Incyte Dermatology

Efficacy and Safety of Ruxolitinib Cream in Adults With Moderate Atopic Dermatitis

Results From TRuE-AD4: A Phase 3b, Randomized, Double-Blind, Vehicle-Controlled Study

MSL-RCM-US-0235 08/26

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Notice

- Some information contained in this presentation may not be included in the approved Prescribing Information for OPZELURA® (ruxolitinib) cream. This presentation is not intended to offer recommendations for any administration, indication, dosage, or other use for OPZELURA in a manner inconsistent with the approved Prescribing Information. Please consult the full Prescribing Information, including boxed warnings, before using or prescribing OPZELURA

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Indication and Usage

- OPZELURA is a Janus kinase (JAK) inhibitor indicated for:
  - the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 2 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable

Limitations of Use

- Use of OPZELURA in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine is not recommended

Contraindications

- None

Please see the Full Prescribing Information, including Warnings & Precautions and Medication Guide for OPZELURA.

FDA, US Food and Drug Administration.
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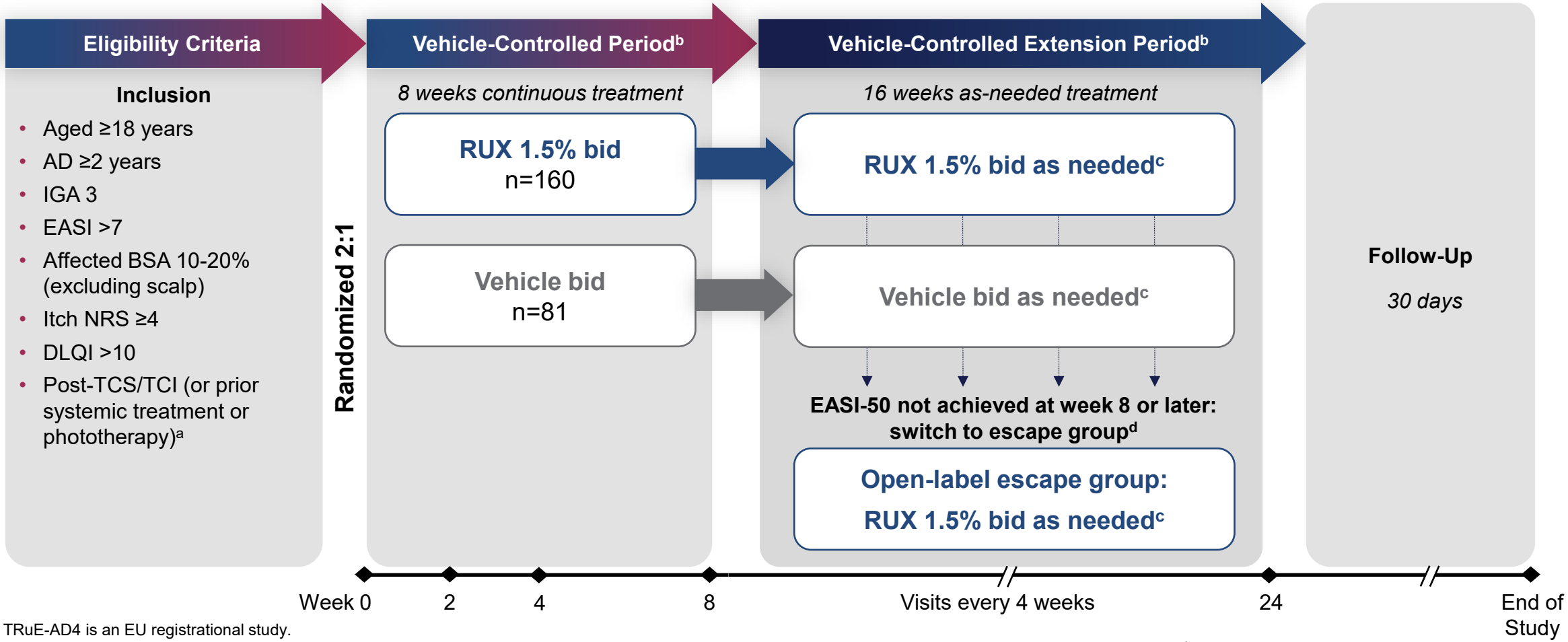
TRuE-AD4: Study Design



TRuE-AD4 is an EU registrational study.

[a] Inadequate response, intolerance, or contraindication to both TCS and TCI. Prior systemic treatment or phototherapy were considered surrogates for post-TCS/TCI. [b] Rescue therapy was not permitted. [c] Patients self-evaluated recurrence of lesions between study visits and treated lesions with active AD (≤20% BSA). If lesions cleared between study visits, patients stopped treatment 3 days after lesion disappearance. If new lesions were extensive or appeared in new areas, patients contacted the investigator to determine if an unscheduled additional visit was needed. Patients were discontinued from study treatment if affected BSA exceeded 20%. [d] To be eligible for the escape group, EASI-50 must not be achieved at 2 consecutive visits ≥1 week apart (1 visit could be unscheduled).

AD, atopic dermatitis; bid, twice daily; BSA, body surface area; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; EASI-50, ≥50% improvement in EASI score from baseline; IGA, Investigator's Global Assessment; NRS, Numerical Rating Scale; RUX, ruxolitinib cream; TCI, topical calcineurin inhibitor; TCS, topical corticosteroid.

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Baseline Patient Demographics and Clinical Characteristics

Demographic characteristics	Vehicle bid (n=81)	RUX 1.5% bid (n=160)
Age, median (range), y	39.0 (19-80)	36.5 (19-88)
<65 y, n (%)	75 (92.6)	147 (91.9)
Female, n (%)	45 (55.6)	86 (53.8)
Race, n (%)		
White	68 (84.0)	126 (78.8)
Black	7 (8.6)	7 (4.4)
Asian	5 (6.2)	20 (12.5)
Other[a]	1 (1.2)	2 (1.3)
Missing/NR	0	5 (3.1)
Europe region,[b] n (%)	55 (67.9)	109 (68.1)

Clinical characteristics	Vehicle bid (n=81)	RUX 1.5% bid (n=160)
Affected BSA, mean (SD), %	15.4 (2.9)	15.0 (3.1)
EASI, mean (SD)	12.8 (3.6)	12.5 (4.3)
<16, n (%)	64 (79.0)	130 (81.3)
≥16, n (%)	17 (21.0)	30 (18.8)
IGA 3,[c] n (%)	81 (100)	159 (99.4)
Itch NRS score,[d] mean (SD)	7.4 (1.5)	7.5 (1.5)
SCORAD, mean (SD)	53.1 (10.4)	53.9 (10.9)
Prior facial/neck involvement, n (%)	58 (71.6)	117 (73.1)
Duration of disease, median (range), y	18.5 (2.5-60.7)	19.1 (2.2-58.1)
Prior therapy in last 12 mo,[e] n (%)		
TCS	78 (96.3)	154 (96.3)
TCI	69 (85.2)	126 (78.8)
Systemic therapy	21 (25.9)	50 (31.3)
Phototherapy	6 (7.4)	15 (9.4)

[a] Includes Native Hawaiian/Pacific Islander. [b] The remaining patients were enrolled in the US, Canada, and Australia. [c] 1 patient had an IGA of 4 at the baseline visit (IGA=3 at screening).
[d] By-visit analysis from a mean of ≥4 of the 7 days immediately prior to the baseline visit. [e] Patients could be included in ≥1 category of prior therapy.
bid, twice daily; BSA, body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; NR, not reported; NRS, Numerical Rating Scale; RUX, ruxolitinib cream; SCORAD, SCORing Atopic Dermatitis; TCI, topical calcineurin inhibitor; TCS, topical corticosteroid.
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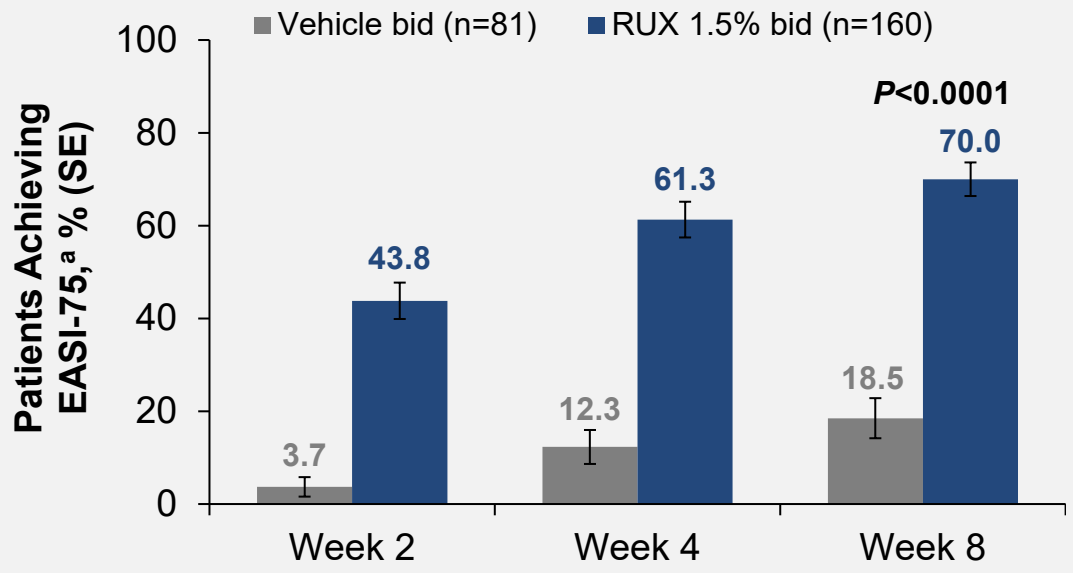
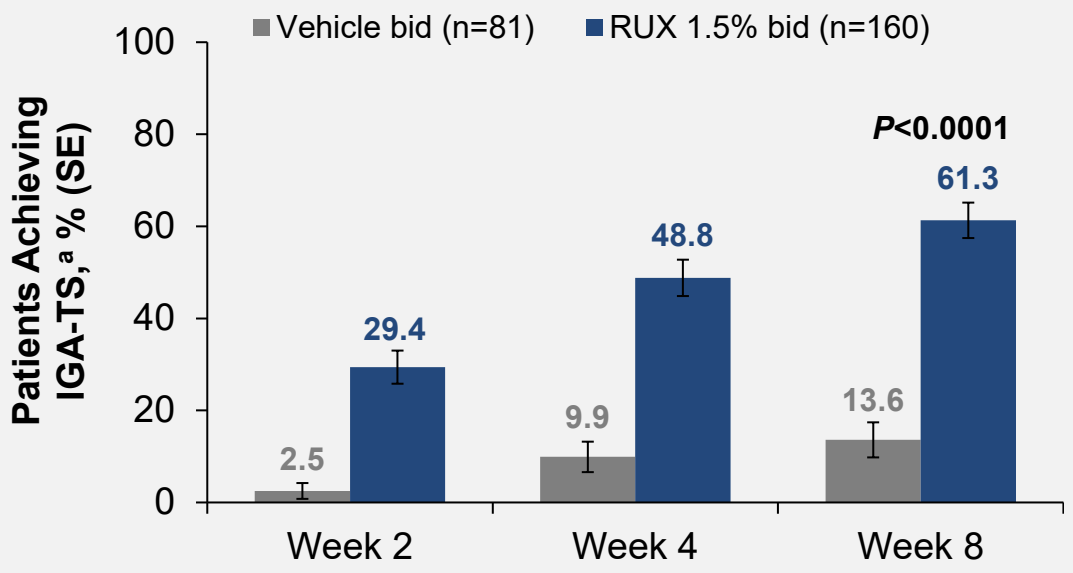
Achievement of EASI-75 and IGA-TS

Co-Primary Endpoints: Week 8

EASI-75



IGA-TS



- ***Improvements were observed as early as week 2 for EASI-75 and IGA-TS, with increasing response rates over time and statistically significant improvements at week 8***
- ***Combined EASI-75 and IGA-TS were achieved in more patients who applied RUX 1.5% bid vs vehicle bid at week 8 (59.4% vs 13.6%; nominal P<0.0001)***

[a] Patients with missing postbaseline values were imputed as nonresponders at weeks 2, 4, and 8. Statistical significance was only assessed at week 8 (co-primary endpoints).
bid, twice daily; EASI-75, ≥75% improvement in Eczema Area and Severity Index score from baseline; IGA-TS, Investigator's Global Assessment–Treatment Success (IGA score of 0 or 1 with a ≥2-point improvement from baseline); RUX, ruxolitinib cream.
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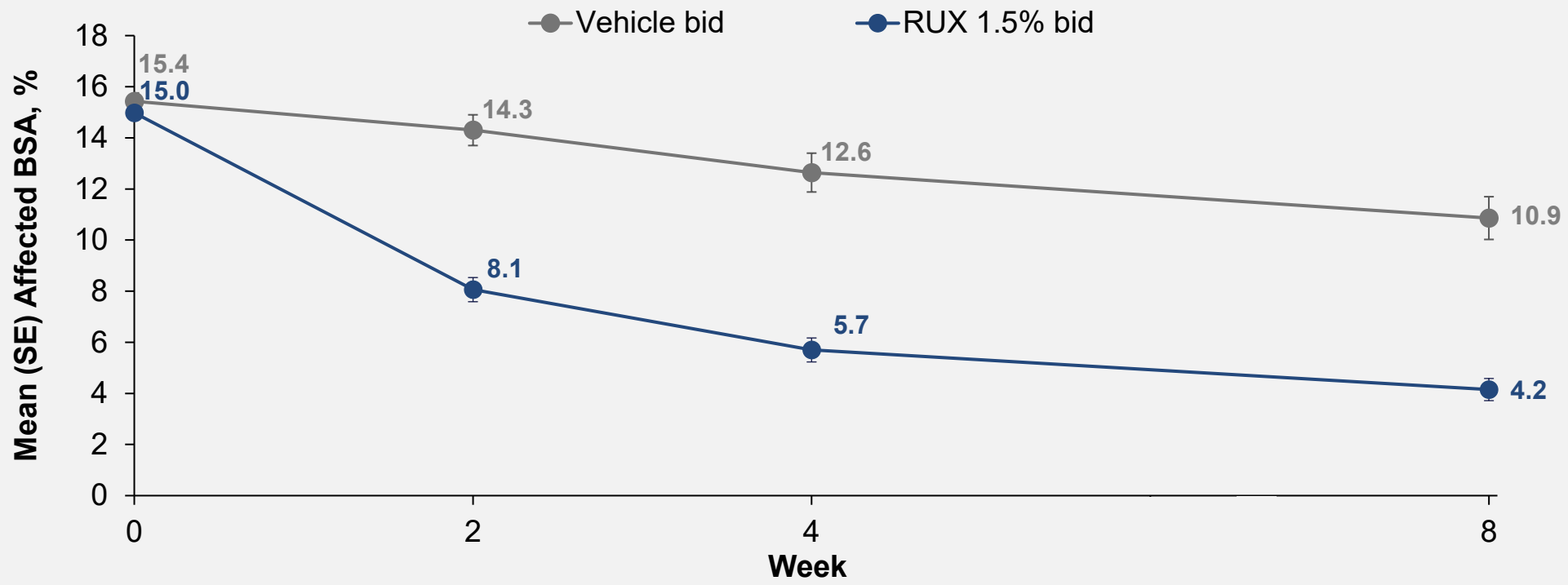
Mean Affected BSA Over 8 Weeks



Separation was observed as early as week 2 for RUX 1.5% vs vehicle with continued reduction in mean affected BSA

No conclusions of efficacy should be made based on these results.
bid, twice daily; BSA, body surface area; RUX, ruxolitinib cream.
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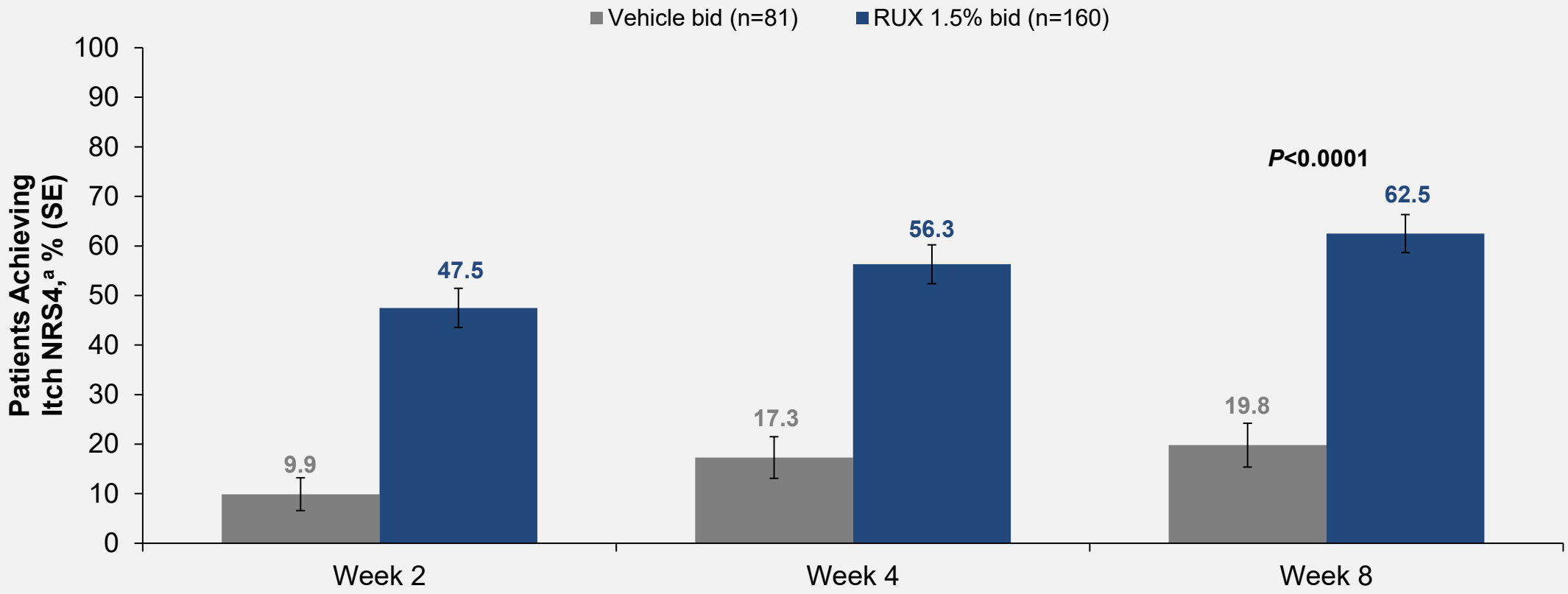
Achievement of Itch NRS4 (by Visit)

Key Secondary Endpoint: Week 8



Itch NRS4 was achieved by a significantly greater percentage of patients with RUX 1.5% vs vehicle at week 8

[a] Patients with missing postbaseline values were imputed as nonresponders at weeks 2, 4, and 8. Statistical significance was only assessed at week 8 (key secondary endpoint).
bid, twice daily; Itch NRS4, ≥4-point improvement in Itch Numerical Rating Scale score from baseline; RUX, ruxolitinib cream.
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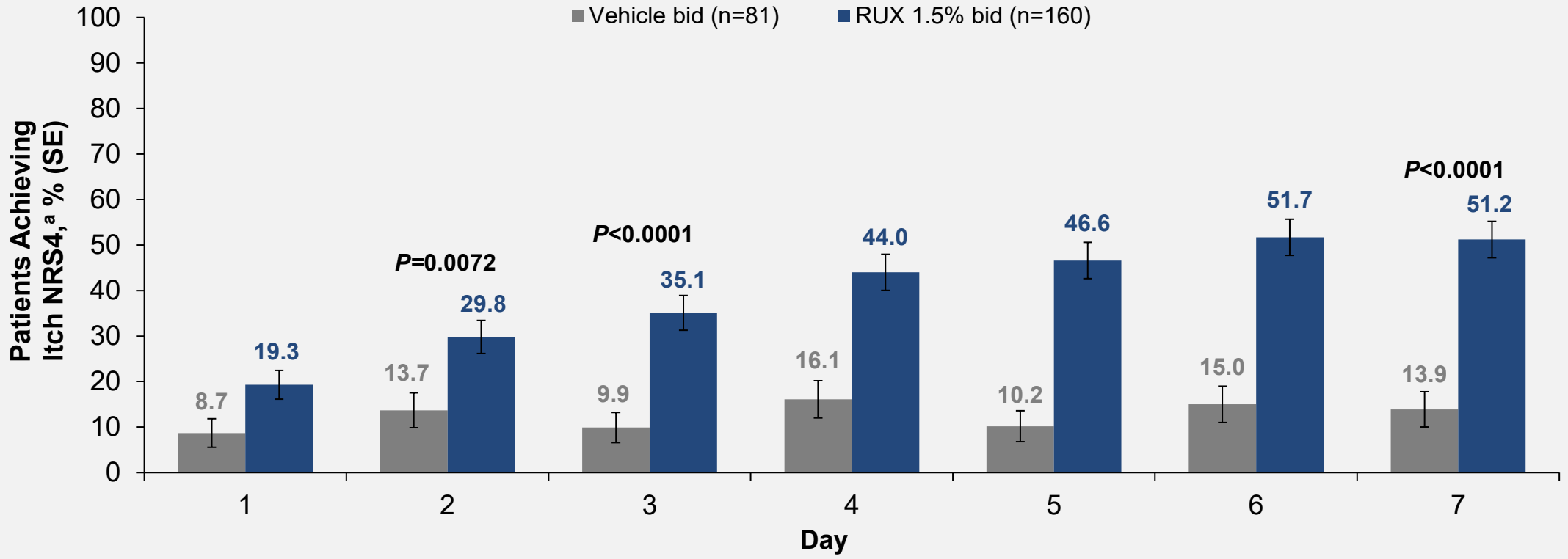
Achievement of Itch NRS4 (First 7 Days)

Key Secondary Endpoints: Days 2, 3, 7



Separation in Itch NRS with RUX 1.5% vs vehicle was observed as early as day 1, with statistically significant improvements at days 2, 3, and 7

[a] Multiple imputation was used to impute patients with missing daily itch data from day 1 to day 7. Differences vs vehicle had *P*<0.05 at all time points; only *P* values tested for statistical significance under alpha control on days 2, 3, and 7 (key secondary endpoints) are shown.

bid, twice daily; Itch NRS4, ≥4-point improvement in Itch Numerical Rating Scale score from baseline; RUX, ruxolitinib cream.

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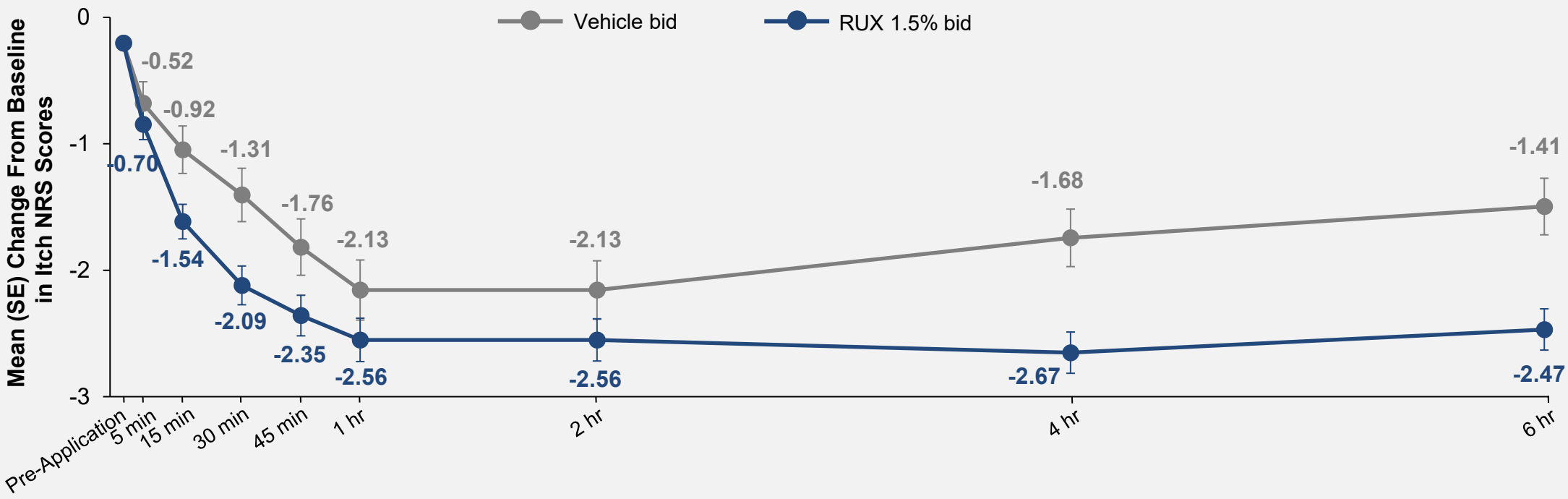
Mean Change From Baseline in Itch NRS Scores (First 6 Hours)



Separation was observed as early as 15 minutes with continued itch reduction maintained through 6 hours in patients treated with RUX 1.5%

No conclusions of efficacy should be made based on these results.
bid, twice daily; NRS, numerical rating scale; RUX, ruxolitinib cream.
Data on File. Incyte Corporation.

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TEAEs During the VC Period

n (%)	Vehicle bid (n=81)	RUX 1.5% bid (n=160)
Patients with TEAE	28 (34.6)	56 (35.0)
Patients with treatment-related TEAE	7 (8.6)	15 (9.4)
Most common treatment-related TEAEs[a]		
Application-site acne	0	7 (4.4)
Acne	0	2 (1.3)
Application-site pain	5 (6.2)	2 (1.3)
Headache	0	2 (1.3)
Patients with grade ≥3 TEAE	1 (1.2)	5 (3.1)[b]
Patients with serious TEAE	1 (1.2)	3 (1.9)[c]
Patients with fatal TEAE	1 (1.2)[d]	0
Patients with TEAE leading to discontinuation of study drug	7 (8.6)	1 (0.6)[e]

Select TEAEs, n (%)[f]	Vehicle bid (n=81)	RUX 1.5% bid (n=160)
Headache	0	3 (1.9)
Herpes zoster	0	1 (0.6)
Nausea	0	1 (0.6)
Contact dermatitis	0	0
Diarrhea	0	0
Folliculitis	1 (1.2)	0
MACE	0	0
Malignancy	0	0
Serious infections	0	0
Thrombosis	0	0

RUX 1.5% bid was well tolerated and associated with few application-site reactions

No serious infections, malignancy, MACE, or thromboses were observed with RUX 1.5% bid

[a] TEAEs occurring in ≥2 patients in the RUX 1.5% bid group. [b] Hypertension in 2 patients, radius fracture, cervical dysplasia (all grade 3; dose not changed), suicide attempt (grade 4; drug withdrawn); all resolved and were judged as not related to treatment. [c] Hypertension, radius fracture, and suicide attempt (1 patient each; not related to treatment). [d] Sudden death (cause unknown). [e] Suicide attempt (sertraline overdose) in a patient with progressively worsening suicidal thoughts starting in the weeks prior to beginning the study drug. The patient was started on sertraline by his physician 7 days prior to the event. The investigator considered the suicide attempt unrelated to the study drug. [f] Based on concerns arising from a systemic pan-JAK inhibitor in older adults with rheumatoid arthritis (MACE, malignancy, serious infections, thromboembolic events, and mortality), other AD topical therapies (contact dermatitis, diarrhea, folliculitis, headache, and nausea), and AD (herpes zoster).
AD, atopic dermatitis; bid, twice daily; JAK, Janus kinase; MACE, major adverse cardiovascular event; TEAE, treatment-emergent adverse event; RUX, ruxolitinib cream; VC, vehicle-controlled.
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Important Safety Information

SERIOUS INFECTIONS
Patients treated with oral Janus kinase (JAK) inhibitors for inflammatory conditions are at risk for serious infections that may lead to hospitalization or death. These include:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis.**
- **Other bacterial or viral infections, including herpes zoster, due to opportunistic pathogens.**

Avoid use in patients with an active, serious infection. If a serious infection develops, stop OPZELURA until the infection is controlled. Carefully consider the benefits and risks of treatment prior to use in patients with chronic or recurrent infection. Closely monitor patients for the development of signs of infection during and after treatment with OPZELURA.

Serious lower respiratory tract infections were reported in the clinical development program with topical ruxolitinib.

No cases of active tuberculosis (TB) were reported in clinical trials with OPZELURA; however, cases were reported in clinical trials of oral JAK inhibitors to treat inflammatory conditions. Consider evaluating patients for latent and active TB infection prior to treatment. Monitor patients for the development of signs and symptoms of TB.

Viral reactivation, including cases of herpes virus reactivation were reported in clinical trials with JAK inhibitors used to treat inflammatory conditions including OPZELURA. If a patient develops herpes zoster, consider interrupting OPZELURA treatment until the episode resolves.

Hepatitis B viral load (HBV-DNA titer) increases, with or without associated elevations in alanine aminotransferase and aspartate aminotransferase, have been reported in patients with chronic HBV infections taking oral ruxolitinib. OPZELURA is not recommended in patients with active hepatitis B or hepatitis C.

POST-MARKETING SAFETY
In a large randomized postmarketing safety study of rheumatoid arthritis (RA) patients 50 years and older with at least one cardiovascular risk factor, the following were higher with an oral JAK inhibitor than with a tumor necrosis factor (TNF) blocker: all-cause mortality, major adverse cardiovascular events (defined as cardiovascular death, myocardial infarction, and stroke), thrombosis, malignancies (excluding non-melanoma skin cancer [NMSC]). Consider the benefits and risks prior to initiating or continuing therapy with OPZELURA. **Discontinue OPZELURA in patients who have experienced a myocardial infarction or stroke.**

MALIGNANCIES
Malignancies were reported in patients treated with OPZELURA. Lymphoma and other malignancies have been observed in patients receiving JAK inhibitors used to treat inflammatory conditions. Patients who are current or past smokers are at increased risk. Inform patients about the symptoms of serious cardiovascular events and the steps to take if they occur.

Consider the benefits and risks prior to initiating therapy with OPZELURA, particularly in patients with a known malignancy (other than successfully treated non-melanoma skin cancers), who develop a malignancy when on treatment, with cardiovascular risk factors, and who are current or past smokers.

Non-melanoma skin cancers, including basal cell and squamous cell carcinoma, have occurred in patients treated with OPZELURA. Perform periodic skin examinations during OPZELURA treatment. Limit exposure to sunlight and UV light with protective clothing and broad-spectrum sunscreen.

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Important Safety Information (cont)

THROMBOSIS

Thromboembolic events were observed in trials with OPZELURA. Thrombosis, including pulmonary embolism (PE), deep venous thrombosis (DVT), and arterial thrombosis have been reported in patients receiving JAK inhibitors used to treat inflammatory conditions. Many of these adverse reactions were serious, and some resulted in death. Avoid OPZELURA in patients at risk. If symptoms of thrombosis occur, discontinue OPZELURA and treat appropriately.

CYTOPENIAS

Thrombocytopenia, anemia, neutropenia, lymphopenia, and leukopenia were reported in the clinical trials with OPZELURA. Consider the benefits and risks for patients who have a known history of these events prior to initiating therapy. Perform CBC monitoring as clinically indicated. Discontinue OPZELURA if symptoms associated with clinically significant decreases in laboratory values occur.

POTENTIAL RISKS RELATED TO JAK INHIBITION

Treatment with oral ruxolitinib has been associated with increases in lipid parameters including total cholesterol, low-density lipoprotein (LDL) cholesterol, and triglycerides, as well as hypoglycemia in patients with diabetes.

ADVERSE REACTIONS

In atopic dermatitis, the most common adverse reactions (≥1%) are nasopharyngitis, bronchitis, ear infection, eosinophil count increased, urticaria, diarrhea, folliculitis, tonsillitis, rhinorrhea, upper respiratory tract infection, COVID-19, application site reaction, pyrexia, and white blood cell decreased.

In nonsegmental vitiligo, the most common adverse reactions (≥1%) are application site acne, application site pruritus, nasopharyngitis, headache, urinary tract infection, application site erythema, and pyrexia.

PREGNANCY REGISTRY

There is a registry that monitors pregnancy outcomes in persons exposed to OPZELURA during pregnancy. Pregnant persons exposed to OPZELURA and healthcare providers should report OPZELURA exposure by calling 1-855-463-3463 or visiting www.opzelura.pregnancy.incyte.com.

LACTATION

Advise women not to breastfeed during treatment with OPZELURA and for approximately four weeks after the last dose (approximately 5-6 elimination half-lives).

Please see Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.

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