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FunPep Co., Ltd.

Announcing the start of Phase III clinical trials for functional peptide SR-0379

On June 1, FunPep Co., Ltd. (FunPep) submitted a clinical trial plan to the Pharmaceuticals and Medical Devices Agency (PMDA) for a Phase III clinical trial of the functional peptide SR-0379 in patients with skin ulcers in Japan. The PMDA has now completed the required inspection and we are pleased to announce that the clinical trial has started.

This Phase III study is a placebo-controlled, double-blind comparative study to evaluate the efficacy and safety of SR-0379 administered under double-blind conditions once daily for 28 days in patients (target number of patients: 120) with skin ulcers (pressure ulcers, diabetic ulcers, leg ulcers, etc.) requiring simple surgical measures (suturing, skin grafting, pedicled flap).

Skin ulcers that require simple surgical measures such as skin grafting have deep skin defects, so it is important to promote the formation of benign granulation, which is a regenerative tissue of the skin, while controlling for infection to improve the condition of the wound base and quickly return the wound condition to a state where skin grafts or other treatments can be applied.

Therefore, the primary endpoint of this study is "the number of days until simple surgical measures can be applied," and it hopes to confirm that the administration of SR-0379 shortens the time until the skin ulcer improves to a state where skin grafts and other measures can be applied.

SR-0379 is a novel functional peptide compound consisting of 20 amino acids. Its main action is to promote angiogenesis and granulation, and it also has antibacterial activity.

A skin ulcer is a condition in which the barrier function of the skin is defective, and various bacteria adhere to the wound surface. Bacterial proliferation and infection can delay wound healing, and more serious conditions can be caused by sepsis; therefore, it is important to control bacteria and infection. SR-0379 has been shown to have antibacterial activity unlike existing drugs that also have wound-healing-promoting activity. In addition, SR-0379 has a simple administration method (spray formulation that can be stored at room temperature) that is easy to use in home medical care, which is expected to become more common in the future, and is therefore expected to contribute to the treatment of a wide range of patients.

Through the development of SR-0379, FunPep aims to contribute to the improvement of patients' quality of life (QOL) by promoting the early recovery of pressure ulcers and other skin ulcers, which are becoming increasingly prominent in an aging society.

< Reference Information >

◆ R&D Pipeline

< Products in Development >

Product	Indication	Region	Clinical Trial Sites	Discovery	Pre clinical	Clinical Trials			Licensee etc.
						Phase I	Phase II	Phase III	
SR-0379	Skin Ulcers	Global	Japan	Phase III Ongoing					Shionogi (Global license)
FPP003 (Target: IL-17A)	Psoriasis	Global	Australia	Phase I/IIa Ongoing					Sumitomo Dainippon (Option for N. America)
	Ankylosing spondylitis		—	Preclinical					
FPP004 (Target: IgE)	Pollinosis (Seasonal allergy rhinitis)	Global	—	Preclinical					TBD
FPP005 (Target: IL-23)	Psoriasis	Global	—	Preclinical					TBD

< Research Themes >

Type	Disease	Partners
Antibody-inducing peptide	Neuropsychiatric disorders	Sumitomo Dainippon (Research agreement on neuropsychiatric disorders)
	Pain	
	High blood pressure	
	Allergies	Shionogi (Collaborative research on pain)
	Thrombosis	MEDIPAL HOLDINGS (R&D support)
	Familial adenomatosis of the colon	
	Others	
Prophylactic vaccines	COVID-19	AnGes (Collaborative research)

Skin Ulcer

Skin ulcers include pressure ulcers (so-called "bedsores"), which often occur in bedridden elderly people; diabetic ulcers, which are a complication of diabetes and are highly prevalent in the elderly; and leg ulcers, which are primarily caused by venous stasis. The treatment of skin ulcers is becoming more and more important in an aging society.

Granulation

Granulation is a red, soft, granular connective tissue that forms during the healing process of skin ulcers.

◆ Antibacterial Mechanism of Action of SR-0379

The skin and immune cells contain a group of peptides called "antimicrobial peptides," which consist of about 20 to 40 amino acids and play a role in the immune defense. Antimicrobial peptides are structurally characterized by the uneven distribution of positively charged hydrophilic and hydrophobic amino acids, which disrupts the cell membranes of bacteria and fungi to produce antimicrobial effects. Since SR-0379 has similar structural characteristics to naturally occurring antimicrobial peptides, it exhibits similar antimicrobial activity. This disrupts the cell membrane of bacteria, etc., making it difficult for resistant forms to develop.

<Antibacterial Mechanism of Action of Antibacterial Peptides >

