Odactra® *(Dermatophagoides farinae and Dermatophagoides pteronyssinus)* – Expanded indication

- On February 27, 2025, ALK announced the FDA approval of Odactra (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*), for the treatment of house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive *in vitro* testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or by positive skin testing to licensed house dust mite allergen extracts. **Odactra is approved for use in individuals 5 through 65 years of age.**
    - **Odactra was previously approved for this indication in individuals 12 through 65 years of age.**
- The approval of Odactra for the expanded indication was based on a randomized, double-blind, placebo-controlled study in 1,399 children 5 through 11 years of age with HDM allergic rhinitis/rhinoconjunctivitis with or without asthma. Patients were randomized to Odactra or placebo. The primary endpoint was the difference between the treatment and placebo groups in the average Total Combined Rhinitis Score (TCRS) during the last approximately 8 weeks of treatment.
    - **The TCRS during the last 8 weeks of treatment was 3.4 and 4.4 with Odactra and placebo, respectively (treatment difference -1.0).** The difference relative to placebo was -22.0% (95% CI: -31.1; -12.0).
- Odactra carries a boxed warning for **severe allergic reactions**.
- The most common solicited adverse reactions (≥ 10%) with Odactra use in patients 5 through 11 years of age were itching in the mouth, throat irritation/tickle, itching in the ear, stomach pain, swelling of the lips, tongue pain, food tastes different, nausea (feel like throwing up), swelling in the back of the mouth, swelling of the tongue, and mouth ulcer.
- The recommended dose of Odactra is **one tablet daily**.
    - **The first dose of Odactra should be administered in a healthcare setting** under the supervision of a healthcare professional with experience in the diagnosis and treatment of allergic diseases. After receiving the first dose of Odactra, the patient should be observed for at least 30 minutes to monitor for signs or symptoms of a severe systemic or a severe local allergic reaction.
    - If the patient tolerates the first dose, the patient may take subsequent doses at home.