



LANDOS  
B I O P H A R M A

Company Update – April 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, future financial position, future revenues, projected costs, 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.

This presentation includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties as well as our own estimates of potential market opportunities. All of the market data used in this prospectus involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.



# Landos Biopharma - Today

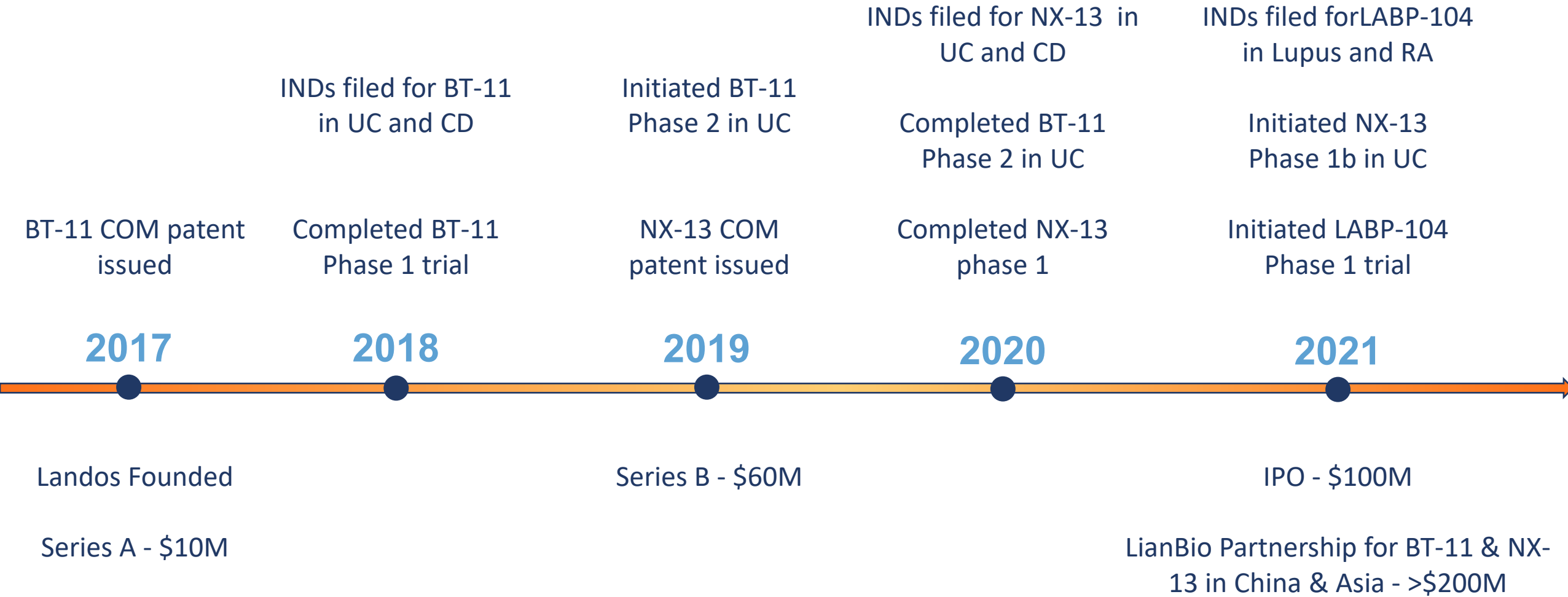
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- Clinical-stage company focused on the discovery and development of oral therapeutics targeting patients with autoimmune diseases, initially IBD
  - Core expertise in the discovery and targeting of novel pathways at the interface of immunity and metabolism utilizing the LANCE® Advanced A.I. platform
- First to target novel pathways LANCL2, NLRX1, and PLXDC2
  - Unique multi-modal effects on both immunity and metabolism
  - Novel gut-restricted and systemic product candidates in clinical development
- BT-11/omilancor Phase 2b for moderate-severe ulcerative colitis patients initiating before the end of 2022
- NX-13 Phase 1b top-line results in moderate-severe ulcerative colitis patients mid-2022
- LABP-104 Phase 1 top-line results in NHV mid-2022
- Extensive global intellectual property portfolio with protection to 2040
- Cash of approximately \$91 million\* with runway into 2H'23

\* (as of December 31, 2021)



# Landos Accomplishments





# Broad Portfolio of Clinical and Preclinical Programs

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## Clinical-Stage Product Candidates

- **Omilancor (BT-11)** (Phase 2b): oral, once-daily, gut-restricted, potentially first-in-class therapeutic targeting LANCL2 for moderate-severe ulcerative colitis
- **NX-13** (Phase 1b): oral, once-daily, gut-restricted, potentially first-in-class therapeutic targeting NLRX1 for moderate-severe ulcerative colitis
- **LABP-104** (Phase 1a): oral, once-daily, potentially first-in-class therapeutic targeting LANCL2 in development for lupus and/or rheumatoid arthritis

## Preclinical-Stage Product Candidates

- **LABP-111**: oral, once-daily, product candidate targeting LANCL2 in development for Type I Diabetes and NASH
- **LABP-66**: oral, once-daily, product candidate targeting NLRX1 in development for Multiple Sclerosis and Alzheimer's Disease
- **LABP-69**: oral, once-daily, product candidate targeting PLXCD2 in development for Rheumatoid Arthritis and Diabetic Nephropathy
- **LABP-73**: oral, once-daily, product candidate targeting NLRX1 in development for Asthma and COPD

A complex network diagram with numerous nodes and connecting lines. The nodes are colored in shades of orange, red, blue, and pink. Some nodes are highlighted with larger circles or double outlines. The lines are thin and grey, creating a web-like structure across the entire image.

# **OMILANCOR**

## **BT-11**



# OMILANCOR (BT-11)



## Drug Profile

- Novel MOA
  - LANCL2 Agonist
  - Designed to downregulate pro-inflammatory signals; Designed to increase T-regs and Anti-inflammatory signals
  - No on-target toxicities associated with the LANCL2 pathway
  - No observed effects from limited systemic immunosuppression
- Administration Route
  - Oral
- Pharmacokinetics and Safety
  - Gut-restricted
  - Limited systemic exposure
  - AE incidence similar to placebo



# OMILANCOR (BT-11)

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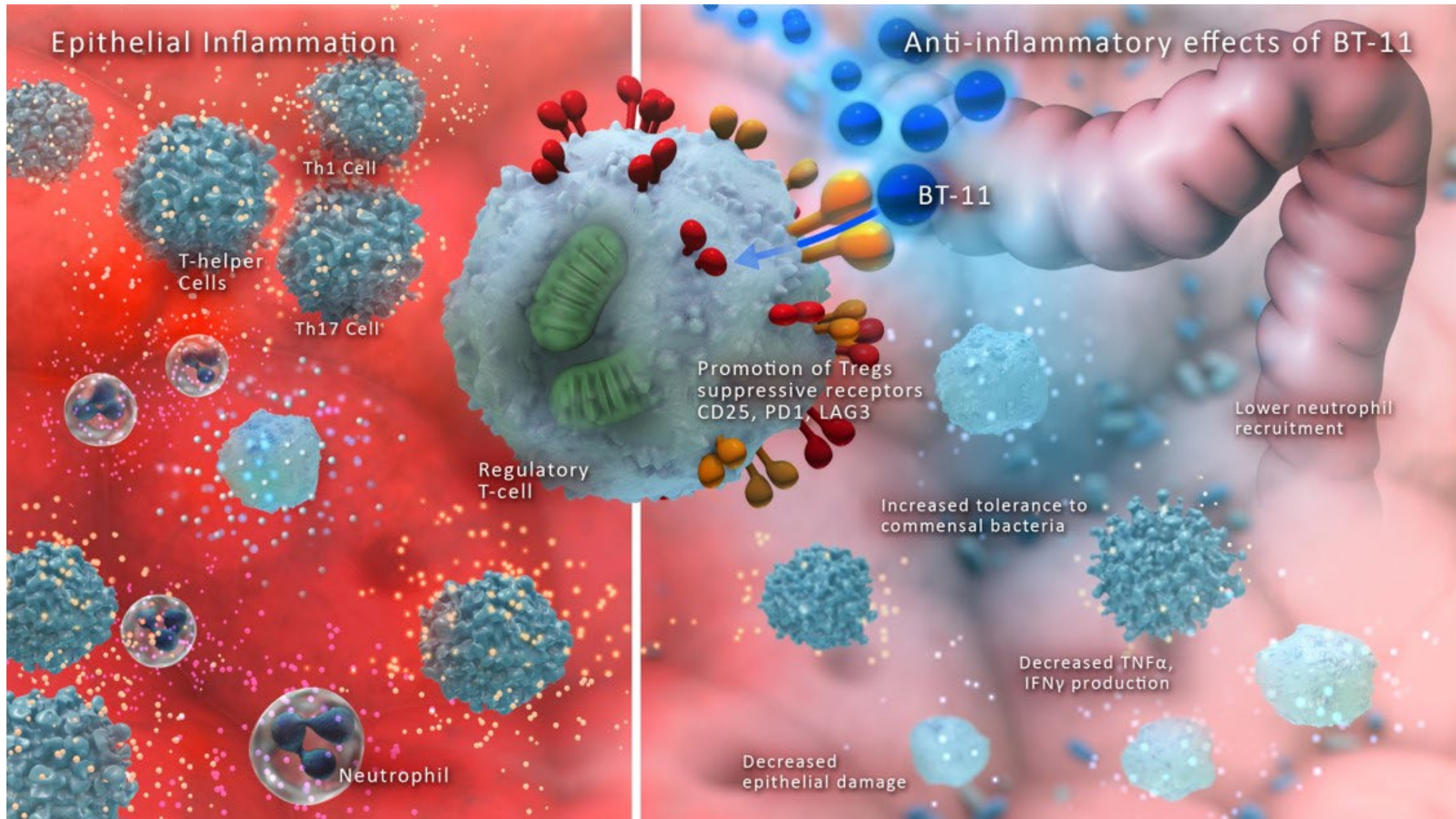
## Indications & Development Stage

- Gastrointestinal (Oral)
  - ulcerative colitis (UC)
- IND approved in June 2018
- Phase 1a – first in human (NHV) – completed in 2018
- Phase 2 – mild-moderate UC study completed in 2021; Phase 2b in moderate-severe UC initiation expected by yearend 2022



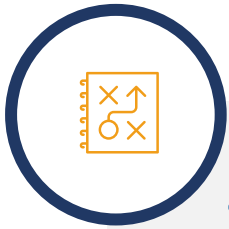


# Omilancor Designed to Act Selectively Activate Novel Target LANCL2 in the Gut





# OMILANCOR (BT-11)

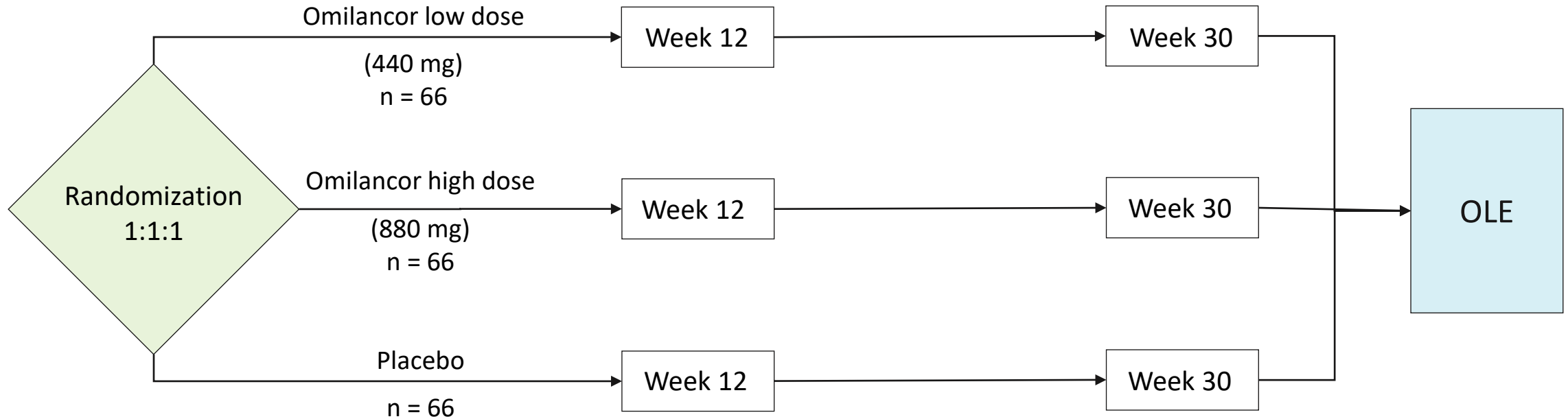


## Clinical Overview

- Phase 1 Results:
  - No systematic absorption
    - High concentration in Stool – 6,000 times higher than in plasma
    - High concentration in Rectum
  - No differences in presentation of adverse events, clinical chemistry, changes in white blood cell counts, ECG and other safety measures at daily doses up to 100 mg/kg (7500 mg) in Phase I (NHV).



# BT-11-201 – Phase 2 Study of Omilancor in Mild-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-moderate ulcerative colitis (UC).

## Key Inclusion Criteria

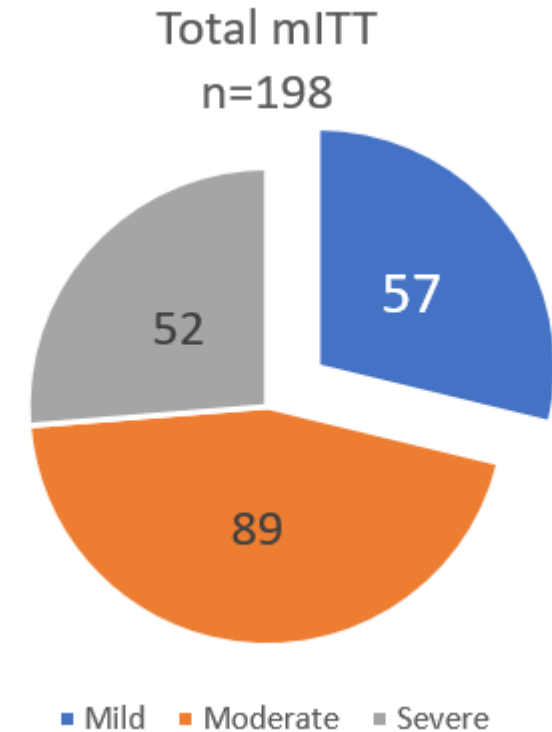
- Male and female subjects with mild-moderate UC defined by a total Mayo Score of 4 to 10 with MES  $\geq 2$  (confirmed by central reader); 5-aminosalicylates (max 4.8 g/day) and oral corticosteroids (max 20 mg/day prednisone or equivalent) must be stable for the 12-week induction period.



## BT-11 – 201 Study Demographics

	Placebo (n = 66)	Omilancor 440 mg (n = 66)	Omilancor 880 mg (n = 66)
Age	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%)

\*previous biologics use capped at 25%, however recruited far fewer than this due to preponderance of mild patients (and recruited ex-U.S.)



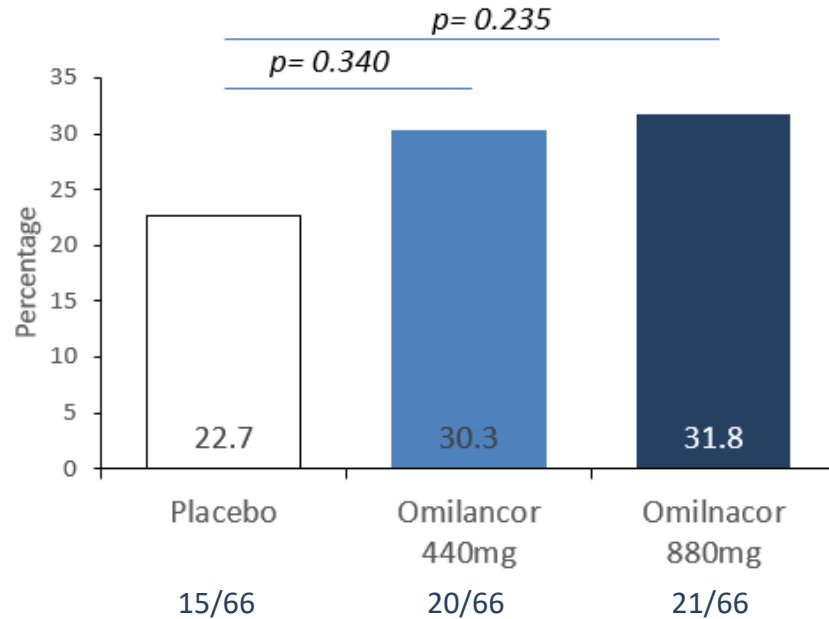
*Higher proportion of mild patients than reflected in the average MCS of >7*



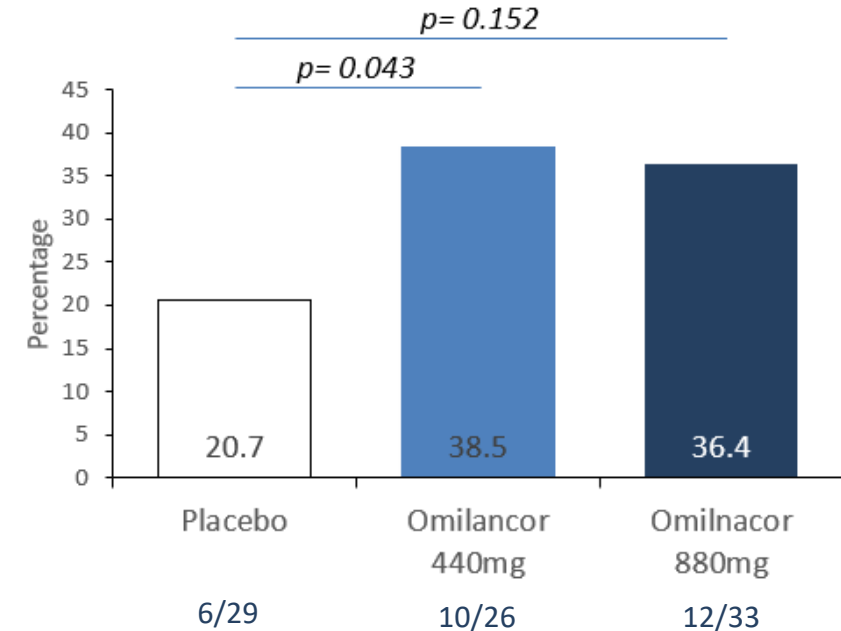
# BT-11-201 Primary Endpoint Analysis – Clinical Remission

## Clinical Remission Week 12 (Induction)

Clinical Remission defined as Mayo Score less than 2, with no subscore above 1



## Durable Clinical Remission Week 12 + 30 (Induction + Maintenance)



Omilancor was NOT statistically significantly better than placebo during the induction phase, however, Omilancor...

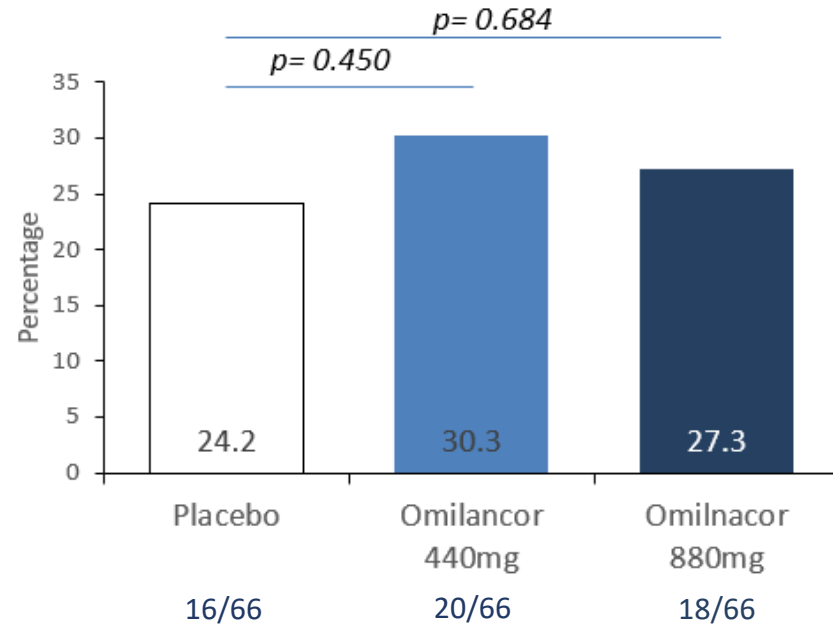
- WAS statistically significantly better than placebo in the maintenance phase
- Demonstrated >30% remission during the induction phase and >36% remission during the maintenance phase
- Achieved impressively high and durable remission rates compared to placebo despite the inclusion of a significant proportion of patients with mild ulcerative colitis (and accompanying high placebo response rates)



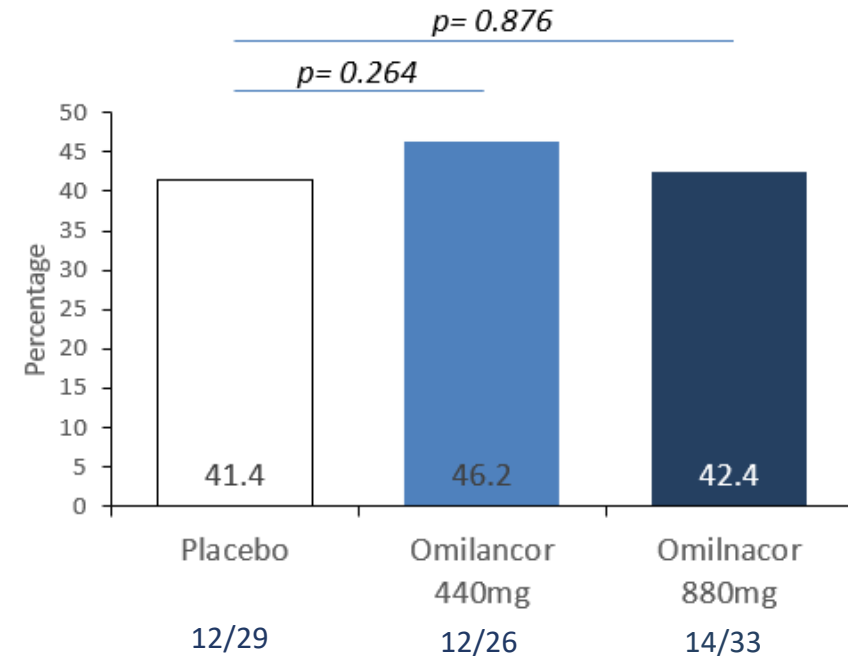
# BT-11-201 Primary Endpoint Analysis – Mucosal Healing

## Mucosal Healing Week 12 (Induction)

Mucosal Healing defined as a combination of MESO-1 and a Geboes score <3.1



## Durable Mucosal Healing Week 12 + 30 (Induction + Maintenance)



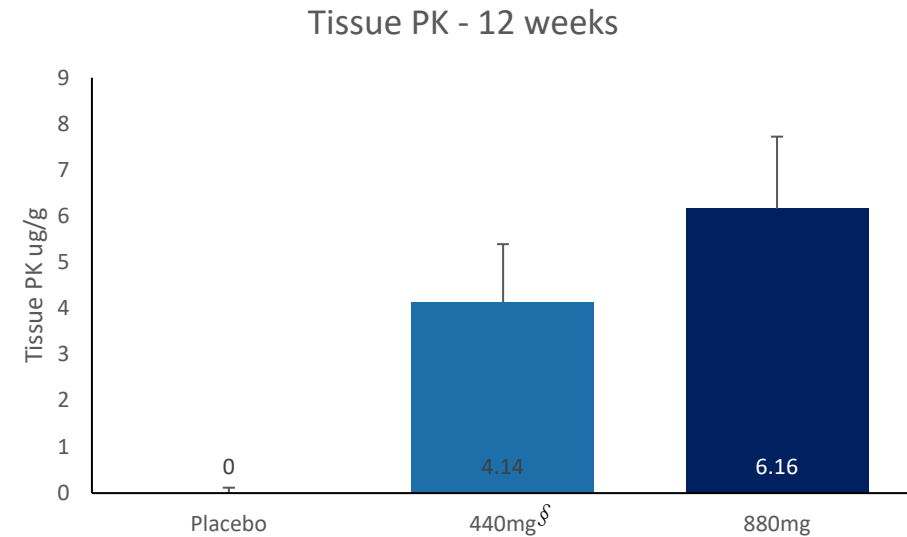
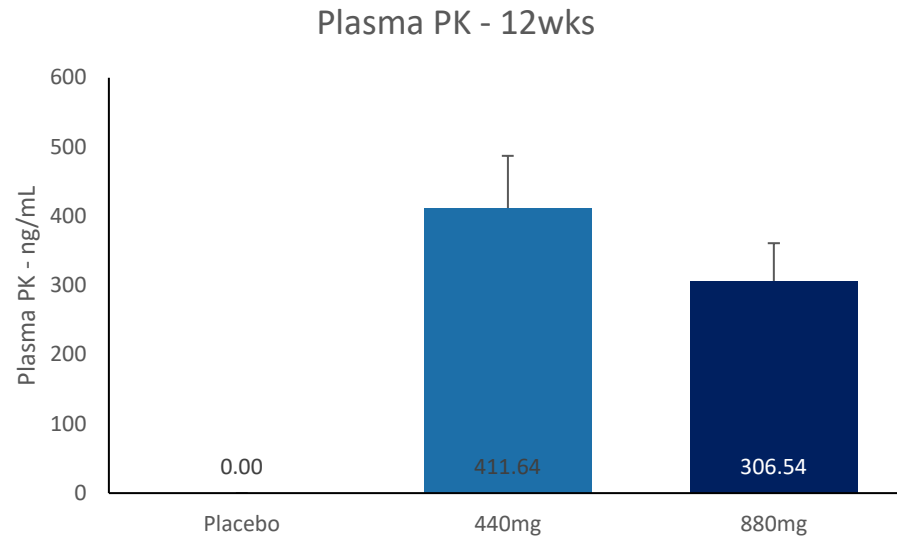
Omilancor was NOT statistically significantly better on mucosal healing than placebo, however, Omilancor achieved...

- ~30% mucosal healing during the induction phase and >40% mucosal healing during the maintenance phase
- A rate of mucosal healing surpassing the rate of mucosal healing in prior studies with anti-TNF and anti-integrins





## BT-11-201 – Tissue PK Values



Omilancor is detectable in both the plasma and the colonic tissue (10x higher in tissue than plasma)

- Colonic tissue levels are significantly lower than those observed in the pig studies

*§ 2 outliers (360ug/g, 450ug/g) in tissue PK 440mg dose group not shown*

A complex network diagram with numerous nodes and connecting lines. The nodes are colored in shades of orange, red, blue, and pink. Some nodes are highlighted with larger, semi-transparent circles. The lines are thin and grey, creating a dense web of connections.

# Post Hoc Analyses





# BT-11-201 Primary Endpoint Analysis by Mayo Score

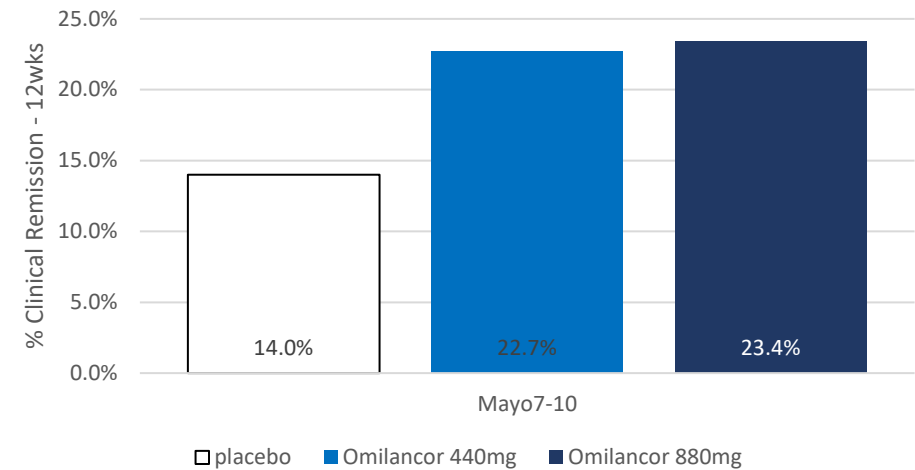
## Clinical Remission

Total Mayo Score	Placebo	Omilancor 440mg	Omilancor 880 mg
Mild (4-6)	50% (8/16)	45.5% (10/22)	52.6% (10/19)
<b>Mod-Sev (7-10)</b>	<b>14% (7/50)</b>	<b>23% (10/44)</b>	<b>23% (11/47)</b>

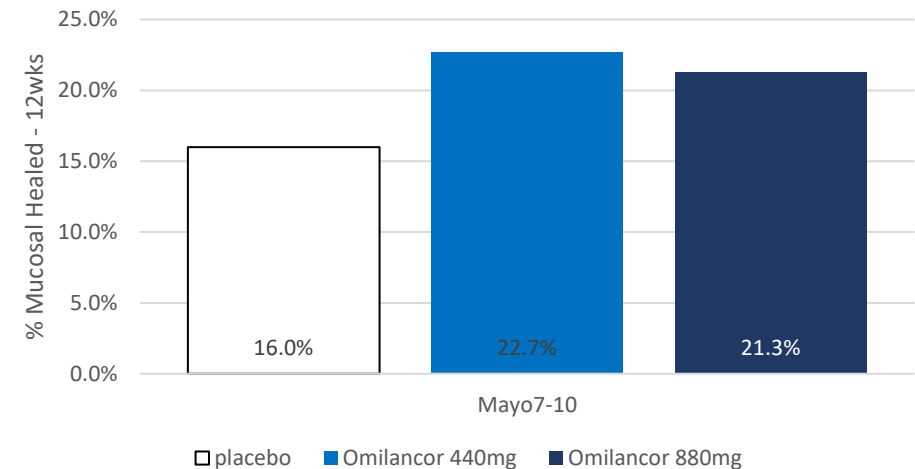
## Mucosal Healing

Total Mayo Score	Placebo	Omilancor 440mg	Omilancor 880 mg
Mild (4-6)	50% (8/16)	45.5% (10/22)	42.1% (8/19)
<b>Mod-Sev (7-10)</b>	<b>16% (8/50)</b>	<b>23% (10/44)</b>	<b>21% (10/47)</b>

## Clinical Remission - Moderate Patients



## Mucosal Healing - Moderate Patients





# BT-11-201 Primary Endpoint Analysis by Mayo Score

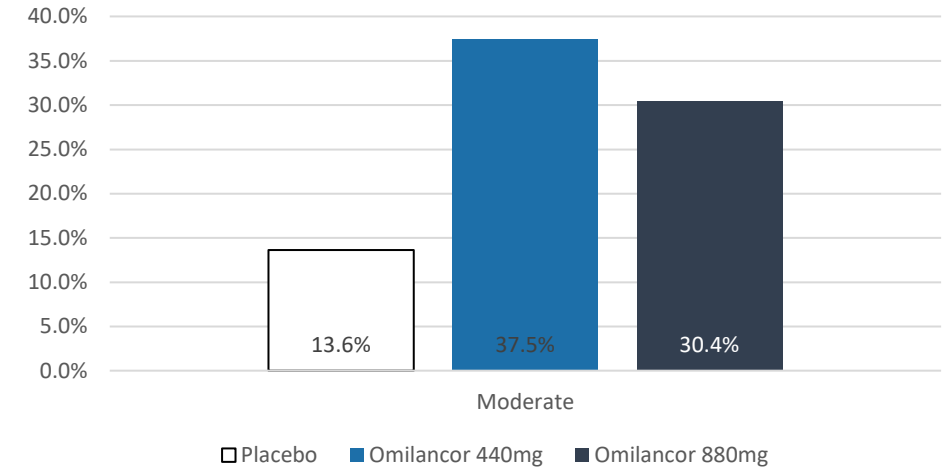
## Durable Clinical Remission

Total Mayo Score	Placebo	Omilancor 440mg	Omilancor 880 mg
Mild (4-6)	42.9% (3/7)	40% (4/10)	50% (5/10)
<b>Mod-Sev (7-10)</b>	<b>13.6% (3/22)</b>	<b>37.5% (6/16)</b>	<b>30.4% (7/23)</b>

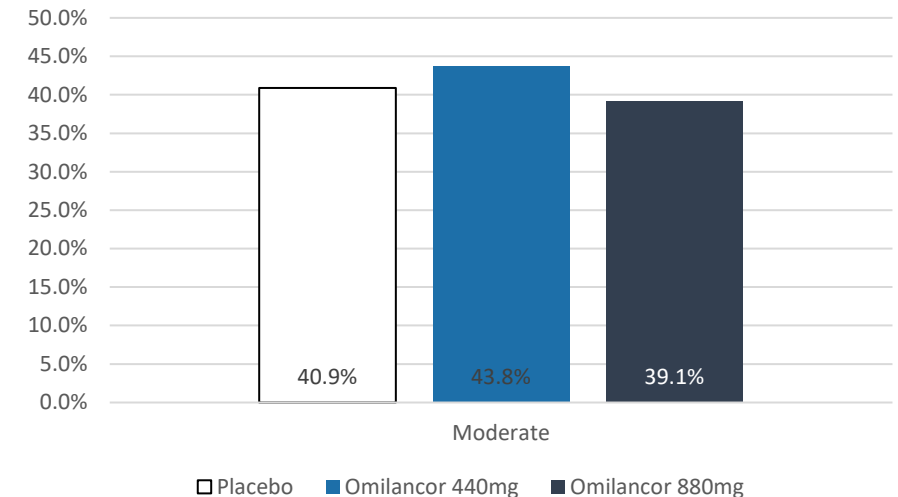
## Durable Mucosal Healing

Total Mayo Score	Placebo	Omilancor 440mg	Omilancor 880 mg
Mild (4-6)	42.9% (3/7)	50% (5/10)	50% (5/10)
<b>Mod-Sev (7-10)</b>	<b>40.9% (9/22)</b>	<b>43.8% (7/16)</b>	<b>39.1% (9/23)</b>

## Durable Clinical Remission- 12+30weeks

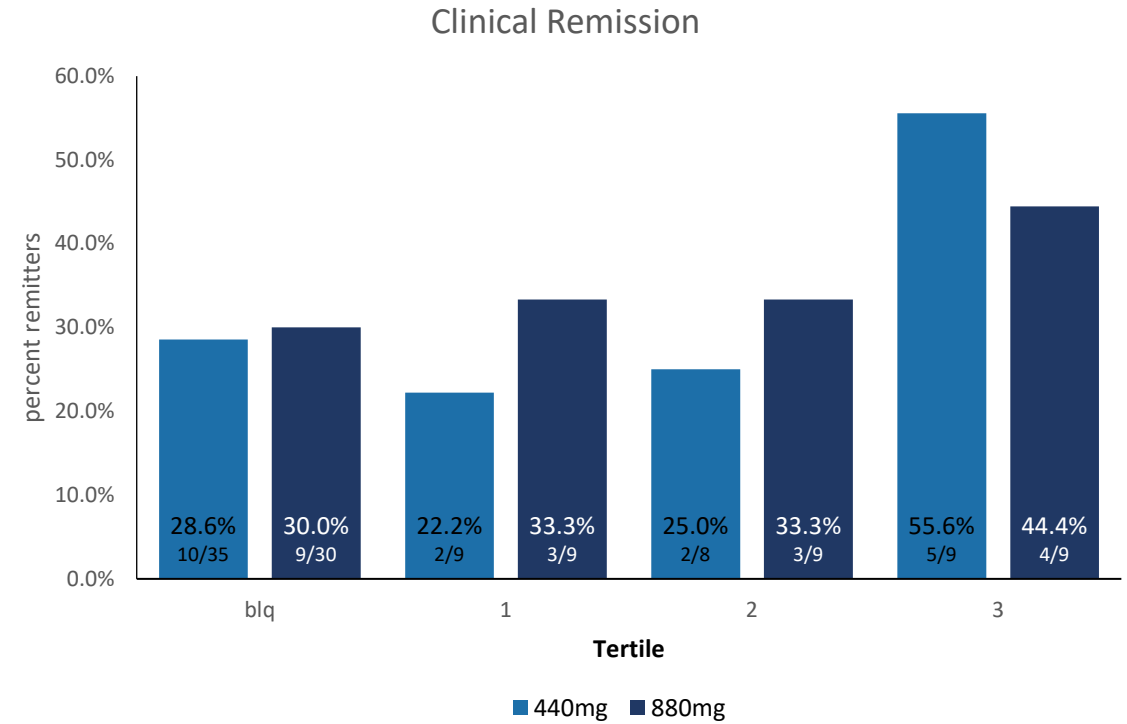
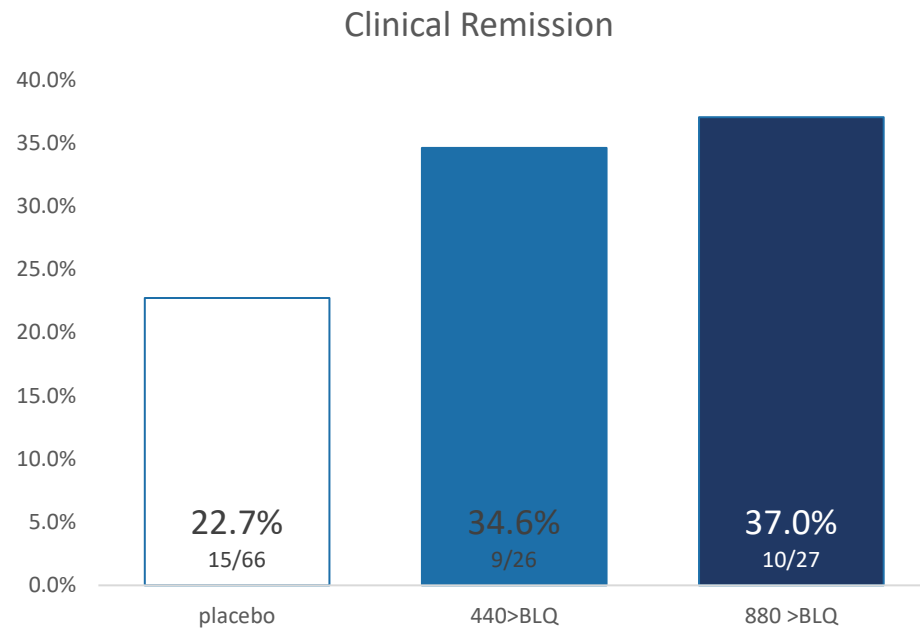


## Durable Mucosal Healing - 12+30weeks





## BT-11-201 – Higher Tissue PK Correlates to Higher Clinical Remission Rates



Patients with detectable tissue PK values have a greater remission rate than those with BLQ measurements

Patients in the highest tertile of PK values have highest remission rates

*Note: the 440 mg and 880 mg tablets had different formulations which may have contributed to the lack of dose response reflected above*

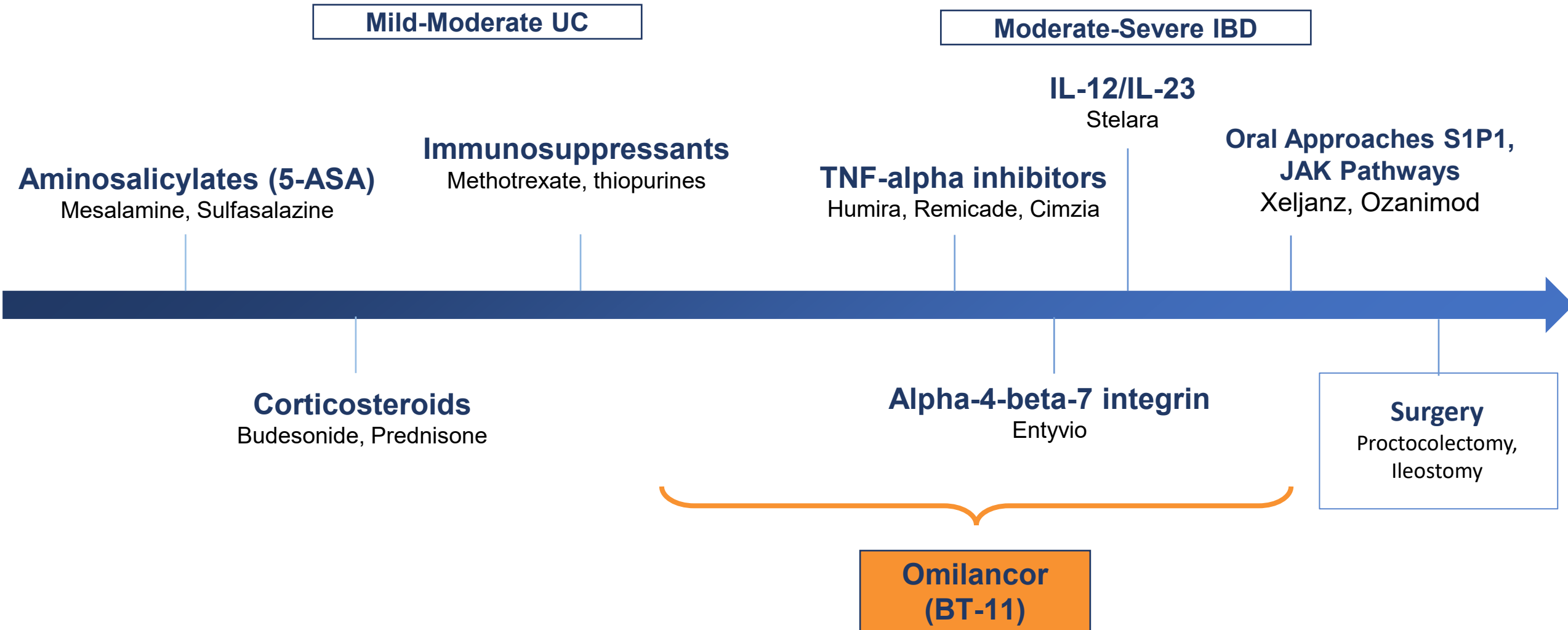


## BT-11-201 Study Results Analysis – Key Learnings

- Omilancor is active and induces >30% rates of both clinical remission and mucosal healing (endoscopic *and* histologic remission) in UC patients
  - Inclusion of patients with mild disease contributed to the high (20 – 23%) placebo response rates observed in the study when typical UC placebo response rates are 10 – 20%
  - Treatment effects of Omilancor were far more pronounced in moderate-severe patients and biologic failure/exposed patients due to lower placebo rates in those patients
  - Far more biologic failure/exposed patients to be included in future UC studies due to their pervasiveness among the moderate-severe UC patient population
- Tissue Concentrations of Omilancor are correlated with disease remission
- LANCL2 was successfully targeted and upregulated with Omilancor treatment
  - Downstream, upregulation of LANCL2 improves the balance of the immune system by increasing key anti-inflammatory markers and reducing key pro-inflammatory markers
- Different formulations of the 440 and 880 mg tablets combined with high insolubility of BT-11 may have contributed to the lack of dose response observed in the study
  - Consistent and more soluble tablet formulation will be used in future studies of Omilancor



# Omilancor (BT-11) Positioned to Address Unmet Need in a Large Segment of IBD Treatment Paradigm



A complex network diagram with numerous nodes and edges. The nodes are represented by small circles in various colors: orange, pink, blue, red, and grey. Some nodes are larger and have a double outline. The edges are thin, light grey lines connecting the nodes. A large, dark blue rectangular box is centered on the page, containing the text 'NX-13'.

**NX-13**



# NX-13

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## Drug Profile

- Novel MOA
  - NLRX1 Agonist
  - Designed to decrease reactive oxygen species and oxidative stress; Designed to decrease pro-inflammatory signals
  - No on-target toxicities associated with the NLRX1 pathway
  - No observed effects from limited systemic immunosuppression
- Administration Route
  - Oral
- Pharmacokinetics and Safety
  - Gut-restricted
  - Limited systemic exposure
  - AE incidence similar to placebo



# NX-13

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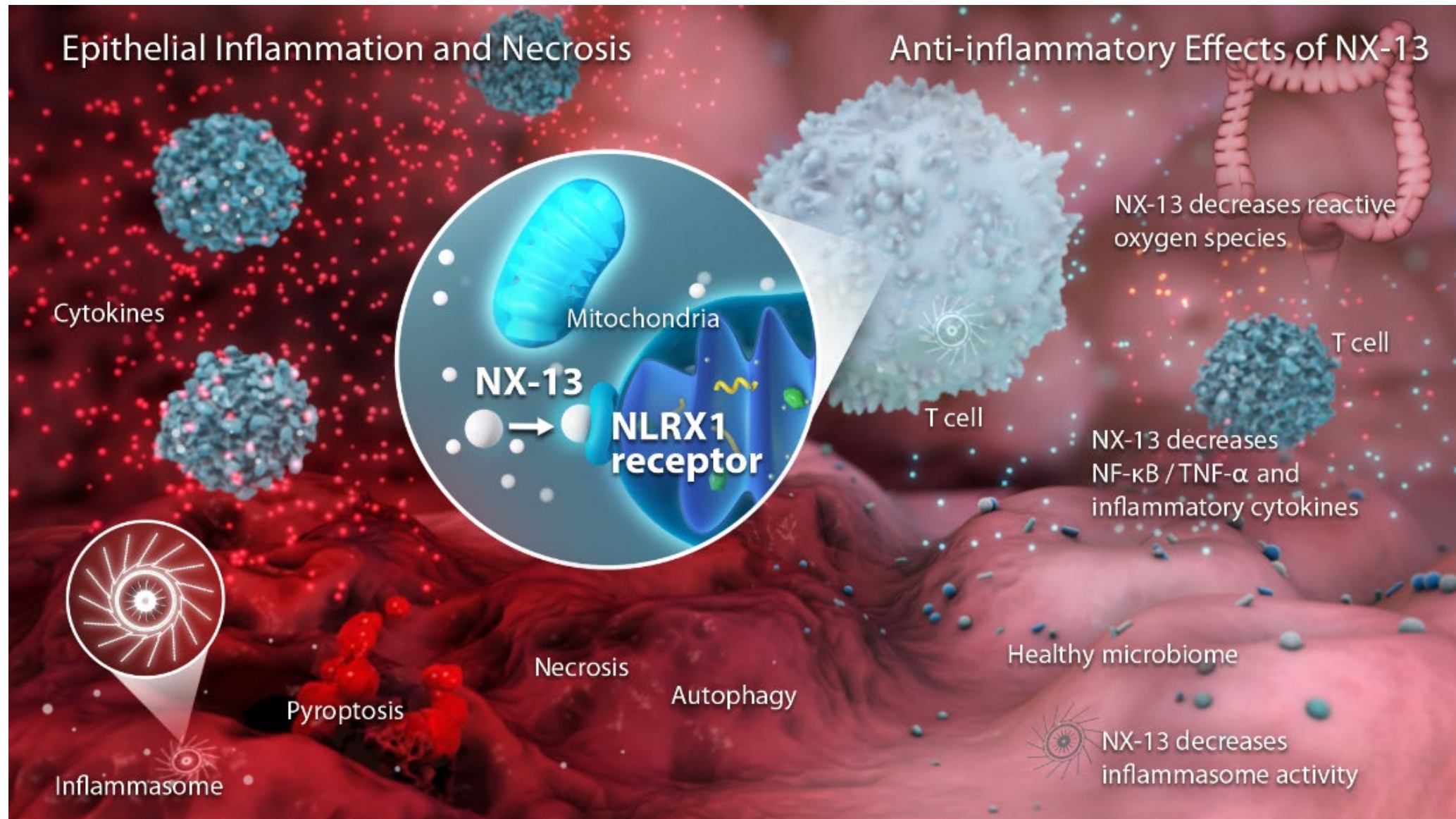
## Indications and Development Stage

- Gastrointestinal
  - ulcerative colitis (UC)
- UC IND filed in 2020
- Phase 1a – first in human (NHV) – completed in 2020
- Phase 1b – moderate UC – initiated in 2021 and on-target for top-line results mid-2022





# NX-13 Designed to Selectively Activate Novel Target NLRX1 in the Gut



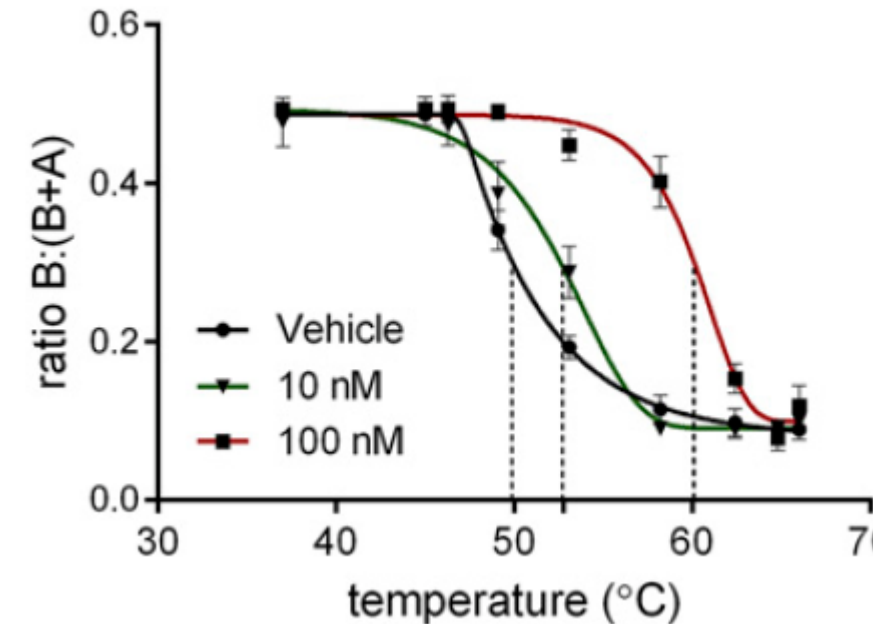


# NX-13 Preclinical Result Highlights

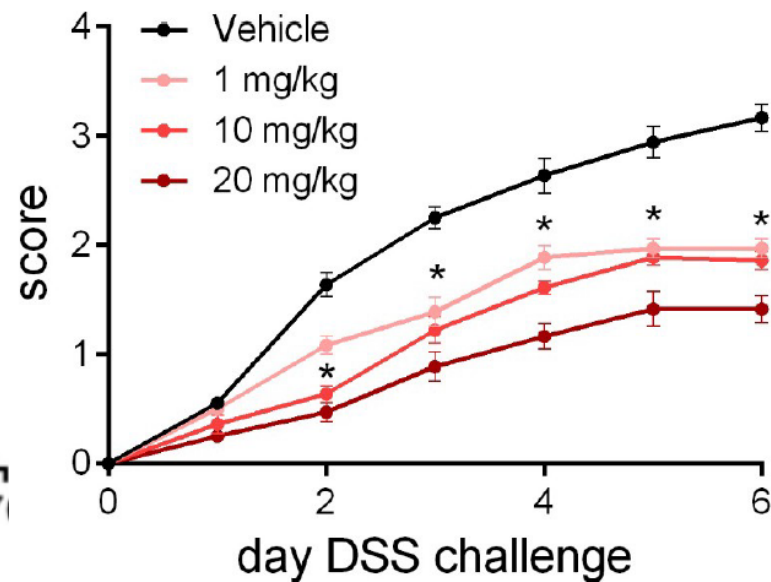
## MOUSE PRECLINICAL STUDIES

Model	Reduction in final DAI (vs. vehicle)	Reduction in leukocytic infiltration
DSS	55%	76%
Adoptive Transfer	72%	52%
Mdr1a-/-	68%	73%

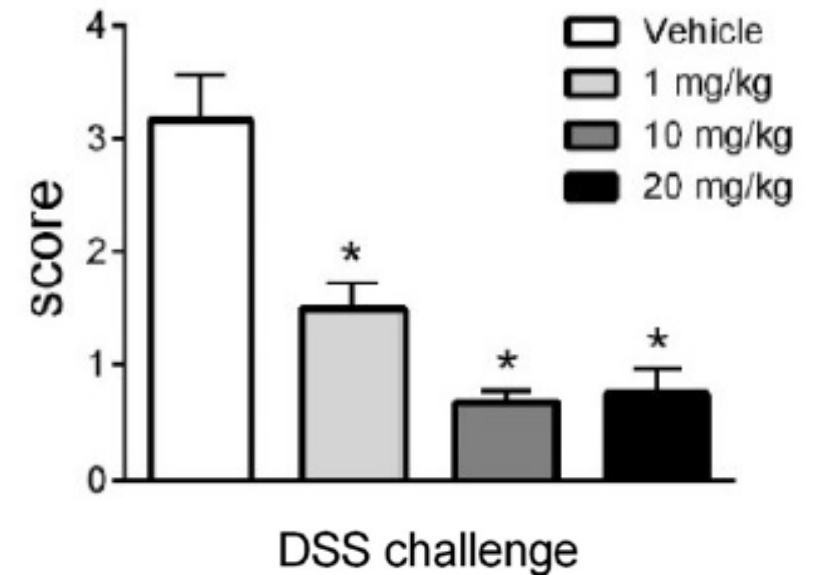
### Thermal Shift



### Disease Activity Index



### Leukocytic Infiltration

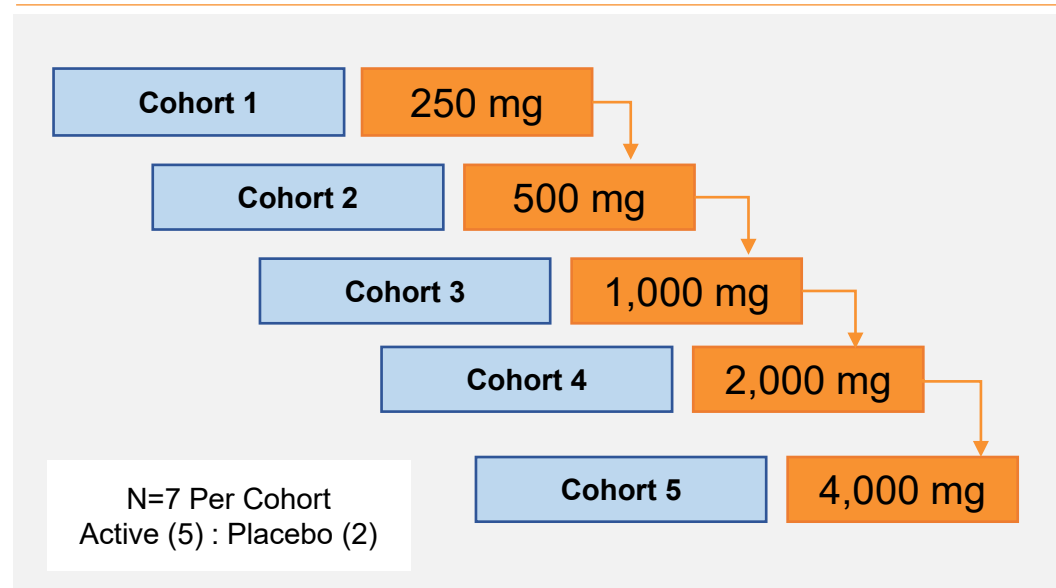




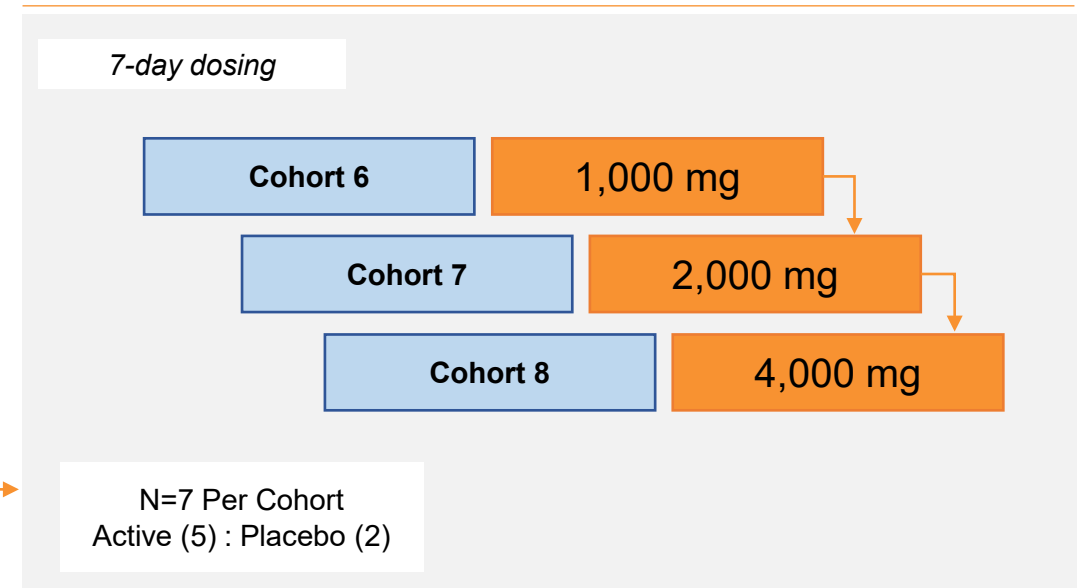
# NX-13 Phase 1a Top-Line Results

- No serious adverse events
- GI concentrations >2500-fold peak plasma concentrations
- All primary and secondary endpoints in safety and tolerability were achieved

## Single Ascending Dose



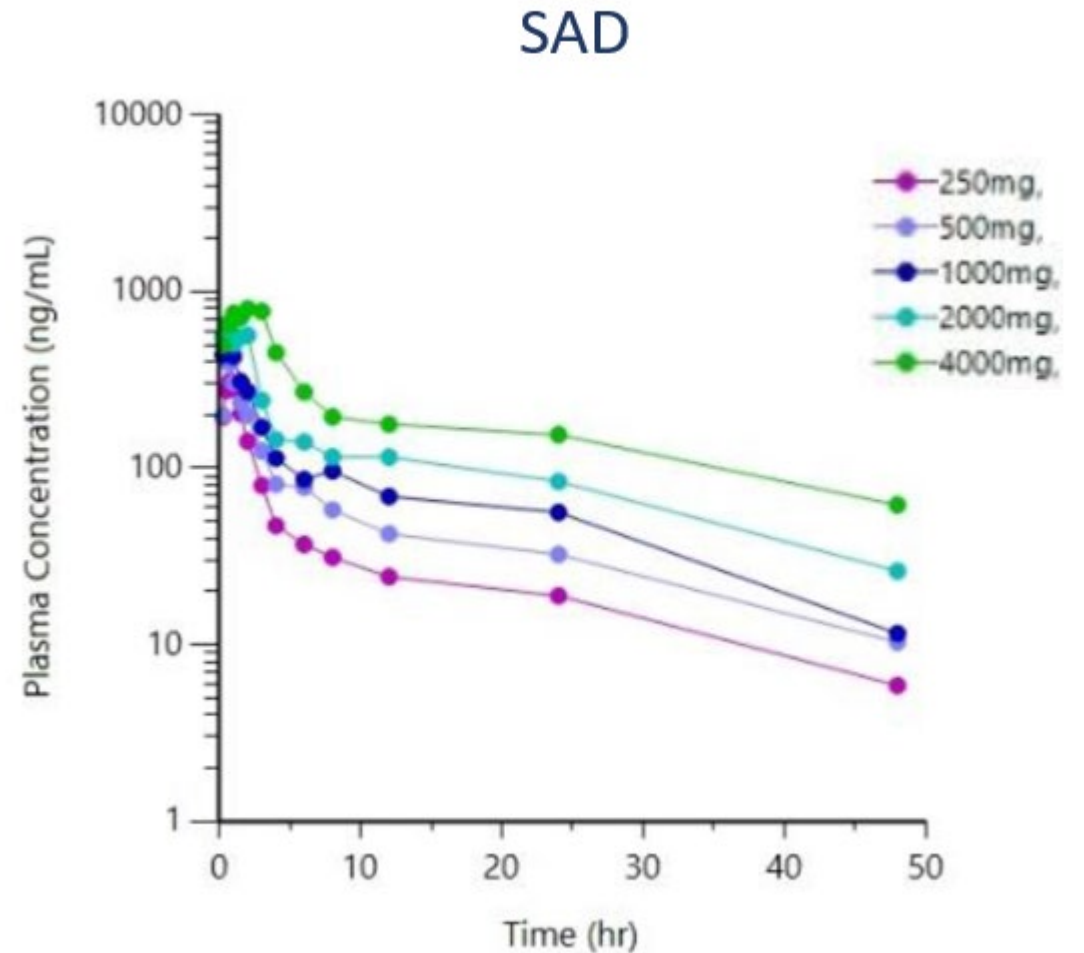
## Multiple Ascending Dose





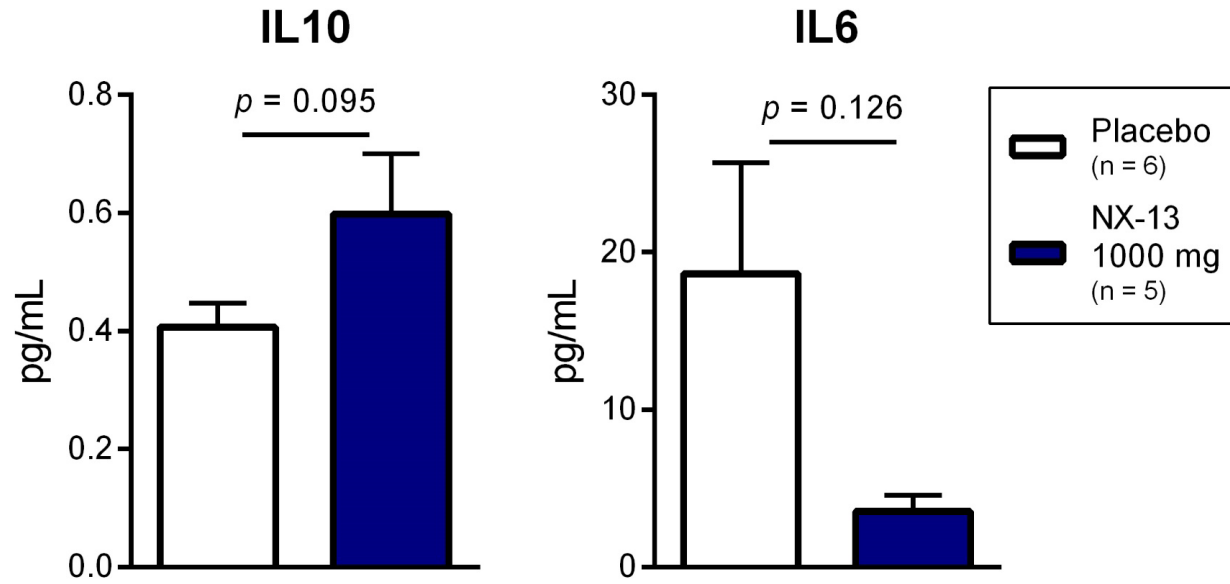
# NX-13 Pharmacokinetics in Normal Healthy Volunteers

- Stool NX-13 concentrations at 250 mg dose clear therapeutic threshold determined in pigs
- GI concentrations >2500-fold peak plasma concentrations
- No plasma accumulation, change in trough levels or plasma profile with 7-day multiple dosing
- Dose proportional response in stool with >2-fold less than dose proportional response in plasma





## NX-13 Promotes Detectable Changes in Cytokines in NHVs



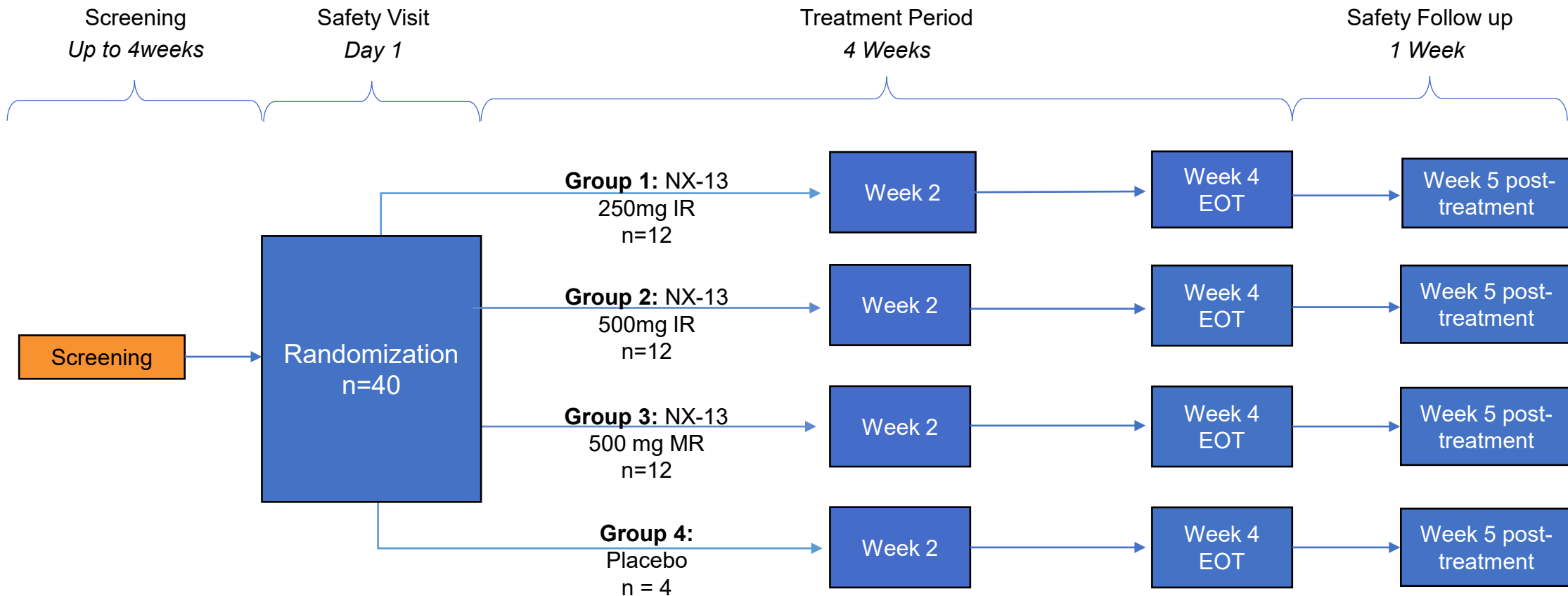
- Serum cytokines from normal healthy volunteers dosed with 1000 mg (lowest dose tested the MAD) or placebo for 7 days results in a nearly 50% increase in IL-10 and over 5-fold reduction in IL-6 relative to placebo





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

- Primary endpoints: Evaluate safety and pharmacokinetics of multiple dose levels
- Expected data readout: mid-2022



A complex network diagram with numerous nodes and edges. The nodes are represented by small circles in various colors: orange, pink, blue, red, and black. Some nodes are larger and have a double outline. The edges are thin, light gray lines connecting the nodes. A large, dark blue rectangular box is centered on the image, containing the text 'LABP-104'.

**LABP-104**



## Drug Profile

- Novel MOA
  - LANCL2 Agonist
  - Designed to downregulate pro-inflammatory signals; Designed to increase T regs and Anti-inflammatory signals
  - No on-target toxicities associated with the LANCL2 pathway
- Administration Route
  - Oral
- Pharmacokinetics and Safety
  - Systemic Exposure
  - Nonclinical safety studies on-going with results from long-term safety studies in Q3'22



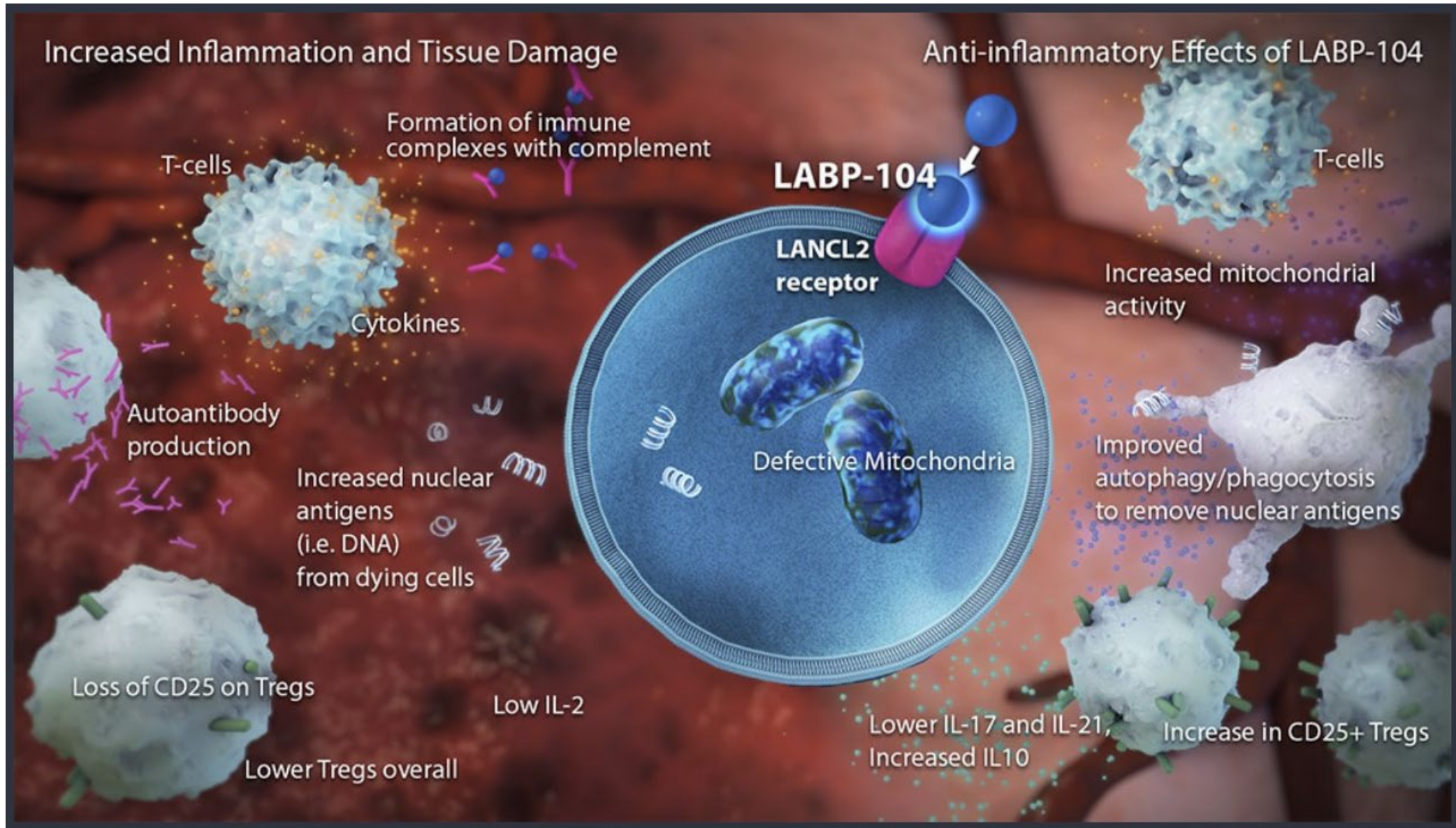


## Indications and Development Stage

- Systemic Lupus Erythematosus (SLE)
- Rheumatoid Arthritis (RA)
- INDs for SLE and RA approved in 2021
- Phase 1a – first in human (NHV) initiated in 2021 with top-line results on-track for mid-2022



# LABP-104 Designed to Activate LANCL2 Systemically in the Blood and Tissue





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  - Core expertise in the discovery and targeting of novel pathways at the interface of immunity and metabolism utilizing the LANCE® Advanced A.I. platform
- First to target novel pathways LANCL2, NLRX1, and PLXDC2
  - Unique multi-modal effects on both immunity and metabolism
  - Novel gut-restricted and systemic product candidates in clinical development
- BT-11/omilancor Phase 2b for moderate-severe ulcerative colitis patients initiating before the end of 2022
- NX-13 Phase 1b top-line results in moderate-severe ulcerative colitis patients mid-2022
- LABP-104 Phase 1 top-line results in NHV mid-2022
- Extensive global intellectual property portfolio with protection to 2040
- Cash of \$91 million\* with runway into 2H'23

\* (as of December 31, 2021)

A background network diagram consisting of numerous small, colored circular nodes (orange, yellow, pink, blue, red) connected by thin, light gray lines, creating a complex web of connections. A dark blue rectangular border is centered on the page, enclosing the text.

**THANK YOU**