

Press Release

July 6th, 2021

TOPADUR Pharma AG announces completion of TOP-N53 First-in-Man Study

Zurich-Schlieren, Switzerland, July 6th, 2021. TOPADUR Pharma AG, a biopharmaceutical start-up company today announced the completion of a Phase 1 dose escalation study of its lead compound, TOP-N53, a first-in-class wound healing drug candidate.

The study was designed to allow for an increase to the next higher dose with six patients per dose level and a total of 30 healthy subjects were enrolled. As a result of the excellent safety profile of TOP-N53, the clinical study advanced through all five intended dose levels. The final results of this study will be reported once full datasets are available for pharmacokinetics, pharmacodynamics, and clinical observations for all enrolled subjects.

"The absence of dose-limiting toxicity gives us great confidence that TOP-N53 will be safe for use in patients following longer-term administration," said Reto Naef, Chairman of the Board of Directors and CEO at TOPADUR Pharma AG. "I'm encouraged by the completion of this study as this is an essential first step into the clinical development of TOP-N53" commented Dr. Naef.

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 gets converted into nitric oxide (NO) and the more potent PDE5 inhibitor TOP-52 in the wound tissue. 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 Diabetic Foot Ulcer (DFU) and Digital Ulcers in Systemic Sclerosis (SSc)

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 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; DFU is the most common reasons for hospitalization and the most frequent cause of lower-extremity amputations.

Systemic Sclerosis 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 SSc are afflicted with recurrent episodes of Raynaud's phenomenon, a painful condition with tissue ischemia-reperfusion cycles due to

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vasospasms and accumulating structural damage to the digital arterioles from oxidative stress that favors the occurrence of digital ulcers. These 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 developed the DualTOP™ technology platform consisting of new dual-acting drugs that target the cGMP-Enzyme Regulation System to stimulate microcirculation, enable tissue regeneration, and avoid local oxygen deficiency.

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

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