication, reinforcing our confidence in its potential as a foundational therapy for B-cell mediated diseases."

This study is a multicenter, randomized, double-blind, placebo-controlled clinical trial in China that enrolled 318 adult patients with IgAN at high risk of progression who had received stable standard therapy. Patients were randomized (1:1) to telitacicept (240 mg) or placebo, subcutaneously once weekly.

Primary Endpoint Achieved
In Stage A of the Phase 3 study, telitacicept achieved the primary endpoint of reducing proteinuria, demonstrating a significant reduction in 24h-UPCRvs. Placebo at 39 weeks compared to placebo (-58.9% vs. -8.8%, $p<0.0001$), 24h-UPCR is an objective and internally recognized regulatory marker for assessing disease activity in IgAN.

Statistically Significant Benefits Across all key Secondary Endpoints
Key secondary endpoints evaluated preservation of kidney function—measured by change in estimated glomerular filtration rate (eGFR), the proportion of patients with a ≥30% decline in eGFR, and remission rates defined by achievement of UPCR threshold <0.8 g/g. Additional endpoints included resolution of hematuria and changes in pharmacodynamic markers such as B-cell counts and serum immunoglobulins.

Treatment with telitacicept achieved statistically significant improvements across all key secondary endpoints at Week 39. Compared with placebo, telitacicept stabilized kidney function (GMR of eGFR relative to baseline, showed stabilization in the telitacicept group (-0.10) in contrast to a decline in the placebo group (-0.77)) and reduced the risk of eGFR decline ≥ 30% (6.3% in the telitacicept group vs. 27.0% in the placebo group). 61% of patients on telitacicept vs.19.5% of patients on placebo achieved 24h-UPCR <0.8 g/g, 42.1% of patients on telitacicept vs. 7.5% of patients on placebo achieved <0.5 g/g, and 24.5% of patients on telitacicept vs. 0.6% of patients on placebo achieved <0.3 g/g, thresholds linked to low risk of disease progression.

Favorable Safety Profile
Telitacicept demonstrated a favorable and well-tolerated safety profile. While overall treatment-emergent adverse events were more frequent with telitacicept (89.3% vs. 78.6%), most were mild or moderate, and serious adverse events occurred less often with telitacicept than with placebo (2.5% vs. 8.2%). No apparent unexpected safety findings were noted.

RemeGen announced that a Biologics License Application (BLA) has been submitted 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 potential 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.

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 IgAN 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 in various indications, including IgAN; telitacicept’s potential as a foundational therapy for B-cell mediated diseases worldwide; the timing of presentation of clinical data; Vor Bio’s development and commercialization plans for telitacicept; 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, including the data for our product candidates may not be sufficient for obtaining regulatory approval to commercialize products; we may not be able to execute our business plans, including meeting our planned clinical and regulatory milestones and timelines, and possible limitations of financial and other resources. 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. The results of the clinical trial described in this press release is based on information reported by RemeGen; Vor Bio has not independently verified this data.

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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