ZymagenX Announces New Publication Demonstrating Improved Statistical Efficiency for Celiac Disease Clinical Trial Endpoints

NEWPORT BEACH, CA, November 12, 2026 – It is a pleasure to announce that a new study, led by ZymagenX, will be published in the prestigious journal BMC Medicine:

"A Continuous Composite Endpoint Methodology Improves Statistical Efficiency: Proof of Concept in Celiac Disease"
(DOI: 10.1186/s12916-026-05380-z)

The study introduces a methodology for combining multiple measures of disease activity into a single continuous composite endpoint (CCE), with the potential to improve statistical power and reduce patient sample-size requirements in clinical trials.

Clinical trials for celiac disease typically evaluate intestinal damage, immune responses, and serologic biomarkers separately. Because these measurements capture different aspects of disease activity and exhibit substantial variability, individual endpoints may not fully characterize treatment responses. The CCE methodology addresses this challenge by standardizing complementary biomarkers onto a common scale and integrating them into a single quantitative endpoint.

The study analyzed two independent clinical datasets representing gluten-induced intestinal injury and recovery following a gluten-free diet. Composite endpoints generally demonstrated reduced variability, larger effect sizes, improved statistical significance, and more consistent identification of patient responses compared with individual biomarkers. Statistical simulations further demonstrated that combining complementary biomarkers could substantially reduce sample-size requirements. In one representative simulation, the estimated sample size for 80% statistical power decreased from approximately 90 patients using an individual biomarker to 45 using a four-component composite endpoint.

"A persistent challenge in celiac disease drug development is the variability of individual clinical trial endpoints, which can make it difficult to detect meaningful biological responses," said Knut E. A. Lundin, Professor of Medicine, University of Oslo. "This study demonstrates the potential value of integrating complementary measures of disease activity into a single quantitative endpoint. Improving statistical power and reducing clinical trial sample-size requirements could have important implications for accelerating therapeutic development in celiac disease and other conditions."

The findings extend ZymagenX's previous work developing the VCIEL composite histologic endpoint, which combines two principal measures of intestinal injury. Although prospective validation is needed, the broader CCE methodology offers a promising approach for improving clinical trial efficiency and evaluating therapeutic responses.

About ZymagenX

ZymagenX, Inc. is a clinical-stage biotherapeutics company supported by a team of world-renowned clinicians, scientists and advisors in celiac disease research. The company is developing Latiglutenase (ZMGX003) for celiac disease therapy. ZymagenX is also developing a minimally-invasive diagnostic for celiac disease management (CypCel™) to assess the state of recovery of a celiac patient adhering to a gluten-free diet or other treatment. www.zymagenx.com

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