

Press Release

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TOPADUR Pharma AG announces positive results from an interim analysis of an ongoing Phase I clinical trial with their new wound healing drug candidate

Zurich-Schlieren, Switzerland, November 10, 2020. TOPADUR Pharma AG, a biopharmaceutical start-up company today announces positive results from an analysis of the first two dose groups of the ongoing Phase 1 clinical of TOP-N53, a first-in-class wound healing drug candidate.

- The safety results from this interim analysis of the first two dose groups suggest that the drug was safe and well-tolerated.
- Moreover, data from the first two groups demonstrated an increase in skin microcirculation.
- Following review of data from this interim analysis, TOPADUR Pharma initiated dosing of the third group of this trial.

This Phase 1 clinical trial is a double-blind, dose-escalation of TOP-N53 in healthy subjects to evaluate its safety and tolerability. In this trial, TOP-N53 is administered subcutaneous to a group of six healthy subjects each. Skin microcirculation, as an exploratory end point in the healthy subjects was measured and the increase was more intense in the second group.

“These first results support the important role of TOP-N53 in the treatment of chronic wounds exemplified by diabetic foot ulcer (DFU) and digital ulcers (DU)”, said Reto Naef, Chairman of the Board of Directors and CEO at TOPADUR Pharma AG. “I’m encouraged by these initial clinical trial results of TOP-N53 as they further build on the positive clinical evidence supporting its novel mechanism of action,” commented Dr. Naef. “I am optimistic that TOP-N53 may provide a promising new treatment option enabling chronic wound to heal for patients afflicted by DFU and DU, disabling and life-threatening conditions.”

About TOP-N53

TOP-N53 is a dual mode of action phosphodiesterase type 5 inhibitor (PDE5) / organic nitrate ester that targets the cGMP-Enzyme Regulation System. In a process called `bioactivation`, TOP-N53 converts into nitric oxide (NO) and the more potent PDE5 inhibitor TOP-52. NO activates soluble guanylyl cyclase (sGC) to synthesize cyclic guanosine-3',5'-monophosphate (cGMP), while TOP-52 and TOP-N53 reduce degradation of cGMP by inhibiting PDE5. TOP-N53 locally applied, increases microcirculation and induces the formation of new blood vessels. This new drug principle demonstrated unprecedented wound healing effects during the preclinical development of the drug candidate.

About DFU and DU in scleroderma

Diabetes mellitus is one of the major health concerns worldwide, affecting 425 million people, and its prevalence is expected to increase to 629 million in 2045. One serious complication of diabetes mellitus is DFU. Impaired local blood circulation and the resulting low tissue oxygenation, nutrient

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supply and waste elimination is a major cause for compromised wound healing in diabetic patients and wounds often become chronic and non-healing. Approximately 15% of all diabetic patients will develop an ulcer in their lifetime, and DFU is the most common reasons for hospitalization and the most frequent cause of lower-extremity amputations.

Scleroderma is a rare, debilitating autoimmune disease of the connective tissue characterized by inflammation, vasculopathy, progressive fibrosis in the skin, joints, internal organs with excessive collagen accumulation. About 95% of patients with scleroderma are afflicted with recurrent episodes of Raynaud's phenomenon, a painful condition with tissue ischemia-reperfusion cycles. These ischemic ulcers are very painful and often result in impaired hand function.

About TOPADUR

TOPADUR is a patient-oriented biotech company enhancing quality of life through cutting-edge research. The Swiss-based biotech company is developing a new class of compounds based on their innovative action on the cGMP-Enzyme Regulation System, targeting high medical needs. TOPADUR's compounds correct the deficit in the cell-cell communication, which can be the cause of chronic wounds resulting from insufficient local blood-circulation. TOPADUR's R&D portfolio consists of promising development candidates in regenerative medicine, oncology, ophthalmology and medical aesthetics.

For more information regarding TOPADUR PHARMA AG, please go to: www.topadur.com

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