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PATROCINADO POR: AstraZeneca · Gebro Pharma · Lilly A MEDICINE COMPANY

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VASCULITIS, MIOPATÍAS Y OTRAS CONECTIVOPATÍAS

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1124: Comparative Effectiveness of Tocilizumab and Tumor Necrosis Factor Inhibitors in Takayasu's Arteritis: Age-Related Differences in Treatment Response

Kaitlin Quinn et al. Bethesda, MD



1124: Comparative Effectiveness of Tocilizumab and Tumor Necrosis Factor Inhibitors in Takayasu's Arteritis: Age-Related Differences in Treatment Response

Objective

- To compare treatment responses to TNF inhibitors (TNFi) and tocilizumab (TCZ) and evaluate age-associated differences in response

Methods

- 151 patients with TAK from two independent cohorts.
- 129 received TNFi and 56 received TCZ.
- Propensity score matching performed as a sensitivity analysis to address confounding by indication.

Results

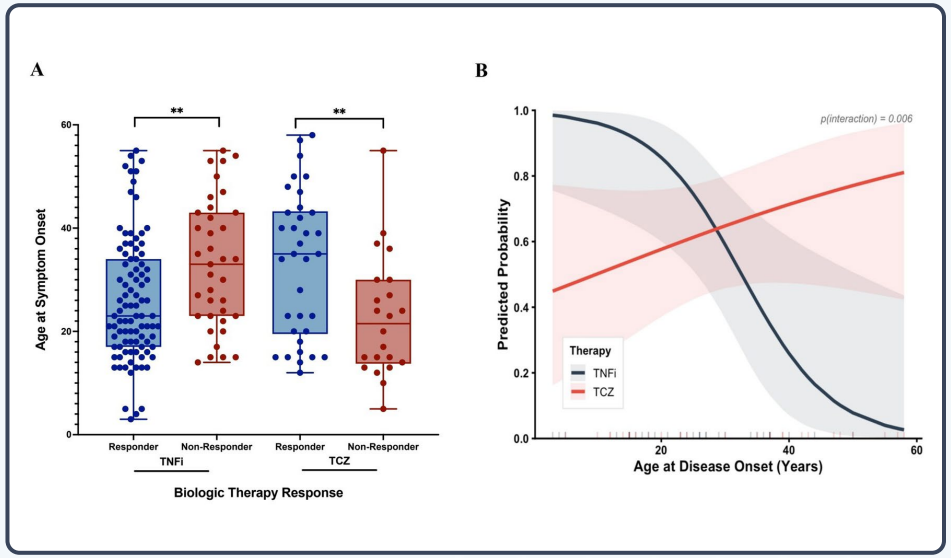
- Similar clinical response rates: TNFi 72.1% vs TCZ 60.7% ($p = 0.17$).
- No significant differences in PGA, ESR, CRP, or FDG-PET outcomes.
- Switching to an alternate TNFi or between TNFi and TCZ resulted in response in 31/33 patients (94%).

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Results (Age-Related Differences in Treatment Response)

- TNFi responders: younger median age at onset than non-responders (23 vs 33.5 years; p = 0.0039).
- TCZ responders: older age at onset than non-responders (35 vs 21.5 years; p = 0.0043).
- Increasing age at onset was associated with greater odds of response to TCZ relative to TNFi (interaction OR 1.19; 95% CI 1.07–1.37; p = 0.006).



Conclusion

- Younger age at disease onset was associated with TNFi response
- Older age at disease onset was associated with TCZ response.
- Patients who do not respond to one biologic class often benefit from an alternative biologic strategy.

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1145: Secukinumab Reduces Glucocorticoid Associated Toxicity in Patients with Recently Relapsed Polymyalgia Rheumatica: Results of Phase 3 REPLENISH Trial

John Stone et al. Boston, MA

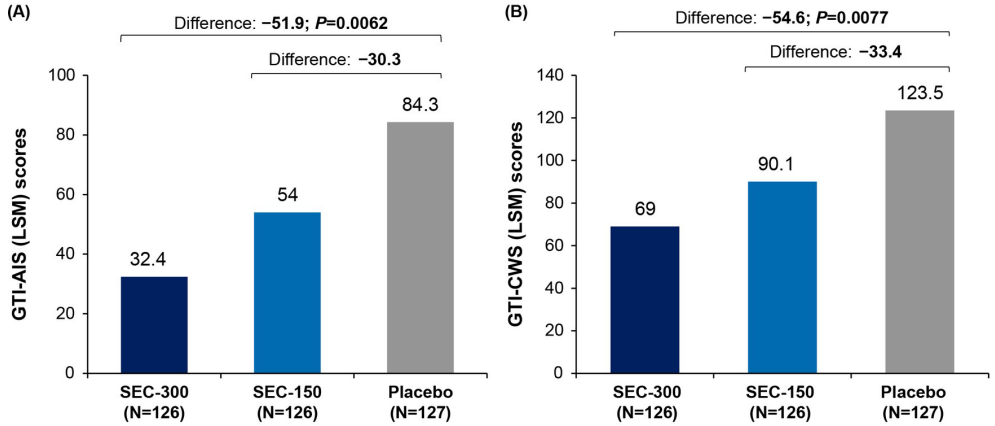


1145: Secukinumab Reduces Glucocorticoid Associated Toxicity in Patients with Recently Relapsed Polymyalgia Rheumatica: Results of Phase 3 REPLENISH Trial

Methods

- Phase 3, randomized, double-blind, placebo-controlled trial in patients aged ≥50 years with recently relapsed PMR.
- SEC 300 mg (n=126), SEC 150 mg (n=126), or placebo (n=127) over 52 weeks, each with a 24week prednisone taper.
- GC toxicity assessed using glucocorticoid toxicity index (GTI) aggregate improvement score (AIS) and GTI-cumulative worsening score (CWS) at Week 52.

Figure 1. Glucocorticoid toxicity at Week 52: GTI- AIS (A) and GTI-CWS (B)



P-values presented are not adjusted for multiple testing.
The GTI-AIS and GTI-CWS score excluding BMD is presented. Lower scores equate to low toxicity. AIS, Aggregate Improvement Score; BMD, bone mineral density; CI, confidence interval; CWS, Cumulative Worsening Score; GTI, Glucocorticoid Toxicity Index; LSM, least squares mean; SEC-150, secukinumab 150 mg; SEC-300, secukinumab 300 mg.

Results

- Both SEC arms showed less GC toxicity vs placebo at Week 52.
- GTI-AIS: 32.4 (SEC-300), 54.0 (SEC-150) vs 84.3 (PBO); p=0.0062 for SEC-300 vs PBO.
- GTI-CWS: 69.0 (SEC-300), 90.1 (SEC-150) vs 123.5 (PBO); p=0.0077 for SEC-300 vs PBO.

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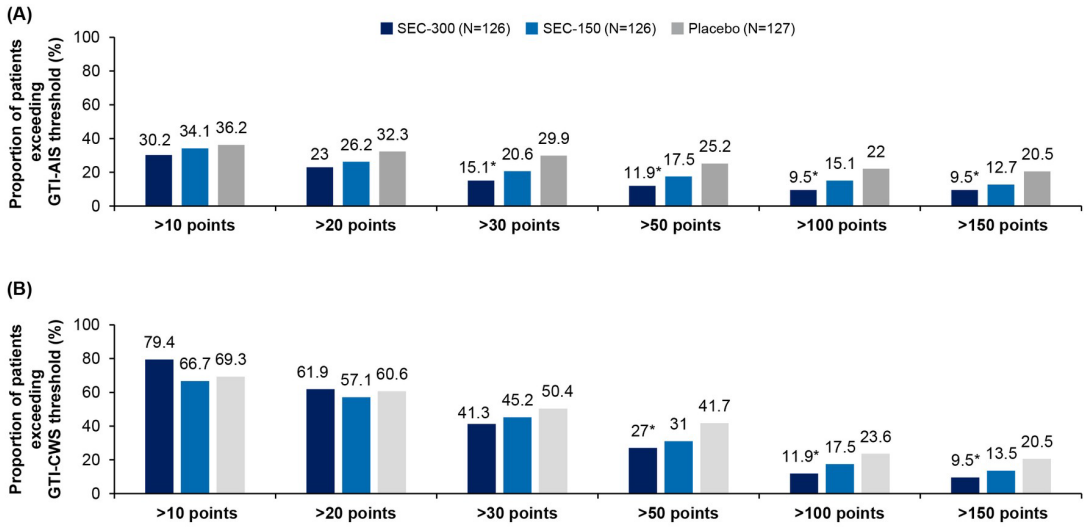
Results

- Both SEC arms demonstrated consistently lower values vs PBO across all GTI domains, including BMI, glucose metabolism, blood pressure, hyperlipidemia, steroid myopathy, skin toxicity, neuropsychiatric toxicity, and infection.
- SEC-300 was associated with improvement over baseline in BMI and neuropsychiatric toxicity.
- Fewer SEC-300-treated patients exceeded GTI thresholds of >50, >100 and >150 points vs PBO ($p<0.05$).

Conclusion

- SEC was associated with less GC toxicity vs placebo at Week 52, supporting consideration of IL17A inhibition as an effective GC-sparing strategy that mitigates GC-associated toxicity in patients with PMR.

Figure 3. Proportion of patients exceeding the GTI-AIS (A) and GTI-CWS (B) (excluding BMD domain) thresholds



*$P<0.05$. P-values are based on chi-square test comparing each treatment arm to placebo Comparision was done at week 52 at each threshold.

AIS, Aggregate Improvement Score; BMD, bone mineral density; BMI, body mass index; CWS, Cumulative Worsening Score; GTI, Glucocorticoid Toxicity Index; SEC-150, secukinumab 150 mg; SEC-300, secukinumab 300 mg.

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1586: Brepocitinib Demonstrates Consistent Clinical Responses Along With Reduced Oral Corticosteroid Use in Dermatomyositis Patients With Interstitial Lung Disease: Results From the Phase 3 VALOR Trial

Aravind Menon et al. Charleston, SC



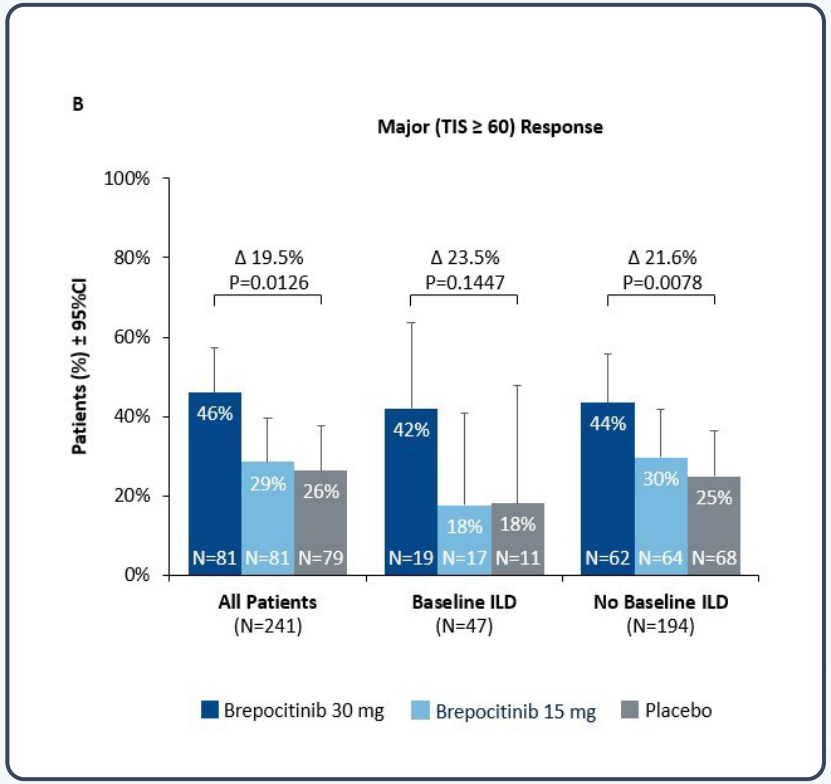
1586: Brepocitinib Demonstrates Consistent Clinical Responses Along With Reduced Oral Corticosteroid Use in Dermatomyositis Patients With Interstitial Lung Disease: Results From the Phase 3 VALOR Trial

Objetives:

- Brepocitinib (an oral, selective TYK2/JAK1 inhibitor) demonstrated eficcacy in a global Phase 3 trial (VALOR) that enrolled adult DM patients.
- This post hoc analysis examines clinical responses among participants with and without baseline ILD

Methods

- Phase 3, 52-week, double-blind, placebo-controlled trial.
- 241 patients with DM randomized 1:1:1 to brepocitinib 30 mg, 15 mg, or placebo once daily.
- 47 patients (20%) had baseline ILD.
- Post hoc subgroup analysis based on baseline ILD status.



Results

- Brepocitinib 30 mg demonstrated consistent efficacy on global myositis disease activity endpoints at Week 52 in patients with and without baseline ILD.

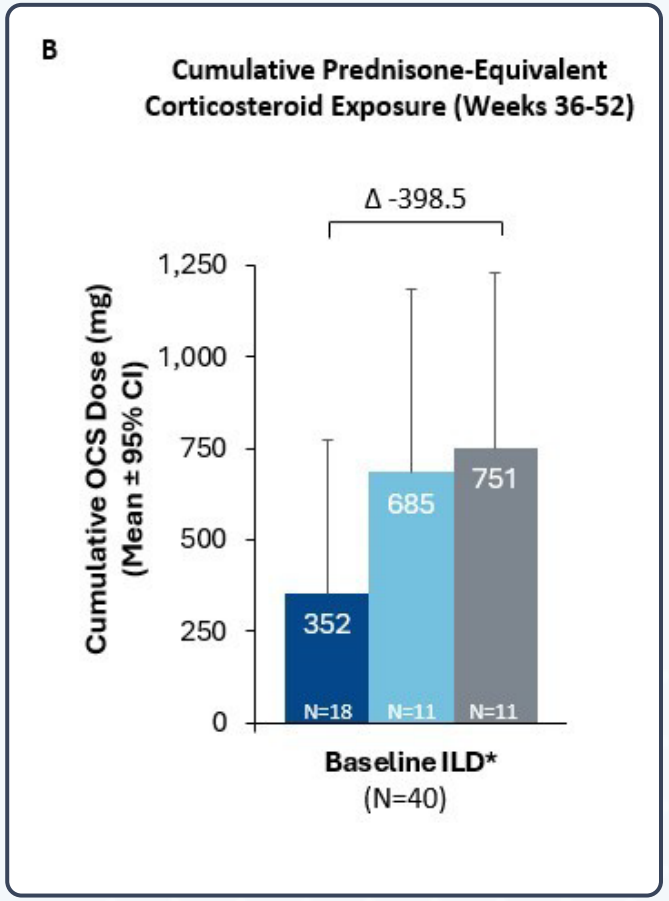
1586: Brepocitinib Demonstrates Consistent Clinical Responses Along With Reduced Oral Corticosteroid Use in Dermatomyositis Patients With Interstitial Lung Disease: Results From the Phase 3 VALOR Trial

Results (Corticosteroid Sparing and Pulmonary Outcomes in DM-ILD)

- Brepocitinib 30 mg was associated with clinically meaningful steroid sparing vs placebo.
- TIS ≥40 with minimal or no OCS (≤2.5 mg/day): 47% (brepocitinib 30 mg) vs 9% (placebo); p=0.0370.
- Cumulative OCS exposure (Weeks 36–52): 352 mg vs 751 mg, respectively.
- Improvements in EMGA Lung-VAS were observed.
- FVC remained stable in all treatment groups over 52 weeks (median change: 0%, +1.0%, and −3.0% for brepocitinib 30 mg, 15 mg, and placebo, respectively.

Conclusion

- Brepocitinib 30 mg was associated with consistent efficacy among DM patients with and without baseline ILD, with similar pulmonary outcomes despite substant ially reduced corticosteroid use compared to placebo.



Aravind Menon et al. Charleston, SC

1892: Clinical Characteristics of Flares of Giant Cell Arteritis: Two-Year Outcomes From the SELECT-GCA Phase 3 Trial

Christian Dejaco et al. Brunico, Italy



1892: Clinical Characteristics of Flares of Giant Cell Arteritis: Two-Year Outcomes From the SELECT-GCA Phase 3 Trial

Objective

- To describe the clinical characteristics of patients with GCA who achieved sustained remission from weeks 28 to 52 in period 1 and experienced a flare in period 2 of the SELECT-GCA trial.

Methods

- Phase 3, randomized, multicenter, double-blind, PBO-controlled trial.
- Period 1 (52 weeks): UPA 15 mg + 26-week GC taper, UPA 7.5 mg + 26-week GC taper, or PBO + 52-week GC taper.
- Period 2 (52 weeks): Patients who achieved sustained remission for ≥24 consecutive weeks were rerandomized (2:1) to continue UPA or switch to PBO.
- Present analysis: UPA15/UPA15 vs UPA15/PBO, with no GC treatment at period 2 entry.

Results

- Flares: 6.0% (4/67) vs 55.9% (19/34) (UPA15/UPA15 vs UPA15/PBO).

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1892: Clinical Characteristics of Flares of Giant Cell Arteritis: Two-Year Outcomes From the SELECT-GCA Phase 3 Trial

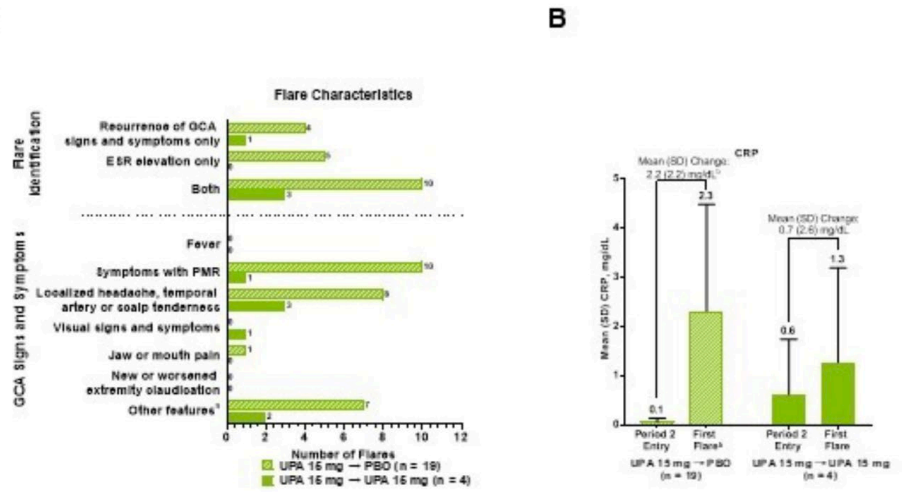
Results (Flare Characteristics)

- Severe flares: 25.0% vs 42.1%.
- Initial GC dose to treat first flare: 9.4 vs 26.3 mg.
- CRP increase: 0.7 vs 2.2 mg/dL.
- ESR increase: 26.0 vs 53.6 mm/h.

Conclusions

- Continuing UPA 15 mg for up to 2 years resulted in fewer and less severe flares than switching to PBO.
- ESR and CRP remained informative for flare detection.

Figure 1. (A) Flare Characteristics and (B) Change in CRP Levels From the Period 2 Entry to First Flare



CRP, C-reactive protein; ESR, erythrocyte sedimentation rate; GCA, giant cell arteritis; PBO, placebo; PMR, polymyalgia rheumatica; UPA, upadacitinib; UPA15→PBO, randomized to UPA 15 mg in study period 1 and switch to PBO in period 2; UPA15→UPA15, randomized to UPA 15 mg in study period 1 and continued UPA 15 mg in period 2.

Figures report data for patients with GCA who achieved remission during study period 1 and experienced a flare in period 2.

[a]Other features were determined by the investigator and included elevated markers of inflammation, characteristic imaging findings, and nonspecific (fatigue in 1 patient).

[b]n = 14.

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