Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens allergen extract) – Expanded indication

- On November 14, 2018, Stallergenes Greer announced the FDA approval of Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens allergen extract), for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for any of the five grass species contained in this product in patients 5 to 65 years of age.
    - Previously, Oralair was approved for use in patients 10 to 65 years of age.
- The approval of Oralair's expanded indication was based on safety data from a 30-day open-label study in 307 children 5 through 9 years of age and a post-hoc analysis of the effectiveness data from a phase 3 study in children by age subgroups.
    - In the open-label safety study, the frequencies of adverse events (eg, local application site reactions) in children 5 through 9 years of age were comparable to those in adults and older children and adolescents.
    - The post-hoc analyses, while not adequately powered to demonstrate uniformly statistically significant treatment effects in the younger age subgroup, showed that treatment effects were numerically similar in children 5 through 9 years of age when compared to children and adolescents 10 through 17 years of age.
- Oralair carries a boxed warning for serious allergic reactions.
- The recommended starting dose of Oralair in children and adolescents 5 through 17 years of age is 100 IR (index of reactivity) on day 1, 200 IR on day 2, and 300 IR on the following days.
    - Oralair should be administered sublingually only.
    - Treatment should be initiated 4 months before the expected onset of each grass pollen season and continued treatment throughout the season.
    - The first dose of Oralair should be administered under the supervision of a physician with experience in the diagnosis and treatment of severe allergic reactions. Patient should be observed for at least 30 minutes.