IXEKIZUMAB, WITH OR WITHOUT CONCOMITANT MTX TREATMENT: IMPROVES THE SIGNS AND SYMPTOMS OF PSA FOR UP TO 52 WEEKS OF TREATMENT

Bernard Combe†, Tsuen-Fang Tsai‡, Satish Odah*, J. Eugene Hufstutter*, Aubrey Trevelin Sprabery*, Chen-Yen Lin†, So Young Park*, Matthew Hufford‡.

Background: Ixekizumab (IXE) is a high affinity monoclonal antibody selectively targeting interleukin (IL)-17A. It was previously demonstrated that IXE, with or without concomitant methotrexate (MTX), was superior to placebo (PBO) in improving the signs and symptoms of patients with psoriatic arthritis (PsA) for up to 24 weeks.1,2

Objectives: To evaluate the efficacy of IXE, with or without continuous concomitant MTX, for up to 52 weeks of treatment in patients with active PsA.

Methods: Patients with active PsA who were biologic naïve (SPIRIT-P1, NCT01695239) or had prior inadequate response or intolerance to tumour necrosis factor inhibitors (SPIRIT-P2; NCT02349295) were randomised to PBO (N=224), 80 mg IXE every 4 weeks (IXE4W, N=229) or every 2 weeks (IXE2W, N=226), after a 160 mg starting dose. In this post-hoc analysis, efficacy was assessed up to Week 52 for the following two subgroups: (i) patients who were treated with IXE as monotherapy i.e. no concomitant conventional disease-modifying anti-therapeutic drugs and (ii) patients who received constant dose of MTX from Week 0 to 52. Patients who had MTX dose change were excluded. Efficacy outcome measurements included American College of Rheumatology (ACR) 20/50/70 responses, minimal disease activity (MDA), and disease activity in psoriatic arthritis (DAPSA) low disease activity (LDA) (score ≤ 14). Patients who discontinued from treatment before Week 52 were included in the analysis. Missing values were imputed using non-responder imputation. All analyses were done post-hoc.

Results: Among patients randomised to IXE at Week 0, 177 (38.9%) patients were treated with IXE monotherapy while 183 (40.2%) patients received constant dose of MTX up to Week 52. The average MTX dose was 15.7 mg/week and 16.0 mg/week for IXE4W and IXE2W, respectively. Week 52 results are presented in Table 1. At Week 52, similar results were observed between the two groups of patients for the different disease activity measures (ACR, MDA, and DAPSA LDA) and there was also a trend for a numerical higher proportion of patients achieving ACR responses with IXE monotherapy compared to patients with concomitant MTX use. Over time (Weeks 0-52), ACR 20, 50, and 70 response rates increased from baseline and were largely similar between the two subgroups (data not shown).

Conclusion: In this post-hoc analysis, IXE treatment showed sustained efficacy in patients with PsA up to one year of treatment, with or without concomitant MTX therapy.

REFERENCES

Table 1. Efficacy Outcomes at Week 52

<table>
<thead>
<tr>
<th>Concomitant Medication: None (N=95) MTX (N=83)</th>
<th>IXE4W</th>
<th>IXE2W</th>
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</thead>
<tbody>
<tr>
<td>ACR 20</td>
<td>66.3%</td>
<td>55.3%</td>
</tr>
<tr>
<td>ACR 50</td>
<td>48.4%</td>
<td>39.8%</td>
</tr>
<tr>
<td>ACR 70</td>
<td>35.8%</td>
<td>27.1%</td>
</tr>
<tr>
<td>DAPSA LDA*</td>
<td>52.6%</td>
<td>39.7%</td>
</tr>
<tr>
<td>MDA</td>
<td>38.3%</td>
<td>35.3%</td>
</tr>
</tbody>
</table>

* score ≤ 14

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So Young Park Employee of: Eli Lilly and Company, Matthew Hufford Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Matteson Arthritis and Rheumatism Center, National Institutes of Health, Merrill Swigg, Eli Lilly, Janssen, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Consultant for: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Speakers bureau: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer Inc, Roche, Sanofi, UCB

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MILD COGNITIVE IMPAIRMENT IN PSORIATIC ARTHRITIS: PREVALENCE AND ASSOCIATED FACTORS

Marco Di Carlo1, Andrea Becciolini2, Antonella Incorvaia1, Giacomo Beci1, Martina Bigioggero2, Ennio Giulio Favalli2, Fausto Salaffi1,1, 1Rheumatological Clinic, Dipartimento di Scienze Cliniche e Molecolari – Università Politecnica delle Marche, Jesi, Italy; 2Gaetano Pini–CTO Institute, Department of Rheumatology, Milan, Italy

Background: A growing body of data demonstrated that systemic inflammation is a predisposing condition for developing cognitive impairment. Different studies highlighted that psoriasis (PsO), a systemic chronic inflammatory disorder, is associated with cognitive impairment. No data are available regarding psoriatic arthritis (PsA) and is present in a relative young age. MCI occurrence is associated with parents/patients. Treatment should be adapted according to the diverse clinical picture of psoriatic arthritis (PsA) suggests the need to identify suitable therapies to address the different combinations of clinical manifestations and comorbidities. The current treatment paradigms recommend early diagnosis and treatment, and a strategic, target orientated approach, aiming at a low disease activity status. The introduction of new treatment modalities highlighted the need for guidelines to prioritize these options for doctors and patients.

Objective: To develop an evidence-based recommendation for the management and treatment of PsA. The management paradigm should cover all domains of psoriatic disease and provide a stepwise tailored treatment options giving clear advice on treatment from the initial diagnosis, including inclusion/exclusion criteria for treatment, monitoring requirements and how to quantify response to treatment.

Methods: A Steering Committee formulated a set of overarching principles for the management of PsA based on evidence derived from a systematic literature review. These were subsequently discussed, amended and voted on by a Task Force of 20 rheumatologists, dermatologists and patient research partners. Using the nominal group technique and Delphi method, 7 domains were identified (peripheral arthritis, axial disease, enthesitis, dactylitis, skin and nails as well as comorbidities including uveitis). A multidisciplinary, evidence- and consensus-based treatment recommendations for PsA were developed for each of the domains based on three consensus discussions. A set of recommendations for a sequential DMARD/biologic treatment algorithm for patients with PsA was also set.

Results: Literature review provided evidence regarding an optimised domain specific, treat-to-target approach to management. The guidelines addressed both drug and non-drug interventions. 20-statements regarding diagnosis, disease activity scoring, US/MRI scanning, and drug therapy were generated. Percentage of positive votes ranged between 86-100%; whereas mean±SD level of agreement was 9.6+0.3.

Conclusion: Although not predominantly of rheumatological interest, the MCI presence should be carried out in all patients with PsA.

References

Disclosure of Interests: None declared


MAKING THE NEXT STEPS IN PSORIATIC ARTHRITIS MANAGEMENT: DOMAIN DRIVEN, TREAT-TO-TARGET, TAILORED MANAGEMENT APPROACH


1Darent Valley Hospital, Rheumatology, Dartford, United Kingdom; 2Tanta University School of Medicine, Rheumatology and Rehabilitation, Tanta, Egypt; 3Benha University school of medicine, Rheumatology and Rehabilitation, Benha, Egypt; 4Zagazig University school of medicine, Rheumatology and Rehabilitation, Zagazig, Egypt; 5Ain Shams University School of medicine, Rheumatology and Rehabilitation, Cairo, Egypt; 6Suez canal university, Rheumatology and Rehabilitation, Ismailia, Egypt; 7Cairo University school of medicine, Rheumatology and Rehabilitation, Cairo, Egypt; 8Assiut University, school of medicine, Rheumatology and Rehabilitation, Assiut, Egypt; 9Alexandria University, school of medicine, Ophthalmology, Alexandria, Egypt; 10Ain Shams University school of medicine, Community and Public Health, Cairo, Egypt

Background: The diverse clinical picture of psoriatic arthritis (PsA) suggests the need to identify suitable therapies to address the different combinations of clinical manifestations and comorbidities. The current treatment paradigms recommend early diagnosis and treatment, and a strategic, target orientated approach, aiming at a low disease activity status. The introduction of new treatment modalities highlighted the need for guidelines to prioritize these options for doctors and patients.

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Conclusion: Although no clear correlation exists between joint inflammation and the skin in every patient, the skin and joint aspects of the disease often must be treated simultaneously. Treatment recommendations for the cardinal physical manifestations of PsA were developed based on a literature review and consensus between rheumatologists, dermatologists and patients. It is anticipated that periodic updates will take place using this framework as new data become available.

Disclosure of Interests: None declared


TAILORED MANAGEMENT APPROACH

S Volunteers: None declared, Antonella Incorvaia: None declared, giacomo beci: None declared, Martina Bigioggero: None declared, Ennio Giulio Favalli: None declared, Fausto Salaffi: Grant/research support from: AbbVie, Roche, Novartis, BMS, Pfizer, Sanofi, Speakers bureau: AbbVie, Roche, Novartis, Pfizer, Sanofi, BMS
