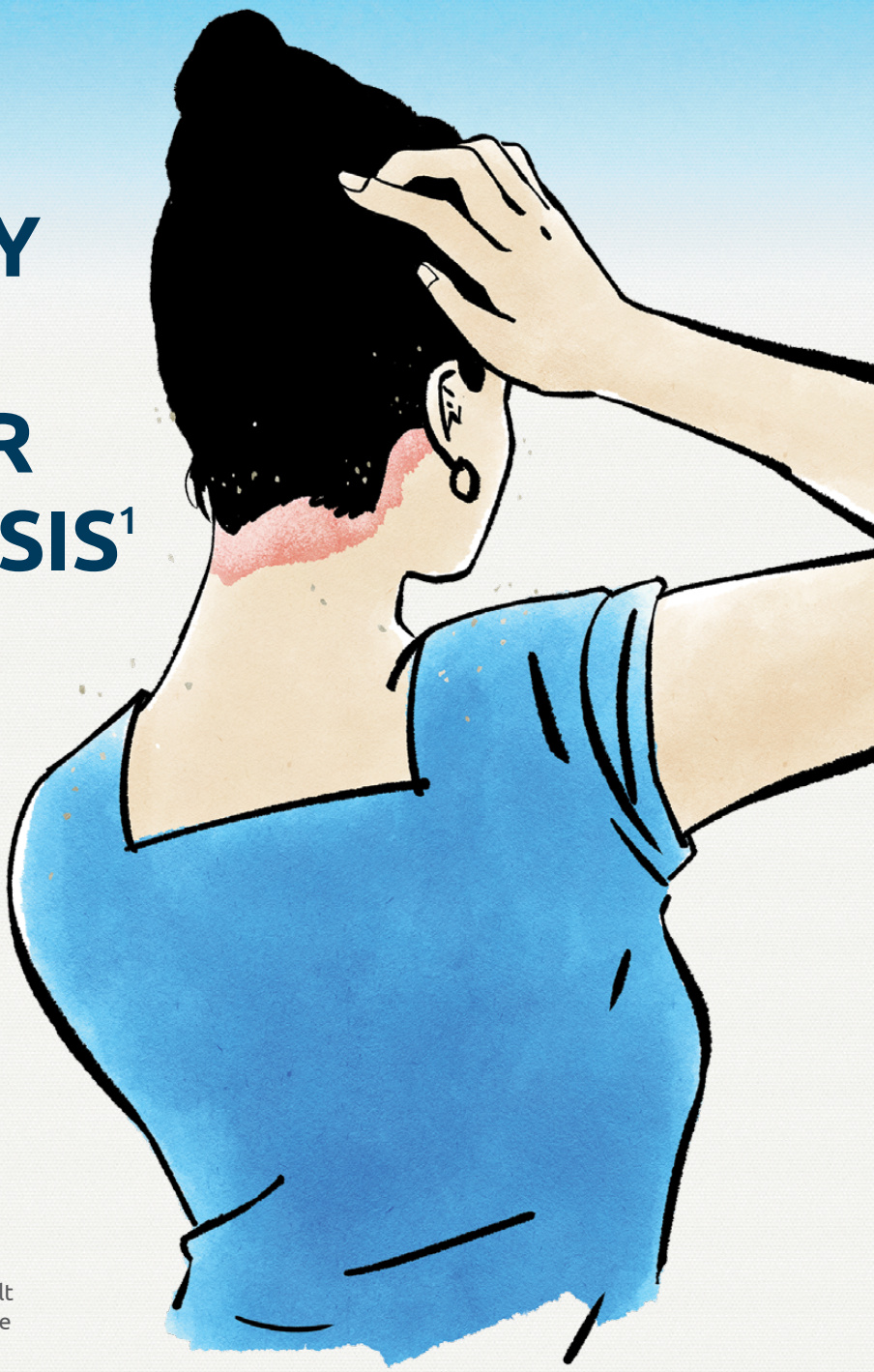
Otezla Clinical Data for Adults with Moderate to Severe Scalp Psoriasis[1,2]

Otezla® (apremilast) 30mg tablets

For adults with moderate to severe plaque psoriasis

THE ONLY ORAL THERAPY WITH DATA IN THE LABEL FOR SCALP PSORIASIS[1]



- A FIRST STEP TO SYSTEMIC THERAPY FOR MODERATE TO SEVERE SCALP PSORIASIS
- *PROGRESS TO OTEZLA*

INDICATIONS

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

Please see Important Safety Information presented throughout and Full Prescribing Information here.

Of the patients who have plaque psoriasis

UP TO 80% ALSO HAVE SCALP INVOLVEMENT[4]

~97% of patients say scalp psoriasis interferes with their daily lives[4]

~50% of psoriasis patients have cycled through ≥4 topicals[3*†]

5x the proportion of patients vs dermatologists cite itching as the most important factor contributing to disease severity (38% vs 7%)[5‡]

CONSIDER A SYSTEMIC THERAPY BEFORE ADDING ANOTHER TOPICAL FOR YOUR PATIENT'S MODERATE TO SEVERE SCALP PSORIASIS[1,4]

*Data derived from Symphony Health Solutions (claims data). Includes any psoriasis (PsO) patient present in the Symphony monthly period to date [August 2014 through July 2018] currently on a topical and has no experience of a prior systemic therapy. A PsO patient is a psoriasis patient with at least 2 PsO diagnoses (based on ICD-9-CM/ICD-10-CM PsO diagnosis codes) in entire history [January 2007 through July 2018]. Continuous eligibility criteria are applied to include only patients who are active (semesterly) in the patient-level data for the 4-year look-back period of August 2014 through July 2018.

†47% of patients in claims data analysis.

‡The MAPP survey provided context on the impact of disease and treatment on patient's daily life from both the patient and physician perspectives. The physician survey included dermatologists (n=391) and rheumatologists (n=390).[3]

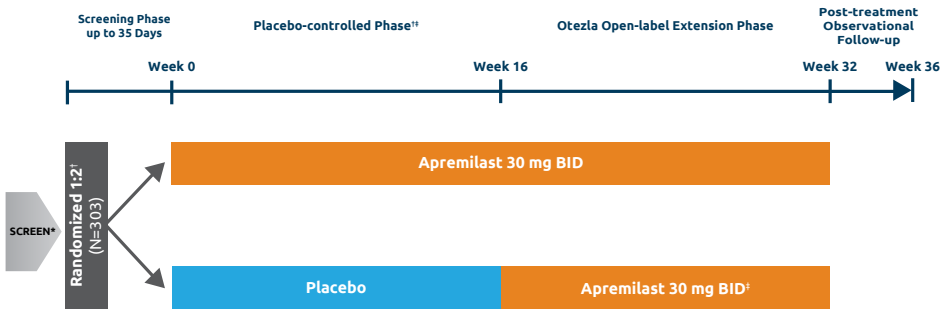
MAPP, Multinational Assessment of Psoriasis and Psoriatic Arthritis survey.

STYLE clinical trial[1-3]

Study design: Phase 3 multicenter, randomized, double-blind, placebo-controlled study of 303 patients with moderate to severe plaque psoriasis of the scalp (ScPGA ≥3). Patients were randomized 2:1 to Otezla® (apremilast) 30 mg twice daily (n=201) or placebo (n=102) for the placebo-controlled phase through week 16, then continued or switched to Otezla for open-label extension phase through week 32. Treatment groups were stratified by baseline ScPGA score (3 [moderate] or 4 [severe]).[1-3]

Selected inclusion criteria: Adults ≥18 years of age with moderate to severe plaque psoriasis (BSA involvement of ≥10%, sPGA ≥3, PASI score ≥12) and moderate to severe plaque psoriasis of the scalp (ScPGA ≥3, SSA ≥20%), with inadequate response or intolerance to ≥1 topical therapy for plaque psoriasis of the scalp.[1,2]

Selected exclusion criteria: Active TB or incompletely treated TB, hepatitis B or hepatitis C positive at screening, and history of HIV.[3]



*Screening up to 35 days before randomization.
†All doses were titrated over the first week of treatment.
‡At week 16, all placebo patients were switched to open-label apremilast 30 mg BID (with dose titration) through week 32.

Patient demographics and disease characteristics[1-3]

Mean age:
- 46.9 years (range 19-84 years)

Male:
- 61.7%

White:
- 75.6%

Baseline ScPGA score of 3 (moderate scalp psoriasis):
- 76.9%

Baseline ScPGA score of 4 (severe scalp psoriasis):
- 23.1%

Mean duration of plaque psoriasis:
- 15.36 years

Mean baseline affected SSA:
- 60.6%

Mean baseline BSA involvement:
- 19.8%

Mean DLQI score:
- 12.6

Mean scalp itch NRS score at baseline:
- 6.7 (range 0-10)

Mean whole body itch NRS score at baseline:
- 7.2 (range 0-10)

Scalp psoriasis treatment history:
- Biologic-naïve: 71.6%
- Failed on 1-2 topicals or shampoo treatments: 58.8%

Concomitant psoriasis therapies during trial:
- For body lesions: unmedicated emollients
- For scalp lesions: nonmedicated shampoos

BID, twice daily; BSA, body surface area; DLQI, Dermatology Life Quality Index; NRS, numeric rating scale; PASI, Psoriasis Area and Severity Index; ScPGA, Scalp Physician Global Assessment; sPGA, static Physician Global Assessment; SSA, scalp surface area; TB, tuberculosis.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

- Diarrhea, Nausea, and Vomiting: Cases of severe diarrhea, nausea, and vomiting have been reported with the use of Otezla. Most events occurred within the first few weeks of treatment. In some cases patients were hospitalized. Patients 65 years of age or older and patients taking medications that can lead to volume depletion or hypotension may be at a higher risk of complications from severe diarrhea, nausea, or vomiting. Monitor patients who are more susceptible to complications of diarrhea or vomiting; advise patients to contact their healthcare provider. Consider Otezla dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting

Please see Important Safety Information presented throughout and Full Prescribing Information here.

The only oral therapy with data in the label for adults with moderate to severe scalp psoriasis[1]

OTEZLA SIGNIFICANTLY IMPROVES SCALP RESPONSE[1,2]

STYLE primary endpoint: proportion of patients achieving an ScPGA response at week 16[1,2]*

Otezla patients

3x as likely to achieve scalp improvement at week 16

vs placebo in the STYLE study

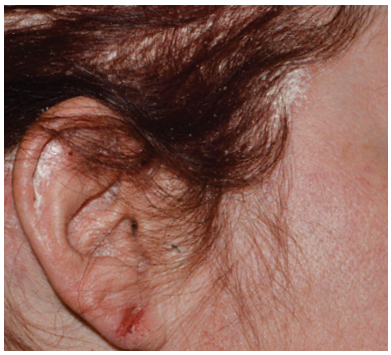
43.3% with Otezla® (apremilast) 30 mg BID (n=201)

vs (*P*<0.0001)

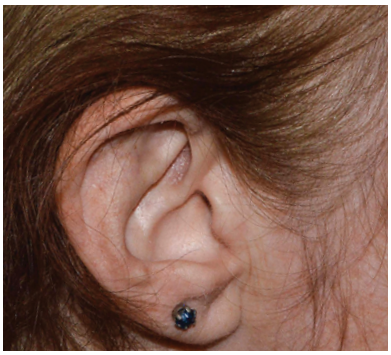
13.7% with placebo (n=102)

*ScPGA response was defined as the proportion of patients achieving an ScPGA score of 0 (clear) or 1 (almost clear) with at least a 2-point reduction from baseline.

Results seen in an Otezla patient (scalp response)



Baseline



Week 16
ScPGA: 0†
3-point improvement in ScPGA score

†Actual clinical trial patient from STYLE.[3] Individual results may vary.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

- Depression: Treatment with Otezla is associated with an increase in depression. During clinical trials 1.3% (12/920) of patients reported depression, compared to 0.4% (2/506) on placebo. Suicidal behavior was observed in 0.1% (1/1308) of patients on Otezla, compared to 0.2% (1/506) on placebo. 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
- Weight Decrease: 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. 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 (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended

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Otezla® (apremilast) 30mg tablets

OTEZLA SIGNIFICANTLY IMPROVES MEASURES OF ITCH AND DLQI[1,2]

Otezla significantly improved scalp itch at 16 weeks, with achievement of response seen as early as 2 weeks (secondary endpoints)[1,2]*

47.1% of patients taking Otezla® (apremilast) achieved a

≥4-POINT IMPROVEMENT FROM BASELINE

in scalp itch NRS score at week 16 vs placebo (21.1%) (*P*<0.0001)[2]

Significant improvement in scalp itch NRS as early as 2 weeks vs placebo (*P*=0.0025)[2]

- 26.1% of patients achieved a ≥4-point improvement from baseline in scalp itch NRS vs placebo (11.5%) at 2 weeks; *P*=0.0025[2]

*In patients with a baseline scalp itch NRS score ≥4 (placebo: n=90; Otezla: n=175).

Significant improvement in whole body itch[1,2†]:

- 45.5% of patients achieved a ≥4-point improvement from baseline in whole body itch NRS scores vs placebo (22.5%) (*P*<0.0001) at week 16
- 20.5% of patients achieved a ≥4-point improvement from baseline in whole body itch NRS vs placebo (3.5%) at 2 weeks; *P*<0.0001

†In patients with a baseline whole body itch NRS score ≥4 (placebo: n=94; Otezla: n=185).

Improvements in health-related quality of life (HRQoL) as measured by DLQI[2]:

- Mean improvement from baseline in DLQI total score was significantly greater with Otezla vs placebo at week 16 (-6.7 vs -3.8; *P*<0.0001)
- The DLQI is a 10-item questionnaire assessing the impact of skin disease on health-related quality of life. Total score ranges from 0 to 30; higher scores indicate poorer quality of life and scores of 11 to 20 indicate a large impact of skin disease on quality of life. The minimal clinically important difference (MCID) in the DLQI is at least a 4-point improvement from baseline[2,3,6]

Adverse reactions[1,2]:

- The most common adverse reactions (≥5%) from weeks 0 to 16 included diarrhea, nausea, headache, and vomiting
- The proportion of patients who discontinued treatment because of any adverse reaction was 6% for patients who received Otezla 30 mg twice daily and 3% for patients who received placebo
- Gastrointestinal adverse reactions that led to discontinuation of treatment were diarrhea (3% vs 0%), nausea (1.5% vs 1%), and vomiting (1.5% vs 0%) in the Otezla group compared to placebo

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions

- Adverse reactions reported in ≥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)

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Otezla® (apremilast) 30mg tablets

#1
PRESCRIBED

For patients starting plaque psoriasis or psoriatic arthritis treatment*

Otezla Clinical Data for Adults with Moderate to Severe Scalp Psoriasis[1,2]

Otezla® (apremilast) 30mg tablets

OTEZLA
A FIRST STEP TO SYSTEMIC THERAPY

PROVEN RESULTS FOR MODERATE TO SEVERE PLAQUE PSORIASIS OF THE SCALP[1,2]

- Otezla® (apremilast) patients were 3x as likely to achieve scalp improvement, an ScPGA response score of 0 (clear) or 1 (almost clear) with at least a 2-point reduction from baseline vs placebo (43.3% vs 13.7%, respectively; *P*<0.0001) at week 16 (primary endpoint)

Consider Otezla when your adult patients with moderate to severe scalp psoriasis complain of itch[1,2]

- 47.1% of patients taking Otezla demonstrated ≥4-point improvement from baseline in scalp itch NRS scores vs placebo at week 16 (21.1%) (*P*<0.0001), with achievement of response seen as early as 2 weeks (26.1% vs 11.5%, respectively; *P*=0.0025)
- 45.5% of patients taking Otezla demonstrated ≥4-point improvement from baseline in whole body itch NRS scores vs placebo at week 16 (22.5%) (*P*<0.0001), with achievement of response seen as early as 2 weeks (20.5% vs 3.5%, respectively; *P*<0.0001)

Otezla has an established safety profile[1,2]

- The most common adverse reactions (≥5%) from weeks 0 to 16 included diarrhea, nausea, headache, and vomiting

Otezla: an oral non-biologic with no label-required lab monitoring[1]

*Data includes information derived from Symphony Health Solutions. The unprojected claims dataset covers 60%-70% of all commercially insured claims, Medicare, Medicaid, and cash prescriptions. Patients are classified as New to Brand (NTB) if over the last 12-month period the patient had not been on their current "brand." NTB includes patients who have had no prior treatment history as well as patients who switched to a brand for the first time from a different prior therapy [April 2014 through May 2020].[3]

IMPORTANT SAFETY INFORMATION (cont'd)

Use in Specific Populations

- Pregnancy: Otezla has not been studied in pregnant women. Advise pregnant women of the potential risk of fetal loss. Consider pregnancy planning and prevention for females of reproductive potential. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Otezla during pregnancy. Information about the registry can be obtained by calling 1-877-311-8972 or visiting https://mothertobaby.org/ongoing-study/otezla/
- Lactation: There are no data on the presence of apremilast or its metabolites in human milk, the effects of apremilast on the breastfed infant, or the effects of the drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Otezla and any potential adverse effects on the breastfed child from Otezla or from the underlying maternal condition
- 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

References: 1. Otezla [package insert]. Thousand Oaks, CA: Amgen Inc. **2.** Van Voorhees A, Gold LS, Lebwohl M, et al. Efficacy and safety of apremilast in patients with moderate to severe plaque psoriasis of the scalp: results of a phase 3b, multicenter, randomized, placebo-controlled, double-blind study. *J Am Acad Dermatol.* 2020. doi:10.1016/j.jaad.2020.01.072 **3.** Data on file, Amgen Inc. **4.** Crowley J. Scalp psoriasis: an overview of the disease and available therapies. *J Drugs Dermatol.* 2010;9(8):912-918. **5.** Van de Kerkhof PC, Reich K, Kavanaugh A, et al. Physician perspectives in the management of psoriasis and psoriatic arthritis: results from the population-based Multinational Assessment of Psoriasis and Psoriatic Arthritis survey. *J Eur Acad Dermatol Venereol.* 2015;29(10):2002-2010. **6.** Thaçi D, Kimball A, Foley P, et al. Apremilast, an oral phosphodiesterase 4 inhibitor, improves patient-reported outcomes in the treatment of moderate to severe psoriasis: results of two phase III randomized, controlled trials. *J Eur Acad Dermatol Venereol.* 2017;31(3):498-506.

Please see Full Prescribing Information here.

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