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One-Page Clinical Summary
OPZELURA™ (ruxolitinib) cream 1.5%

OPZELURA was approved by the FDA on September 21, 2021, 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.[1] Use of OPZELURA in combination with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.

The following are a few key points about atopic dermatitis (AD):

- AD is a chronic, highly pruritic, relapsing inflammatory skin disease; the pathophysiology of AD is mediated by inflammatory cytokines that perpetuate and exacerbate the itch-scratch cycle.[2,3]
- Itch is among the most prominent, burdensome, and distressing symptoms of AD.[2]

The efficacy and safety of OPZELURA was evaluated as monotherapy in two, identically designed, Phase III, double-blind, randomized, multicenter, vehicle-controlled studies (TRuE-AD1, [N = 631]; TRuE-AD2 [N = 618]), in patients 12 years of age and older with AD.[4] Patients were randomly assigned to OPZELURA, ruxolitinib cream 0.75%, or vehicle cream, and applied treatment twice daily (BID) to affected areas (3 to ≤20% body surface areas [BSA]) throughout an 8-week vehicle control (VC) period. Eligible patients could continue treatment for an additional 44 weeks with OPZELURA in an extension study.[5] Enrolled patients were 70% White, 23% Black, and 4% Asian. Patients had an Investigator's Global Assessment (IGA) Score at baseline of either 2 (25%) or 3 (75%) on a 0-4 severity scale. Mean affected BSA was 9.8%, and 39% of patients had facial involvement at baseline.[1] Primary and select key secondary endpoints for OPZELURA compared to vehicle, were as follows:

- In both TRuE-AD1 and TRuE-AD2, a significantly greater proportion of patients who applied OPZELURA achieved the primary endpoint of Investigator's Global Assessment-Treatment Success (IGA-TS) at Week 8 vs vehicle, (defined as an IGA score of 0 or 1 with ≥2-grade improvement from baseline; 53.8% and 51.3% vs 15.1% and 7.6%, respectively; P<0.0001).[1,4]
- At 8 weeks, OPZELURA was also associated with a clinically meaningful reduction in itch (Itch-NRS4 [Itch Numerical Rating Scale]; ≥4-point improvement in itch intensity versus baseline, assessed on a 0 [no itch] to 10 [worst imaginable itch] scale; 52.2% and 50.7% vs 15.4% and 16.3%; P<0.0001), a key secondary endpoint in the TRuE-AD clinical studies.[1,4] Itch NRS4 response was seen as early as Day 3 (TRuE-AD1: OPZELURA, 18.4%; vehicle, 4.2%; TRuE-AD2: OPZELURA, 13.2%; vehicle, 0%). [6]
- A significantly greater proportion of patients treated with OPZELURA achieved 75% reduction in Eczema Area and Severity Index (EASI-75) compared to patients treated with vehicle (62.1% and 61.8% vs 24.6% and 14.4%, respectively; P<0.0001) at Week 8. Starting at Week 2, treatment with OPZELURA showed substantially greater improvement in mean percentage change in EASI scores versus vehicle. In TRuE-AD1 and TRuE-AD2, respectively, 46% and 50% of patients on OPZELURA vs 56% and 44% of patients on vehicle had a baseline EASI score of 1.1–7.[6]
- The most common treatment emergent adverse events (TEAEs) occurring in ≥1% patients treated with OPZELURA (N = 499) were nasopharyngitis (n = 13 [3%]), diarrhea (n = 5 [1%]), bronchitis (n = 4 [1%]), ear infection (n = 4 [1%]), eosinophil count increase (n = 4 [1%]), urticaria (n = 4 [1%]), folliculitis (n = 3 [1%]), tonsillitis (n = 3 [1%]), and rhinorrhea (n = 3 [1%]).[1] The most common treatment-related adverse event was burning at the application site (OPZELURA, n = 4 [0.8%]; vehicle, n = 11 [4.4%]).[4]
- In TRuE-AD1, 542 patients entered a 44-week extension phase, which 430 (79.3%) completed; similarly, in TRuE-AD2, 530 patients entered a 44-week extension phase, which 401 (75.7%) completed.[5] Among patients initially randomized to OPZELURA and who had remained on their regimen during the extension (TRuE-AD1, n = 161; TRuE-AD2, n = 126), the median cumulative time off treatment due to lesion clearance was 116 days (range, 2 – 286) and 145.5 days (range, 2 – 312), respectively.
- The Prescribing Information for OPZELURA has boxed warnings for the risks of Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events (MACE), and Thrombosis. Additional Warnings and Precautions are also included in the Prescribing Information for the risks of Thrombocytopenia, Anemia and Neutropenia and for Lipid Elevations.
- OPZELURA is a topical cream applied as a thin layer to affected areas of the skin on up to 20% of body surface area (no more than 60 mg per week).[1] Patients should stop using once signs and symptoms of atopic dermatitis resolve. If signs and symptoms do not improve within 8 weeks, patients should be re-examined by their healthcare provider. For topical use only. Not for ophthalmic, oral, or intravaginal use.

Please see the accompanying Prescribing Information and Medication Guide for more information. Should you need additional information, please contact Incyte Medical Information at 1-855-463-3463.

References: 1. OPZELURA [Prescribing Information] Wilmington, DE: Incyte. 2. Silverberg JI, et al. *Ann Allergy Asthma Immunol.* 2018;12(3)1:340-347. 3. Langan SM, et al. *Lancet*. 2020;396(10247):345-360. 4. Papp K, et al. *J Am Acad Dermatol*. 2021a. 5. Papp K, et al. Presented at: Revolutionizing Atopic Dermatitis Virtual Conference; June 13, 2021b; Virtual. 6. Data on File, Incyte Corporation.