

Affecting approximately 1% of the world's population, Celiac disease is a chronic inflammatory disease that attacks the small intestine when gliadin protein (found in wheat and barley) is detected by the immune system.<sup>1</sup> Symptoms include diarrhea, bloating, abdominal pain, and more rarely, rashes and malnutrition. Scientists have been developing a cure to decrease, or even prevent, symptoms of celiac disease to replace a restrictive gluten-free diet. However, further clinical research and trials are needed to be conducted to ensure the effectiveness and consumers' safety.

TAK-101, created by the Takeda Pharmaceutical Company, created an intravenous drug that can reduce the symptoms of Celiac disease and protect villi within our intestines, which are essential for the human body to absorb nutrients from food. The TAK-101 drug blocks the signal to produce an inflammatory response by inhibiting gliadin-specific effector T-cells. In Phase 2 clinical trial, 33 patients with celiac disease were separated into two groups. Prior to the trial, participants have been following a gluten-free diet for at least six months and had no symptoms or positive antibody blood tests. One group received the TAK-101 drug by injections, while the other group got injections of a placebo. The pro-inflammatory cytokine interferon-gamma measures how immune T-cells respond to gluten and triggers the activation and release of MHC II, leading to an antigen-specific immune response. On the sixth day of the trial, study subjects who were administered TAK-101 had 2.01 interferon-gamma spot forming units compared to 17.58 in the placebo group.<sup>2</sup> The group that received the drug nearly had a 90 percent reduction in reactions and had minor intestinal damage compared to the placebo drug.<sup>3</sup> Although initial

---

<sup>1</sup> Singh, P., Arora, A., Strand, T. A., Leffler, D. A., Catassi, C., Green, P. H., Kelly, C. P., Ahuja, V., & Makharia, G. K. (2018). Global Prevalence of Celiac Disease: Systematic Review and Meta-analysis. *Clinical Gastroenterology and Hepatology Systematic Reviews and Meta-Analyses*, 16(6). <https://doi.org/10.1016/j.cgh.2017.06.037>

<sup>2</sup> Kelly, C. P., Murray, J. A., Leffler, D. A., Getts, D. R., Bledsoe, A. C., Smithson, G., First, M. R., Morris, A., Boyne, M., Elhofy, A., Wu, T. T., Podojil, J. R., Miller, S. D., & TAK-101 Study Group (2021). TAK-101 Nanoparticles Induce Gluten-Specific Tolerance in Celiac Disease: A Randomized, Double-Blind, Placebo-Controlled Study. *Gastroenterology*, 161(1), 66–80.e8. <https://doi.org/10.1053/j.gastro.2021.03.014>

<sup>3</sup> Kelly, C. P., Murray, J. A., Leffler, D. A., Getts, D. R., Bledsoe, A. C., Smithson, G., First, M. R., Morris, A., Boyne, M., Elhofy, A., Wu, T. T., Podojil, J. R., Miller, S. D., & TAK-101 Study Group (2021). TAK-101 Nanoparticles Induce Gluten-Specific Tolerance in Celiac Disease: A Randomized, Double-Blind, Placebo-Controlled Study. *Gastroenterology*, 161(1), 66–80.e8. <https://doi.org/10.1053/j.gastro.2021.03.014>

trials prove to be successful, the safety and efficacy of TAK-101 are still questionable. In the next phase of the study, researchers will investigate the correlation between interferon-gamma and its effect on celiac disease and how long will the treatment of TAK-101 last.