December 23, 2024

Commencement of an Additional Phase III Clinical Trial of the functional peptide SR-0379

On December 6, 2024, FunPep Co., Ltd. (“FunPep”) submitted a clinical trial plan notification for an additional Phase III clinical trial (SR0379-JP-SU-02, hereinafter referred to as “Trial 02”) of SR-0379, a functional peptide currently under development for the treatment of skin ulcers. We are pleased to announce that the Pharmaceutical and Medical Devices Agency (PMDA) has completed its review and FunPep will commence Trial 02.

SR-0379 is an investigational functional peptide composed of 20 amino acids.

Controlling bacteria and infection is crucial in the treatment of skin ulcers, where the skin's barrier function is impaired and various bacteria adhere to the wound surface. SR-0379 has the advantage of combining the promotion of wound healing through angiogenesis and granulation tissue formation with antibacterial activity. Additionally, we anticipate SR-0379 will be used by a wide range of skin ulcer patients due to its convenient administration method: a spray formulation that can be stored at room temperature.

Through the development of SR-0379, we aim to promote early recovery from skin ulcers such as pressure ulcers and diabetic ulcers, which are becoming increasingly important in an ageing society, and contribute to improving the quality of life of patients.

SR-0379 is currently being jointly developed in Japan by FunPep and Shionogi & Co.,Ltd.

A Phase III clinical trial (SR0379-JP-SU-01, hereinafter referred to as the “Trial 01”) targeting patients with skin ulcers was conducted from June 2021. The results showed a statistically significant improvement in the primary endpoint, ‘number of days to surgical intervention,’ in a post-hoc subgroup analysis (ulcer size [long axis × short axis] < 36 cm^2). Additionally, no adverse events considered to be causally related to the investigational drug were reported, confirming the high safety profile of SR-0379.

Trial 02 is a placebo-controlled, double-blind, comparative trial that will evaluate the efficacy and safety of once daily administration of SR-0379 or placebo for 28 days in the patient group that demonstrated efficacy in Trial 01 (ulcer size [long axis × short axis] < 36 cm^2, target number of subjects: 142).