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USE OF AUTOLOGOUS IL-10 PRODUCING REGULATORY TR1 CELLS FOR CELL THERAPY TREATMENT OF CRONH'S DISEASE.

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Abstract: IL-10 producing regulatory Tr1 cells were discovered in 1997 based on their properties to prevent in vitro bystander T-cell proliferation and to inhibit in vivo chronic colitis in mice. In 2001, TxCell biotech was founded on the idea that such regulatory cell populations could have a strong efficacy also in humans in severe chronic inflammatory conditions. As a preclinical proof of concept, mouse Tr1 directed against the antigen ovalbumin were found to display not only a preventive but also a curative activity in chronic colitis in mice through the secretion of the immunosuppressive cytokine IL-10. A reproducible manufacturing process for human Tr1 cell production was set-up in GMP conditions. Long term in vivo toxicity and pharmacokinetic studies were performed in mice and in vitro toxicity studies of human Tr1 cell products showed a safety profile compatible with the use of these lymphocytes for cell therapy. Based on these preclinical elements, a clinical trial will be initiated to determine if the use of IL-10 producing regulatory Tr1 cells for cell therapy is an important technological breakthrough in the treatment of chronic inflammatory conditions and in patients for which no curative treatments already exists.

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