

Press Release

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TOPADUR Pharma AG announces positive results from TOP-N53 First-in-Human Study

Zurich-Schlieren, Switzerland, October 5th, 2021. TOPADUR Pharma AG, a clinical-stage biopharmaceutical start-up company developing ground-breaking therapies for aging diseases, today announced positive results from a First-in-Human study evaluating the safety, tolerability and efficacy of TOP-N53, a first-in-class wound healing drug candidate.

TOP-N53 FIH study met the primary and secondary endpoints demonstrating a favorable safety and tolerability profile in all the healthy subjects recruited.

The results on skin blood flow, an exploratory endpoint, measured by Laser Speckle Contrast Imaging (LSCI) are very encouraging. The overall efficacy profile of TOP-N53 showed a dose-dependent increase in blood flow that lasted 24h in the highest two dose groups, at single-digit microgram range.

“These positive results confirm the potential of TOP-N53 to become a disruptive therapy for chronic wounds,” said Reto Naef, Chairman of the Board of Directors and CEO at TOPADUR Pharma AG. “We look forward to continuing the clinical development of TOP-N53 to provide a future therapy to enable the healing of chronic wounds like digital ulcers or diabetic foot ulcers.

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 Ulcers and Digital Ulcers in Systemic Sclerosis

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 Diabetic Foot Ulcer (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, and 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. It is characterized by inflammation, vasculopathy, progressive fibrosis in the skin, joints, internal organs with excessive collagen accumulation. About 95% of patients with systemic sclerosis are afflicted with recurrent episodes of Raynaud’s phenomenon, a painful condition with tissue ischemia-

Press Release

reperfusion cycles due to 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 developing disruptive therapies for aging diseases. The Swiss-based biotech company developed the DualTOP™ technology platform consisting of new dual-acting drugs that increase the levels of cGMP 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 and medical aesthetics. The DualTOP™ technology will contribute to promoting long healthy life.

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

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