2016. ART

OL/Adacolumn/ UC/ Induction

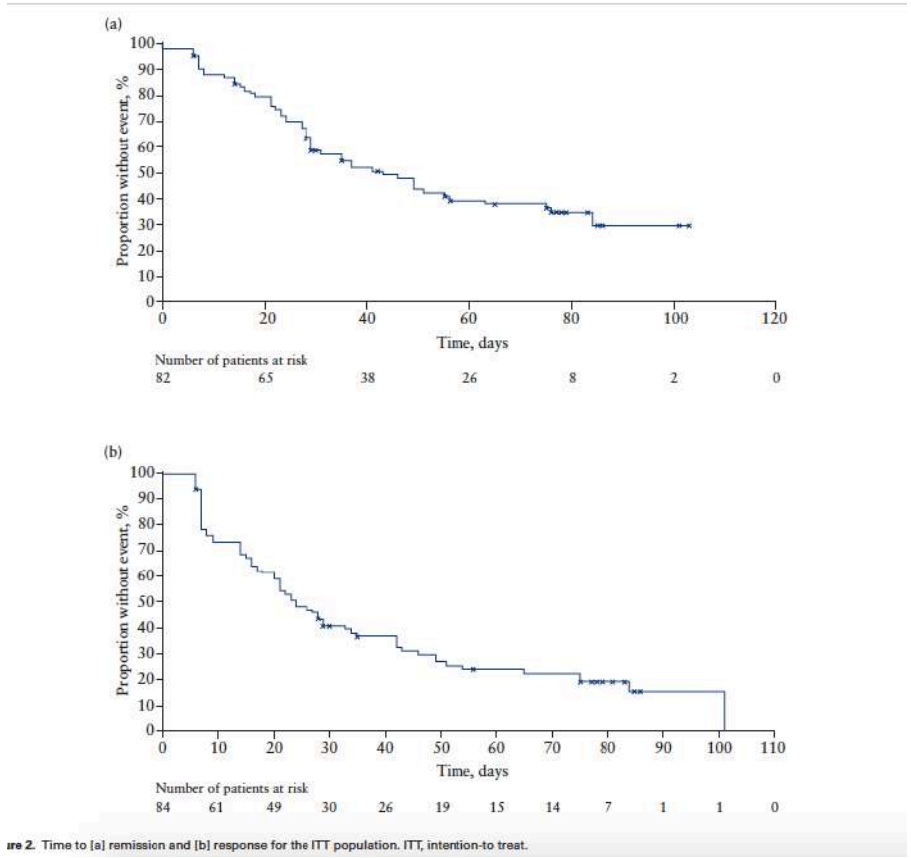
Safety and Efficacy of Granulocyte/Monocyte Apheresis in Steroid Dependent Active UC with Insufficient Response or Intolerance to Immunosuppressants and/ or Biologics [the ART Trial]: 12-week Interim Results

Single-arm, open-label, multicentre trial.
Patients with mod-severe UC steroid dependent with insufficient response to immunosuppresantes &/or biologics.
Once-weekly Adacolumn apheresis over 5 consecutive weeks; this could be extended for up to 10 once-weekly dependent upon treatment response. Other therapies allowed.

Primary endpoints: clinical remission rate [clinical activity index ≤ 4] at Week 12

Results:
- W12 clinical remission: ITT population 39.3% and PP 37.5%.
- W12 clinical response: 56% ITT and 53.1% PP
- W12 steroid free remission: 22.6% ITT and 35.7% PP
- Majority of adverse events were mild-moderate

Conclusion:
At Week 12, Adacolumn provided significant clinical benefit in a large cohort of steroid-dependent ulcerative colitis patients with previous failure to immunosuppressant &/or biologic treatment, with a favourable safety profile. These results are consistent with previous studies and support Adacolumn use in this difficult-to-treat patient subgroup.



re 2. Time to [a] remission and [b] response for the ITT population. ITT, intention-to treat.

Dignass A et al. J Crohns Colitis. 2016; 812-820