



June 6, 2022

Notice Concerning the Completion of Subject Enrollment for the Phase I/IIa Clinical Study of Antibody-Inducing Peptide FPP003

FunPep Co., Ltd. ("FunPep") announced today that it has completed subject enrollment for the Phase I/IIa clinical study of its antibody-inducing peptide FPP003 for the treatment of psoriasis vulgaris in Australia.

This Phase I/IIa study is a dose escalation study (36 patients) of FPP003 in psoriasis vulgaris, which is being conducted as a FIH study (First in Human study). While the primary endpoint is safety, efficacy will also be evaluated in an exploratory manner.

Antibody-inducing peptides are peptide therapeutic vaccines that are expected to have therapeutic effects by inducing antibody production in the patient's body.

Unlike antibody drugs manufactured in biomanufacturing facilities, antibody-inducing peptides can be produced by chemical synthesis, thus reducing manufacturing costs. Furthermore, once these peptides are administered, immune cells in the patient's body continuously produce antibodies for a period of time, thus allowing for a longer drug administration interval. With these features, FunPep hopes to develop antibody-inducing peptides as an alternative to expensive antibody drugs that can reduce medical costs, thereby contributing to solving the health economic issues that are becoming more serious in developed countries as well as reducing the burden on patients.

FunPep's strength is that we possess the drug discovery platform technology for antibody-inducing peptides. In collaboration with Osaka University Graduate School of Medicine, we are conducting drug discovery research on antibody-inducing peptides for various diseases.

The target protein of FPP003, IL-17A, plays an important role in the pathogenesis of various inflammatory diseases, and precedent anti-IL-17A antibody drugs have obtained regulatory approval for a wide range of diseases including psoriasis vulgaris, psoriatic arthritis, ankylosing spondylitis and nr-axSpA (non-radiographic axial Spondyloarthritis). FunPep is also developing FPP003 with a view to worldwide marketing in Japan, the U.S., Europe and other countries, and is currently conducting a Phase I/IIa clinical trial in Australia for psoriasis vulgaris.

FPP003 is a development compound created in collaboration with Sumitomo Pharma Co. FunPep has an option agreement with Sumitomo Pharma for the exclusive rights to develop and commercialize FPP003 in North America for the treatment of all diseases, and Sumitomo Pharma holds the preferential negotiating rights for all territories outside North America including Japan.

< Reference Material >

◆ R&D Pipeline

< Products in Development >

Product	Indication	Region	Clinical trial sites	Discovery	Preclinical	Clinical Trials			Alliance
						P1	P2	P3	
SR-0379	Skin Ulcers	Global	Japan			Phase III Ongoing			Shionogi (Global license)
FPP003 (Target : IL-17A)	Psoriasis	Global	Australia			Phase I/IIa Ongoing			Sumitomo Pharma (Option for N.America)
	Ankylosing spondylitis		Japan			Phase I Ongoing * * Investigator initiated trial			
FPP004 (Target : IgE)	Pollinosis (Seasonal allergy rhinitis)	Global	—		Preclinical				TBD
FPP005 (Target : IL-23)	Psoriasis	Global	—		Preclinical				TBD
FPP006	COVID-19	Global	—		Preclinical				TBD

< Research Themes >

Type	Indication	Academia	Partners
Antibody inducing peptide	Neuropsychiatric disease	Osaka University (Research collaboration on antibody-inducing peptide)	Sumitomo Pharma (Research agreement on Neuropsychiatric disease)
	Pain		
	High blood pressure		
	Allergy-related diseases	Kumamoto University (Research collaboration on dyslipidemia)	Shionogi (Research collaboration on pain)
	Thrombosis		
	Dyslipidemia		Medipal Holdings (R&D support agreement)
	Others		

Antibody-inducing Peptides

On the strength of AJP001, a functional peptide that is the result of research conducted at the Osaka University Graduate School of Medicine, FunPep is advancing research and development of "antibody-inducing peptides," therapeutic vaccines for chronic diseases such as inflammatory and allergic diseases.

In order to induce antibody production in vivo, it is necessary for B cells to recognize target proteins (antigens) and for B cells to be activated by stimulation from helper T cells. However, antibodies are not produced against self-antigens (e.g., self-proteins), which are the target proteins of chronic diseases, because helper T cells are not activated. For this reason, antibody-inducing peptides are designed to induce antibody production against target self-proteins by binding the "epitope" portion (B cell epitope) recognized by B cells to the "carrier" portion containing the T cell epitope recognized by helper T cells.

The strengths of our antibody-inducing peptides are: (1) the use of our proprietary functional peptide "AJP001" as the "carrier"^(Note) and (2) the technological know-how to design and select the "epitope" according to the characteristics of the target protein (physicochemical properties, steric structure, and biological functions). FunPep calls these two strengths together the "STEP UP (Search Technology of EPitope for Unique Peptide vaccine)" drug discovery platform.

(Note) Generally, biological substances are used as "carriers," but since these carriers contain not only T-cell epitopes but also B-cell epitopes, antibodies against the carriers are also produced. Therefore, repeated administration of the carrier may result in stronger immune induction against the carrier and weaker immune induction against the target protein. On the other hand, when AJP001 is used as a carrier, antibodies against AJP001 are not produced, so antibody production can be induced specifically for the target protein.

※ "Antibody-inducing peptides" is a registered trademark of FunPep.

◆ STEP UP Drug Discovery Platform

