Tofacitinib in acute severe ulcerative colitis (TACOS): A randomized controlled trial: Tofacitinib in ASUC

Single center, double blind, placebo controlled trial. Adult patients admitted with acute-severe UC (ASUC) were randomized to receive tofacitinib 10mg q8h or matching placebo for 7 days while continuing IV steroids (hydrocortisone 100mg q6h).

After day 7 the study was unblinded as an open label. All patients received tapering steroids, those in TOFA arm continued on TOFA 10mg BD and the placebo arm on 5ASA +thiopurines,

<u>Primary endpoint:</u> Response to treatment (decline in Lichtiger index >3points) without needing rescue therapy by day 7

## Results: N=104

- At day 7, 83.01% TOFA vs 58.82% placebo, p=0.007 achieved the primary outcome.
- Need for rescue therapy at day 7 was 11.32% TOFA vs 31.37% placebo, OR 0.27, 95%CI 0.09-0.78, p=0.01
- At day 90, cumulative probability of need for rescue therapy at day 90 was 0.13 for those receiving TOFA vs 0.38 placebo, p=0.003

## Conclusion:

In patients with ASUC, combination of tofacitinib and corticosteroids improved treatment responsiveness and decreased the need for rescue therapy.



