Opzelura® (ruxolitinib) – New indication

- On July 18, 2022, Incyte announced the FDA approval of Opzelura (ruxolitinib) for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.
    - Use of Opzelura in combination with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.
- Opzelura is also approved for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
- Opzelura, a topical JAK inhibitor, is the first FDA approved treatment for vitiligo.
- Vitiligo is a chronic autoimmune disease characterized by depigmentation of skin that results from the loss of pigment-producing cells known as melanocytes. In the U.S., more than 1.5 million people are diagnosed with vitiligo. Approximately 85% of the overall affected population is suffering from nonsegmental vitiligo.
- The approval of Opzelura for the new indication was based on two double-blind, randomized, vehicle-controlled trials of identical design (TRuE-V1 and TRuE-V2) in a total of 674 adult and pediatric patients aged 12 years and older with vitiligo. In both studies, patients were randomized to treatment with Opzelura or vehicle cream for 24 weeks. The primary efficacy endpoint was the proportion of patients achieving at least 75% improvement in facial Vitiligo Area Scoring Index (F-VASI75) at week 24.
    - In TRuE-V1, F-VASI75 was achieved in 29.9% and 7.5% of patients with Opzelura and vehicle, respectively (treatment difference 22.5, 95% CI: 14.2, 30.8).
    - In TRuE-V2, F-VASI75 was achieved in 29.9% and 12.9% of patients with Opzelura and vehicle, respectively (treatment difference 16.9, 95% CI: 7.8, 26.0).
- Opzelura carries a boxed warning for serious infections, mortality, malignancy, major adverse cardiovascular events (MACE), and thrombosis.
- The most common adverse reactions (≥ 1%) with Opzelura use for vitiligo were application site acne, application site pruritus, nasopharyngitis, headache, urinary tract infection, application site erythema, and pyrexia.
- Opzelura is applied as a thin layer twice daily to affected areas of up to 10% body surface area. Satisfactory patient response may require treatment with Opzelura for more than 24 weeks. If the patient does not find the repigmentation meaningful by 24 weeks, the patient should be re-evaluated by the healthcare provider.
    - More than one 60-gram tube per week or one 100-gram tube per 2 weeks should not be used.
    - Refer to the Opzelura drug label for dosing for atopic dermatitis.