
TregTacRes Trial - First-in-class First-in-Human Phase I/IIa study in living-donor kidney transplant patients

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More than 10% of adults suffer from immune disorders, and millions live with transplants. Current therapies suppress the immune system non-specifically, targeting both harmful and protective cells alike, and usually require lifelong immunosuppression with severe side effects. There is therefore a strong need for novel, curative approaches that restore natural immune balance.

Regulatory T cells (Treg, <1% of all immune cells, also called “peacekeepers”) control immune responses and maintain immune balance. Preclinical and early clinical studies by the team and others have shown that Treg, when isolated, expanded and activated in specialized cultures, and then transferred *in vivo*, can sustainably suppress unwanted immune reactions (immune tolerance). However, Treg are also inhibited by immunosuppressants.

The scientists have developed, using a safe gene-editing approach, a novel Treg product resistant to Tacrolimus, a key immunosuppressant. This “first-in-class” product will be tested for the first time in kidney transplant patients as an adjunctive therapy next to immunosuppression. The therapy will be accompanied by a comprehensive biomarker program. The goal is to reduce immunosuppression and its side effects.
