

Topas Therapeutics Announces First Patient Enrolled in Phase 1 Trial with TPM203 in Pemphigus Vulgaris

- First program from the Topas platform to enter clinical testing
- TPM203 is one of several proprietary programs being developed by Topas
- Pemphigus vulgaris is an orphan indication that currently has no cure

Hamburg, 18 December 2019.

Topas Therapeutics GmbH (Topas), a Hamburg, Germany-based private platform company leveraging the natural tolerance induction capabilities of the liver, today announced that the first patient has been enrolled in a first-in-human Phase 1 trial evaluating TPM203 in patients with pemphigus vulgaris (PV), an orphan autoimmune disease. TPM203 is Topas' most advanced program and the first one from the Company's proprietary Topas Particle Conjugates (TPC) platform technology to enter the clinic.

“The initiation of the first clinical study with our lead product candidate is an exciting and at the same time value-generating step forward for Topas,” said Timm Jessen, PhD, Chief Executive Officer. “Pemphigus vulgaris is a well characterized disease with extensive knowledge on the most related autoimmune antigen and biomarkers available. It provides a very good setting to demonstrate the successful translation of our Topas Particle Conjugates platform into the clinic. While treatments do exist for this painful condition, there currently is no cure, and we look forward to advancing TPM203 with the goal of helping patients with this debilitating disease.”

The Phase 1 trial is an open-label study designed to evaluate the safety, tolerability, and pharmacokinetics of TPM203, as well as to explore early signs of effectiveness for TPM203 to induce antigen-specific immune tolerance in this patient population. The study has a single-ascending dose phase, followed by a multiple dose phase. The trial is planned to treat 24 patients and will be conducted at approximately seven sites in Germany; the coordinating investigator is Prof. Michael Hertl from the Dept. of Dermatology and Allergology at University Medical Center Marburg.

Topas Particle Conjugates technology platform harnesses the liver's natural immunology capabilities

Topas' technology platform harnesses the natural mechanisms of the liver to promote immune tolerance to blood borne antigens. Small peptide-loaded nanoparticles, Topas Particle Conjugates (TPCs), mimic such blood borne antigens and are taken up by liver sinusoidal endothelial cells (LSECs). LSECs present these antigens to T cells under anti-inflammatory conditions conducive to the induction of tolerogenic regulatory T cells (Tregs) and/or by other mechanisms. Tregs are pivotal for immune tolerance, and their in vivo generation serves to re-instate healthy immune balance (homeostasis) and provide a cure for diseases characterized by undesirable or dysregulated inflammatory immune reactions. The fast and active uptake of circulating TPCs by LSECs leads to rapid clearance of the particles from the bloodstream,

allows an exact dosing of the antigen residing in the liver and avoids undesired immune reactions. TPCs provide major competitive advantages, including in vivo traceability, dose-ability, biodegradability and scalability along GMP requirements.

About Pemphigus Vulgaris

PV, an orphan disease, is an autoimmune condition involving a painful blistering on the skin and mucous membranes. If extensive, blistering can lead to life-threatening fluid loss, infection, and disfigurement. In this disease, patients have autoantibodies against desmogleins (proteins that play a role in connecting cells), which disrupt the connections between the squamous cells of the epidermis and cause blisters that can easily burst. Treatment consists of immunosuppressive agents; prognosis is variable, but many patients have a higher than normal mortality rate, and there is no cure.

About Topas Therapeutics

Topas Therapeutics GmbH is a private Hamburg, Germany-based biotechnology company focused on developing products to address areas of major unmet need, including autoimmune diseases, allergies and anti-drug antibodies. The Topas Particle Conjugates technology platform induces antigen-specific immune tolerance by harnessing the liver's natural immunology capabilities. The Company has several proprietary programs; lead product candidate TPM203 has recently entered clinical testing for pemphigus vulgaris, an orphan disease. Other programs are in anti-drug antibodies, celiac disease, Type 1 diabetes, as well as a multiple sclerosis program that is available for partnering. Topas has a research and option agreement with Eli Lilly and Company focused on antigen-specific tolerance induction, and a multi-year agreement with Boehringer Ingelheim to collaborate in the field of anti-drug antibodies. Topas' investors include: Epidarex Capital, Gimv, EMBL Ventures, Evotec and Boehringer Ingelheim Venture Fund. For additional information, please visit: www.topas-therapeutics.com.

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