Telitacicept Receives NMPA Conditional Approval for the Treatment of IgA Nephropathy in China

June 8, 2026

First and only approved BAFF/APRIL-targeting therapy for IgA nephropathy (IgAN)

Approval based on positive interim Phase 3 TELIGAN results generated by collaborator RemeGen and recently published in The New England Journal of Medicine

IgAN marks the fourth 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 conditionally approved telitacicept for the treatment of adult patients with IgAN.

The conditional approval is supported by positive efficacy and safety data from RemeGen's completed Phase 2 trial (18C014) and Phase 3 TELIGAN trial (18C021 Part A) in IgAN. 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 delighted to see telitacicept receive NMPA conditional approval in IgA nephropathy, representing an important achievement for the field and the first regulatory approval of a BAFF/APRIL-targeting therapy for IgAN," said Jean-Paul Kress, M.D., Chief Executive Officer and Chairman of Vor Bio. "We congratulate our collaborator RemeGen on the successful development, regulatory submission, and approval of telitacicept in China. Together with the positive Phase 3 TELIGAN results recently published in *The New England Journal of Medicine*, this milestone further validates the potential of dual BAFF/APRIL inhibition to address the underlying immunopathology of IgAN and supports our belief that telitacicept has the potential to become a foundational therapy across multiple autoimmune diseases globally."

The NMPA approval was supported by positive results from the Phase 3 TELIGAN trial, a multicenter, randomized, double-blind, placebo-controlled study evaluating telitacicept in adults with IgAN. The primary endpoint was change from baseline in urinary protein-to-creatinine ratio (UPCR) at Week 39.

In the primary analysis, patients treated with telitacicept 240 mg achieved a 59% reduction in UPCR from baseline at Week 39, corresponding to a 55% placebo-adjusted reduction. The study met its primary efficacy endpoint and demonstrated a favorable safety profile.

As previously reported in *The New England Journal of Medicine*, telitacicept treatment was also associated with encouraging preservation of kidney function. Estimated glomerular filtration rate (eGFR) remained largely stable through 39 weeks of treatment, while greater declines were observed in the placebo arm. Additional findings included reductions in circulating CD19+ B cells and serum immunoglobulin levels, including IgA, consistent with telitacicept's mechanism of action.

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 IgA 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.

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 dual BAFF/APRIL inhibition to address the underlying immunopathology of IgAN; telitacicept's potential to become a foundational therapy across multiple autoimmune diseases globally potential for telitacicept to become a best-in-class dual BAFF/APRIL therapy across autoimmune diseases and to deliver meaningful benefit for patients globally; 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. 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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