Odactra™ House Dust Mite – New drug approval

- On March 1, 2017, the FDA announced the approval of ALK's Odactra House Dust Mite (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) allergen extract, as immunotherapy for house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by *in vitro* testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* HDMs, or skin testing to licensed HDM allergen extracts.
    - Odactra is approved for use in adults 18 through 65 years of age.
    - Odactra is not indicated for the immediate relief of allergic symptoms.
- HDM allergies are a reaction to tiny bugs that are commonly found in house dust. Dust mites, close relatives of ticks and spiders, are too small to be seen without a microscope.
    - Dust mites are found in bedding, upholstered furniture, and carpeting.
    - Individuals with HDM allergies may experience a cough, runny nose, nasal itching, nasal congestion, sneezing, and itchy and watery eyes.
- Odactra exposes patients to house dust mite allergens, gradually training the immune system in order to reduce the frequency and severity of nasal and eye allergy symptoms.
    - Odactra is the first sublingual allergen extract indicated to treat HDM allergies.
- The safety and efficacy of Odactra were based on placebo-controlled trials involving approximately 2,500 patients with HDM allergies. Participants reported their symptoms and the need to use symptom-relieving allergy medications.
    - During treatment, patients taking Odactra experienced a 16% - 18% reduction in symptoms and the need for additional medications vs. those who received placebo.
- Odactra carries a boxed warning regarding the risk of severe allergic reactions.
- Odactra is contraindicated in patients with severe, unstable or uncontrolled asthma; history of any severe systemic allergic reaction; history of any severe local reaction after taking any sublingual allergen immunotherapy; history of eosinophilic esophagitis; and hypersensitivity to any of the inactive ingredients contained in Odactra.
- Other warnings and precautions of Odactra include epinephrine, upper airway compromise, eosinophilic esophagitis, asthma, concomitant allergen immunotherapy, and oral conditions.
- The most common solicited adverse reactions reported (≥10%) with Odactra use were throat irritation/tickle, itching in the mouth, itching in the ear, swelling of the uvula/back of the mouth, swelling of the lips, swelling of the tongue, nausea, tongue pain, throat swelling, tongue ulcer/sore on the tongue, stomach pain, mouth ulcer/sore in the mouth, and taste alteration/food tastes different.
- The recommended dose of Odactra is one tablet sublingually once daily.
    - The first dose of Odactra should be administered under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases.
    - Patients should be observed in the office for at least 30 minutes following the initial dose.

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— Auto-injectable epinephrine should be administered to patients prescribed Odactra and patients should be instructed in the proper use of emergency self-injection of epinephrine.

- The Biologics License Application for the HDM tablet was originally submitted by Merck in February 2016 under a partnership agreement with ALK. Since then, the partnership has ended and all North American rights to the HDM tablet portfolio have been repatriated to ALK following a six-month, managed handover between the two companies.

- ALK's launch plans for Odactra are pending. Odactra will be supplied as 3 blister packages, each containing 10 tablets.