TARGETING IMPROVED TREG SELECTIVITY WITH THE IL-2 MUTEIN EFAVALEUKIN ALFA: RATIONALE FOR IL-2 THERAPY IN ULCERATIVE COLITIS

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Efavaleukin alfa, an IL-2 mutein Fc fusion protein, demonstrated selective regulatory T cell expansion with minimal inflammatory cell activation in preclinical and phase 1 studies, supporting its evaluation in ulcerative colitis.

KEY POINTS

- In human cell cultures and cynomolgus monkeys, efavaleukin alfa produced more selective regulatory T cell expansion than aldesleukin, with lower inflammatory cell activation and reduced proinflammatory cytokine production except at the highest doses.
- In phase 1 studies, efavaleukin alfa achieved mean peak regulatory T cell increases of 4.7-fold above baseline in healthy subjects and 17.4-fold in systemic lupus erythematosus patients, with peak expansion at 8 days post-dose and sustained elevation through follow-up.
- Minimal changes were observed in conventional T cells, CD8+ T cells, B cells, or natural killer cells with efavaleukin alfa treatment.
- The most common adverse events in phase 1 studies were mild-moderate injection site reactions, with no dose-limiting toxicities, treatment-related serious adverse events, or deaths reported.
- These findings support an ongoing phase 2b study of efavaleukin alfa induction therapy in patients with moderate to severe active ulcerative colitis.

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