Lead article



HS considered underdiagnosed and difficult to treat; new therapy may offer solution

by LOUISE GAGNON, Correspondent, The Chronicle

he approval of a biologic for the treatment of hidradenitis suppurativa (HS),

the availability of a new topical formulation of adapalene-benzoyl peroxide, and vigilance regarding the dermatologic signs of the Zika virus are all developments that are top of mind for Canadian dermatologists in 2016.

HS

The approval of adalimumab by Health Canada for the treatment of long-term manmoderate-to-severe HS signals the first-ever treatment in Canada indicated for HS, which can be a challenging disease to treat. "I think this is a major step formild HS or more ward for these patients with modersevere HS, adaliate to severe disease who have been frustrated with lack of effective treatmumab would ment options," said Dr. Melinda J. Gooderham, a dermatologist and director of SKiN Centre for Dermatology in Peterborough, Ont.

years. Now, Health Canada recognizes it as an effective and safe therapy [for HS]. The payers must recognize this as an option."

Dr. Benjamin Barankin, a dermatologist and co-founder of the Toronto Dermatology Centre, agreed that therapies have been used off-label to treat HS, and that an approved therapy will present an option for



Dr. Melinda Gooderham



Dr. Benjamin Barankin



to have an existing drug that has been around for years approved for treatment [of HS]. We have comfort with this therapy [adali-Dr. Marlene Dytoc mumab] to treat psoriasis and other conditions. We know how



Dr. Mark Lupin

Linzon, director at Forest Hill Dermatology in Toronto, noted that patients may be referred for

another reason,

but that HS is

actually identi-

fied during the

Dr. Charlene

the medication

works, and it has

a terrific safety

profile."

"This [approval by Health Canada] will improve access to therapy instead of having to try to get this medication for off-label use, which has been difficult in the past few

agement of the disease in moderate-to-severe stages. For more

Dr. Charlene Linzon

not be a therapeutic choice, explained Dr. Barankin.

"It will be a way to control the disease medically, and the therapy will most likely be used chronically," he said.

"The treatment can address the inflammation and prevent some of the scarring that can occur. It is nice



Dr. Gail Nield examination. "It's a condition that patients may not

want to talk about and are embarrassed about," said Dr. Linzon. "It's a condition that is underdiagnosed and difficult to treat. It's a good thing to have a new treatment available."

Acne

Dr. Marlene Dytoc, director and der-

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Indication and clinical use:

ROSIVER (ivermectin) Cream, 1% is for the topical treatment of inflammatory lesions (papules and pustules) of rosacea in adults 18 years of age or older.

Relevant warnings and precautions:

- Risk of local skin reactions, allergic reactions, and skin irritation
- · Avoid concomitant use of potentially irritating topical products or procedures
- Caution in pregnant women
- Risk of serious adverse reactions in nursing infants (nursing women should discontinue nursing or the drug)

For more information:

Please consult the Product Monograph at http://galderma.ca/ Portals/4/pdf/ROSIVER_productmonograph.pdf for important information relating to adverse reactions, drug interactions, and dosing/administration information which have not been discussed in this advertisement.

The Product Monograph is also available by calling us at 1-800-467-2081.

References:

- 1. ROSIVER™ Product Monograph. Galderma Canada Inc. April 22, 2015.
- 2. Stein Gold L et al; Efficacy and safety of ivermectin 1% cream in treatment of papulopustular rosacea: results of two randomized, double-blind, vehiclecontrolled pivotal studies. J Drugs Dermatol. 2014;13(3):316-323. A phase 3, multicentre, randomized, double-blind, 12-week, vehiclecontrolled, parallel-group study assessing the efficacy and safety of ROSIVER once daily in 683 patients with moderate to severe papulopustular rosacea (IGA score of 3 or 4). The co-primary efficacy endpoints were the success rate based on the IGA outcome (percentage of patients "clear" and "almost clear" at Week 12 of the study) and absolute change from baseline in inflammatory lesion counts.
- 3. Taieb A et al; Ivermectin Phase III Study Group. Superiority of ivermectin 1% cream over metronidazole 0.75% cream in treating inflammatory lesions of rosacea a randomized, investigator-blinded trial. Br J Dermatol. 2015;172(4):1103-10. An investigator-blinded, multicentre, randomized, parallel-group study comparing the efficacy and safety of ROSIVER once daily with metronidazole 0.75% cream twice daily in 962 patients with moderate to severe papulopustular rosacea (IGA score of 3 or 4) over a 16-week treatment period. The primary efficacy endpoint was percent change in inflammatory lesion counts from baseline to week 16.

IGA: Investigator Global Assessment.

Advances include new treatment for AKs

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matologist, MDSkinHealth, and clinical professor of medicine, University of Alberta in Edmonton, noted that research published in January of this year suggested that monthly laboratory monitoring of all patients taking oral isotretinoin for acne is not necessary (JAMA Dermatol 2016 Jan 1; 152(1):35–44).

"The research concludes that we do not have to be so rigorous with our monitoring of [isotretinoin]," said Dr. Dytoc, although monthly monitoring in female patients is justified because isotretinoin is teratogenic.

Dr. Mark Lupin, a dermatologist in Victoria, B.C., and clinical instructor in the Department of Dermatology and Skin Science in the Faculty of Medicine at the University of British Columbia in Victoria, said CIPisotretinoin is a therapeutic option that is much more readily absorbed in the absence of a high-fat meal, which eliminates a barrier to efficacy.

"The absorption is approximately 83 per cent greater with CIPisotretinoin than with regular isotretinoin in the fasted state," said Dr. Lupin. "We have been prescribing isotretinoin for about 40 years, but we tell patients that they need to take it with the main meal of the day. Many people today have variations in their diet, so it has been a plus to have CIPisotretinoin as a treatment option, from the point of view of compliance" (J Am Acad Dermatol 2013 Nov; 69(5):762-767).

A modified concentration of adapalene and benzoyl peroxide, available in a pump, will offer alternatives to patients who want to avoid systemic therapy for acne.

"It's good for the patient who doesn't want to go on oral [isotretinoin] therapy," said Dr. Barankin. "It is a nice addition to our armamentarium. A patient may need aggressive topical therapy. The adapalene-benzoyl peroxide combination does not present any antibiotic resistance issues. It covers comedonal and non-comedonal acne."

Zika virus

For travellers to tropical climates particularly for women who are pregnant, epidemiologists are warning about the danger of being infected with the Zika virus transmitted by the Aedes mosquito. There is a suspected link between Zika virus in women who became pregnant and babies born with microcephaly. "With globalization and with global warming, we are starting to see outbreaks of disease that are vector transmitted," explained Dr. Gail Nield, a dermatologist in Woodbridge, Ont. who travels to Haiti to offer medical dermatology services.

"Globally, viruses like Zika seem Atopic dermatitis to transmit so quickly."

Infection with the Zika virus may be asymptomatic 70 to 80% of the time, but it can produce a maculopapular eruption and blood tests may be needed to confirm a diagnosis of Zika virus, explained Dr. Nield, who recently saw a patient with Zika virus in her local Woodbridge practice.

AKs

Dermatologists will soon have another option for treating actinic keratoses with the availability of a treatment that combines fluorouracil and salicyclic acid. "The salicyclic acid will help with penetration of fluorouracil, so that fluorouracil works better and there is improved efficacy," said Dr. Barankin. "The price point will likely be reasonable as well."

Salicylic acid is also being added to a new topical formulation of CeraVe, a ceramide-based moisturizer. Dr. Barankin noted the new formulation will offer benefit to patients with conditions such as keratosis pilaris, ichthyosis, psoriasis, and hyperkeratosis of the elbows and knees.

Psoriasis

Patients with psoriasis are likely to see another treatment option with the expected approval of certolizumab pegol, which has been used to treat psoriatic arthritis. "It's a medication in the TNF [tumour necrosis factor]alpha family," said Dr. Barankin. "There are very good data to support its use for psoriatic arthritis."

For patients with scalp psoriasis, a form of delivery new of calcipotriol/betamethasone gel that comes with an applicator will facilitate application of the therapy and avoid messy contact with the gel. "It would be easier for patients with arthritis who have difficulty applying the gel," said Dr. Barankin.

Emerging biologic therapies for atopic dermatitis are under study in Phase II, noted Dr. Gooderham. "They work differently from dupilumab, which blocks IL-4 and IL-13," said Dr. Gooderham. "It's too early to tell if they will work as well [as dupilumab]. We do see that people are responding in the [Phase II] studies."

A recent article sought to describe the quality of life impact of moderateto-severe AD in adults who were entering a Phase II b trial of dupilumab and found a proportion of 380 patients (with a mean age of 37 years and many of whom said they had AD most of their lives), experienced challenges such as pruritus, sleep disturbance, anxiety, and depression (J Am Acad Dermatol 2016; Jan 14).

In addition, research about the pathways that are being targeted by the biologics that have been developed to treat AD continues, noted Dr. Gooderham. Furthermore, pediatric studies in dupilumab are underway.

"The first [pediatric] patients are now in an open-label extension study," said Dr. Gooderham. "More pediatric studies are planned [with dupilumab]. We may see pediatric approval of dupilumab [for AD] not too far after approval of the therapy for adults. Usually, pediatric approval of a drug takes place years after approval in adults."

Non-proprietary and brand names of

therapies: adalimumab (Humira, AbbVie); isotretinoin (Accutane, Roche); CIP-isotretinoin (Epuris, *Cipher); adapalene/benzoyl peroxide* pump (TactuPump, Galderma); fluorouracil 5 mg and salicylic acid 100 mg solution (Actikeral, Cipher); CeraVe (Valeant); certolizumab pegol (Cimzia, UCB); calcipotriol 50 mcg/g and betamethasone 0.5 mg/g (Dovobet Gel, LEO); dupilumab (not approved in Canada).

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