TOFACITINIB

2017 OCTAVE 1

RCT / TOFA 10mg BD vs placebo/ Mod-Severe UC/ Induction Conclusion:

In patients with moderately to severely active UC, tofacitinib more effective as induction therapy than placebo.

2017 OCTAVE 2

RCT / TOFA 10mg BD vs placebo/ Mod-Severe UC/ Induction Conclusion:

In patients with moderately to severely active UC, tofacitinib more effective as induction therapy than placebo.

2017 OCTAVE sustain

RCT / TOFA 5mg BD vs 10mg BD vs placebo/ Mod-Severe UC (responders from OCTAVE 1&2)/Maintenance Conclusion:

In patients with moderately to severely active UC, tofacitinib more effective as maintenance therapy than placebo.

2020 OCTAVE OPEN OL/ Tofa dose de-escalation or escalation/ Mod-Severe UC /Maintenance Conclusion:

Following TOFA de-escalation in patients in remission on 10 mg BD,25.4% lost remission by m12. For induction responders who dose-escalated following failure on 5 mg BD, 49.1% achieved remission by m12.

2021 RIVETING

RCT/Tofa de-escalation to 5 mg BD after 2y on 10 mg BD being in stable remission vs continue 10mgBD Conclusion:

Remission at 6m: 77.1% and 90.0% in 5 & 10 mg BID groups, respectively. For those de-escalated, those in deep endoscopic remission & those without prior TNFi failure were more likely to maintain remission.

TOUR

Observ/TOFA/ UC/ induction Conclusion:

Tofacitinib resulted in a rapid and persistent improvement in UC disease activity PROs. The safety findings were consistent with the established safety profile of tofacitinib.