

Press Release

Zurich-Schlieren, Switzerland, January 5th, 2024

Topadur Pharma AG receives CHF 1.76 million from Innosuisse for the Phase 2a clinical trial with TOP-N53 in the treatment of digital ulcers

Swiss biotech start-up Topadur Pharma AG is pleased to announce that it has been awarded a Start-up Innovation Project grant from Innosuisse. With this funding, Innosuisse is supporting a Proof-of-Concept, Phase 2a clinical trial in patients with digital ulcers (DU) in systemic sclerosis (SSc). The grant of CHF 1.76 million once again confirms the Swiss Innovation Agency's confidence in Topadur's research and vision. The total cost of the project is around CHF 2.9 million.

"With the Proof-of-Concept, we are entering the pivotal phase in which our drug candidate must prove its efficacy in patients," said Pascal Brenneisen, CEO of Topadur Pharma AG. "We are convinced that we can significantly improve the treatment of DU in SSc patients and thus improve their quality of life."

Systemic sclerosis and digital ulcers

SSc is a rare, rheumatic autoimmune disease of the connective tissue that causes vascular abnormalities, inflammation, and progressive fibrosis in the skin, joints, and internal organs. A characteristic symptom of SSc is the development of chronic, non-healing cutaneous wounds, such as DU on the fingertips. About 50% of the patients with SSc develop DU during the course of the disease. SSc patients experience severe disability due to DU: They suffer from debilitating pain and severe hand disability. Consequently, simple daily activities are often impossible. DU can lead to severe complications such as gangrene and subsequent amputation. There are currently no drugs on the market approved to treat this indication, highlighting the pressing unmet medical need.

About TOP-N53

The active ingredient TOP-N53 enhances microcirculation in the tissue and promotes the formation of new blood vessels due to an increase in the important intracellular messenger cGMP, which is believed to be deficient in many vascular diseases including SSc. TOP-N53 is based on a dual mode of action. It is similar to Sildenafil on one hand, but also releases an important endogenous messenger, nitric oxide, which is reduced in diseases like systemic sclerosis and, together with the first active component, increases cGMP. TOP-N53 was specifically developed for topical and local treatment. In October 2021, TOP-N53 received Orphan Drug Status from the European Medicines Agency (EMA). The results from the Phase 1 clinical trial had met both primary and secondary endpoints of safety and tolerability, and exploratory efficacy (skin blood flow) in healthy volunteers.

About the approved Start-up innovation project

The main objectives of this Phase 2a study is to evaluate the safety and tolerability, and efficacy to improve microcirculation in the wound after topical application of TOP-N53 on DU in patients with SSc. This open-label, placebo-controlled trial will be conducted in SSc patients with DU in France.

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About Topadur

Topadur is a patient-oriented biotech company developing disruptive therapies for aging diseases. The Swiss-based biotech company developed the proprietary DualTOP™ technology platform consisting of new dual-acting drugs that increase cGMP levels to stimulate microcirculation, enable tissue regeneration, and avoid local oxygen deficiency. Topadur's R&D portfolio consists of promising development candidates in regenerative medicine, oncology, ophthalmology, gastrointestinal diseases and medical aesthetics. The DualTOP™ technology will contribute to promoting long healthy life.

For more information regarding Topadur Pharma AG, please visit: www.topadur.com

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