

Please join us for a presentation on: **Psoriasis and Psoriatic Arthritis: Two Interrelated Diseases, One Treatment**

Wednesday Nov 11, 2015

Cabernet Grill

2805 South State Highway 16
Fredericksburg, TX

Otezla® (apremilast) is indicated for the treatment of:

- adult patients with active psoriatic arthritis.
- patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

Please see Important Safety Information on the next page.

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PROGRAM OVERVIEW

A presentation on the use of Otezla for the treatment of adult patients with active psoriatic arthritis and patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy given jointly by a rheumatologist and dermatologist.

PROGRAM AGENDA

6:30PM Registration

7:00PM Presentation and Dinner

Event Code:45501

Hosted by:Melissa Russo

To register for this event, please visit

<http://celgenereg.tsgmeded.com/> and enter the event code above.

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Indication and Important Safety Information

INDICATIONS

Otezla® (apremilast) is indicated for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

Otezla is indicated for the treatment of adult patients with active psoriatic arthritis.

IMPORTANT SAFETY INFORMATION

Contraindications

Otezla® (apremilast) is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation.

Warnings and Precautions

Depression: Carefully weigh the risks and benefits of treatment with Otezla for patients with a history of depression and/or suicidal thoughts/behavior, or in patients who develop such symptoms while on Otezla. Patients, caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes, and they should contact their healthcare provider if such changes occur.

Psoriasis: Treatment with Otezla is associated with an increase in adverse reactions of depression. During clinical trials, 1.3% (12/920) of patients treated with Otezla reported depression compared to 0.4% (2/506) on placebo; 0.1% (1/1308) of Otezla patients discontinued treatment due to depression compared with none on placebo (0/506). Depression was reported as serious in 0.1% (1/1308) of patients exposed to Otezla, compared to none in placebo-treated patients (0/506). Suicidal behavior was observed in 0.1% (1/1308) of patients on Otezla, compared to 0.2% (1/506) on placebo. One patient treated with Otezla attempted suicide; one patient on placebo committed suicide.

Psoriatic Arthritis: During clinical trials, 1.0% (10/998) of patients treated with Otezla reported depression or depressed mood compared to 0.8% (4/495) treated with placebo; 0.3% (4/1441) of patients treated with Otezla discontinued treatment due to depression or depressed mood compared with none in placebo treated patients (0/495). Depression was reported as serious in 0.2% (3/1441) of patients exposed to Otezla, compared to none in placebo treated patients (0/495). Suicidal ideation and behavior were observed in 0.2% (3/1441) of patients on Otezla, compared to none on placebo (0/495). Two patients who received placebo committed suicide compared to none on Otezla.

Weight Decrease: Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla.

Psoriasis: Body weight loss of 5-10% occurred in 12% (96/784) of patients treated with Otezla and in 5% (19/382) of patients treated with placebo. Body weight loss of $\geq 10\%$ occurred in 2% (16/784) of patients treated with Otezla compared to 1% (3/382) of patients treated with placebo.

Psoriatic Arthritis: Body weight loss of 5-10% was reported in 10% of patients taking Otezla and in 3.3% of patients taking placebo. Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla.

Drug Interactions: Apremilast exposure was decreased when Otezla was co-administered with rifampin, a strong CYP450 enzyme inducer; loss of Otezla efficacy may occur. Concomitant use of Otezla with CYP450 enzyme inducers (eg, rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended.

Adverse Reactions

Psoriasis: Adverse reactions reported in $\geq 5\%$ of patients were (Otezla%, placebo%): diarrhea (17, 6), nausea (17, 7), upper respiratory tract infection (9, 6), tension headache (8, 4), and headache (6, 4).

Psoriatic Arthritis: Adverse reactions reported in $\geq 2\%$ of patients taking Otezla, that occurred at a frequency at least 1% higher than that observed in patients taking placebo, for up to 16 weeks (after the initial 5-day titration), were (Otezla%, placebo%): diarrhea (7.7, 1.6); nausea (8.9, 3.1); headache (5.9, 2.2); upper respiratory tract infection (3.9, 1.8); vomiting (3.2, 0.4); nasopharyngitis (2.6, 1.6); upper abdominal pain (2.0, 0.2).

Use in Specific Populations

Pregnancy and Nursing Mothers: Otezla is Pregnancy Category C; it has not been studied in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether apremilast or its metabolites are present in human milk. Caution should be exercised when Otezla is administered to a nursing woman.

Renal Impairment: Otezla dosage should be reduced in patients with severe renal impairment (creatinine clearance less than 30 mL/min); for details, see Dosage and Administration, Section 2, in the Full Prescribing Information.

Please see accompanying Full Prescribing Information.



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