CRISPR Therapeutics Provides Update on Zugocabtagene Geleucel (Zugo-cel) in Refractory Rheumatologic Autoimmune Diseases

Systemic sclerosis (SSc) data presented at ACR Convergence 2026 showed 83% (5/6) of patients receiving standard lymphodepletion achieved a clinical response (rCRISS-25) at Month 3, with all responders maintaining response

Zugo-cel has been well tolerated in all 21 patients dosed to date, with no cytokine release syndrome (CRS) above Grade 2 and no immune effector cell-associated neurotoxicity syndrome (ICANS) or immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome (IEC-HS)

All nine patients with idiopathic inflammatory myopathy (IIM) achieved a moderate or major Total Improvement Score (TIS) response

ZUG, Switzerland and BOSTON, Nov. 08, 2026 (GLOBE NEWSWIRE) -- CRISPR Therapeutics (Nasdaq: CRSP), today provided an update on zugocabtagene geleucel (zugo-cel; formerly CTX112™), its investigational CRISPR/Cas9 gene-edited allogeneic CAR-T cell therapy targeting CD19, in the ongoing Phase 1 basket trial in refractory rheumatologic autoimmune diseases, including systemic lupus erythematosus (SLE), systemic sclerosis (SSc) and idiopathic inflammatory myopathy (IIM). Preliminary clinical data from the Phase 1 study have been encouraging, and zugo-cel has been well tolerated to date. As of October 15, 2026, 21 patients have been dosed across the SLE, SSc and IIM cohorts. Data from the SSc cohort were presented in a poster session at the American College of Rheumatology (ACR) Convergence 2026.

“Patients living with refractory autoimmune diseases such as systemic sclerosis, myositis and lupus often face progressive disease and a lifelong burden of immunosuppressive treatment,” said Naimish Patel, M.D., Chief Medical Officer of CRISPR Therapeutics. “The responses we are seeing across these indications, together with a favorable tolerability profile, are encouraging and reinforce our belief that an off-the-shelf allogeneic CAR-T therapy has the potential to offer these patients a meaningful new treatment option. We are grateful to the patients and investigators participating in this study and look forward to continuing to advance zugo-cel.”

Systemic Sclerosis Data Presented at ACR Convergence 2026

As of the data cut-off on July 21, 2026, seven patients with SSc dosed at the 100 million CAR+ cell dose level had at least three months of follow-up:

- At Month 3, 83% (5/6) of patients who received standard lymphodepletion achieved a revised Composite Response Index in Systemic Sclerosis (rCRISS)-25 response, including two patients who achieved the more stringent rCRISS-50 response.
- All five responders have maintained their response, including four patients who have completed at least six months of follow-up.
- The seventh patient, who received reduced lymphodepletion, showed improvement in multiple rCRISS components at Month 3.

Update Across the Rheumatology Basket Trial

As of October 15, 2026, 21 patients have been dosed in the rheumatology basket: four in the SLE cohort, eight in the SSc cohort and nine in the IIM cohort. The SSc cohort includes one patient dosed after the July 21, 2026 data cut-off for the ACR presentation. Encouraging results are being observed across indications:

- All nine patients with IIM, including two with immune-mediated necrotizing myopathy (IMNM), two with dermatomyositis (DM) and five with antisynthetase syndrome (ASyS), achieved a moderate or major Total Improvement Score (TIS) response.
- In SLE, two of three evaluable patients have maintained drug-free DORIS remission through at least Month 9, including one patient beyond one year.
- Zugo-cel has been well tolerated in all 21 patients, with no dose-limiting toxicities, CRS above Grade 2, ICANS, IEC-HS, severe infections, clinically significant hypogammaglobulinemia, prolonged cytopenias, GvHD or deaths reported to date.
- Dose escalation is ongoing, with the six patients dosed to date at the 200 million CAR+ cell dose level showing higher CAR-T cell expansion than at the 100 million CAR+ cell dose level.

In addition to the rheumatology basket, zugo-cel is being evaluated in a Phase 1 basket trial in autoimmune hematologic diseases and in a Phase 1 trial in autoimmune neurologic diseases.

About Zugocabtagene Geleucel (zugo-cel; formerly CTX112)

Zugocabtagene geleucel (zugo-cel) is a wholly-owned, allogeneic chimeric antigen receptor (CAR) T cell therapy product candidate targeting Cluster of Differentiation 19 (CD19), in development for both autoimmune and immuno-oncology indications. The off-the-shelf therapy leverages CRISPR/Cas9 for targeted gene knockout and CAR insertion, enabling immune evasion and enhanced T effector cell potency, and is administered following a standard lymphodepletion regimen without the need for human leukocyte antigen (HLA) matching. In autoimmune disease, zugo-cel is being investigated in three ongoing basket trials. The rheumatology basket trial is enrolling adult patients with systemic lupus erythematosus (SLE), systemic sclerosis (SSc), and idiopathic inflammatory myopathy (IIM). The hematology basket trial is enrolling patients with immune thrombocytopenic purpura (ITP) and warm autoimmune hemolytic anemia (wAIHA). The autoimmune neurologic basket trial is enrolling patients with progressive multiple sclerosis (PMS), neuromyelitis optica spectrum disorder (NMOSD), myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD), N-methyl-D-aspartate receptor (NMDAR) and leucine-rich glioma-inactivated protein 1 (LGI1) autoimmune encephalitis (AIE), and stiff person syndrome (SPS). In immuno-oncology, zugo-cel is being investigated in a trial in adult patients with relapsed or refractory B-cell malignancies.

About CRISPR Therapeutics

CRISPR Therapeutics is a leading biopharmaceutical company focused on developing transformative gene-based medicines for serious human diseases. Founded over a decade ago as an early pioneer in CRISPR/Cas9 gene editing, the Company has evolved from a pioneering research-stage organization into an industry leader, marking a historic milestone with the approval of CASGEVY® (exagamglogene autotemcel [exa-cel]), the world's first CRISPR-based therapy, for eligible patients with sickle cell disease and transfusion-dependent beta thalassemia. Today, CRISPR Therapeutics is advancing a broad, diversified pipeline spanning hemoglobinopathies, cardiovascular disease, autoimmune disease, oncology, regenerative medicine and rare diseases. The Company is also expanding its gene editing toolkit through SyNTase™ editing, its novel, proprietary platform designed to enable precise, efficient, and scalable gene correction. To accelerate its impact, CRISPR Therapeutics has established strategic collaborations with leading biopharmaceutical partners, including Vertex Pharmaceuticals. CRISPR Therapeutics AG is headquartered in Zug, Switzerland, with its wholly-owned U.S. subsidiary, CRISPR Therapeutics, Inc., and R&D operations based in Boston, Massachusetts and San Francisco, California. To learn more, visit www.crisprtx.com.

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Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements made by Dr. Patel in this press release, as well as regarding any or all of the following: (i) CRISPR Therapeutics preclinical studies, clinical trials and pipeline products and programs, including, without limitation, status of such studies and trials, potential expansion into new indications and expectations regarding data, safety and efficacy generally; (ii) data included in this press release and the above-described poster presentation, as well as the ability to use data from ongoing and planned clinical trials for the design and initiation of further clinical trials; and (iii) the therapeutic value, development, and commercial potential of gene editing technologies and therapies, including CRISPR/Cas9, as well as other technologies. Risks that contribute to the uncertain nature of the forward-looking statements include, without limitation, the risks and uncertainties discussed under the heading "Risk Factors" in CRISPR Therapeutics most recent annual report on Form 10-K and in any other subsequent filings made by CRISPR Therapeutics with the U.S. Securities and Exchange Commission. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they are made. We disclaim any obligation or undertaking to update or revise any forward-looking statements contained in this press release, other than to the extent required by law.

This press release discusses investigational therapies and is not intended to convey conclusions about efficacy or safety as to those investigational therapies or uses of such investigational therapies. There is no guarantee that any investigational therapy will successfully complete clinical development or gain approval from applicable regulatory authorities.

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