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The FDA Endocrinologic and Metabolic Drugs Advisory Committee has recommended for approval Teplizumab, a humanized anti-CD3 monoclonal antibody shown in a randomized clinical trial to delay development of type 1 diabetes in children as young as age 8 years after a single 14-day course of the drug.

UCSF Diabetes Center investigators **Jeffrey Bluestone**, **Stephen Gitelman**, and our UCSF TrialNet team <u>published</u> a pivotal clinical trial on its efficacy in delaying the onset of type 1 diabetes for at least two years in *New England Journal*, serving as an anchor for the approval.

Many Diabetes Center faculty shared their congratulations and excitement for the news. "It's so inspirational to see what they have accomplished, and what it means for the future of diabetes prevention," said **Suneil Koliwad**, after the news was announced by Interim-Director **Mark Anderson** yesterday. **Matthias Hebrok** quickly summarized this as "a great validation of decade-long efforts."

Qizhi Tang, who did related-research in her first postdoctoral project in Jeff's lab at University of Chicago twenty years ago, said "it has been a real privilege to witness the journey of this successful translational effort."

If approved, Teplizumab will be the first disease-modifying therapy in T1D.

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