



February 14, 2023

**Announcement of Preliminary Results of Phase I/IIa Clinical Trial
of Antibody Inducing Peptide FPP003
~Confirmed antibody production against the target protein IL-17A in humans~**

FunPep Co., Ltd. ("FunPep") is pleased to announce the preliminary results of the ongoing Australian Phase I/IIa clinical trial (the "Study") of antibody-inducing peptide FPP003 for the treatment of psoriasis vulgaris.

This study was conducted as a FIH study (First in Human Study) of FPP003 and demonstrated, as follows, safety and tolerability as well as a sustained increase in anti-IL-17A antibody titer (the antibody against the target protein IL-17A) (positive rate of approximately 80%).

The results of this FIH study demonstrate that our antibody-inducing peptide (peptide therapeutic vaccine) induces antibodies in humans against "autologous protein" (IL-17A), a target molecule of chronic diseases. This supports the development concept of our proprietary drug discovery platform technology "STEP UP" and the antibody-inducing peptide project.

<Overview>

This is a Phase I/IIa clinical study (dose escalation study (4 cohorts (0.5 to 15 mg)) conducted as the FIH study of FPP003. FPP003 or placebo was administered subcutaneously three times (days 1, 15 and 29) in a double-blind fashion to 36 patients with psoriasis vulgaris.

<Major Preliminary Results>

- At 4 weeks (Day 60) after the third dose of the study drug, an increase in anti-IL-17A antibody titer (antibody against the target protein IL-17A) was observed in 78% (positive rate, 7/9 cases) of FPP003 patients in the high-dose cohort (Cohort 4: 15 mg)*. The increase in antibody titer was sustained until the end of the observation period (Day 120) in all positive patients (7/9). Placebo-treated patients (cohort 4), however, did not show elevated anti-IL-17A antibody titers (0/3 cases).
- Other than local reactions, which are frequently seen with vaccines, no clinically relevant adverse reactions have been observed with FPP003 at this time.

* Cases in which antibody titers increased fourfold or more compared to baseline were judged "positive" in reference to the positive criteria for infectious disease vaccines (influenza, SARS-CoV2).

Detailed results of this study will be presented at upcoming conferences.

Toshimi Miyoshi, President and CEO of the Company, commented, "With these preliminary results, we believe we have achieved a clinical Proof of Concept (POC) and the antibody-inducing peptide project has reached an important milestone in the drug development process."

FPP003 is a compound developed in collaboration with Sumitomo Pharma Co. FunPep has an option agreement with Sumitomo Pharma regarding exclusive development and commercialization rights for all diseases in North America, and Sumitomo Pharma holds preferential negotiating rights for regions outside of 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					Shionogi (Global license)
FPP003 (Target : IL-17A)	Psoriasis	Global	Australia	Phase I/IIa				Sumitomo Pharma (Option for N.America)	
	Ankylosing spondylitis		Japan	Phase I *			* 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

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

