Vor Bio Announces Publication of China Phase 3 Study of Telitacicept in Systemic Lupus Erythematosus in The New England Journal of Medicine

October 16, 2025

Trial met primary endpoint achieving statistically significant improvement in disease activity, with 67.1% of patients responding with telitacicept versus 32.7% with placebo

Dual inhibition of BAFF and APRIL validated as a transformative B-cell approach, highlighting telitecicept's potential as a disease-modifying therapy for systemic lupus erythematosus

BOSTON, Oct. 16, 2025 (GLOBE NEWSWIRE) -- Vor Bio (Nasdaq: VOR), a clinical-stage biotechnology company transforming the treatment of autoimmune diseases, today announced that results from a Phase 3 study in China evaluating telitacicept in systemic lupus erythematosus (SLE) sponsored by its collaborator, RemeGen Co., Ltd., (HKEX: 9995, SHA: 688331), were published in *The New England Journal of Medicine* (NEJM).

"We are humbled by what these results represent for patients and the scientific community, and by the recognition that comes with their publication in *The New England Journal of Medicine*, which underscores the global acceptance of the quality and rigor of clinical research emerging from China. For the first time, a therapy in a Phase 3 trial is delivering more than double the clinical response seen with the current standard of care in lupus. These data present a compelling case for potentially broadening telitacicept's use as a new standard of care worldwide," said Jean-Paul Kress, M.D., Chief Executive Officer and Chairman of Vor Bio. "Lupus has challenged researchers and clinicians for decades. To see a dual BAFF/APRIL approach deliver this level of efficacy, durability, and consistency across multiple indications, while maintaining a favorable safety profile, affirms our belief that telitacicept has the potential to redefine how autoimmune diseases are treated."

"These data support the central role of B-cells in the pathobiology of lupus. By targeting both BAFF and APRIL, it was possible to achieve excellent clinical results that suggest the effective restoration of immune balance in at least some of the patients. With this mechanism of action, telitacicept could significantly reduce the burden of lupus," said Ronald van Vollenhoven, M.D., Ph.D., Professor of Rheumatology at Amsterdam University Medical Center. "This approach could represent an important new addition to the therapeutic landscape for lupus."

The study, conducted at 42 hospitals in China, evaluated telitacicept in 335 patients with active SLE despite standard therapy. The study met its primary endpoint with 67.1% of patients who received telitacicept achieving a modified SLE Responder Index-4 (SRI-4) response compared with 32.7% on placebo ($P<0.001$) at week 52. More telitacicept-treated patients met a modified SRI-4 response as early as week 4 than those who received placebo. This difference was sustained at week 52.

Improvements were also seen across multiple secondary measures:

- **Disease activity:** At week 52 SELENA-SLEDAI score reduction from baseline of ≥4 points occurred in 70.1% of the telitacicept group versus 40.5% of placebo patients. The mean change in SELENA-SLEDAI score was -4.95 for telitacicept versus -1.0 for placebo. SELENA-SLEDAI is a 24-item weighted lupus activity score that ranges from 0-105 with higher scores indicating greater disease activity.
- **Physician's Global Assessment:** Greater reductions were observed with telitacicept (-0.79 vs. -0.40).
- **Time to SLE flare**: Median time to flare was 198 days on telitacicept versus 115 days on placebo.
- **Steroid dose reduction:** The proportion pf patients taking ≤7.5mg/day of glucocorticoid (or prednisone equivalent) or with ≥25% reduction in glucocorticoid dose from baseline over weeks 44-52 was 44.9% in the telitacicept group versus 34.7% for placebo.
- **Kidney involvement:** Among patients with baseline proteinuria, more achieved clinically meaningful reductions (71.8% vs. 55.1% on placebo).

Safety findings were consistent with previous studies. The most common drug-related adverse events were upper respiratory tract infection (31.7% vs. 19.0% on placebo), injection-site reactions (12.6% vs. 0.6% on placebo), and reductions in immunoglobulin levels. Serious adverse events occurred less frequently with telitacicept (7.2% vs. 14.3% on placebo).

About Systemic Lupus Erythematosus (SLE)
SLE is a chronic, systemic autoimmune disease that can affect multiple organs and lead to irreversible damage. More than half of patients develop organ injury within 2–6 years of diagnosis. Despite available therapies, including glucocorticoids, antimalarials,

immunosuppressants, and biologics, many patients continue to experience active disease, underscoring the urgent need for new treatment options.

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 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.

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
telitecicept’s potential to be a disease-modifying therapy and reduce the burden of systemic lupus erythematosus and to redefine how autoimmune diseases are treated; the potential of the results of the Phase 3 study of telitacicept in systemic lupus erythematosus to broaden telitacicept’s use as a new standard of care worldwide; and the potential of the BAFF - APRIL dual-target mechanism to be an important new addition to the therapeutic landscape for lupus.

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. Vor

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