Odactra™ House Dust Mite (Dermatophagoides farinae and Dermatophagoides pteronyssinus) – Expanded indication

- On January 20, 2023, the FDA approved ALK-Abello's Odactra House Dust Mite (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*), as immunotherapy 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 persons 12 through 65 years of age.**
    - Odactra was previously approved for this indication in adults only.
    - Odactra is not indicated for the immediate relief of allergic symptoms.
- Odactra carries a boxed warning for severe allergic reactions.
- The most common solicited adverse reactions (≥ 10%) in adolescent patients (12 through 17 years of age) treated with Odactra were throat irritation/tickle, itching in the mouth, itching in the ear, tongue pain, stomach pain, swelling of the uvula/back of the mouth, swelling of the lips, swelling of the tongue, throat swelling, nausea, tongue ulcer/sore on the tongue, mouth ulcer/sore in the mouth, and diarrhea.
- The recommended dose of Odactra for all ages is one tablet sublingually daily.
    - The first dose of Odactra should be administered in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases.
    - If the patient tolerates the first dose, the patient may take subsequent doses at home.