Cabaletta Bio®

CAR T cell therapy for autoimmune disease:

CABA-201 (rese-cel) and the RESET clinical trials

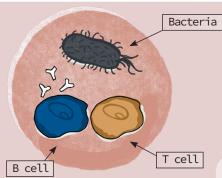
What is the immune system?

Our immune system is designed to protect us.1

It helps our body fight infections.1

The immune system is made up of organs and special cells that work together.1

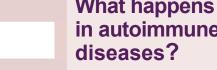




The immune system includes both B cells and T cells.1

These cells find and attack harmful invaders like bacteria and viruses.1

What happens in autoimmune diseases?



In autoimmune diseases, things can go wrong. For example, instead of targeting harmful invaders, B cells can mistakenly target healthy tissues and organs.2,3

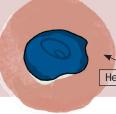


This can have effects all over the body. Such as:2,3

- Inflammation
- Damage to organs
- Day-to-day symptoms

The symptoms can be long-lasting and severe.2,3

Patients may also need long-term immunomodulatory treatment.4



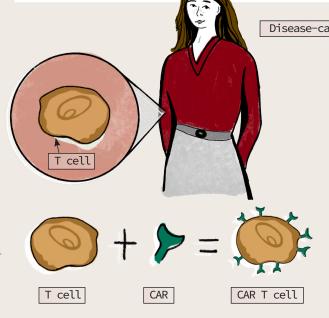
Disease-causing B cell

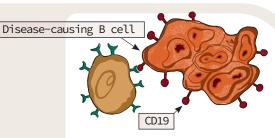
Healthy B cell

What is **CAR T cell** therapy?

CAR T cell therapy uses a patient's own T cells to treat disease.5

T cells are extracted from the patient. A specialized receptor, called a CAR-or "chimeric antigen receptor" —is introduced into the T cell. This makes CAR T cells.5





The CAR can be designed to recognize a specific marker called CD19.5

CD19 is only found on the surface of B cells, including those that cause disease.5

Once the CAR T cells recognize CD19, they can destroy the B cell.5

CD19-CAR T cell therapy was initially developed—and has been approved by regulatory agencies like the FDA—to treat certain B-cell related blood cancers.5,6

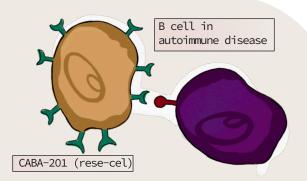
What is CABA-201 (rese-cel)?

CABA-201 is an investigational CAR T cell therapy.⁷

CABA-201 is being studied in the RESET clinical trial program, across various autoimmune diseases.^{7,8}

The aim is to get rid of disease-causing B cells and allow the body to replace them with new, healthy B cells.^{7,8}

CABA-201 is being studied for its potential to reset the immune system.^{7,8}



What should patients know about the RESET clinical trial program?



If a physician decides that a patient is eligible for the trial, T cells are collected from the patient's blood. This process is known as leukapheresis.^{7,9}



Next, in a cell-therapy manufacturing facility, CAR is introduced to T cells to make them recognize CD19 on the surface of B cells.^{7,9}
The CAR T cells are

then multiplied.7,9



This prepares their body to receive the new CAR T cells.^{7,9}

of preconditioning

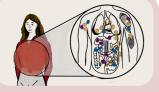
therapy.7,9



The CABA-201 therapy is then given as a one-time infusion by vein.^{7,9}

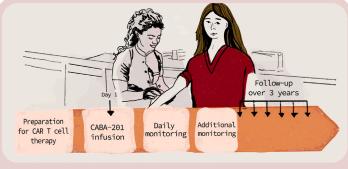
Therapy with CAR T cells may cause serious and potentially life-threatening side effects.⁵

The potential risks of participating in this clinical trial will be explained to the patient before they decide whether to participate.9



Once inside the body, the CABA-201 cells multiply and travel to different tissues.

They target B cells, including those that may cause the autoimmune disease. The CABA-201 cells in the body usually reduce in number within 4 weeks of infusion.^{7,9}



Doctors carefully monitor how well the therapy is working, both in the short and long term. Patients in the RESET™ trial need to return to the trial site regularly for follow-up visits for up to 3 years after infusion. This is to monitor the effect of CABA-201 on their disease. Longer-term follow-up may be performed remotely.^{7,9}

If you're interested in participating in the RESET™ study, please discuss this with your doctor.

For more information visit:



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CAR, chimeric antigen receptor; RESET, REstoring Self Tolerance.

1. Johns Hopkins Medicine: The Immune System. Available at: https://www.hopkinsmedicine.org/health/conditions-and-diseases/the-immune-system (accessed March 2025). 2. Schett G, et al. Ann Rheum Dis. 2024;83(11):1409–1420. 3. Johns Hopkins Medicine: What Are Common Symptoms of Autoimmune Disease? Available at: https://www.hopkinsmedicine.org/health/wellness-and-prevention/what-are-common-symptoms-of-autoimmune-disease (accessed March 2025). 4. American Academy of Allergy, Asthma & Immunology: Immunosuppressive Medication for the Treatment of Autoimmune Disease. Available at: https://www.aaaai.org/conditions-treatments/related-conditions/immunosuppressive (accessed March 2025). 5. Schett G, et al. Nat Rev Rheumatol. 2024;20(9):531–544. 6. Cappell KM, Kochenderfer JN. Nat Rev Clin Oncol. 2023;20(6):359–371. 7. Peng BJ, et al. Mol Ther Methods Clin Dev. 2024;32(2):101267. 8. Cabaletta Bio: Patients. Available at: https://www.cabalettabio.com/patients (accessed March 2025). 9. Cabaletta Bio: Data on File.