June 13, 2023



# Announcement of Newly Developed Compound for Antibody-Inducing Peptide against Pollinosis: FPP004X, an antibody-inducing peptide against the target protein IgE

FunPep Co., Ltd. ("FunPep") is pleased to announce that we have developed a new compound, FPP004X, an antibody-inducing peptide against the target protein IgE (Immunoglobulin E) and have started pre-clinical studies.

FunPep plans to develop FPP004X for pollinosis (seasonal allergic rhinitis) in Japan. Pollinosis is an allergic disease that causes excessive allergic reactions to plant pollen such as that from Japanese cedar and cypress. Typical symptoms include sneezing, runny nose, nasal congestion, and itchy eyes.

In 2019, Pollinosis prevalence in Japan was as high as 42.5% for all types and 38.8% for cedar pollinosis, the most common type of pollinosis in Japan.<sup>i</sup> As of 2019, each prevalence has increased by more than 10% compared to 10 years prior (2008), making pollinosis a societal problem.

Antibody-inducing peptides are therapeutic peptide vaccines that are expected to have therapeutic effects by inducing the production of antibodies against target proteins in the patient's body.

IgE plays an important role in allergic reactions and is involved in the development of allergic diseases. FPP004X, an antibody-inducing peptide against the target protein IgE, is expected to have a sustained effect on pollinosis because it causes immune cells in the body to produce antibodies against IgE for a sustained period. Due to the long-lasting effect of the vaccine, we will continue the development of FPP004X with the aim of providing patients with a new, highly convenient treatment option that can relieve symptoms throughout the pollinosis season (the period of pollen scattering) if administered prior to the start of the season.

Regarding the R&D project for this antibody-inducing peptide against the target protein IgE, we suspended the development of FPP004, which is in the preclinical stage, to conduct exploratory research for a backup compound in view of prioritizing development resources. As we succeeded in creating FPP004X, a candidate compound with a favorable profile, in this exploratory research, we have now started preclinical studies of the newly developed FPP004X in place of FPP004.

<sup>i</sup> Matsubara A et al. Epidemiological Survey of Allergic Rhinitis in Japan 2019: preliminary report -Otolaryngologists and their family members. Nippon Jibiinkoka Gakkai Kaiho 2020; 123(6):485-490.

### < Reference Material >

## R&D Pipeline

<products development="" in=""></products>									
Product	Indication	Region	Clinical trial sites	Discov ery	Preclini	Clinical Trials			Allianas
					cal	P1	P2	P3	Amance
SR-0379	Skin Ulcers	Global	Japan			Phase III			Shionogi (Global license)
FPP003 (Target:IL-17A)	Psoriasis	Global	Australia		Phase I/I	lla	* Investigator initiated trial	Sumitomo Pharma	
	Ankylosing spondylitis		Japan		Phase I *			r initiated trial	(Option for N.America)
FPP004X (Target:lgE)	Pollinosis (Seasonal allergy rhinitis)	Global	-	Preclini	cal				TBD
FPP005 (Target:IL-23)	Psoriasis	Global	-	Preclini	cal				TBD
FPP006	COVID-19	Global	-	Preclini	cal				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 "antibodyinducing 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

