Telitacicept Receives NMPA Approval for the Treatment of Sjögren's Disease in China

June 8, 2026

First regulatory approval for Sjögren's disease (SjD)

First and only approved therapy for SjD in China

Approval based on positive Phase 3 results generated by collaborator RemeGen demonstrating statistically significant and clinically meaningful improvements in both ESSDAI and ESSPRI

SjD marks the fifth indication approval for telitacicept

BOSTON, June 08, 2026 (GLOBE NEWSWIRE) -- Vor Bio (Nasdaq: VOR), a clinical-stage biotechnology company transforming the treatment of autoimmune diseases, and RemeGen Co., Ltd., (HKEX: 9995, SHA: 688331) today announced that China's National Medicinal Products Administration (NMPA) has approved telitacicept for the treatment of adult patients with SjD.

The approval is supported by positive efficacy and safety data from RemeGen's Phase 3 clinical program in Sjögren's disease. RemeGen independently developed telitacicept and is responsible for its development, regulatory approvals, and commercialization in China. Vor Bio holds exclusive rights to develop and commercialize telitacicept outside of Greater China.

"We are thrilled to see telitacicept become the first and only approved therapy for Sjögren's disease in China, marking the first regulatory approval ever for this indication," said Jean-Paul Kress, M.D., Chief Executive Officer and Chairman of Vor Bio. "The approval represents a landmark moment for patients who have long lacked approved treatment options and reflects the strength of the clinical evidence supporting telitacicept. Notably, telitacicept is the only therapy to demonstrate statistically significant and clinically meaningful improvements in both ESSDAI and ESSPRI, underscoring its potential to address both systemic disease manifestations and the symptoms that matter most to patients. We congratulate RemeGen on this achievement and believe this fifth approved indication for telitacicept further reinforces its potential to become a foundational therapy across autoimmune diseases."

The NMPA approval was supported by a nationwide multicenter, randomized, double-blind, placebo-controlled Phase 3 study evaluating telitacicept in patients with SjD. The primary endpoint was change from baseline in EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) score at Week 24.

In the primary analysis, patients treated with telitacicept achieved statistically significant reductions in ESSDAI score compared with placebo, with efficacy observed in both the 160 mg and 80 mg treatment groups and sustained through Week 48. Telitacicept also demonstrated clinically meaningful improvements in EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI), supporting benefit across both systemic disease activity and symptoms important to patients. The study met its primary efficacy endpoint and demonstrated a favorable safety profile.

About Telitacicept
Telitacicept is a novel recombinant fusion protein designed to treat autoimmune diseases through dual inhibition of 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).

Vor Bio is advancing telitacicept in global Phase 3 trials in gMG and SjD to support potential regulatory approvals 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.

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 to address both systemic disease manifestations and the symptoms that matter most to patients; telitacicept's potential to become a foundational therapy across autoimmune diseases; 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. 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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