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10;75(3):499-510


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Disclosure of Interests: Jordi Gratacos-Masmith Speakers bureau: MSD, Pfizer, Abbvie, Janssen Cilag, Novartis, Celgene y Lilly, Consultant of: MSD, Pfizer, Abbvie, Janssen Cilag, Novartis, Celgene y Lilly, José Luis Alvarez Vega Speakers bureau: Abbvie, Amgen, MSD, Lilly, Roche, Estee, UCB, Menarini, Pfizer, GSK, BMS, Janssen, Novartis, Gb., Grant/research support from: Abbvie, Amgen, MSD, Lilly, Roche, Estee, UCB, Menarini, Pfizer, GSK, BMS, Janssen, Novartis, Gb., Emma Beltrán Speakers bureau: Abbvie, Bristol, Celgene, Janssen, Lilly, MSD, Novartis, Pfizer, Roche and UCB, Consultant of: Abbvie, Bristol, Celgene, Janssen, Lilly, MSD, Novartis, Pfizer, Roche and UCB, ANA URRUTICOECHEA-ARANA: None declared., Abad Hernández Speakers bureau: MSD, Pfizer, Kern, Novartis, Biogen, Sandoz, Amgen, Sanofi, Lilly, Roche and Janssen-Cilag, Consultant of: MSD, Abbvie, Pfizer, Kern, Novartis, Biogen, Sandoz, Amgen, Sanofi, Lilly, Roche and Janssen-Cilag, Inmaculada Ros Consultant of: Abbvie, Amgen, Grant/research support from: MSD, Roche, Novartis, Lilly, Pfizer, Amgen, Eva Pascual Shareholder of: Amgen, Employee of: Amgen, Juan Carlos Torres Speakers bureau: Abbvie, Amgen, Lilly, Novartis, Janssen, Pfizer, Consultant of: Amgen, Lilly, Novartis, Janssen, Pfizer, Grant/research support from: Amgen, Lilly, Novartis, Janssen, Pfizer.

Disclosure of Interests: None declared.

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AB0544 EFFICACY AND SAFETY OF TILDRAKIZUMAB IN PATIENTS WITH AND WITHOUT METABOLIC SYNDROME: 5-YEAR POOLED DATA FROM reSURFACE 1 AND reSURFACE 2

A. B. Gottlieb1, N. Mehta2, A. Menter3, A. M. Mendelsohn1, R. Rozzo5, M. Lebwohl.1 1Icahn School of Medicine at Mount Sinai, Department of Dermatology, New York, United States of America; 2National Institutes of Health, National Heart, Lung and Blood Institute, Bethesda, United States of America; 3Baylor Scott & White, Division of Dermatology, Dallas, United States of America; 4Texas A&M College of Medicine, Division of Dermatology, Dallas, United States of America; 5Sun Pharmaceutical Industries, Inc., Medical Affairs, Princeton, United States of America

Background: Patients with psoriasis and metabolic syndrome (Mets) may have reduced absolute Psoriasis Area and Severity Index (PASI) response and long-term drug survival. Tildrakizumab is approved for the treatment of moderate to severe plaque psoriasis in the US, EU, Australia, and Japan. Efficacy and safety of tildrakizumab were previously shown to be comparable in patients with vs. without Mets at 1 and 3 years of treatment.1

Objectives: This post hoc analysis of pooled data from reSURFACE 1 and reSURFACE 2 (NCT01722331/NCT01729794) assessed tildrakizumab efficacy and safety through up to 5 years of treatment in patients with psoriasis with and without Mets.

Methods: reSURFACE 1 and 2 were 3-part, double-blind, randomized controlled phase 3 trials with long-term extensions evaluating tildrakizumab 100 or 200mg monotherapy at Weeks 0, 4, and every 12 weeks thereafter in adults with moderate to severe plaque psoriasis.2 Patients who achieved ≥50% improvement from baseline PASI score (PASI 50 response) at both week 28 and at the end of the phase 3 studies could enter the long-term extension studies continuing the same dose of tildrakizumab.3 This post hoc analysis reports results from a pooled data analysis through up to 5 years of tildrakizumab exposure from patients with and without Mets by National Cholesterol Education Program-Adult Treatment Panel III criteria who continuously received the same dose of tildrakizumab throughout the base studies and entered the long-term extensions. Efficacy was assessed as change from baseline PASI score; missing data were handled using multiple

AB0543 CHARACTERISTICS AND TREATMENT CHANGES IN PATIENTS WITH PSORIATIC ARTHRITIS SEEN IN A COMBINED DERMATOLOGY-RHEUMATOLOGY CLINIC

K. Klaydianou1, M. Stavropoulou1, P. Panagakis1, M. Papoutsakis1, A. Panagiotopoulos3, C. Koutsianas1, A. Stratigos4, D. Rigopoulos1, D. Vassilopoulos1. 1Hippokration General Hospital, 2nd Department of Medicine and Laboratory, Clinical Immunology - Rheumatology Unit, National and Kapodistrian University of Athens, School of Medicine, Athens, Greece; 2National and Kapodistrian University of Athens, School of Medicine, Athens, Greece; 3National and Kapodistrian University of Athens, School of Medicine, Athens, Greece; 4Department of Dermatology, School of Medicine, National and Kapodistrian University of Athens, Greece.

Background: Data on patients with Psoriasis (Pso) referred to a combined Der-
matology-Rheumatology outpatient Clinic (Derm-Rheum) with suspected psori-
atic arthritis (PsA) is limited.

Objectives: To assess patient characteristics and treatment changes in PsA
cases referred to a Derm-Rheum Clinic.

Methods: Prospective study of Pso patients referred to a combined Derm-
Rheum Clinic from February 2018 to June 2020 in a Tertiary University
Hospital.

Results: Among 151 patients with Pso referred to the Clinic, 129 (85%) with a
final diagnosis of PsA were included. In 73% of patients (n=94) PsA was diag-
nosed there for the 1st time. 56% were females with a mean age of 55 years and
a median disease duration of 14.2 years. At initial evaluation, 95% had peripheral
arthritis, 45% nail involvement, 23% axial involvement, 12% enthesis and 6%
dactylitis with a median DAPSA score of 20.5 and PASI score of 1.6, respective-
ly. 31% of the patients were not receiving any systemic treatment, 45% were on bi-
ologics (30% as monotherapy, 15% in combination with non-biologics), 29% were
on non-biologics (14% as monotherapy, 15% in combination with biologics or
targeted synthetic agents) and 10% were on targeted synthetic (ts) agents. At last
visit (median follow-up: 15 months) only 8% did not receive any systemic therapy
(p<0.001 compared to 1st visit), 62% were on biologics (39% monotherapy – 23% in combination with non-biologics, p<0.001), 46% were on non-biologics (20% as monotherapy – 26% in combination with biologics or ts agents, p=0.01) and 10% of the patients were on aprimilast. The median DAPSA and PASI scores at last visit were 5.3 and 0, respectively.

Conclusion: About 2/3 of patients with Pso referred to a combined Derm-
Rheum Clinic with suspicious musculoskeletal complaints were diagnosed for
the 1st time as PsA. During follow-up the percentage of PsA patients who started
or continued systemic therapy significantly increased with significant improve-
ment of disease activity indices. These data emphasize the value of combined
Derm - Rheum Clinics for earlier diagnosis and more efficacious treatment of
PsA patients.

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Disclosure of Interests: None declared.

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imputation. Safety was assessed from exposure adjusted incidence rates of serious adverse events (SAEs) and treatment-emergent AEs of special interest.

**Results:** Analyses included 70/265 patients with/without MetS receiving tildrakizumab 100 mg and 64/241 patients with/without MetS receiving tildrakizumab 200 mg. Median percentage change from baseline PASI score is shown in Figure 1. Among patients with/without MetS receiving tildrakizumab 100 mg, 78.6%/87.9% achieved PASI 75, 57.1%/83.8% achieved PASI 90, and 25.7%/32.5% achieved PASI 100 response at week 24; the PASI 75, PASI 90, and PASI 100 response rates at week 24 in patients with/without MetS receiving tildrakizumab 200 mg were 76.6%/85.1%, 46.9%/81.4%, and 26.6%/36.5%, respectively. Safety outcomes over the 5-year extension period were consistent with the known safety profile of tildrakizumab. Rates of SAEs were <8.5 per 100 patient-years among all patients, and there were no new safety signals in patients with vs without MetS (Table 1).

### Table 1. SAEs and TEAEs of special interest by MetS status through up to 5 years of tildrakizumab exposure

<table>
<thead>
<tr>
<th>MetS Status</th>
<th>TIL 100 mg</th>
<th>TIL 200 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without MetS</td>
<td>With MetS</td>
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</tr>
<tr>
<td>n=265</td>
<td>n=70</td>
<td>n=241</td>
</tr>
<tr>
<td>(EAIR per 100 PY)</td>
<td>53 (4.61)</td>
<td>22 (17.23)</td>
</tr>
<tr>
<td>TEAEs of special interest</td>
<td>24 (2.09)</td>
<td>6 (1.97)</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>10 (0.87)</td>
<td>2 (0.66)</td>
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<td>Maligatoracies</td>
<td>5 (0.44)</td>
<td>1 (0.33)</td>
</tr>
<tr>
<td>Nonmelanoma skin cancer</td>
<td>3 (0.26)</td>
<td>1 (0.33)</td>
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<tr>
<td>Confirmed extended MACE</td>
<td>3 (0.26)</td>
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Incidence rates reported as events per 100 PY. Excluding nonmelanoma and melanoma skin cancer. Not considered of special interest in the extension study. AE, adverse event; EAIR, exposure adjusted incidence rate; MACE, major adverse cardiovascular events; MetS, metabolic syndrome; PY, patient-years; SAE, serious AE; TEAE, treatment-emergent AE; TIL, tildrakizumab.

**Discussion of Interests:** Alice B Gottlieb Shareholder of: Xbiotech (only stock options, which she has not used); Consultant of: Anaptys Bio, Avotres Therapeutics; Beiersdorf; Boehringer Ingelheim; Bristol-Myers Squibb Co.; Eli Lilly; Janssen; LEO Pharma; Novartis; Sun Pharmaceutical Industries, Inc.; UCB; and Xbiotech. Grant/research support from: Boehringer Ingelheim; Janssen; Novartis; Sun Pharmaceutical Industries, Inc.; UCB; and Xbiotech. Nehal Mehta Grant/research support from: Grants to the NIH from AbbVie, Celgene, Janssen, and Novartis.; Employee of: Full-time employee of the US government., Alan Menter Speakers bureau: AbbVie, Abbott Labs, Amgen, Anacor, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen Biotech, LEO Pharma, Merck & Co., Novartis, Sienna, and UCB.; Consultant of: AbbVie, Abbott Labs, Amgen, Anacor, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen Biotech, LEO Pharma, Merck & Co., Novartis, Sienna, and UCB.; Grant/research support from: AbbVie, Abbott Labs, Amgen, Anacor, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen

**Conclusion:** The efficacy and safety of tildrakizumab were maintained in patients with and without MetS following 5 years of treatment.

**References:**

1. Lebwohl, M et al. JAAAD. 2020;S0190-9622(20)32637-2.

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