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Advancing Care in Pediatric Atopic Dermatitis

Announcer:

You're listening to *DermConsult* on ReachMD. This medical industry feature, titled "Advancing Care in Pediatric Atopic Dermatitis," is sponsored by Incyte Pharmaceuticals. Here's your host, Dr. Jennifer Caudle.

Dr. Caudle:

Welcome to ReachMD. I'm your host, Dr. Jennifer Caudle, and today, we'll be exploring how we can improve outcomes in pediatric atopic dermatitis. Joining me are Doctors Ghali and Chase who have been compensated by Incyte for their participation.

Dr. Ghali is a pediatric dermatologist and the founder of Pediatric Dermatology of North Texas in Dallas, Texas. Dr. Ghali, welcome to the program.

Dr. Ghali:

Thanks for having me.

Dr. Caudle:

Of course. Also with us is Dr. Chase who treats children and adults with atopic dermatitis and allergic disease. She's a partner at Saint Paul Allergy and Asthma in Saint Paul, Minnesota and she's also an Associate Professor of Medicine at the University of Minnesota, Minneapolis. Dr. Chase, thank you for joining us today.

Dr. Chase:

Thank you, it's great to be here.

Dr. Caudle:

Well, it's great to have you both.

And before we get started, let's review some Important Safety Information for OPZELURA Ruxolitinib Cream, 1.5 percent.

Announcer:

INDICATIONS AND USAGE

OPZELURA is 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.

Important Safety Information

Serious Infections

Serious infections leading to hospitalization or death, including tuberculosis and invasive fungal, bacterial, viral, and other opportunistic infections, have occurred in patients receiving Janus kinase (JAK) inhibitors for inflammatory conditions.

Mortality

Higher rate of all-cause mortality, including sudden cardiovascular death, was observed in patients treated with JAK inhibitors for

inflammatory conditions.

Malignancies

Lymphoma and other malignancies have been observed in patients treated with JAK inhibitors for inflammatory conditions.

Major Adverse Cardiovascular Events (MACE)

Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) was observed in patients treated with JAK inhibitors for inflammatory conditions.

Thrombosis

Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis, some fatal, have occurred in patients treated with JAK inhibitors for inflammatory conditions.

Important Safety Information will be discussed in more detail, later in this video.

Dr. Caudle:

So let's dive right in. Based on the results from the TRuE-AD3 trial, we have ruxolitinib cream, or OPZELURA, as a treatment option for children ages two and older with atopic dermatitis. So, Dr. Ghali, what does this option mean for your patients, and, how do you determine who's a good candidate?

Dr. Ghali:

OPZELURA's approval for ages two and older really addressed an unmet need in pediatric atopic dermatitis, because, in my experience, many patients are not adequately controlled on traditional topical therapies like topical steroids and topical calcineurin inhibitors.^{1,2}

Now, when I'm thinking about who might be a good candidate, I generally look at patients with a mild to moderate atopic dermatitis that have a total of five to 15 percent body surface area involvement.² Many of these patients are looking to manage their disease with topical therapies, but may not be getting the level of control that they want. So for those patients, having an additional treatment option can help fill an important gap between traditional topical therapies and more advanced systemic treatments, while also supporting long-term disease management.

Dr. Caudle:

And how about you, Dr. Chase, how are you incorporating OPZELURA in your practice, and how do you approach patient selection?

Dr. Chase:

I look for patients that have either tried and failed topical corticosteroids or topical calcineurin inhibitors, or have a specific area of dermatitis that is refractory to those therapies or otherwise really bothersome, like on the hands or the face.²

In my practice, I find that I have a lot of pediatric patients where parents are reluctant to continue topical steroid therapies. And many of the kids that I see have difficulty with topical calcineurin inhibitors due to burning or stinging sensations.^{3,4} So, in my experience, for those kinds of patients, OPZELURA is a good option.

A lot of my patients have said OPZELURA has provided relief—which is a big deal for little kids, especially ones that are squirmy.

Dr. Caudle:

Well, that's really great to hear, Dr. Chase. And, let's take a closer look at the findings from the TRuE-AD3 trial.

Dr. Caudle:

TRuE-AD3 enrolled 330 children ages two to 11 who had mild-to-moderate atopic dermatitis BSA involvement between three to 20 percent and investigators global assessment, or IGA, scores of two or three.² Children were randomized to monotherapy OPZELURA, ruxolitinib cream 0.75 percent or vehicle and were instructed to apply twice daily continuously for an initial eight-week period.² Eligible patients could continue to the 44 week extension period where OPZELURA was applied twice daily for as needed use, which is similar to real-world usage.⁵

The primary endpoint was the proportion of patients achieving IGA treatment success, or IGA-TS, at week eight, which is defined as having an IGA score of zero or one with a two point or greater improvement from baseline.² Secondary endpoint was the percentage of children aged two to 11 with 75 percent improvement in Eczema Area and Severity Index, also known as EASI-75, at week eight, and EASI-90 was an exploratory endpoint.^{5,6}

So, you know with all that in mind, Dr. Ghali, can you walk through some of OPZELURA's efficacy results?

Dr. Ghali:

The response we see with OPZELURA after eight weeks with continuous use was that more than 70 percent of patients receiving OPZELURA achieved an IGA score of zero or one, compared to around 20 percent with the vehicle. That's a three-fold difference in just eight weeks.⁵

The separation between the OPZELURA and vehicle arms was observed early, with differences in the proportion of patients achieving an IGA score of zero or one seen as early as week two.⁵

And the extended study shows that response can be sustainable with as-needed use, because at 52 weeks, 72 percent of patients had an IGA score of zero or one, even for patients who switched from vehicle to OPZELURA.⁵

Due to the this data being apart of the extension period, the data is reported as observed, and no conclusions of safety or efficacy can be made.

And the data for EASI-75 and EASI-90 showed a similar trend. 67.2 percent of children treated with OPZELURA achieved EASI-75, compared to 15.4 percent with the vehicle. Even with the more stringent EASI-90 endpoint, 43.5 percent of children reached 90 percent or more improvement compared to 10.8 percent with the vehicle.^{5,6}

And this is the kind of pattern I'm seeing in my own practice; I've had patients with this kind of improvement.

Dr. Chase:

I agree with you, Dr. Ghali. I have seen the same patterns in my practice in the short and in the long term. Looking at the data, kids who started on OPZELURA from day one of TRuE-AD3 spent almost five cumulative months off treatment. So once these kids had clear skin, many of them were able to stay off therapy and maintain control for an extended period of time.^{5,7}

And looking at the broader long-term cohort of 44 weeks, kids spent about half of that time between week eight and week 52 off treatment because their lesions had cleared with as-needed use.^{5,7}

So, this really reinforces that OPZELURA can be used in a flexible, as-needed way, helping kids manage flares without requiring continuous, ongoing treatment.⁵ And that can make a meaningful difference for both kids and their families when it comes to management and care of atopic dermatitis.

Dr. Caudle:

For those just tuning in, you're listening to *DermConsult* ReachMD. I'm Dr. Jennifer Caudle and today I'm speaking with Dr. Fred Ghali and Dr. Nicole Chase about the role of ruxolitinib in pediatric atopic dermatitis care.

So now that we've reviewed the efficacy data, let's take a closer look at safety. Dr. Chase, what were the short-term and long-term findings for OPZELURA?

Dr. Chase

In the first eight weeks, the most common adverse reactions occurring in patients were upper respiratory tract infections, COVID-19, application site reactions, pyrexia, and decrease in white blood cells.²

And another key point to highlight here is that the discontinuation rate was relatively low at 0.8 percent with OPZELURA,⁶ and neither atrophy nor striae were reported in either group for the entirety of the trial.⁷

For long-term safety, the most common adverse reaction was upper respiratory tract infection, similar to the first eight weeks, followed by nasopharyngitis, COVID-19, gastroenteritis viral infection, otitis media, diarrhea, ear infection, pyrexia, and vomiting.⁷

It's worth noting that this trial took place during the COVID-19 pandemic, which provides additional context for reported respiratory and viral events. Additionally, the most commonly reported adverse reactions were not among the serious risks described in the Boxed Warning, which include serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis.²

So taken together, these results show that there was low treatment discontinuation and a consistent safety profile throughout the study.^{2,6}

Dr. Caudle:

So let's look at how this translates into clinical practice. Dr. Ghali, how do you feel that patients have tolerated OPZELURA?

Dr. Ghali:

One thing I'd highlight from the safety results is that five percent of patients on OPZELURA reported application site reactions, which I think really speaks to the overall tolerability.^{3,4,7} And from a practical standpoint, tolerability matters because it can influence how comfortable patients are using a topical treatment and how easily it fits into their treatment routine.

Historically, managing atopic dermatitis usually meant using different topical therapies for different situations.¹ For example, in my experience with traditional topical steroids, I often have to consider where the atopic dermatitis is located when selecting treatment, and balance the treatment's potency based on skin thickness. And side effects associated with topical steroids, like skin thinning, also need to be considered.¹ But in my experience, OPZELURA as a non-steroidal treatment overcomes a lot of these barriers that we see with topical steroids.

Dr. Caudle:

And how about you, Dr. Chase, how do you approach counseling families about using OPZELURA, and what strategies have you found effective in maintaining treatment persistence?

Dr. Chase:

I try and emphasize to families that eczema is a chronic, relapsing remitting disease, and they're likely going to need a toolbox of things on hand for flares.¹ So when I talk to them about OPZELURA, we talk about why OPZELURA is a good tool to have in the toolbox.

I first start by setting expectations of when they may begin to see improvements. But when patients experience relief and the treatment is comfortable to use, it can build confidence and encourage continued use when needed.

For pediatric patients, I know parents are busy, so if they don't have to apply something every single day once symptoms resolve, they really appreciate that—and honestly, the kids do too. A lot of parents also want to minimize the amount of time their children spend on medications, so when I'm discussing treatment options, I look for ones that can fit more easily into a family's routine while still helping them manage the disease effectively.

But as an allergist, I also take some time explaining the genetic and underlying atopic nature of an allergy disease so families understand that while eczema may come and go, having effective tools available can help them manage it over the long term.¹

Dr. Caudle:

Before we wrap up, anything else that clinicians should know about prescribing OPZELURA in appropriate patients?

Dr. Chase:

Yes, in my experience, most insurance companies cover OPZELURA. Actually, over 90 percent of patients with private or commercial insurance have access to OPZELURA after a topical corticosteroid, though coverage may vary by plan.⁷ Prior authorization typically includes criteria such as age, diagnosis of mild to moderate atopic dermatitis, and appropriate treatment considerations. But, I also make sure to include body surface area and an IGA score so that insurance knows I'm following recommendations set by the FDA and it verifies that the patient meets the criteria for mild to moderate atopic dermatitis.²

Dr. Ghali:

Agreed and well said, and patient support programs can also make a big difference in bridging access gaps. Programs like Opzelura OnTrac and the Enhanced Services Network, or ESN, help streamline prior authorizations, provide education, offer affordability support—like bridge programs or copay assistance—to help patients start and stay on treatment.

Dr. Caudle:

Well, those are great insights for us to think on as we come to the end of today's program. I'd like to thank my guests, Dr. Fred Ghali and Dr. Nicole Chase, for sharing their perspectives on our evolving approach to managing pediatric atopic dermatitis.

Dr. Ghali and Dr. Chase, it was great speaking with you both today.

Dr. Ghali:

Thank you for having me.

Dr. Chase:

Yes, thank you.

Dr. Caudle:

And for ReachMD, I'm Dr. Jennifer Caudle.

Please stay tuned to hear some Important Safety Information.

Voiceover:

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.

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 ($\geq 1\%$) 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.

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](#) at opzelura.com.

Announcer:

This medical industry feature was sponsored by Incyte Pharmaceuticals. If you missed any part of this discussion or to find others in this series, visit *DermConsult* on ReachMD.com, where you can Be Part of the Knowledge.

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