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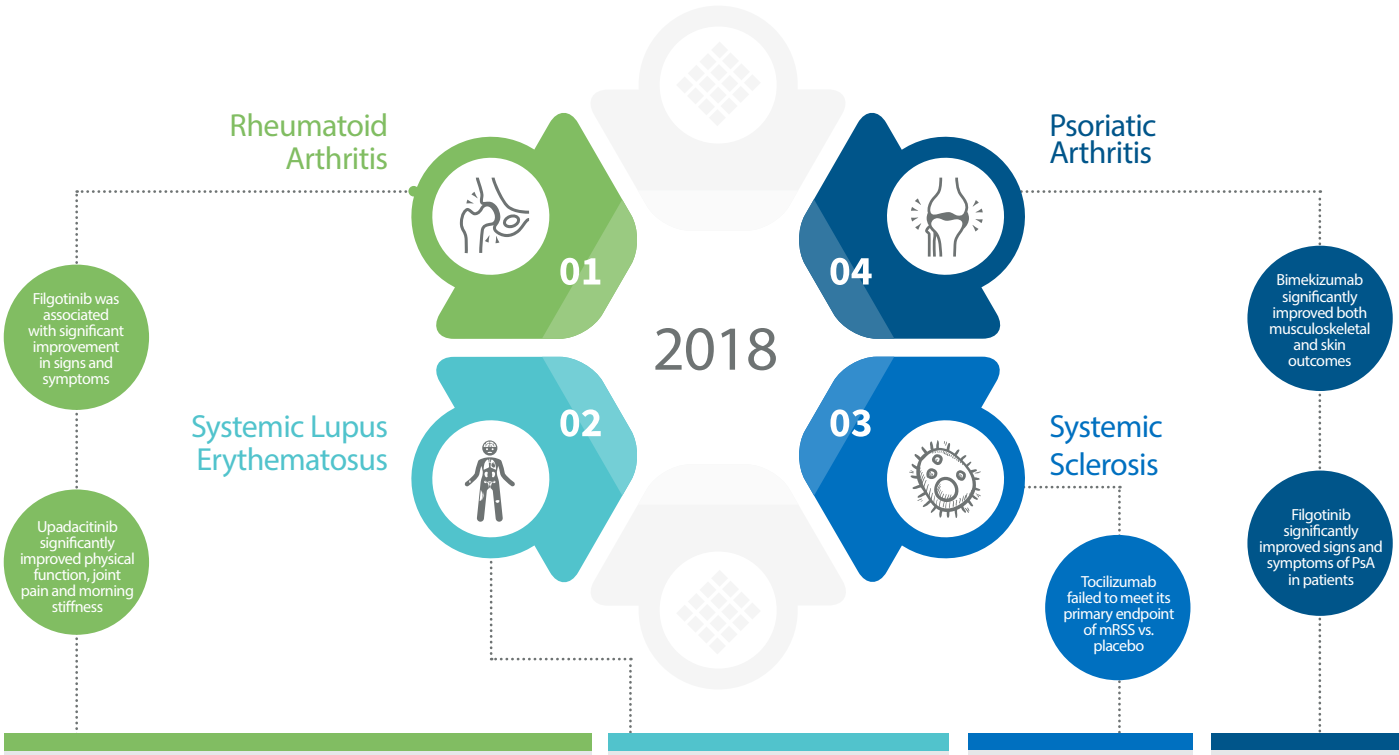
Highlights from 2018 ACR/ARHP Annual Meeting

Updates on drugs under development, new research and recommendations were presented at the ACR/ARHP 2018 Annual Meeting.



RA prevention

High interest in identifying and treating pre-RA or early RA patients, with multiple ongoing RA prevention trials. ACPA positivity has been correlated to development of RA, with higher levels leading to increased risk of developing RA within a shorter period. The B-cell receptor clone test may predict risk for RA and could be an indication for treatment to prevent disease.

Assessment of remission in RA

ACR/ EULAR recommend using Boolean/CDAI/SDAI for assessment of remission instead of DAS28 which overestimates the response.

Filgotinib for RA patients with inadequate response to bDMARDS

In a phase 3 study of patients with moderate to severe RA and inadequate response to bDMARDs, treatment with Filgotinib was associated with significant improvement in signs and symptoms of RA vs. placebo even in patients with ≥ 3 prior bDMARD therapies

- ACR20: ~67% (Filgotinib 200mg) vs. ~32% (placebo) in patients with ≥ 3 prior bDMARD therapies

Peficitinib in combination with MTX

Peficitinib in combination with methotrexate (Phase 3 trial) demonstrated significant clinical improvement and inhibition of radiographic joint damage

- ACR20, 50, and 70 response rates at week 12 were significantly higher among patients treated with peficitinib 100 or 150 mg/day than placebo, at 58.6% and 64.4% versus 21.8%, 29.9% and 46.0% versus 7.6%, and 12.1% and 23.6% versus 2.4%, respectively

JAK inhibitor Upadacitinib

In the Phase 3 'SELECT Monotherapy trial', upadacitinib significantly improved physical function, joint pain and morning stiffness in addition to health-related quality of life versus placebo

Lupus low disease activity score

Currently the end point of remission is not well defined, making treat-to-target challenging. Lupus Low Disease Activity Score (LLDAS) achievement is emerging as a goal for SLE patients. Patients staying longer in LLDAS demonstrate better outcomes.

Baricitinib in SLE

In a Phase 2, randomized, double blind trial, baricitinib an oral JAK 1/2 inhibitor, at 4mg dose was associated with significant clinical improvements on SLEDAI-2K, SRI-4 vs. placebo, however the 2 mg dose did not demonstrate statistically significant improvement

Trial failures

- Lulizumab (anti-CD28 mAb) in a double blind, placebo controlled Phase 2 trial failed to meet its primary and secondary end points
- In a Phase 3 trial, Abatacept when administered over background therapy of mycophenolate and corticosteroids to patients with proliferative Lupus nephritis (class III or IV ± V), failed to meet the primary end point of CRR (complete renal response). However, abatacept treated patients had a rapid and sustained improvement in proteinuria over a period of 3 years. eGFR recovery occurred earlier and improvements in SLE biomarkers were more pronounced in the abatacept arm

Systemic sclerosis

In a Phase 3 study in patients with active SSc, tocilizumab failed to meet its primary endpoint of mRSS vs. placebo, however the change in FVC, favored tocilizumab

Bimekizumab

In a Phase 2b trial, Bimekizumab, a monoclonal antibody that neutralizes both IL-17A and IL-17F, significantly improved both musculoskeletal and skin outcomes among patients with active psoriatic arthritis (at week 24, ACR50 response was achieved in 26.8% of patients who received 16 mg, 41.5% who received 160 mg, 46.3% who received 160 mg after a 320-mg loading dose, and 24.4% who received 320 mg throughout the study vs. 7.1% who received placebo)

Filgotinib

In the Phase2 EQUATOR study, filgotinib significantly improved signs and symptoms of PsA in patients with active disease (ACR20: 80% vs. 33% in placebo)