2022. SERENE-CD

Phase 3/ ADA / CD / Induction

High versus standard adalimumab induction dosing regimens in patients with moderately to severely active CD: Results from the SERENE-CD induction study

Double blind RCT induction and maintenance regimens in mod-sev CD patients with: ADA 40 mg/eow (SIR) vs ADA 40 mg/ew (HIR)

- Clinical adjusted (CA) based on symptoms, biomarkers vs TDM (Therapeutic Drug Monitoring) based on symptoms, biomarkers, ADA levels.

- Induction Primary outcome: Remission at w4; endoscopic remission w12; number of adverse events
- Secondary outcomes: Sustained remission; clinical response w4 and endoscopic response w12; remission w12; steroid free remission; endoscopic remission w12; changes in FC, CRP, SES-CD.

Results:
No statistical difference for primary endpoints: clinical remission, endoscopic response/remission, deep remission and steroid free remission.

- CA group CRP level was the main driver of dose change vs ADA level in TDM group.
- The maintenance part of the study is still ongoing

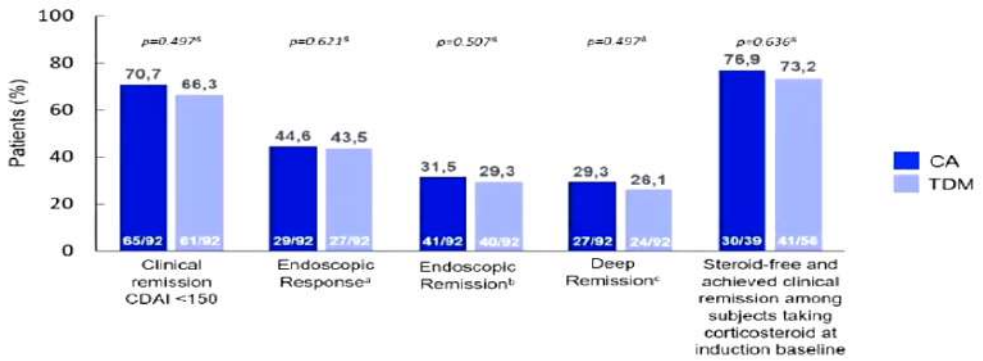
Conclusions:
No differences between CA or TDM regimens with respect to the key exploratory efficacy endpoints. Both dosing regimens were generally well-tolerated with a similar safety profile.

HIR Higher regimen
SIR Standard regimen

INDUCTION

Endpoints	HIR (n=308)	SIR (n=206)	p-value[a]
1. Sustained clinical remission at both Wks 4 and 12, n (%)	119 (38.6)	72 (35.0)	0.305
2. Clinical remission at Wk 4 and endoscopic response at Wk 12, n (%)	67 (21.8	42 (20.4)	0.675
3. Clinical remission at Wk 12, n (%)	192 (62.3)	106 (51.5)	0.008*
4. Proportion of pts taking CS at BL who discontinued CS and achieved clinical remission at Wk 12, n/N (%)	80/153 (52.3)	47/100 (47.0)	0.309
5. Endoscopic remission (SES-CD ≤4 and ≥2-point reduction versus BL, and no subscore >1 in any individual variable) at Wk 12, n (%)	88 (28.6)	54 (26.2)	0.694
12. Clinical response (decrease in CDAI ≥70 points from BL) at Wk 12, n (%)	257 (83.4)	154 (74.8)	0.015*

MAINTENANCE w56



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