Telitacicept Demonstrates Clinically Meaningful and Statistically Significant Impact on ESSDAI Compared to Placebo in Late-Breaking China Phase 3 Results in Primary Sjögren's Disease at ACR 2025

October 14, 2025

Telitacicept met primary and all secondary endpoints, demonstrating clinically meaningful improvements in disease activity versus placebo

~71.8% of patients receiving telitacicept 160mg achieved ≥3-point ESSDAI (EULAR Sjögren's Syndrome Disease Activity Index) *reduction vs 19.3% on placebo at 24 weeks*

Sustained efficacy and favorable safety profile through 48 weeks support potential best-in-disease profile in primary Sjögren's disease (pSD)

Company evaluating timing of global Phase 3 clinical study in primary Sjögren's disease
Vor Bio to host a conference call on Tuesday, October 28, 2025 at 4:30PM ET

BOSTON, Oct. 14, 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), reported positive 48-week results from its Phase 3 study conducted in China evaluating telitacicept in primary Sjögren's disease. The study met its primary endpoint of change from baseline in ESSDAI at week 24, as well as all secondary endpoints, with the telitacicept 160mg dose achieving highly significant p values ($p<0.0001$) for every endpoint at week 24 and 48 compared to placebo. The results will be presented in the late-breaking poster session at the American College of Rheumatology (ACR) Convergence 2025 on October 28, 2025 from 10:30am to 12:30pm CT in Chicago, Illinois.

"With today's Phase 3 results in primary Sjögren's disease, we are thrilled to announce that telitacicept is demonstrating disease-modifying potential in a condition that has long lacked any approved treatment. We believe these are clear data which can help pave a path towards a brighter future for this deserving community. The consistency of benefit through 48 weeks, together with a reassuring safety profile, supports telitacicept's potential to become the first treatment that addresses the root biology of Sjögren's disease rather than managing symptoms alone," said Jean-Paul Kress, M.D., Chief Executive Officer and Chairman of Vor Bio. "Based on these promising results, we are evaluating the timing of a global Phase 3 clinical study in primary Sjögren's disease, which represents a significant opportunity to expand into and bring telitacicept's benefits to patients worldwide."

"Primary Sjögren's disease represents a substantial unmet need in rheumatology, with patients facing years of fatigue, pain, and systemic complications without a truly effective therapy," said Ronald van Vollenhoven, M.D., Ph.D., Professor of Rheumatology at Amsterdam University Medical Center. "I am impressed how these data show that dual BAFF/APRIL inhibition with telitacicept could offer a clear impact on both disease activity and patient-reported outcomes."

The China Phase 3 trial was a randomized, double-blind, placebo-controlled trial in patients with active, anti-SSA-positive primary Sjögren's disease. A total of 381 patients were randomized to receive weekly subcutaneous injections of telitacicept 160mg, telitacicept 80mg, or placebo for 48 weeks, in addition to standard therapy. During weeks 24-48, participants with inadequate response to treatment in the placebo group could switch to telitacicept 160mg or telitacicept 80mg at a ratio of 1:1 under blind conditions.

The primary endpoint of the study was change from baseline in ESSDAI at week 24, with secondary endpoints including changes in ESSDAI and ESSPRI (EULAR Sjögren's Syndrome Patient Reported Index) at 12, 24, 36, and 48 weeks, as well as the proportion of patients achieving clinically meaningful improvements (≥3-point decrease in ESSDAI and achievement of low disease activity [ESSDAI <5]) at 24 and 48 weeks.

Key Findings from the 48-Week Results

- **Mean change in ESSDAI**: At week 24, -4.4 (160mg), -3.0 (80mg), and -0.6 (placebo); at week 48, -4.6 (160mg), -3.2 (80mg), and -0.4 (placebo), demonstrating durable, dose-dependent improvement in systemic disease activity.
- **Mean change in ESSPRI**: At week 24, -1.88 (160mg), -1.31 (80mg), and -0.36 (placebo); at week 48, -2.56 (160mg), -1.74 (80mg), and -0.41 (placebo), showing sustained symptomatic benefit in dryness, fatigue, and pain.
- **≥3-point ESSDAI improvement**: At week 24, 71.8% (160mg), 47.1% (80mg), and 19.3% (placebo); at week 48, 73.0% (160 mg), 49.1% (80mg), and 16.5% (placebo).
- **Participants with ESSDAI <5 (low disease activity)**: At week 24, 49.6% (160mg), 28.8% (80mg), and 10.9% (placebo); at week 48, 55.0% (160mg), 32.7% (80mg), and 12.2% (placebo).
- **Participants with ≥1-point or ≥15% ESSPRI reduction**: At week 24, 86.2% (160mg), 63.0% (80mg), and 32.2%

(placebo); at week 48, 89.1% (160mg), 75.4% (80mg), and 33.3% (placebo).

- **Change from baseline in MFI-20 total (fatigue)**: At weeks 24 and 48, telitacicept 160mg produced a statistically significant and clinically meaningful reduction in fatigue versus 80mg and placebo, with improvements sustained through the open-label extension.
- Telitacicept demonstrated a favorable safety profile comparable to placebo and consistent with prior studies across other autoimmune indications, including systemic lupus erythematosus, rheumatoid arthritis, myasthenia gravis, and IgA nephropathy. No new safety signals were observed. Most adverse events were mild to moderate in severity.

About Sjögren's Disease (formerly known as Sjögren's Syndrome)
Sjögren's disease is a chronic autoimmune condition in which overactive B cells drive inflammation, damaging moisture-producing glands and, in many cases, other organs. Hallmark symptoms include dry eyes and dry mouth, alongside fatigue, pain, and systemic complications affecting the skin, lungs, kidneys, and nervous system. About one-third of patients develop significant extraglandular involvement, and the disease carries an elevated lymphoma risk, often leading to substantial impairment in daily life.

One of the most common rheumatic autoimmune diseases, Sjögren's remains underdiagnosed, with roughly half of cases unrecognized and women comprising the vast majority of patients. Despite its prevalence and burden, no systemic disease-modifying therapies exist; current care focuses on symptom management with incomplete relief.

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 the potential of telitacicept in primary Sjögren's disease, including the potential to have a best-in-class profile, to be disease-modifying, to become the first treatment that addresses the root biology of Sjögren's disease rather than managing symptoms alone, and offer a clear impact on both disease activity and patient-reported outcomes; our belief that the Phase 3 Primary Sjögren's data are clear data which can help pave a path towards a brighter future for this deserving community; telitacicept's market opportunity in primary Sjogren's disease; the possibility of Vor Bio initiating a global Phase 3 clinical study in primary Sjögren's disease; 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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