



LANDOS  
B I O P H A R M A

# NX-13 Phase 1b Clinical Trial Data

AUGUST 2022





# Forward Looking Statements

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This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation, including statements regarding our strategy, future operations, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions are intended to identify forward looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are subject to a number of risks, uncertainties and assumptions. Risks regarding our business are described in detail in our Securities and Exchange Commission filings, including in our Annual Report on Form 10-K for the year ended December 31, 2021. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. The forward-looking statements contained in this presentation reflect our current views with respect to future events, and we assume no obligation to update any forward-looking statements except as required by applicable law.



# Positive Top-Line Results Highlight Strong Company Momentum



## Support potential of NX-13 as important, new treatment for Ulcerative Colitis (UC)

- NX-13 targets a novel pathway
- NX-13 showed a favorable safety and tolerability profile in UC patients across a range of oral, once-daily doses
- Results indicate promising early signals regarding efficacy\*



## Validate sharpened strategic focus on pursuing the most promising target indications

- Strong scientific foundation and promising pipeline of oral, once-daily clinical-stage assets — omilancor, NX-13 and LABP-104



## Comprehensive review of clinical development plans near completion

- Focused on optimizing successful outcomes for clinical stage assets, strengthening team and advancing mission of addressing therapeutic gap for patients with autoimmune diseases
- On track to provide update later this year

\*Study was not designed or powered for exploratory clinical endpoints therefore results are hypothesis-generating only.



# Roadmap for NX-13 Development



## What we learned in the Phase 1b trial:

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- Favorable safety profile and tolerability in active UC across the study
- Indications of clinical improvement signals\* seen as soon as
  - 2 weeks in patient symptoms; and
  - 4 weeks by endoscopy in exploratory endpoints



## What we still need to determine:

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- Conducting further analysis of clinical, pharmacokinetic, and pharmacodynamic data
  - Guidance on doses and population stratification
  - Site and mechanism of drug action

## What's next:

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Announcing timing and study design for Phase 2 proof of concept trial later this year

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**NX-13 Phase 1b  
Clinical Trial Data**



# NX-13 Overview



## Mechanism of Action

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Targets NLRX1 pathway, a mitochondrial-associated regulatory NOD-like receptor



## Drug Profile

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Orally active and gut-restricted, allowing target engagement within the GI tract



## Recent & Upcoming Milestones

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Recently completed successful Phase 1b trial  
Announcing timing and study design for Phase 2 proof of concept trial later this year



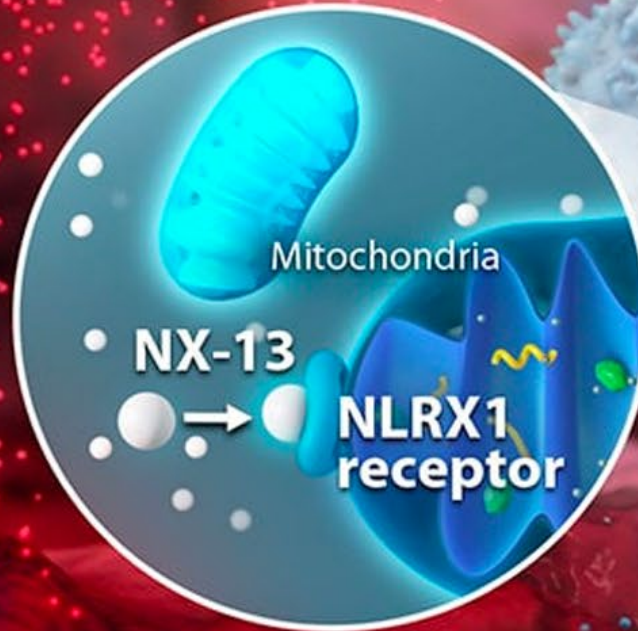


# NX-13 Selectively Targets Novel Target NLRX1 in the Gut

Epithelial Inflammation and Necrosis

Anti-inflammatory Effects of NX-13

Cytokines



NX-13 decreases reactive oxygen species

T cell

T cell

NX-13 decreases NF- $\kappa$ B / TNF- $\alpha$  and inflammatory cytokines



Pyroptosis

Necrosis

Autophagy

Healthy microbiome



NX-13 decreases inflammasome activity



# Phase 1b Study Design of NX-13 in Active UC

## Primary Objective:

To assess the safety and tolerability of NX-13 after multiple oral dose administration in subjects with active ulcerative colitis (UC)

## Key Inclusion Criteria:

- Male and female subjects 18-75 years old;
- Active UC >90days;
- Total Mayo Score of 4 to 10 (enrolled population average 7.6);
- MES  $\geq$  2 (confirmed by central reader);
- Baseline fecal calprotectin >250ug/g;
- 5-aminosalicylates stable for >1month, throughout trial;
- Bio-naïve or 8-week washout period if previously on biologics







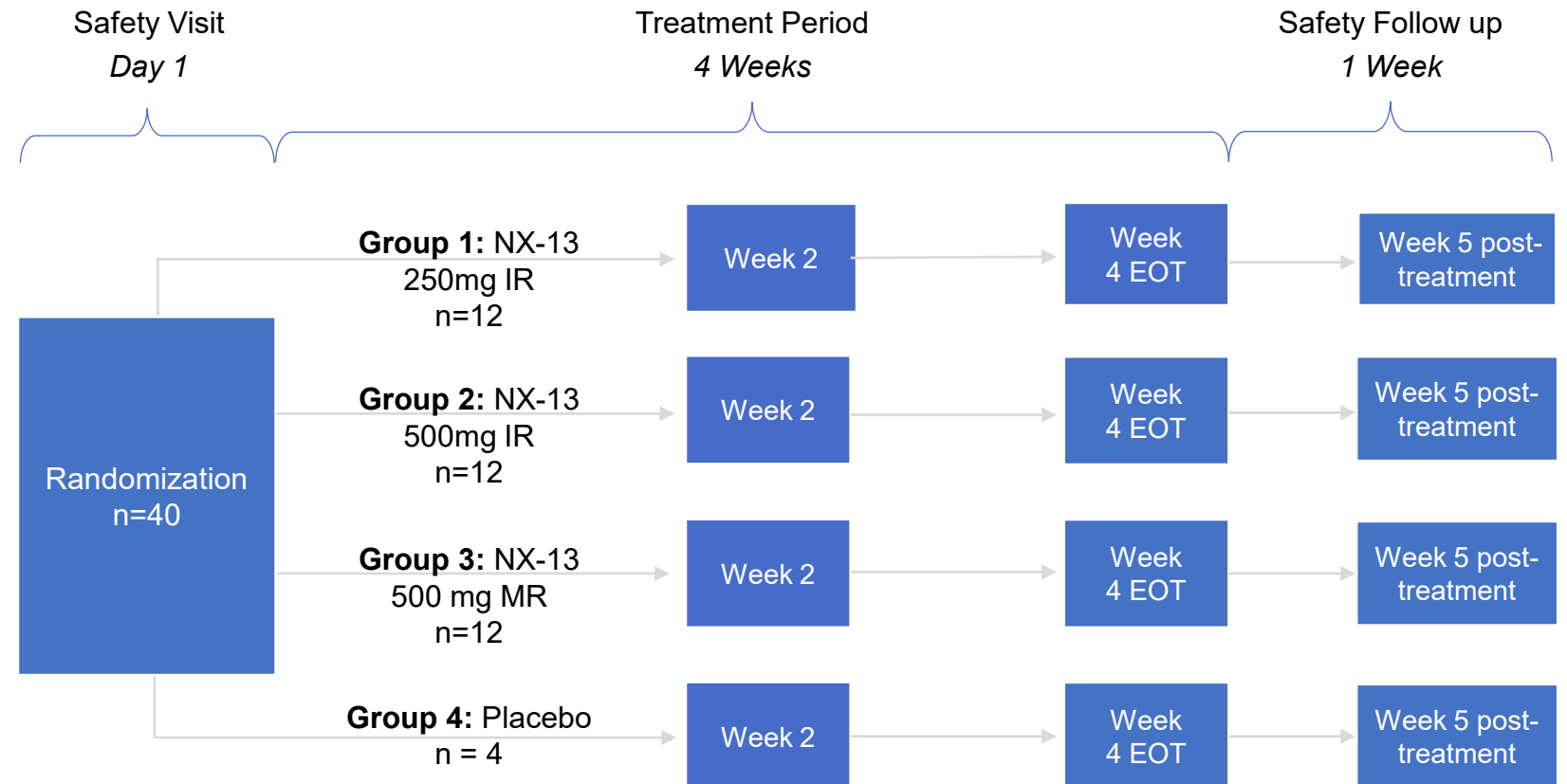
# Phase 1b Study Design of NX-13 in Active UC



Primary endpoints:  
Evaluate safety and  
pharmacokinetics of  
multiple dose levels



Promising signals of  
clinical efficacy despite  
relatively short trial  
duration



IR = Immediate Release; MR = Modified Release

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# NX-13 was Well-Tolerated and Shows Promising Efficacy Signals in Active UC



**Safety:** NX-13 was generally well tolerated, consistent with non-clinical, Phase 1a data

- No Serious Adverse Events
- 3 unrelated Adverse Events (AEs) of note



**Pharmacokinetics:**  
Plasma levels were generally low

- Modified Release tablet produced a flattened, prolonged exposure profile
- Tissue levels fell below the limit of quantification in a portion of patients in all dose groups, suggesting need for higher sensitivity assay



**Efficacy:** 4 weeks of low dose, immediate release NX-13 (250mg IR) once daily induced:

- Clinical response in 8/11 patients
- Clinical remission in 3/11 patients
- Endoscopic response in 4/11 patients
- Symptomatic Remission (Stool Frequency=0, Rectal Bleeding=0) in 8/11 patients
- Fecal Calprotectin Normalization in 5/11 patients

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# NX-13 Phase 1b Trial Safety Evaluations

	Placebo (n = 4)	NX-13 250mg (n=11)	NX-13 500mg (n=10)	NX-13 500mg MR (n=11)
<b>Serious AEs</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Mild/Moderate TEAEs</b>	1 (20%)	2 (18.2%)	3 (27.3%)	6 (54.5%)
<b>GI</b> ( <i>abdominal pain, UC worsening, pancreatitis, constipation</i> )	1 (20%)	0	1 (9.1%)	3 (27.3%)
<b>Renal</b> ( <i>congenital PCKD, increased creatinine, kidney stones</i> )	0	0	0	1 (9.1%)
<b>General/Cardiac</b> ( <i>A.Fib, Anemia, Weakness, Dizziness</i> )	1 (20%)	0	2 (18.2%)	0
<b>Clinical Chemistry</b> ( <i>GGT increase, HLD, hypocalcemia, hypophosphataemia</i> )	0	1 (9.1%)	2 (18.2%)	2 (18.2%)
<b>Infections / Infestations</b> ( <i>UTI, COVID</i> )	0	1 (9.1%)	0	1 (9.1%)

3 unrelated AEs of note:

- UC Flare (withdrew)
- A.Fib/Panic attack (withdrew)
- Mild pancreatitis (continued)

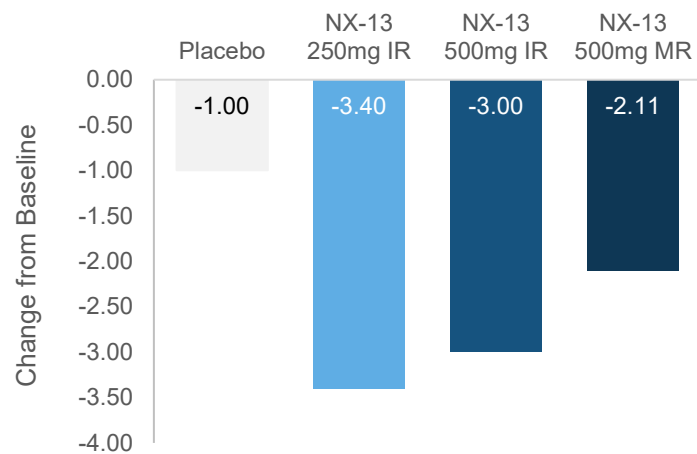
**No additional changes noted in clinical chemistry, hematology, vital signs, physical exam and ECG from baseline**

HLD = hyperlipidaemia; GGT = Gamma-Glutamyltransferase



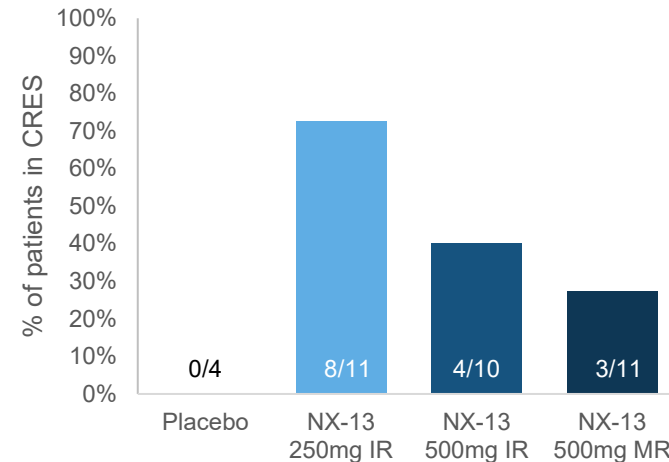
# NX-13 Treated Patients Experienced Reductions in Total Mayo Score after 4 weeks

## Total Mayo Score Change from Baseline



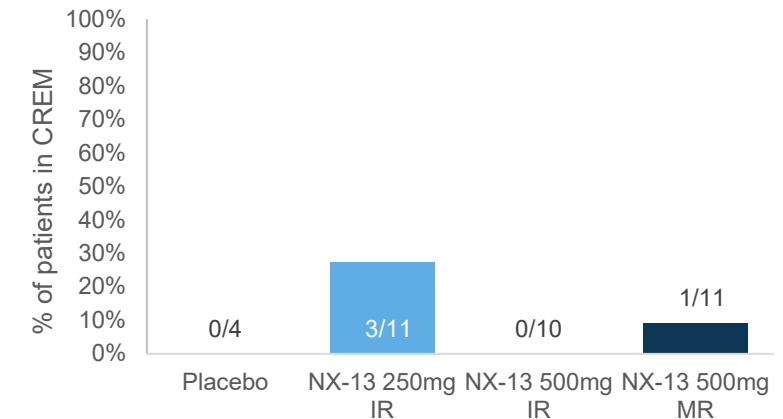
## Clinical Response

Defined as CFB of -3, or -30% in Mayo Score



## Clinical Remission

Defined as Mayo Score less than 2, with no subscore above 1



- Patients who received the 250mg dose experienced the greatest reduction of Total Mayo Score: -3.40 (range -7, 0), representing an average 48% reduction from baseline score.
  - 500mg patients also experienced clinically meaningful reductions of -3.00 and -2.11 on the IR and MR doses, respectively
- 72% (8/11) of the 250mg group achieved clinical response; 27% (3/11) achieve clinical remission after just 4 weeks of treatment

IR= Immediate Release; MR= modified release designed to dissolve at the terminal ileum

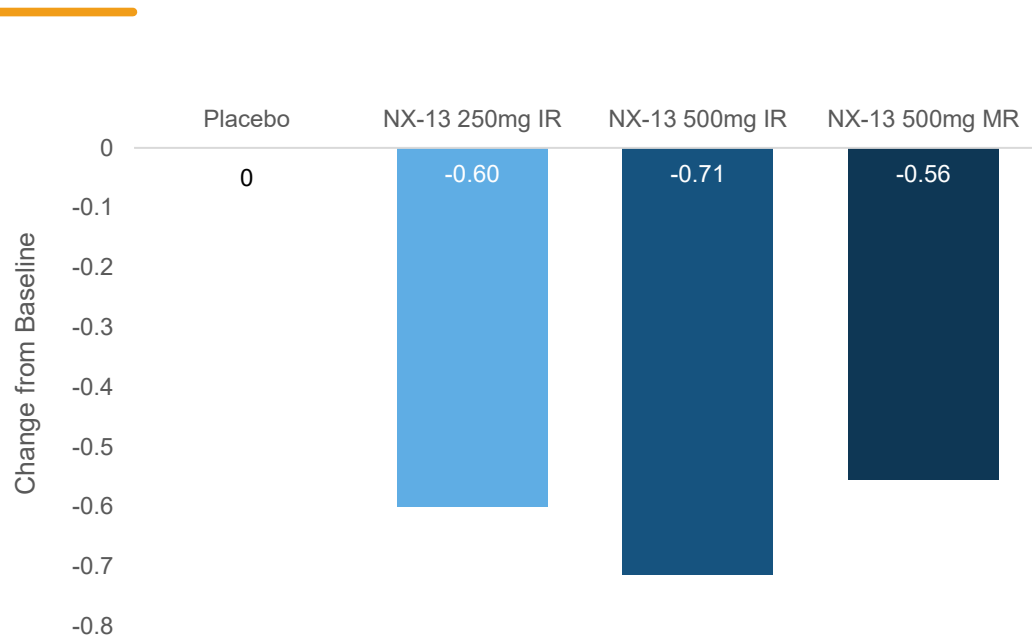
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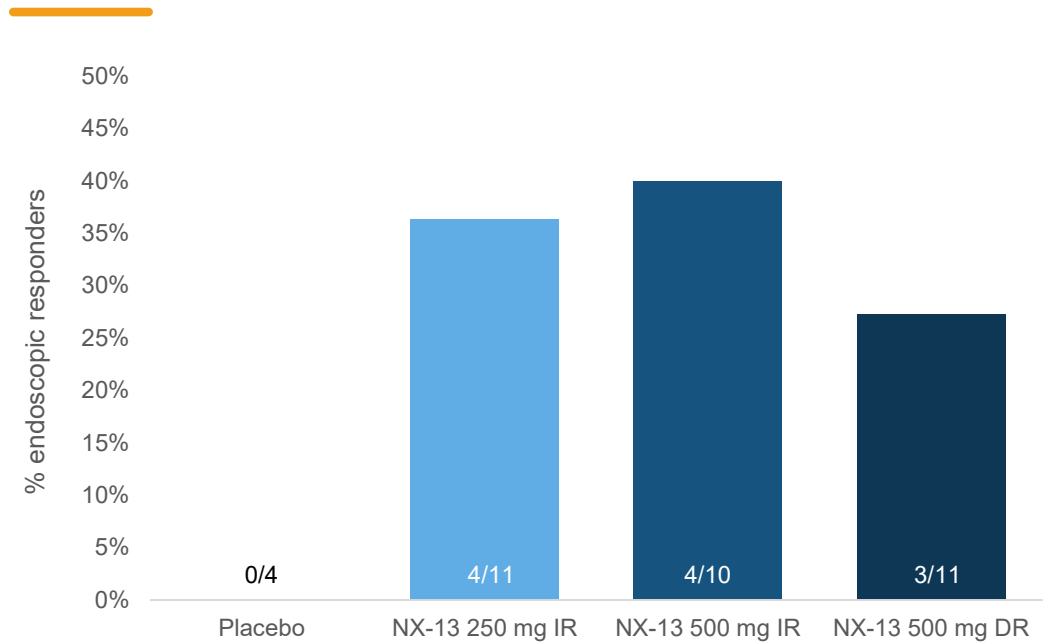


# Endoscopic Improvement at All Doses Driving Reduction of Mayo Score

## Mayo Endoscopy Score Change from Baseline



## Endoscopic Response (MES CFB -1)



- Patients treated with ALL doses of NX-13 experienced reductions in MES on average
  - 27-40% endoscopic response **after just 4 weeks** of treatment across dosage groups

FCP = Fecal Calprotectin; Normalization defined as an FCP score reduction to below 250.

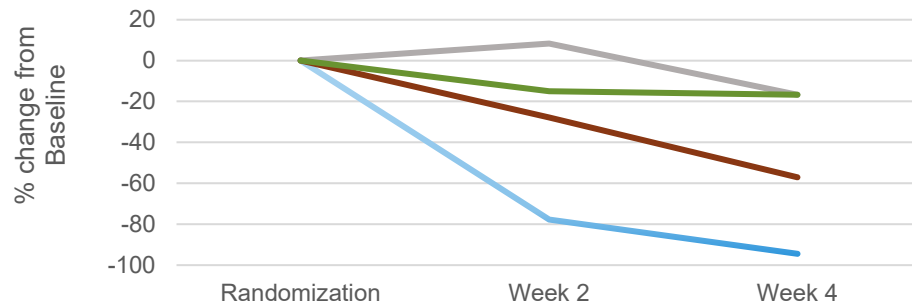
MES = Mayo Endoscopy Score; PROs = Patient Reported Outcomes

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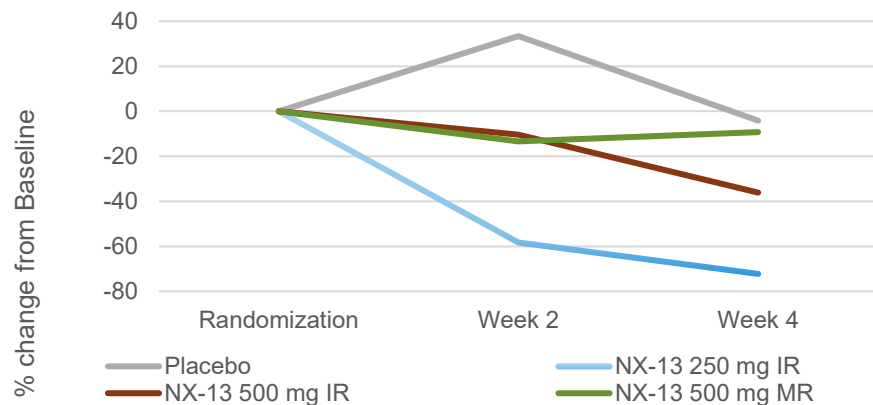


# NX-13 Supported **Symptomatic Remission** in Rectal Bleeding and Stool Frequency

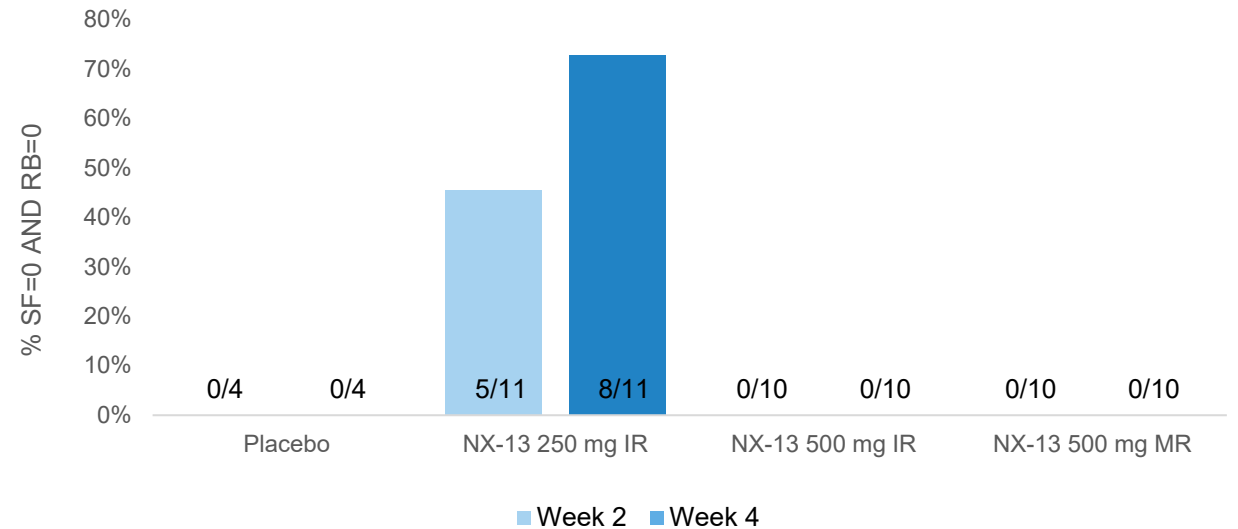
## Rectal Bleeding Change from Baseline



## Stool Frequency Change from Baseline



## Resolution of SF + RB



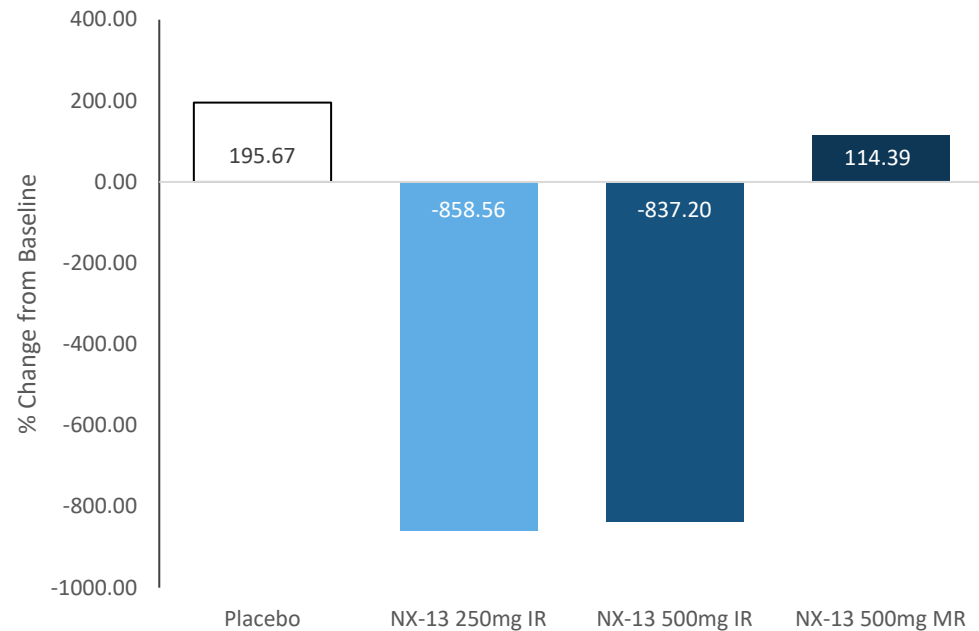
- Patients in the 250mg group had the greatest reduction of Rectal Bleeding and Stool Frequency at 2 weeks, with further reduction at 4 weeks
- Majority of patients saw complete resolution of BOTH rectal bleeding and stool frequency after 4 weeks of treatment with NX-13 250mg, once daily

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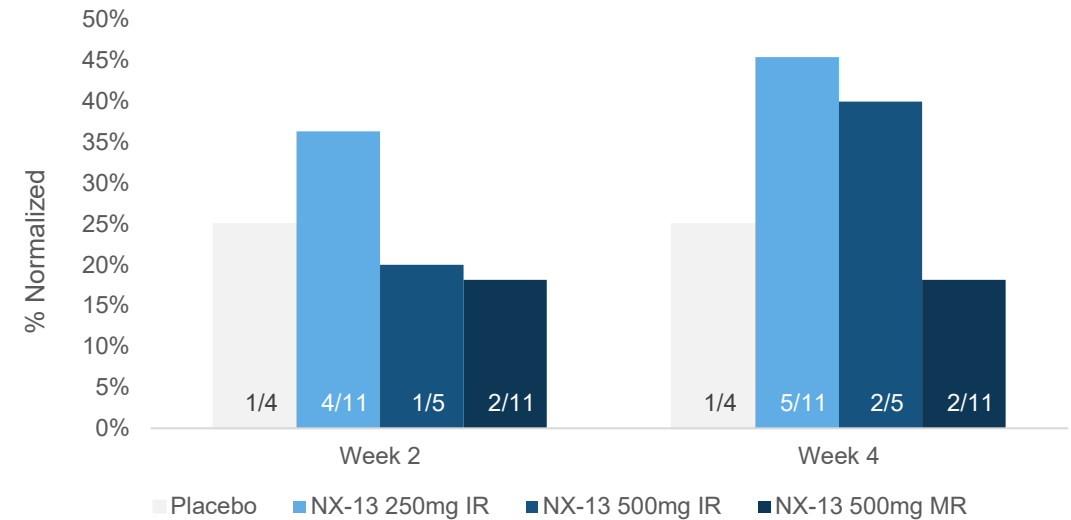


# Fecal Calprotectin (FCP) Change and Normalization

## Week 4 FCP Change from Baseline



## FCP Normalization (FCP decrease to <250)



- Immediate release (IR) groups had the greatest decrease of Fecal Calprotectin at 4 weeks on average
- Rates of Fecal Calprotectin Normalization mirrored Clinical Remission and Endoscopic response
  - Changes were seen as early as 2 weeks

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