LANDOS BIOPHARMA

UEGW PRESENTATION | OCT 2021

Safety, Pharmacokinetics, and Immunological Effects of Omilancor (BT-11) in a Phase 2 Randomized, Double-Blind, Placebo-Controlled Trial of Patients with Ulcerative Colitis

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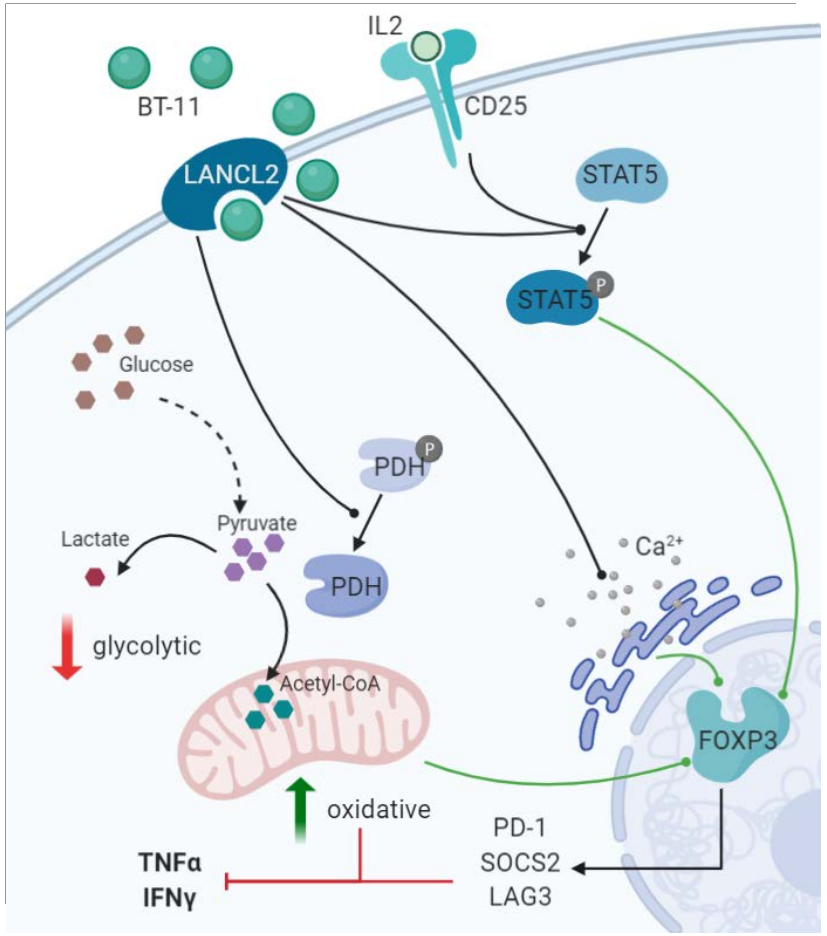
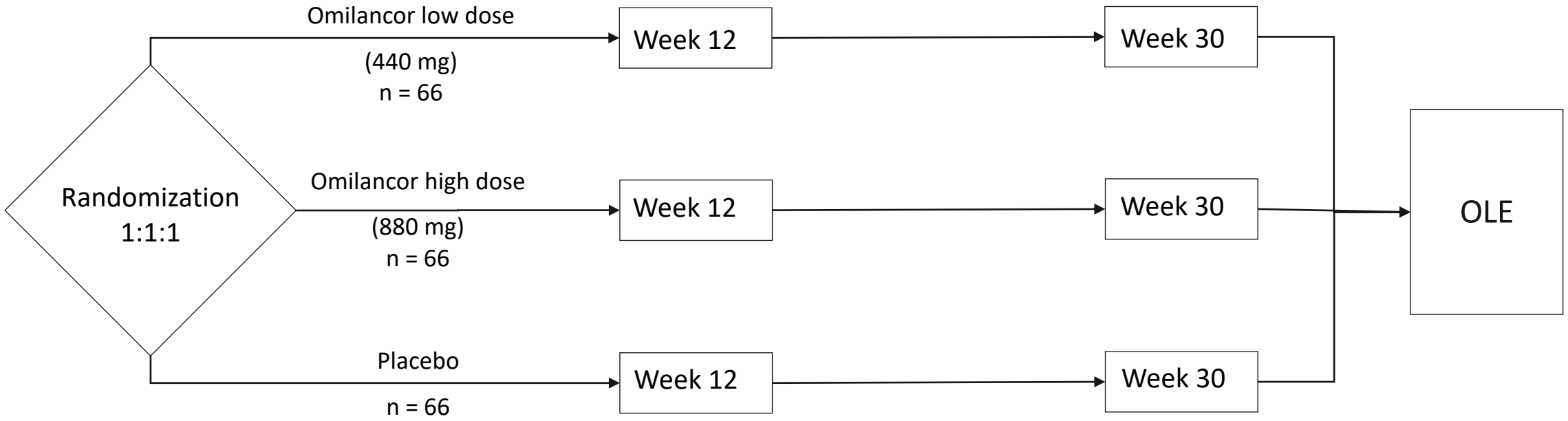
Omilancor Activates Novel Target LANCL2

- Multipronged immunometabolic mechanism of action
  - Supports regulatory T cell (Treg) stability and suppressive effects
  - Decreases production of inflammatory mediators (TNFα, IFNγ, MCP1, IL-6, IL-8)
  - Restores dysregulated metabolism in immune and epithelial cells of the gut



Phase 2 Study of Omilancor in Mild to Moderate UC

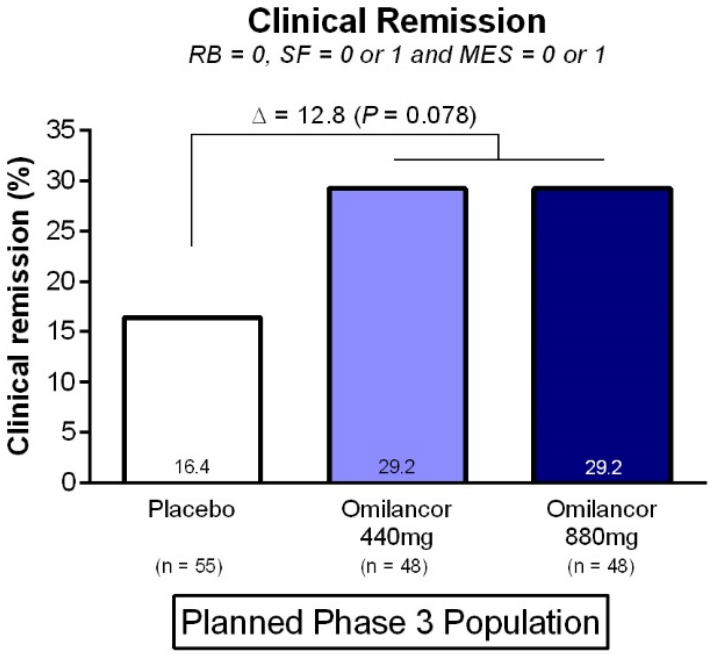


- Primary Objective
- The primary objective of this proof-of-concept study was to establish the efficacy of oral BT-11 in inducing clinical remission at Week 12 in subjects with mild to moderate ulcerative colitis (UC).
- Key Inclusion Criteria
- Male and female subjects with mild to moderate UC defined by a total Mayo Score of 4 to 10 with MES ≥ 2 (confirmed by central reader); 5-aminosalicylates (max 4.8 g/day) and oral corticosteroids (max 20 mg/day prednisone or equivalent) must be stable for the 12-week induction period.

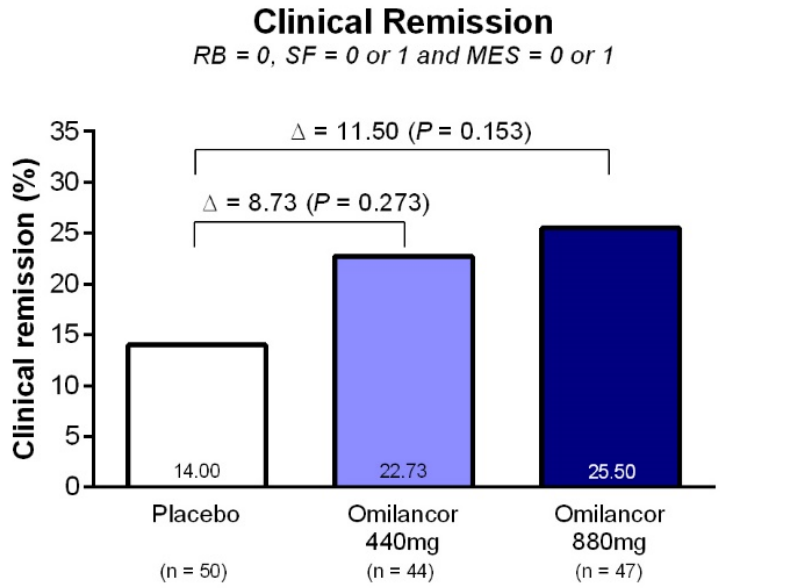
Study Demographics

	Placebo (n = 66)	Omilancor 440 mg (n = 66)	Omilancor 880 mg (n = 66)
Age – yr	43.3	43.1	43.3
Male sex – no. (%)	35 (53.0%)	26 (39.4%)	44 (66.7%)
Baseline Total MCS	7.52	7.15	7.33
Baseline MES	2.53	2.61	2.56
Corticosteroid use at baseline – no. (%)	13 (19.7%)	12 (18.1%)	13 (19.7%)
Previous biologic use – no. (%)	3 (4.5%)	3 (4.5%)	3 (4.5%)

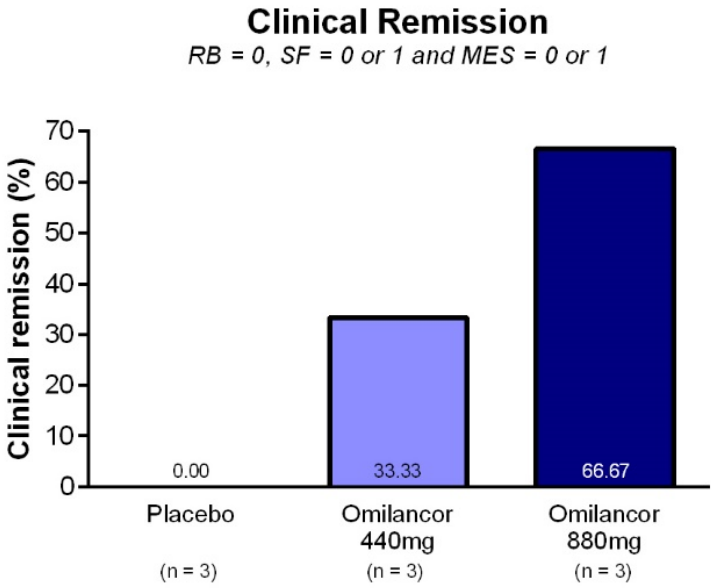
Omilancor induces clinical remission at 440 and 880 mg once daily



Planned Phase 3 Population

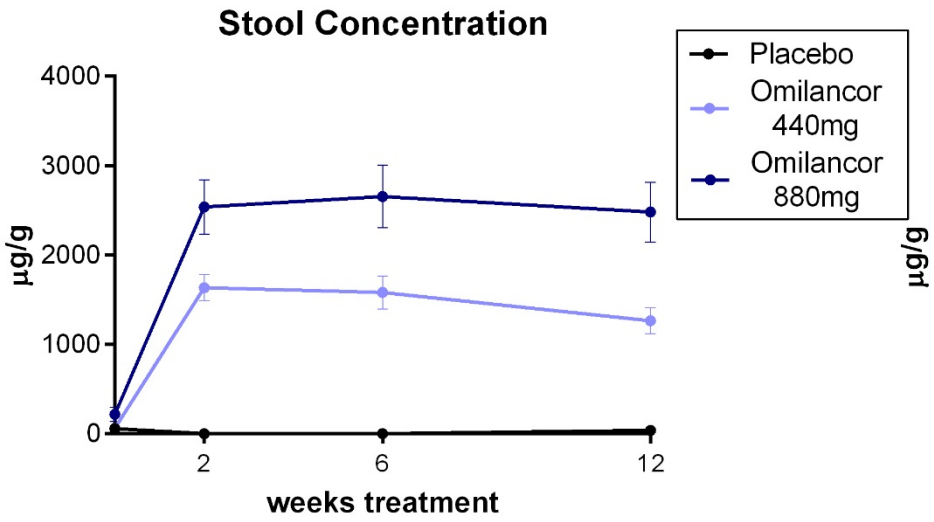


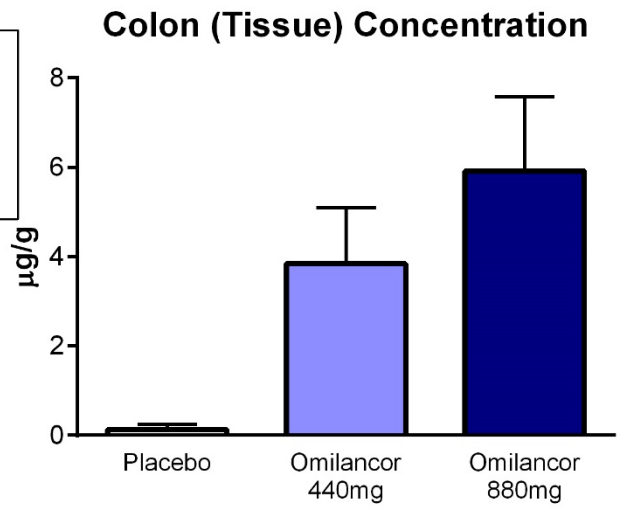
Subjects with total Modified Mayo score ≥ 7 at baseline

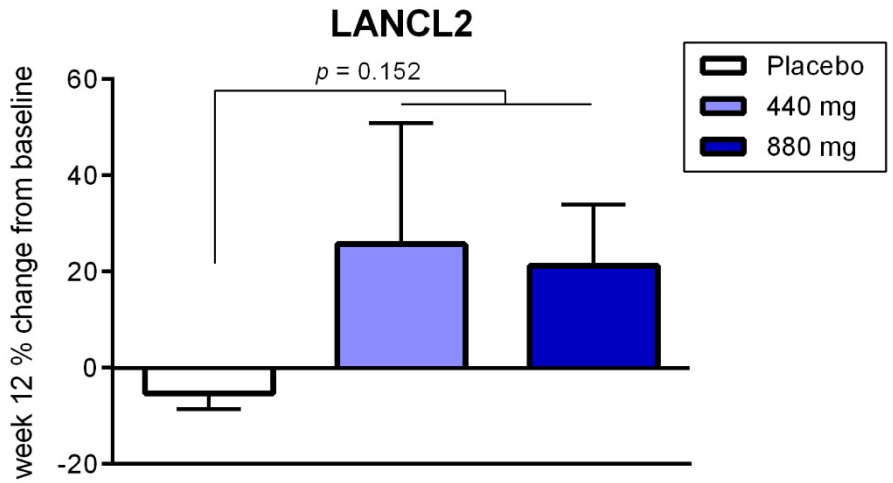


Subjects with previous exposure to biologics

PK Results Validate LANCL2 Target Engagement at both Doses Tested





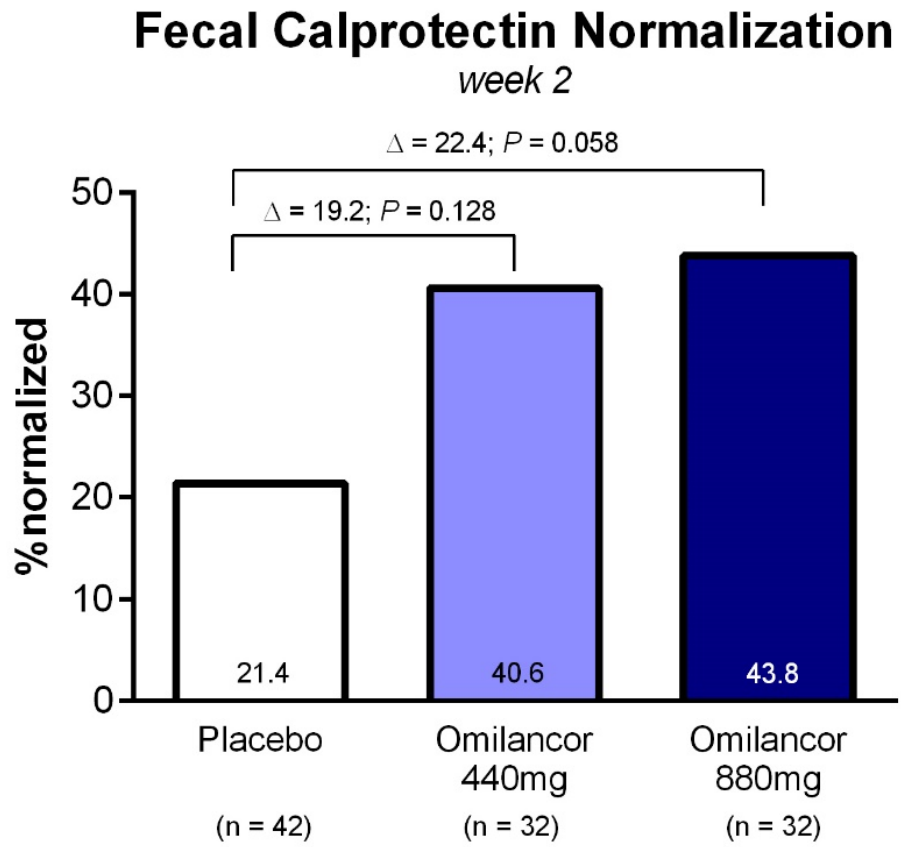


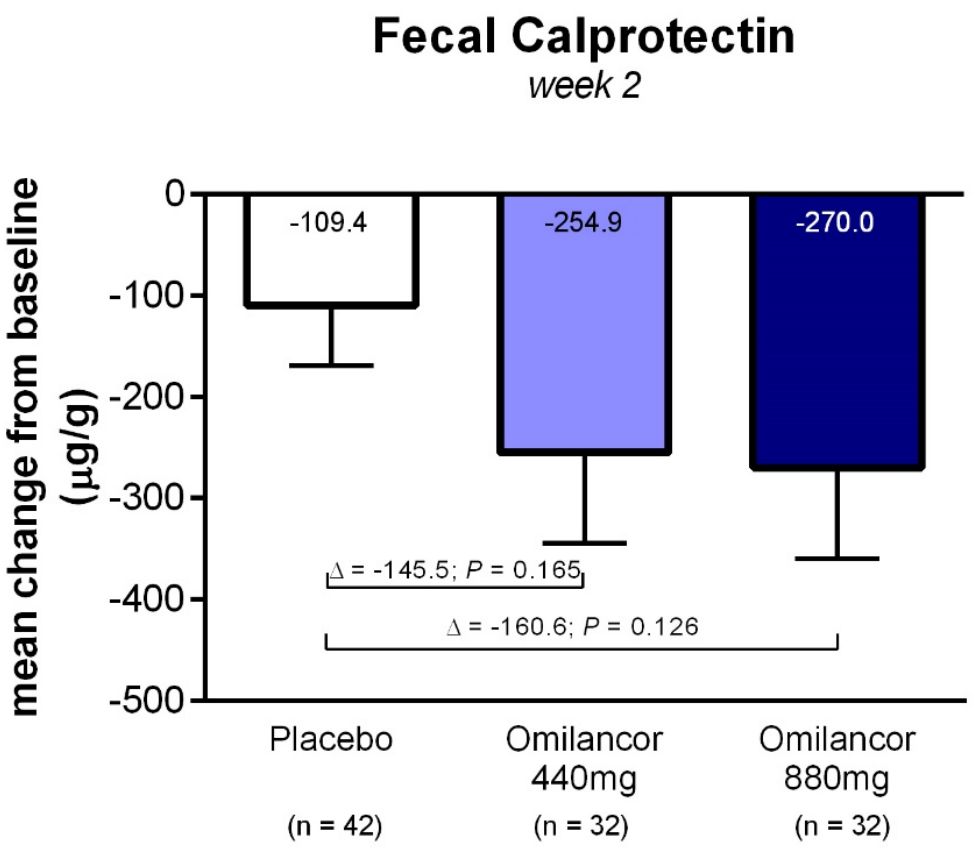
- Omilancor stool concentrations stable between 2 and 12 weeks of dosing
- No significant difference in stool concentrations between UC patients after 12 weeks and healthy volunteers after 7 days
- Stool and tissue concentration scale in a near dose-proportional manner
- 440 and 880 mg doses effectively clear therapeutic threshold, engage LANCL2, and increase LANCL2 expression in the colon

No differences in AE profile observed between omilancor and placebo

	Placebo (n = 66)	Omilancor 440 mg (n = 66)	Omilancor 880 mg (n = 66)
Subjects reporting ≥ 1 AE – no. (%)	20 (30.3%)	18 (27.3%)	20 (30.3%)
Total AEs – possibly related or higher	10	16	11
Total AEs – definitely related	0	0	0
Infections and Infestations	5 (7.6%)	4 (6.1%)	5 (7.6%)
Lymphopenia	1 (1.5%)	0 (0%)	0 (0%)
AEs experienced in ≥ 5% of subjects			
Ulcerative colitis worsening	5 (7.6%)	7 (10.6%)	7 (10.6%)

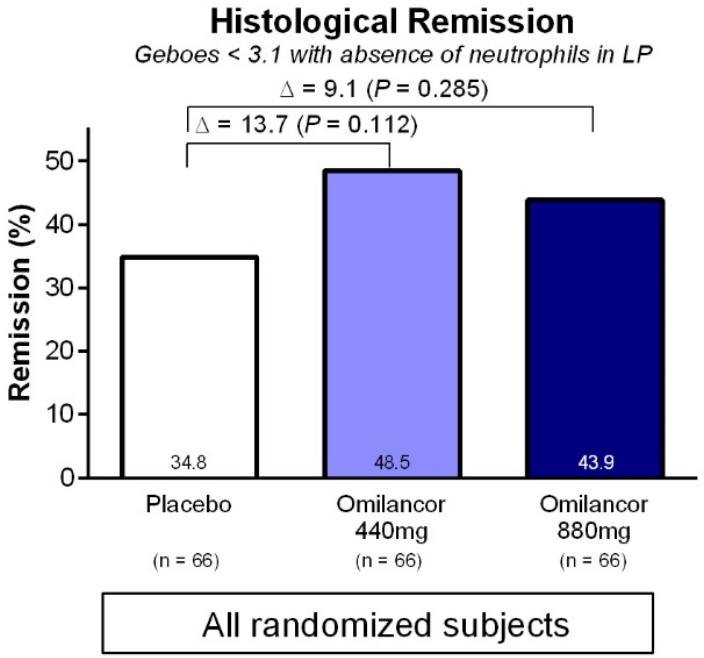
Omilancor promotes FCP normalization after 2 weeks of treatment



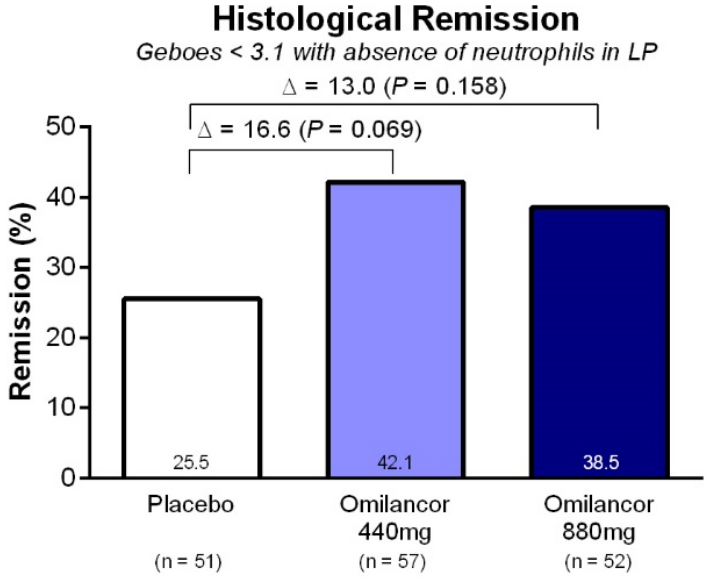


Fecal calprotectin considered normalized at < 250 ug/g
Inclusive of subjects with abnormal levels at baseline

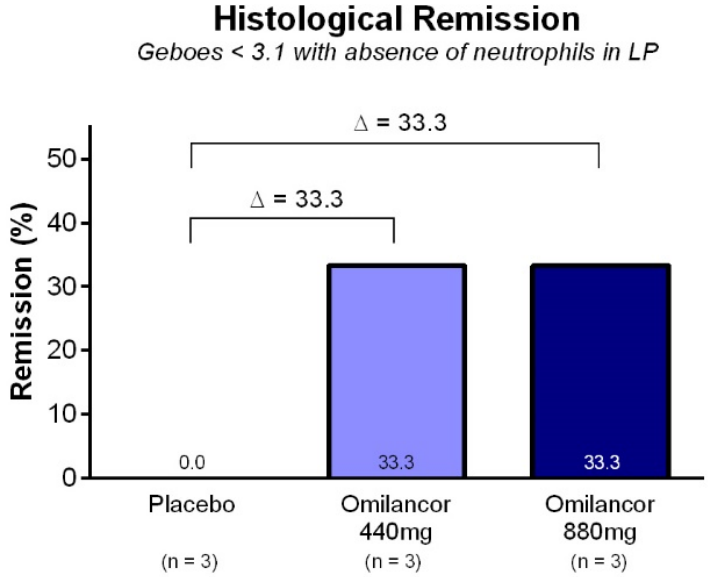
Omilancor induces histological remission



All randomized subjects

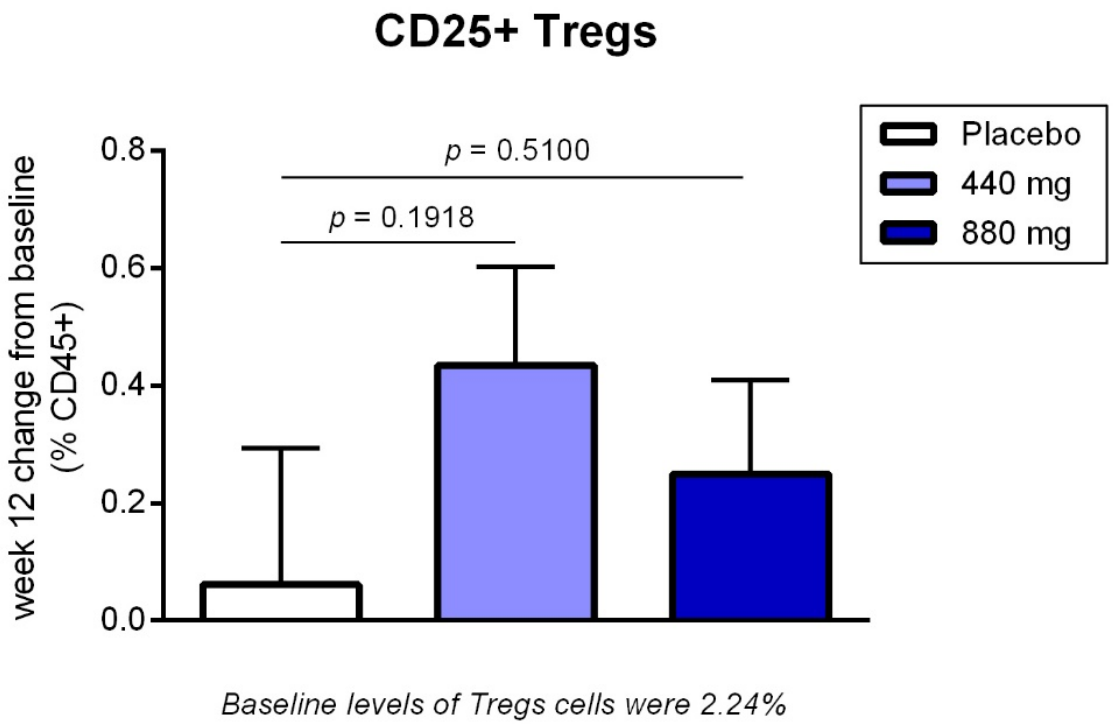


Subjects with increased chronic inflammatory infiltrate or higher at baseline

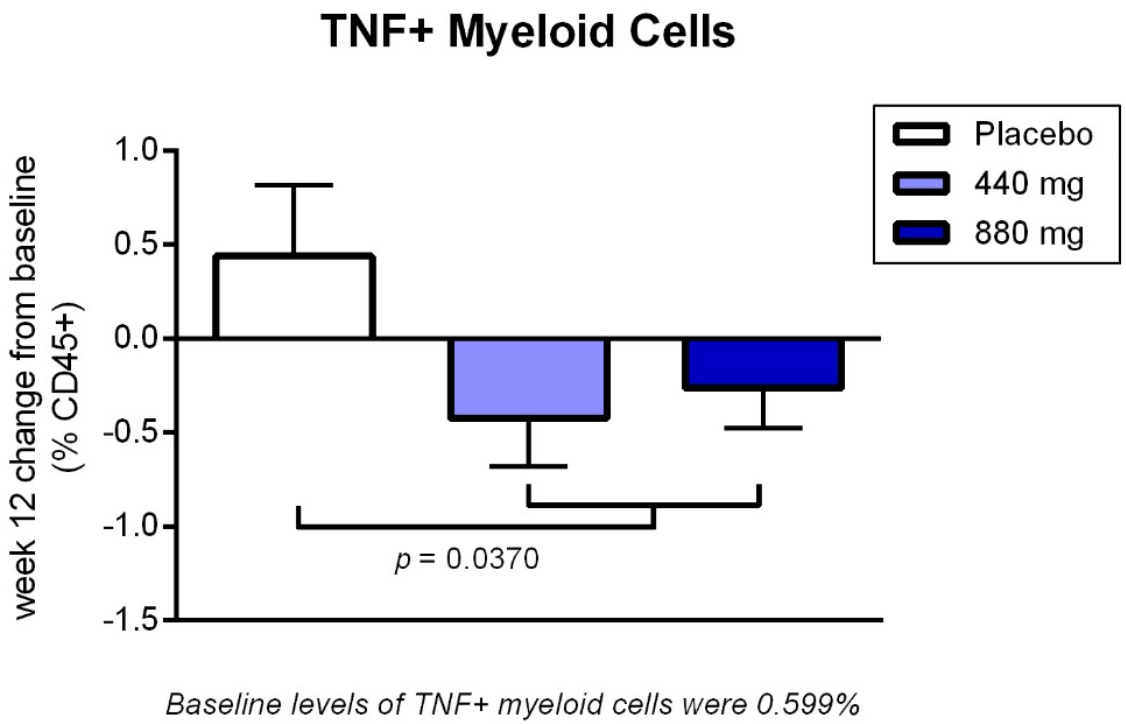


Previous biologics use

Mechanistic Validation in Tregs and TNF+ Cells by Flow Cytometry

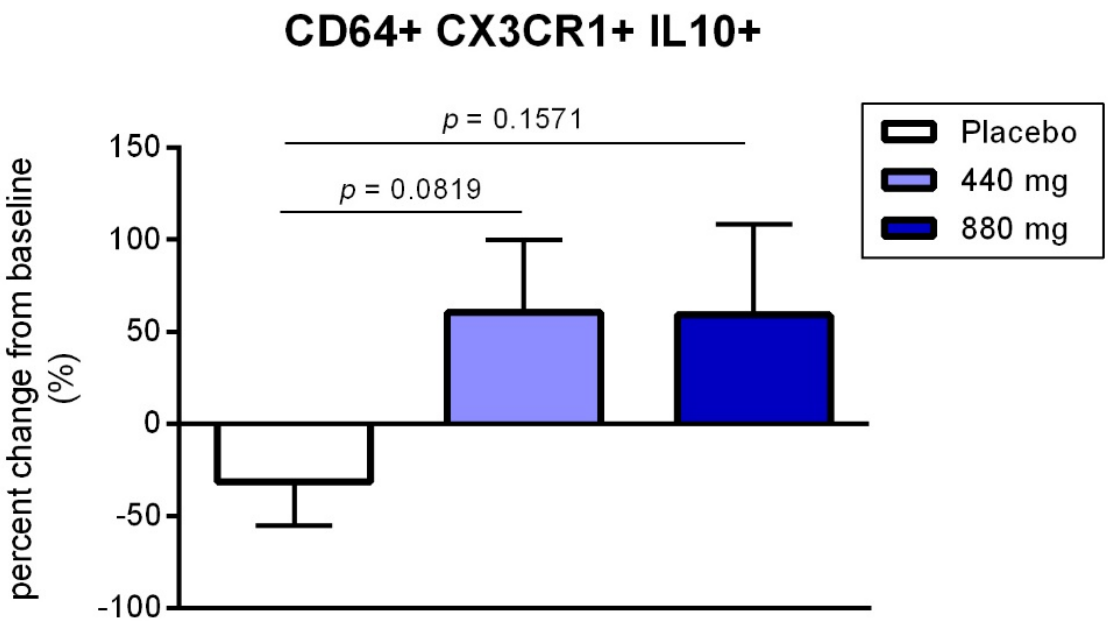


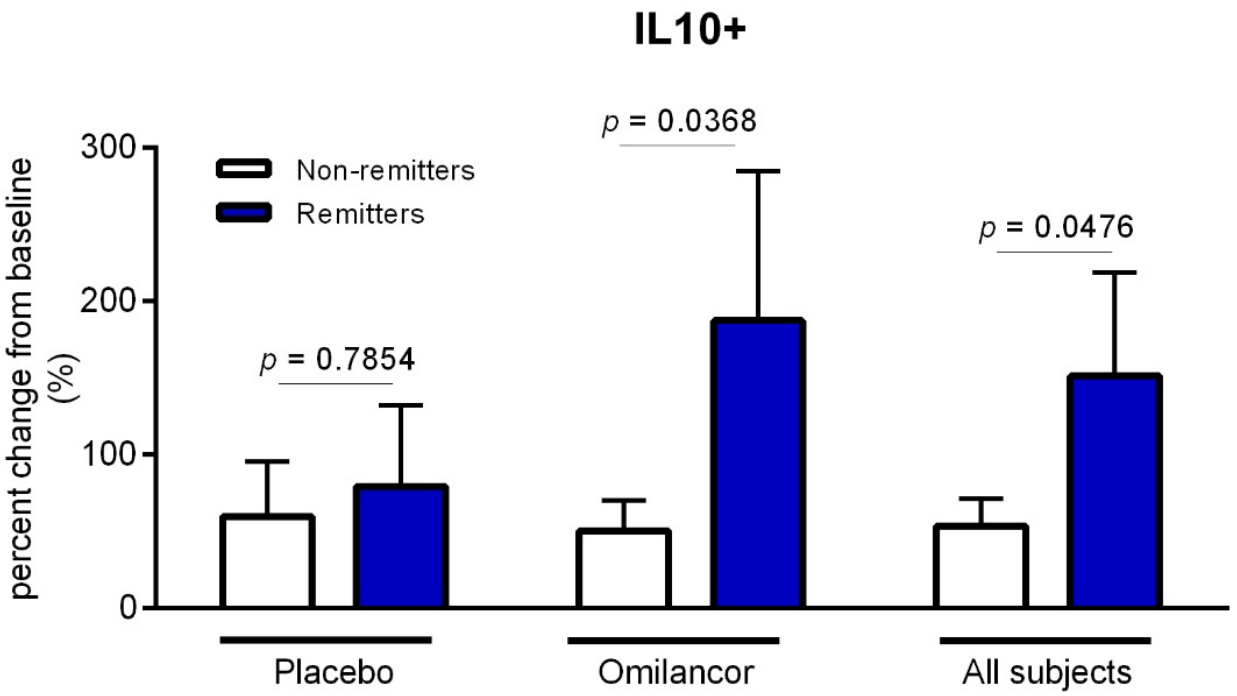
Baseline levels of Tregs cells were 2.24%



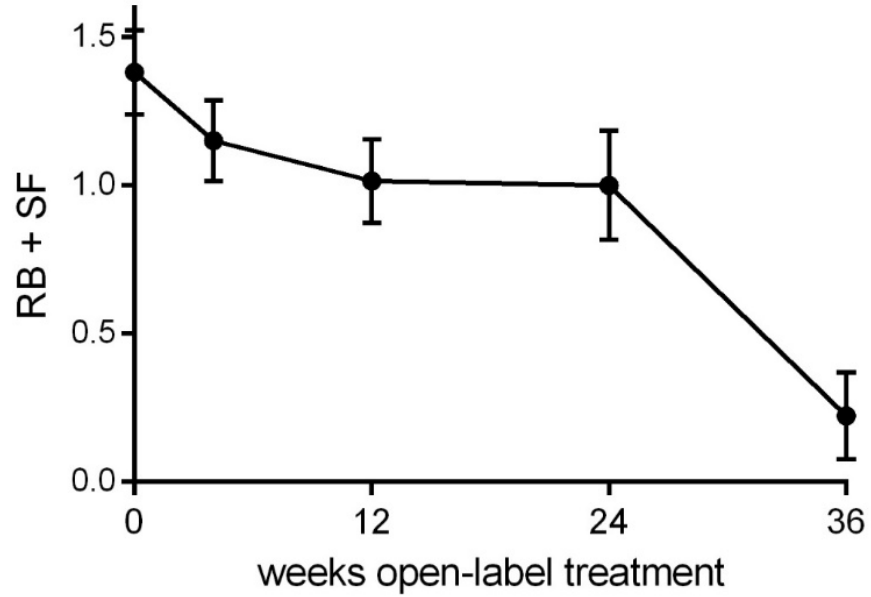
Baseline levels of TNF+ myeloid cells were 0.599%

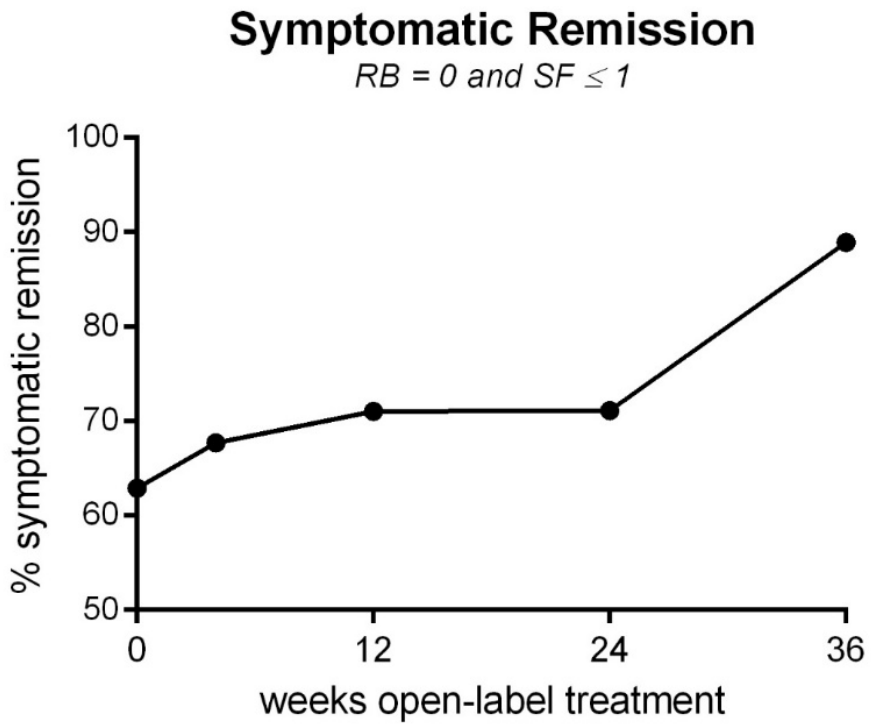
IL10+ Cells are associated with remission in omilancor-specific manner





Patients treated with omilancor maintain low Mayo scores and UC symptoms beyond 1 year of treatment





- Nearly 90% of patients achieving remission thresholds in stool frequency and rectal bleeding after 36 weeks of open-label treatment.
- Clinical remission (based on 3-component Mayo) was observed in 36.1% (Δ = 16.7%) of the omilancor 880 mg group and 35.5% (Δ = 16.1%) of the omilancor 440 mg group during the blinded maintenance phase.

PACIFY: A Global Pivotal Phase 3 Program of Omilancor in Mild to Moderate UC

- During a positive End of Phase 2 Meeting with the FDA, Landos and the FDA agreed on key elements of pivotal global Phase 3 program that are necessary to prepare for regulatory approval
- Two independent placebo-controlled trials enrolling 1,378 UC patients assessing clinical remission at Weeks 12 and 52 of treatment.
- If interested in learning more or becoming an investigator visit **www.pacifytrials.com** or contact **clinical@landosbiopharma.com**

PACIFY™