2016. ADMIRE-CD

Phase 3/Cx601/pCD/ Induct+Maintain

Expanded allogeneic adipose-derived mesenchymal stem cells (Cx601) for complex perianal fistulas in CD: a phase 3 randomised, double-blind controlled trial

Randomized double-blind, parallel-group study in patients with perianal Crohn's disease treatment-refractory with draining complex perianal fistulas.
Excluded recto vaginal fistulas, rectal/anal stenosis, active proctitis, diverting stomas and perianal abscess >2cm.
Non or mild active luminal CD with complex perianal fistulas maximum of 2 internal and 3 external openings, were randomised to: Cx601 added on to standard care or placebo.

Primary outcome: Combined remission at w24, defined as the clinical assessment of closure of all treated external openings that were draining at baseline, and the absence of collections >2 cm of the treated perianal fistulas in at least two of three dimensions, confirmed by masked central MRI

Results:

- A significantly greater proportion of patients treated with Cx601 vs placebo achieved combined remission in the ITT (53 of 107 [50%] vs 36 of 105 [34%], p=0.024) and modified ITT populations (53 of 103 [51%] vs 36 of 101 [36%]; p=0.021).

Conclusions:
Cx601 is an effective and safe treatment for complex perianal fi stulas in patients with CD who did not respond to conventional or biological treatments, or both.

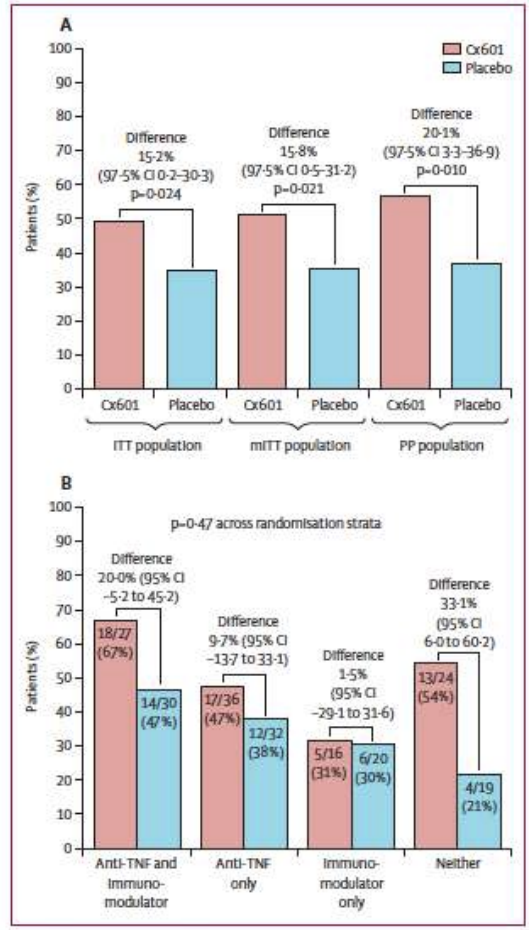

Figure 2: **Primary endpoint**
Combined remission at week 24 in (A) ITT, mITT, and PP populations; and (B) according to randomisation stratification factors (ie, Crohn's disease treatments being received at the time of randomisation) in the mITT population. Cx601=allogeneic, expanded, adipose-derived stem cells. mITT=modified intention to treat. ITT=intention to treat. PP=per protocol. TNF=tumour necrosis factor.

Panés J et al. Lancet. 2016;388 (10051): 1281-1290