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> *"The once-in-a-time treatment approach [with autologous CD19-CAR T cells] leading to sustained drug-free remission is particularly attractive and unprecedented in autoimmune disease."*
> Müller *et al.* (2026) Nature Medicine.[16]

Autoimmune diseases: the next frontier in cell and gene therapy

Autoimmune disorders (AID) are complex conditions that can lead to poor quality of life, or in some cases, to death.[1] The standard of care includes essential treatments to control the disease, but some AID patients develop severe phenotypes that are unresponsive to approved drugs.[2] Cell and gene therapy (CGT) is emerging as a promising approach for such cases.[3,4]

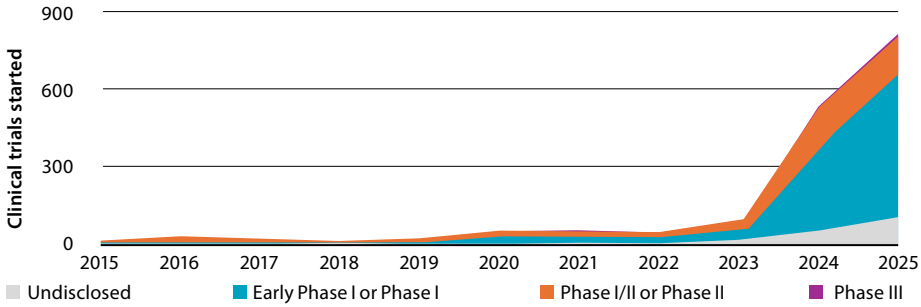
Immune regulation

One experimental approach leverages regulatory T cells to suppress the pathogenic autoimmune response. Therapeutic regulatory T cells are generated from blood via *ex vivo* manipulation and then infused into the patient.[4,5]

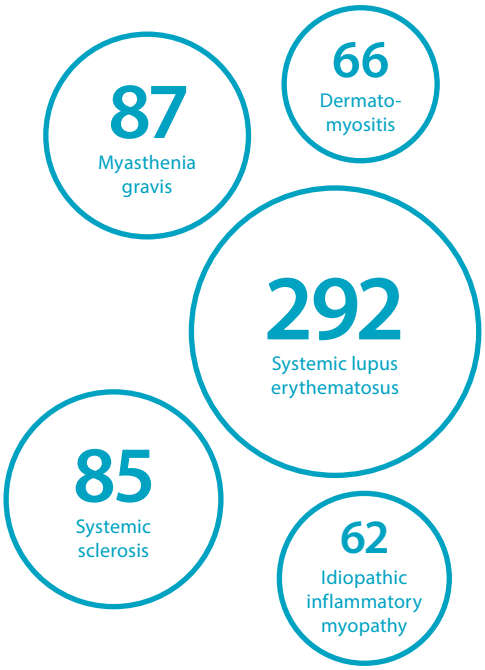
Immune reset

Another treatment type aims for an "immune reset." After a complete elimination of the cells causing the autoimmune reaction, the immune compartment is reconstituted from healthy precursors.[6–9] Approaches use hematopoietic stem cell transplantation, CAR T cell therapies, or bispecific antibodies directed at B cells.[3,10,11] Recent studies treating patients with systemic lupus erythematosus (SLE) and other B cell-mediated AID with CD19-targeting CAR T cells have shown deep, stable, and safe pathogenic B cell eradication.[3,12–16] Furthermore, some case studies suggest therapeutic potential in other AID, including neurological disorders[17], ulcerative colitis[18], hemophilia A[19], and pediatric AID[20–22].

Cell therapies gain ground in autoimmunity



Cell therapy clinical trials started worldwide each year to treat autoimmune diseases.
Source: Beacon by Hanson Wade.



Top 5 autoimmune indications represented in cell therapy clinical trials started worldwide, 2020–2025.
Source: Beacon by Hanson Wade.

Discover more details

Your partner in point-of-care cell therapy solutions

Next-generation strategies could revolutionize the CGT space in the near future. These innovative tactics for immune modulation include new targeting strategies, like CD22 or BCMA, and chimeric autoantibody receptor (CAAR) T cells that eliminate autoreactive B cells using an autoantigen as the binding domain.[3] The same approach has been extended to other cytotoxic cells, like NK cells.[23,24] Additionally, any of these engineered strategies can be combined with the tolerogenic function of regulatory T cells, for example CAR T regs, to switch the environment of targeted B cells through paracrine activity.[25]

Miltenyi Biotec has accompanied developments in CGT for hematological malignancies and AID from day one. Delivering turnkey solutions, workflows, and services, we empower clinicians and therapy developers to turn innovations into effective care.

24+
Peer-reviewed publications mention CliniMACS Prodigy® for manufacturing cell products to treat AID

25+
Over **25 years of CGT expertise** and relentlessly pushing boundaries

Tools and expertise for future-ready cell manufacturing and analytics

VISIT

Jumpstart your cell manufacturing with **platforms, products, and services** designed to harness immune cells and bring life-changing therapies from bench to bedside.

VISIT

Fast-track CAR T cell manufacturing with our **Cell Manufacturing Enabling Package (CMEP)**. Empower your processes and team efficiently and compliantly.



VISIT

Streamline the **quality control and monitoring** of cell products with flow cytometric solutions designed for insights right where it matters.

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