Press Release

September 10, 2020

TOPADUR Pharma AG announces the start of clinical development with their new wound healing drug candidate

Zurich-Schlieren, Switzerland, September 10, 2020. TOPADUR Pharma AG, a biopharmaceutical start-up company today announces dosing of first healthy subjects in Phase 1 clinical trial evaluating the safety and tolerability of TOP-N53, a first-in-class wound healing drug candidate.

TOP-N53 locally applied, increases microcirculation and induces the formation of new blood vessels. TOP-N53 has demonstrated unprecedented potency and efficacy in preclinical models. “We are very positive it will address an important need for patients with non-healing cutaneous 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.

The Phase 1 clinical trial will evaluate the safety and tolerability of single ascending doses of TOP-N53 in healthy subjects. "The enrollment of the first subjects in this trial is a major event in the clinical development program for this promising drug candidate," commented Dr. Naef. "If successful, the trial will provide important validation for our innovative approach to treat debilitating and rare wound healing diseases."

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. 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 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.

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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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