Telitacicept Achieved Primary Endpoint in Phase 3 Clinical Study for Primary Sjögren's Disease

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Phase 3 results position telitacicept as potential best-in-disease profile in primary Sjögren's disease

Telitacicept demonstrated a favorable safety profile

Vor evaluating timing of global Phase 3 clinical study in primary Sjögren's disease

Data anticipated to be presented at an upcoming medical conference

CAMBRIDGE, Mass., Aug. 13, 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 a Phase 3 clinical study in China evaluating telitacicept in adults with primary Sjögren's disease. Details of the study results are planned to be presented at an upcoming medical conference.

“For decades, patients with primary Sjögren's disease have faced limited treatments options, and telitacicept offers a potential option for these patients which targets the root cause of this devastating autoimmune disease. In an indication where therapeutic progress has been measured in incremental steps, the results from telitacicept suggest the potential for a best-in-disease profile and could set a new benchmark in the field,” said Jean-Paul Kress, M.D., Chief Executive Officer and Chairman of the Board. “By targeting both BAFF and APRIL, telitacicept addresses the upstream and downstream autoimmune signaling cascade, offering the possibility of truly modifying the disease instead of simply managing symptoms. This dual-target profile has also shown transformative potential in myasthenia gravis, our lead indication, highlighting telitacicept as a potential pipeline-in-a-product with broad applicability across autoimmune diseases. Sjögren’s represents a significant global expansion opportunity for Vor beyond myasthenia gravis, further extending the reach and impact of our portfolio.”

The Phase 3 clinical study in China achieved the primary endpoint of improving disease activity measured by a reduction in EULAR Sjögren's syndrome disease activity index (ESSDAI), a comprehensive 12-domain index measuring systemic disease activity severity against placebo. 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 primary Sjögren’s disease, which will become telitacicept’s fourth 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 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.

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 to have a best-in-disease profile in primary Sjögren’s disease, telitacicept’s safety profile, potential regulatory approval of telitacicept in primary Sjögren’s disease, 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 is 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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