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Summary

# TPM502, A TOLERIZING NANOPARTICLE MIXTURE FOR CELIAC DISEASE TREATMENT, INDUCES LONG-LASTING PHENOTYPIC CHANGES IN HLA-DQ2.5-GLIADIN-SPECIFIC TETRAMER+ CD4+ T CELLS, INDICATING ANTIGEN-SPECIFIC IMMUNOMODULATORY EFFECTS

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**TPM502, a nanoparticle-based antigen-specific immunotherapy, induced tolerance in HLA-DQ2.5-positive celiac disease patients through T-cell immunomodulation, with significant reductions in gluten-specific T-cell activation and ex vivo cytokine secretion in a phase 2a trial.**

## KEY POINTS

- In 36 celiac disease patients on a gluten-free diet (12 placebo, 24 TPM502), activation markers CD38, ICOS, and OX40 on gluten-specific CD4+ T cells significantly decreased across all TPM502 dose levels after a second gluten challenge compared to placebo ($p < 0.0001$).
- TPM502 treatment induced phenotypic changes consistent with T-cell exhaustion or anergy, including enhanced expression of co-inhibitory receptors TIGIT and PD-1 ($p < 0.0001$) and reduced CD127 expression ($p < 0.01$), persisting until study end.
- Ex vivo IL-2 and IFN-γ secretion by gluten-specific T cells showed significant and dose-dependent reductions after TPM502 treatment.
- At the highest TPM502 dose, gliadin-specific CD4+ regulatory T cells (CD25+CD127-) and CD39+ T cells increased, suggesting induction of regulatory T-cell states.
- TPM502 demonstrated a good safety and tolerability profile in this phase 2a double-blind, randomized, placebo-controlled study.
- This represents the first longitudinal tetramer-based flow cytometry analysis in celiac disease patients, directly characterizing gluten-specific T cells in peripheral blood.

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