Opzelura™ (ruxolitinib) – New drug approval

- On September 21, 2021, Incyte announced the FDA approval of Opzelura (ruxolitinib) cream, for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
    - 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 the first FDA approved topical JAK inhibitor.
- The efficacy of Opzelura was established in two identical, double-blind, randomized, vehicle-controlled studies in a total of 1,249 patients aged 12 and older with atopic dermatitis. In both studies, patients were randomized to Opzelura 1.5% cream, ruxolitinib 0.75% cream, or vehicle twice daily for 8 weeks. The primary endpoint was the proportion of patients at week 8 achieving Investigator's Global Assessment (IGA) treatment success (IGA-TS) defined as a score of 0 (clear) or 1 (almost clear) with ≥ 2 grade improvement from baseline (severity scale of 0 to 4). Efficacy was also assessed using a ≥ 4-point improvement in Itch Numerical Rating Scale (NRS) (scale of 0 to 10).
    - In study 1, IGA-TS was achieved in 53.8% of patients treated with Opzelura vs. 15.1% with vehicle (treatment difference 38.9, 95% CI: 30.3, 47.4). Itch NRS improvement was achieved in 52.2% and 15.4% of patients, respectively (treatment difference 36.7, 95% CI: 25.5, 48.0).
    - In study 2, IGA-TS was achieved in 51.3% of patients treated with Opzelura vs. 7.6% with vehicle (treatment difference 44.1, 95% CI: 36.2, 52.0). Itch NRS improvement was achieved in 50.7% and 16.3% of patients, respectively (treatment difference 35.8, 95% CI: 24.4, 47.2).
- Opzelura carries boxed warnings for serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis.
- Additional warnings and precautions for Opzelura include thrombocytopenia, anemia, and neutropenia; and lipid elevations.
- The most common adverse reactions (≥ 1%) with Opzelura use were nasopharyngitis, diarrhea, bronchitis, ear infection, eosinophil count increased, urticaria, folliculitis, tonsillitis, and rhinorrhea.
- The recommended dosing and administration for Opzelura is an application of a thin layer twice daily to affected areas of up to 20% body surface area.
    - More than 60 grams per week should not be used.
    - Use should be stopped when signs and symptoms (eg, itch, rash, and redness) of atopic dermatitis resolve. If signs and symptoms do not improve within 8 weeks, patients should be re-examined by their healthcare provider.
- Opzelura will be priced (wholesale acquisition cost) at $1,950 per 60-gram tube.

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- Incyte launch plans for Opzelura are pending. Opzelura will be available as a 1.5% cream supplied in a 60-gram tube.

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