

the GCA cohort vs 36.3 (± 107.2) days in the GnP cohort ($p < 0.001$). Although the mean (SD) daily dose of GC (prednisone equivalent) was similar in both cohorts (27.6 [± 28.20] vs 27.7 [± 25.18] mg), the mean (SD) cumulative GC dose was significantly higher in the GCA cohort than the GnP cohort (3503.0 (± 4622.6) mg vs 503.7 (± 1593.51) mg; $p < 0.001$). This indicates that GCA pts had chronic GC exposure over the study period while GnP pts likely utilized higher dose GC burst therapy less frequently. The number of incident complications associated with GC use were significantly greater in the GCA cohort, and included hypertension, diabetes, skin toxicity, infections, neuropsychiatric effects, gastrointestinal complications, ocular effects, and cardiovascular disease ($p < 0.05$).

Conclusion: The overall GC burden in pts with GCA is significantly higher than the general population and may result in downstream complications related to GC exposure. The incidence of GC-related complications was statistically significantly higher in GCA pts compared with GnP pts, even with a short duration of GC use. The early onset of these complications may be a significant contributor to long-term healthcare costs in GCA pts.

Acknowledgments: Study and medical writing (provided by Gauri Saal, MA, Economics, Prime, Knutsford, UK, under the direction of authors) were funded by Sanofi, Inc.

Disclosure of Interests: Rajeshwari Puneekar Shareholder of: Sanofi, Employee of: Sanofi, Patrick LaFontaine Shareholder of: Sanofi, Employee of: Sanofi, John H. Stone Grant/research support from: Roche, Consultant of: Roche

DOI: 10.1136/annrheumdis-2020-eular.4263

OP0276

CLINICAL PATTERNS AND FOLLOW-UP OF INFLAMMATORY ARTHRITIS AND OTHER IMMUNE-RELATED ADVERSE EVENTS INDUCED BY CHECKPOINT INHIBITORS. A MULTICENTER STUDY

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Background: Immune checkpoint inhibitors (ICI), such as anti-CTLA-4 and anti-PD1/PD-L1 monoclonal antibodies, have produced impressive clinical results in different types of cancer. However, immune-related adverse events (irAEs) may develop a wide spectrum of disabling syndromes. Knowledge of different rheumatic irAEs induced by ICI is increasing over the last years, however clinical patterns, time to onset of different irAEs according to treatment and follow-up are less well known.

Objectives: To describe different clinical patterns of rheumatic irAEs induced by ICI and their rheumatic and oncologic outcomes.

Methods: We included consecutive patients with rheumatic irAEs from 3 different referral centers in Barcelona with special emphasis in articular irAEs. Four main clinical syndromes were identified: inflammatory arthritis (IA), non-inflammatory arthralgias (NIA), psoriatic arthritis (PsA)-like and polymyalgia (PMR)-like. We conducted a baseline visit and then follow-up in order to determine their clinical pattern, treatment response and outcome. Longitudinal visits were done from January 2017 to January 2020. Patients with other non-articular diagnosis were not included in the follow-up analysis.

Results: We included 55 patients. A total of 34 patients were male (61.8%) with a mean age of 65.0 \pm 11.4 years. Oncologic underlying diagnosis was lung carcinoma in 24 (43.6%) patients, followed by melanoma in 17 (29%), urothelial cancer in 4 (7.3%), breast in 2 (3.6%) and 2 (3.6%) acute myeloid leukemia among others. Seven (12.7%) patients received ICI as combined therapy. Different ICI were used including: Pembrolizumab in 21 (38.2%), Nivolumab 13 (23.6%), Atezolizumab 6 (10.9%), Nivolumab + ipilimumab 5 (9.0%), Durvalumab 3 (5.5%), Pembrolizumab + epacadostat in 2 (3.6%), 2 anti TIM3, Atezolizumab+ Ibasertib, Avelumab and Ipilimumab in one case each. 12 out of 55 patients had an underlying rheumatic disease before ICI treatment. Eleven patients developed other irAEs before or at the same time as rheumatic syndromes (mainly colitis and thyroiditis). Main rheumatic irAE included: IA in 23 (41.8%), NIA in 16 (29.1%), PsA-like in 6 (10.9%), PMR-like in 5 (9.1%) among others. Time from ICI to irAEs was 8.3 \pm 8.4 months (mo). irAE presented earlier in patients with combined ICI therapy than in patients with monotherapy (6.5 \pm 4.0 vs 8.6 \pm 8.9 mo, $p = \text{NS}$, Figure 1A). Time (in mo) from ICI initiation to irAE onset was different according to treatments. For Nivolumab 10.0 \pm 10.6, Anti TIM3 10.0 \pm 1.4, Durvalumab 9.0 \pm 2.0, Ipilimumab 7.98 \pm 9.21, Pembrolizumab 7.28 \pm 7.53, Avelumab 6.0 and Atezolizumab 4.4 \pm 5.38 mo (Figure 1B). Time from ICI initiation and onset also differs among rheumatic irAEs (Figure 2). Mean time follow-up was 13.4 \pm 10.9 mo. At the last visit, 45% were under GC, mean dose of 3.6 mg/d (range 0-40). DMARD were needed in 15% of patients (6 patients MTX, 1 with LEF and 1 SFZ). At the last visit, 11 (22.9%) patients remain with persistent arthritis, 25% intermittent flares and 52% had a self-limited pattern. Regarding

oncologic outcome, 30.2% were on remission, 30.2% in partial response and 39.6% with tumor progression. Eleven (20%) of patients died.

Conclusion: We described different clinical patterns according treatment and irAEs. Combined ICI therapy and patients treated with Atezolizumab had earlier onset of symptoms. Vasculitis and PMR-like syndromes appear in earlier phases. After a mean follow-up of around 1 year, one-quarter of the patients remain with persistent arthritis and 15% require DMARD therapy.

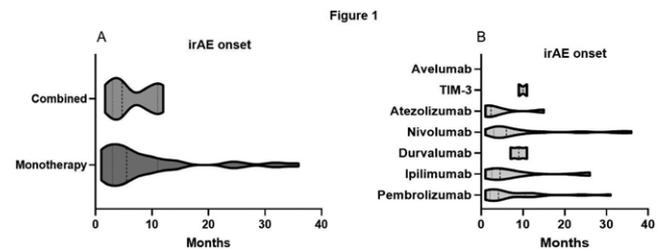
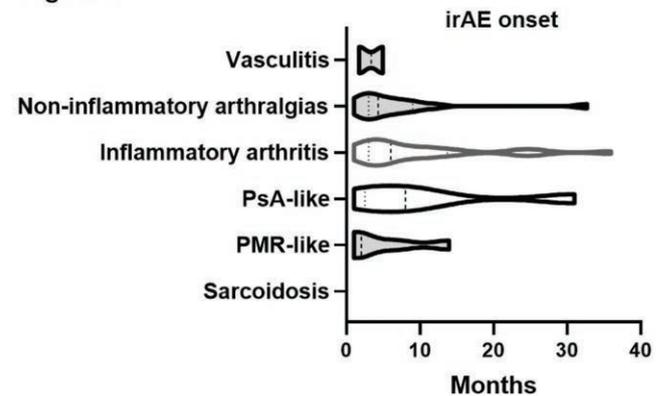


Figure 2



Disclosure of Interests: Jose A. Gómez-Puerta Speakers bureau: Abbvie, BMS, GSK, Lilly, Pfizer, Roche, Carolina Perez-García: None declared, David Lobo Prat: None declared, Roberto Gumucio: None declared, Fabiola Ojeda: None declared, Ana Milena Millán Arciniegas: None declared, Sebastian Rodríguez García: None declared, Virginia Ruiz Speakers bureau: Lilly, Pfizer, Héctor Corominas Speakers bureau: Abbvie, Lilly, Pfizer, Roche

DOI: 10.1136/annrheumdis-2020-eular.4308

OP0277

AURORA PHASE 3 STUDY DEMONSTRATES VOCLOSPORIN STATISTICAL SUPERIORITY OVER STANDARD OF CARE IN LUPUS NEPHRITIS (LN)

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Background: Voclosporin (VCS) is a novel high potency calcineurin inhibitor (CNI) with a favorable metabolic profile and a consistent predictable dose response potentially eliminating the need for therapeutic drug monitoring. LN occurs more frequently and is more severe in Hispanic/Latino ethnicity SLE patients. The recently completed phase 3 AURORA study builds on the favorable efficacy seen in the Phase IIb AURA-LV study in patients with active LN.

Objectives: Document efficacy and safety of VCS vs placebo over one year when used with 2 grams of MMF daily and a rapid steroid taper in patients with active LN.

Methods: AURORA is a Phase III multicenter, randomized, double-blind, placebo-controlled 52-week study of active LN patients. Patients were randomized 1:1 to VCS (23.7 mg BID) or placebo in combination with mycophenolate (MMF, 1 g BID) and rapidly tapered oral steroids. The primary endpoint was renal response (RR) at 52 weeks, defined as UPCR of ≤ 0.5 mg/mg, eGFR ≥ 60 mL/min, or no confirmed decrease from baseline in eGFR of $> 20\%$, presence of sustained, low dose steroids and no administration of rescue medication. Ethnicity subgroup analyses of RR was also undertaken given the higher severity of disease in the Hispanic/Latino LN patients.

Results: There were 357 patients enrolled, 88% female, median age of 31 and 33% of Hispanic/Latino ethnicity. Renal response by intention to

