



August 24, 2023

Exercise of Option by MEDIPAL HOLDINGS CORPORATION
~Selects FPP004X, a Pollinosis Vaccine, as a Promising Target Development Product~

FunPep Co., Ltd. ("FunPep") is pleased to announce that MEDIPAL HOLDINGS CORPORATION ("MEDIPAL") has selected FPP004X, an anti-IgE antibody-inducing peptide under development for pollinosis, as a new target development product eligible for profit sharing and other benefits.

MEDIPAL has previously selected FPP003, an anti-IL-17A antibody-inducing peptide, and FPP005, an anti-IL-23 antibody-inducing peptide as target development products eligible for profit sharing and other benefits. This time, MEDIPAL has newly selected FPP004X, an anti-IgE antibody-inducing peptide, as a promising target development product.

MEDIPAL and FunPep entered into an alliance agreement in February 2016 for research and development support for an antibody-inducing peptide project. Under the alliance agreement, FunPep has received an upfront payment and a three-year R&D funding from MEDIPAL to research antibody-inducing peptides against a variety of target proteins to build its R&D pipeline.

In turn, upon selecting a certain number of target development products among antibody-inducing peptides generated from this research, MEDIPAL retains the right to receive a certain percentage of upfront payments and development milestone payments received by FunPep from pharmaceutical companies that have licensed the selected target development products from FunPep. Furthermore, FunPep will make efforts to ensure MEDIPAL obtains preferential negotiating rights for wholesale sales in Japan and one other specified country during licensing negotiations with pharmaceutical companies.

FunPep is developing 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.¹ Due to the fact that as of 2019, each prevalence has increased by more than 10% compared to 10 years prior (2008), pollinosis has become a societal problem.

Antibody-inducing peptides are peptide therapeutic vaccines that are expected to have therapeutic effects by inducing antibody production in the patient's body. IgE (Immunoglobulin E) 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 FPP004X is administered prior to the pollinosis season.

References

- ⁱ 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.

About MEDIPAL HOLDINGS CORPORATION

Corporate Name : MEDIPAL HOLDINGS CORPORATION

Representative : Shuichi Watanabe, Representative Director, President and CEO

Established : May 6, 1923

Line of Business : As a holding company, MEDIPAL HOLDINGS controls, administers and supports the operating activities of companies in which it holds shares in the Prescription Pharmaceutical Wholesale Business; the Cosmetics, Daily Necessities and OTC Pharmaceutical Wholesale Business; and the Animal Health Products and Food Processing Raw Materials Wholesale Business, and conducts business development for the MEDIPAL Group.

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< 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 IIa *			* Investigator initiated trial	
FPP004X (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

