



March 12, 2025

Commencement of Allergy Vaccine Clinical Trial
～Development of a therapeutic vaccine targeting pollen allergy, the so-called “national disease”～

On February 10, 2025, FunPep Co., Ltd. (“FunPep”) submitted a clinical trial plan notification for a Phase I clinical trial of an allergy vaccine (antibody-inducing peptide FPP004X) currently under development for pollen allergy. We are pleased to announce that the Pharmaceuticals and Medical Devices Agency (PMDA) has completed its 30-day review and FunPep will now commence the clinical trial.

Pollen allergy is caused by an excessive allergic reaction to pollen from plants such as cedar and cypress. Typical symptoms include sneezing, runny nose, nasal congestion, and itchy eyes. According to a nationwide epidemiological survey in Japanⁱ, the prevalence of pollen allergy in 2019 was 42.5% for all types of pollen allergy, with cedar pollen allergy accounting for 38.8% of cases. These figures represent an increase of over 10% compared to 2008. The market for pharmaceuticals (oral medications) for allergic rhinitisⁱⁱ, including pollen allergy, was approximately 170 billion yen in 2019.

As a result, the government has recognized pollen allergy as a social issue and is actively addressing pollen allergy.

Antibody-inducing peptide FPP004X is an allergy vaccine that is expected to produce therapeutic effects by inducing the *in vivo* production of antibodies against IgE (Immunoglobulin E). IgE is a type of antibody that works to eliminate foreign substances that enter the body, and when it binds to allergens such as pollen, it triggers an allergic reaction. FPP004X is expected to produce sustained effects against allergies by inducing immune cells to produce anti-IgE antibodies for a period of time. Leveraging this feature, FunPep aims to provide patients with a new, convenient treatment option by administering the vaccine prior to the onset of pollen season to alleviate symptoms throughout the season, with pollen allergy as the primary indication.

For FPP004X, an option agreement was signed with Shionogi & Co., Ltd. in March 2024, whereby the company holds an option right to acquire exclusive worldwide research, development and commercialization rights for all diseases.

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.

ⁱⁱ Ministerial Conference on Pollen Allergy “Pollen Allergy Countermeasures” (MHLW)