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## Topas Therapeutics Initiates Phase 2a Clinical Trial for TPM502 in Celiac Disease; Appoints Chief Business Officer and Chief Operating Officer

- Building on positive clinical data from Topas' Phase 1 study of TPM203 in pemphigus vulgaris patients, the Phase 2a study in celiac disease patients initiates clinical development for TPM502 and aims to achieve clinical proof of concept
- Recent leadership team expansion reflected by the additions of Christian Schröter as COO and Mireia Gómez-Angelats as CBO

Topas Therapeutics, a clinical stage biotech company developing novel antigen-specific immune tolerance therapies to treat autoimmune disorders, announced today the launch of a Phase 2a clinical study ([NCT05660109](#)) evaluating the safety, tolerability and pharmacodynamics of TPM502 in patients with celiac disease. Engineered leveraging the company's Topas Particle Conjugates (TPCs) nanotechnology, TPM502 is a mixture of nanoparticles carrying gluten specific antigenic peptides comprising the major gluten epitopes for HLA-DQ2.5 present in the majority of celiac disease patients. The company has received approval to initiate TPM502's clinical development in a Phase 2a study based on TPM502 preclinical data and clinical results from the Phase 1 study assessing Topas' TPC TPM203 in patients with pemphigus vulgaris. Celiac disease is an autoimmune disorder affecting multiple millions of patients worldwide who suffer from symptoms ranging from mild digestive discomfort to severe long-lasting complications.

*“The Phase 2a study will determine the capacity of TPM502 to promote immune tolerization in celiac disease patients and will confirm the safety profile of TPCs. It will also further establish the potential of the Topas platform to generate novel therapeutics for the treatment of T-cell-mediated diseases,”* commented **Cristina de Min, MD, Chief Medical Officer of Topas Therapeutics**. *“The development of TPM502 is a significant step*

*forward in the advancement of our immune tolerance-based clinical pipeline and illustrates our mission to bring novel disease-modifying treatments to patients with limited pharmacological options.”*

The multi-center, double-blind, randomized, placebo-controlled Phase 2a trial will include 42 adult patients diagnosed with celiac disease and will evaluate the safety, tolerability and pharmacodynamic effects of 2 administrations of TPM502 in dose escalating cohorts. Immune tolerance and symptom severity will be assessed following exposure to gluten. For more information on the Ph2a, please visit [clinicaltrials.gov](https://clinicaltrials.gov).

The company also announced two appointments to its executive management team. Mireia Gómez-Angelats, PhD, has joined as Chief Business Officer and Christian Schröter, PhD, as Chief Operating Officer, adding significant international pharmaceutical experience to Topas’ leadership as the company moves to mid-stage clinical development. Topas most recently welcomed Cristina de Min, MD, who joined the company as Chief Medical Officer at the end of 2021.

**Erich F. Greiner, Executive Chairman at Topas Therapeutics commented:** *“Topas is moving at a fast pace with the initiation of its second clinical study. We look forward to adding Christian and Mireia’s expertise to the executive team. They each bring two decades of experience in the pharmaceutical industry, which will be invaluable as Topas advances its platform into clinical development.”*

Prior to joining Topas Therapeutics, Dr. Christian Schröter worked at Merck Group for more than 20 years, in multiple countries and at increasing levels of responsibility. He was notably Head of Strategy, Global Healthcare Operations, and Senior Director, Pharma Business Integration. He obtained his PhD in immunology at the University of Tübingen.

Dr. Gómez-Angelats brings a track record of pharmaceutical experience from the US and Europe, in roles with increasing responsibilities in business development and R&D at Novartis, Bristol Myers Squibb, Johnson & Johnson and Almirall. Mireia holds a PhD in biochemistry and molecular biology from the University of Barcelona.

Biographies of Mireia Gómez-Angelats and Christian Schröter are available [here](#).

**About Celiac Disease**

Celiac disease is an autoimmune disorder characterized by an aberrant immune reaction to ingested gluten that results in damage to the small intestine. It affects 1% of the population and manifests through a wide range of digestive as well as non-digestive symptoms. Diagnosed patients are limited to a gluten-free diet, nevertheless, in a third of cases, severe symptoms persist despite gluten avoidance. There is currently no available medical treatment for celiac disease.

## **About Topas Particle Conjugates**

Topas Particle Conjugates are polymer-coated iron oxide nanoparticles comprising a proprietary biocompatible polymer and conjugated disease-relevant antigens. They are designed to deliver antigens to liver sinusoidal endothelial cells, which have potent immune-tolerogenic capabilities including triggering antigen presentation to T cells and tolerance induction. In clinical and preclinical studies, TPCs have elicited an outstanding safety profile and rapid clearance. The TPC platform has generated two clinical-staged drug candidates, TPM502 and TPM203, and has the potential to address multiple indications across the spectrum of autoimmune and inflammatory diseases.

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## **About Topas Therapeutics**

Topas Therapeutics is committed to developing novel disease-modifying treatment options for patients suffering from autoimmune and inflammatory diseases. With a versatile and personalized platform, Topas designs and produces antigen-specific nanoparticle conjugates aimed to elicit immune tolerization in T-cell mediated diseases. Based in Hamburg, Germany, Topas Therapeutics is led by a seasoned team of biotech/pharma experts and is backed by an international consortium of investors including BioMedPartners, Boehringer Ingelheim Venture Fund, EMBL Ventures, Epidarex Capital, Evotec, Gimv, Vesalius Biocapital III.

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