Transcript Details
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Achieving Clearer Skin with a Rosacea Treatment

Announcer:
Welcome to ReachMD.

This medical industry feature, titled “Achieving Clearer Skin with a Rosacea Treatment" is provided in partnership with Galderma Laboratories, L.P.

Dr. Hilary Baldwin is a paid consultant for Galderma Laboratories, L.P.

Here's your host Dr. Jennifer Caudle.

Dr. Caudle:
One of the most frequently encountered skin diseases in dermatology practices is rosacea, which is a chronic inflammatory skin condition affecting more than 16 million Americans, both women and men, and because this condition is most commonly characterized by facial redness and/or pustules and papules, it can often be mistaken for acne. But we also know that the impact of rosacea is not only skin deep, with patients reporting psychosocial impacts of dealing with their disease, and that’s why on today’s program we’ll explore the current therapeutic landscape for dermatologists addressing this disease, and we’ll review a treatment option for helping patients achieve clearer skin.

Coming to you from the ReachMD studios in Fort Washington, Pennsylvania, I’m your host, Dr. Jennifer Caudle. Joining me to discuss a treatment approach to help patients with rosacea is Dr. Hilary Baldwin. She is the Medical Director of the Acne Treatment Center in Brooklyn, New York, she is a Clinical Associate Professor of Dermatology at Rutgers Robert Wood Johnson Medical Center, and she is the past President of the American Acne and Rosacea Society.

Dr. Baldwin, welcome to the program.

Dr. Baldwin:
Thank you so much for having me.

Dr. Caudle:
Well, we are excited that you are here. So to start, Dr. Baldwin, let’s level-set our understandings of rosacea and its impacts on patient quality of life. So, what should we know about this condition from your vantage point as a dermatologist?

Dr. Baldwin:
I think it’s entirely appropriate that we start our conversation with a discussion of quality of life. After all, rosacea, although it may be associated with systemic inflammatory diseases, is, after all, a cutaneous condition in which the impact on the patient is profound and sometimes limits his or her daily choices and interactions. We have multiple National Rosacea Society surveys to look at that indicate the magnitude of the suffering. One showed that 90% of rosacea sufferers reported a loss of self-esteem, another that patients indicated that they are willing to give up to a year of their life for a cure, and another German study in which patients were asked for a monetary commitment, and the average patient was willing to spend close to $1,000 a year to be clear.

Our patients are embarrassed, depressed, and socially isolating, even before COVID-19.
One survey asked participants to look at digitally-enhanced photographs of patients with and without rosacea lesions. On the pictures of patients with lesions, they were deemed to be frustrated, angry, less clean and less likely to be in a relationship or even to have a professional job. So our patients are not the only ones judging themselves; others are judging them as well. In my practice patients tell me of dates broken, speeches not given, promotions not sought. They tell me of unsolicited comments by friends suggesting that they

wash their face more, eat less gluten, and my all favorite, drink more water. I've had many patients, mostly men, tell me that their red noses erroneously signal to the world an excessive compulsion with alcohol. Studies back this up, showing that the patients feel stigmatized by their condition. Overall, many of our patients are suffering, and some of them, unfortunately, are suffering in silence.

Dr. Caudle:
What potential attributes and factors make patients more susceptible to having rosacea?

Dr. Baldwin:
Well, of course, rosacea is very common, with estimates of 16 million patients in the U.S. alone. There are generalities about the patients more likely to present with disease, but the bottom line is that anyone can fall victim. The most common patient type is certainly one who presents between the ages of 30 and 50, and it appears that women are 2–3 times more likely to have the condition than men, but this may just be a reflection of the presentation bias. Historically, it's been said that patients of Northern European descent are more likely affected, but much data generated in the very recent past shows this to be maybe a reporting error. After all, erythema is more readily noted in lighter-skinned patients, and there is a failure, perhaps, to maintain a high index of suspicion with patients of color. Phymatous changes, though, are far more likely to occur in men than in women.

Dr. Caudle:
So now I'd like to turn our attention to the current therapeutic landscape for rosacea. First off, what are the main types of treatment most commonly used in clinical practice?

Dr. Baldwin:
The therapeutic options for rosacea can be grouped into behavioral, pharmacologic and procedural. Behavioral includes avoidance of any triggers that the patient might have noticed as well as practicing good skin care, which includes gentle cleansers and quality moisturization done on a daily basis. Procedural treatments include intense pulsed light and pulsed dye lasers, which are used primarily to remove the background redness and telangiectasia. Various surgical and laser ablative techniques are also used to remove phymatous material.

FDA-approved pharmacologic treatments include numerous topical preparations and a single oral drug. Before choosing among the various products, the patient phenotype has to be considered. Does the patient have primarily vascular disease, primarily papules and pustules or, perhaps, a combination of the two? This is important because the drugs at our disposal are relatively specific for erythema or inflammatory lesions, and combination disease is going to require combination therapy. For papules and pustules we have topical azelaic acid, metronidazole and ivermectin as well as oral doxycycline, and for erythema we have topical brimonidine and oxymetazoline.

Dr. Caudle:
For those of you who are just joining us, this is ReachMD, and I'm your host, Dr. Jennifer Caudle. Today I am speaking with Dr. Hilary Baldwin about treatment priorities to help patients with rosacea achieve clearer skin.

So, Dr. Baldwin, earlier we talked about the current therapeutic landscape for rosacea, and now I'd like to focus on a specific treatment option called SOOLANTRA® (ivermectin) Cream, 1% and discuss highlights from its clinical trials. Can you give us an overview of this treatment and discuss any information on ivermectin's proposed mechanism of action?

Dr. Baldwin:
Sure. SOOLANTRA Cream contains 1% ivermectin and is used once daily for the treatment of the papules and pustules of rosacea for which it is efficacious and well-tolerated. The exact mechanism of action of SOOLANTRA Cream in treating rosacea is unknown, but ivermectin has several proposed functions. Orally ivermectin has served as an effective antiparasitic drug for decades in veterinary practices for heartworm protection and to treat life-threatening helminth infections in humans, such as onchocerciasis and strongyloides. It is known to kill lice, to kill scabies and to kill Demodex, which is through to play a role in the pathogenesis of rosacea. It also has numerous anti-inflammatory activities. In particular, it has been shown that ivermectin decreases cellular and humoral immune responses known to be aberrantly upregulated in rosacea.

Dr. Caudle:
What can you tell us about the safety and efficacy data for SOOLANTRA Cream?

Dr. Baldwin:
The efficacy of SOOLANTRA Cream was evaluated in 2 identical, multicentered, double-blind, vehicle-controlled studies with more than 1,300 patients. Patients were 18 or above and had either moderate or severe rosacea with between 15 and 70 inflammatory lesions with a mean of 31 at baseline. The co-primary endpoints were treatment success, clear or almost clear, and at least a 2-grade improvement and mean change of inflammatory lesion count over time. By week 12, nearly 40% of patients had achieved treatment success, which is

a very difficult endpoint to reach, compared to nearly 12% of patients on vehicle cream.

It's important to note that in the long-term safety study, treatment success continued to improve over that seen at the end of the 12-week endpoint reaching its apex at 28 weeks with 71% success. This is a clinically relevant data point since patients who may or may not have reached their goal at week 12 should be encouraged to continue on drug. Mean lesion count reduction was 20.5 lesions at week 20 compared to 12 lesions on vehicle. It was a statistical difference between active and vehicle as early as week 2, so not only did it work well, but it worked rapidly.

As far as safety is concerned, SOOLANTRA Cream was very well-tolerated, actually showing fewer adverse events than with vehicle cream. In clinical trials with SOOLANTRA Cream, the most common adverse reactions occurring with an incidence of 1% or less included skin burning sensation and skin irritation.

Dr. Caudle:
Continuing on the efficacy track, Dr. Baldwin, I understand there were some comparative studies conducted for this treatment with respect to achieving clearer skin. What can you tell us about that?

Dr. Baldwin:
Well, a study was performed in Europe that compared the efficacy and tolerability of once-daily SOOLANTRA (ivermectin) Cream, 1%, to METROCREAM®, which is metronidazole topical cream 0.75%, twice daily for 16 weeks. Again, these patients had moderate-to-severe disease with 15 to 70 inflammatory lesions, this time with a mean of 32, and the co-primary endpoints, again, were IGA success, clear or near clear, and mean percent reduction of inflammatory lesions. At all timepoints of the study, SOOLANTRA Cream showed statistically significantly superior results in both IGA and the percent lesion reduction with a delta of about 10% throughout. When clear, an IGA of 0, and almost clear, an IGA of 1, were considered separately, 60% more patients achieved clear with SOOLANTRA Cream versus MetroCream topical cream.

Dr. Caudle:
Were there any particular findings on the tolerability index for these treatments that we should know about? And on the subject of adverse events, how do these treatments compare?

Dr. Baldwin:
Both drugs were well-tolerated, but SOOLANTRA Cream showed fewer incidences of related adverse events than MetroCream topical cream. An important data point when examining adverse events is always the discontinuation rate, as this gives us a window into the significance of the AE to the patient. Was it bothersome enough for the patient to withdraw from the study? Six SOOLANTRA Cream subjects dropped out of the study, 3 due to AEs, whereas 13 MetroCream topical cream patients withdrew, 10 due to AEs. In clinical trials with SOOLANTRA Cream, the most common adverse reactions occurring with an incidence of 1% or less included skin burning sensation and skin irritation. SOOLANTRA Cream is formulated for tolerability, utilizing Cetaphil® moisturizing cream as the basis for the vehicle.

Dr. Caudle:
Before we wrap up our discussion, Dr. Baldwin, were there any other notable findings from the data presented or additional takeaways you'd like to share with our audience?

Dr. Baldwin:
Yes. We haven't discussed yet the duration of response or the need for retreatment, because since rosacea is a chronic disease, it's going to require chronic therapy, and we have some data that looks into differences in long-term response between MetroCream topical cream and SOOLANTRA Cream. In that study that we just talked about, there was a continuation study after that first 16-week active period. Everyone who had achieved clear or almost clear was evaluated for an additional 36 weeks for a total of 52 weeks. All medication use was initially discontinued, and then the patients were followed over time. If at any point their disease recurred, they were allowed to restart the very same medication.

Efficacy endpoints evaluated were time to first relapse, which means that they got to mild disease or worse, relapse rate and the number of days free from treatment observed every 4 weeks from week 16 to week 52. Thirty-three percent more SOOLANTRA-treated patients who achieved clinical success did not need retreatment compared with MetroCream topical cream-treated subjects. The median time to first relapse was 30 days longer, 115 days versus 85 days, with SOOLANTRA Cream, giving patients 30 more treatment-free days than with MetroCream topical cream. Drug holidays are often appreciated by patients, and SOOLANTRA cream gives them the opportunity to take one if it's advised by their dermatologists.

Dr. Caudle:

Well, with those takeaways in mind, I'd like to thank my guest, Dr. Hilary Baldwin, for helping us better understand this evolving treatment landscape towards achieving clearer skin for patients with the inflammatory lesions of rosacea.

Dr. Baldwin, it was great having you on the program today.

Dr. Baldwin:
It was a pleasure. Thank you so much for having me.

Announcer:
Indication: SOOLANTRA® (ivermectin) Cream, 1% is indicated for the treatment of inflammatory lesions of rosacea. Not for oral, ophthalmic or intravaginal use. **Adverse Events:** In clinical trials with SOOLANTRA Cream, the most common adverse reactions (incidence less than or equal to 1%) included skin burning sensation and skin irritation.

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