Topas Therapeutics Announces Positive Topline Results from Phase 2a Trial Evaluating TPM502 in Patients with Celiac Disease

- **TPM502 demonstrated a good safety profile in celiac disease patients**
- **The data indicates proof of concept that TPM502 induced targeted, antigen-specific tolerogenic effects in humans**
- **TPM502-induced antigen-specific effects were observed to persist throughout the study follow-up period**
- **The study data supports the potential application of the Topas platform in a broad range of autoimmune and immune-mediated diseases**

Hamburg, Germany, October 15th, 2024 – Topas Therapeutics today announced positive topline results from its Phase 2a trial evaluating lead candidate, TPM502, in patients with celiac disease. The study data serves as the first clinical proof of concept for Topas' proprietary nanoparticle platform and its potential to induce targeted, antigen-specific tolerogenic effects.

The international, multi-center, double-blind, randomized, placebo-controlled Phase 2a trial (NCT05660109) was initiated in 2023 to investigate the safety, tolerability and pharmacodynamics of two infusions of TPM502 in adult patients with celiac disease. Pharmacodynamic parameters were assessed through a gluten challenge after patients received treatment with TPM502 or placebo. Initial analysis showed that antigen-specific markers of tolerance induction exhibited a clear dose-response that reached statistical significance. Further, these antigen-specific effects persisted throughout the study's follow-up period. TPM502 was safe at all doses investigated. Topas intends to submit the full data and analysis for presentation at an upcoming scientific conference and for publication in a peer-reviewed journal.

"This first look at the TPM502 Phase 2a data is an important milestone for the Topas team and our mission to demonstrate that our platform induces antigen-specific tolerogenic effects. The data generated in this study underscore the potential of this versatile, novel modality in a broad spectrum of autoimmune and immune-mediated diseases," said **Hugo Fry, CEO of Topas Therapeutics**. *"We believe these results provide a valuable springboard to the next stage of development for Topas and position the company extremely well in the immune-tolerance space."*

Topas' lead candidate, TPM502, leverages the company's proprietary platform, a nanotechnology-based modality designed to induce targeted, antigen-specific immune tolerance. TPM502 is comprised of a mixture of nanoparticles that carry the major gluten epitopes for HLA-DQ2.5, present in the majority of celiac disease patients. TPM502 has been developed to establish long-term immune tolerance that will offer significant therapeutic benefit to celiac patients, who currently have no treatment options.

The initiation of the Phase 2a study for TPM502 builds on promising preclinical data and the excellent safety profile demonstrated in the Phase 1 study assessing Topas' TPM203 in pemphigus vulgaris patients. The company's next development steps for TPM502 will be based on the full data analysis.

About Topas Therapeutics

Topas Therapeutics, a clinical stage biotech company, is advancing a highly differentiated and versatile approach to establish immune tolerance in autoimmune and immune-mediated diseases. Our proprietary Topas Platform, comprising antigen-coupled nanoparticles, targets liver sinusoidal endothelial cells to drive T cells toward tolerance. The topline readout from our Phase 2a clinical trial in celiac disease validates the power of this new drug modality and its potential to address a broad range of immune-mediated indications, positioning us to deliver significant therapeutic benefits to patients.

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For further information: https://topas-therapeutics.com/

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