BIORA™ Therapeutics

Reimagining therapeutic delivery

UNMET NEEDS IN ULCERATIVE COLITIS

BT-600 PHASE 1 TRIAL RESULTS

July 17, 2024

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We cannot assure you that we will realize the results, benefits or developments that we expect or anticipate or, even if substantially realized, that they will result in the consequences or affect us or our business in the way expected. Forward-looking statements are not historical facts and reflect our current views with respect to future events. Given the significant uncertainties, you should evaluate all forward-looking statements made in this presentation in the context of these risks and uncertainties and not place undue reliance on these forward-looking statements as predictions of future events. All forward-looking statements in this presentation apply only as of the date made and are expressly qualified in their entirety by the cautionary statements included in this presentation. We disclaim any intent to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances, except as required by law.

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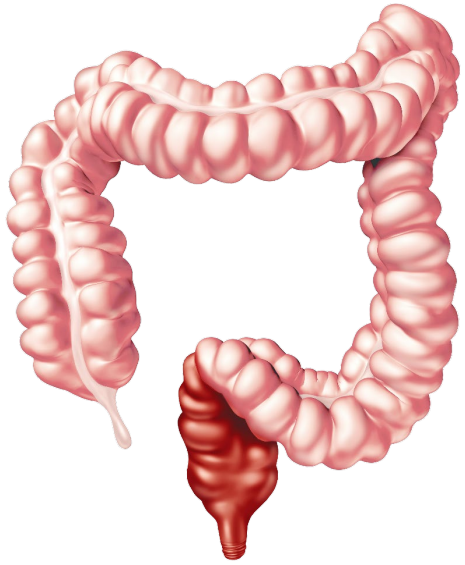
UNMET NEEDS IN ULCERATIVE COLITIS

Bruce E. Sands, MD, MS

Chief of the Dr. Henry D. Janowitz Division of Gastroenterology
Dr. Burrill B. Crohn Professor of Medicine
Icahn School of Medicine at Mount Sinai
Mount Sinai Hospital, New York

Clinical presentation of ulcerative colitis

E1: PROCTITIS

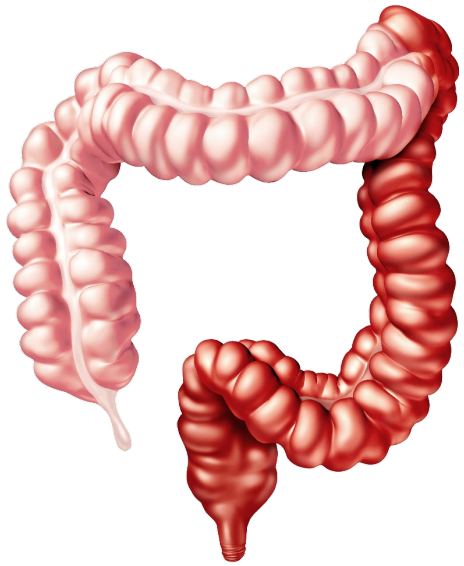


SYMPTOMS

Rectal bleeding, tenesmus, urgency

30–60% of patients

E2: DISTAL COLITIS

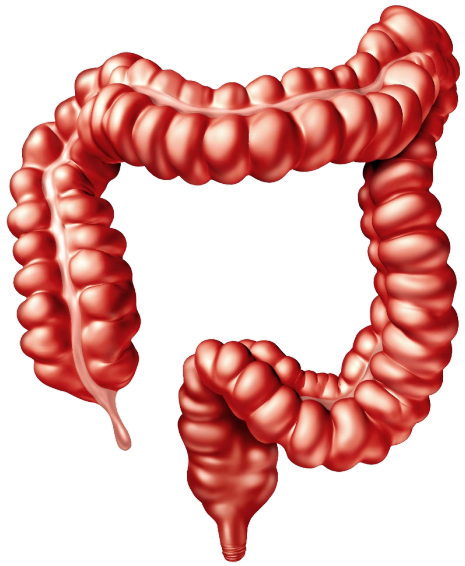


SYMPTOMS

E1 plus diarrhea, abdominal cramping

16–45% of patients

E1: PANCOLITIS



SYMPTOMS

E2 plus constitutional symptoms (fatigue, fever)

15–35% of patients

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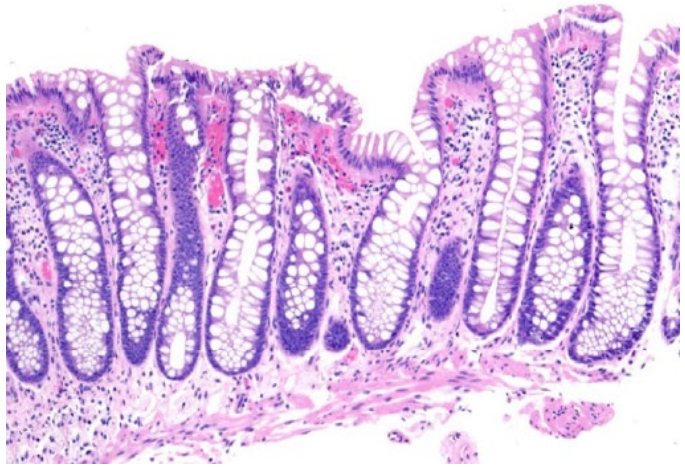
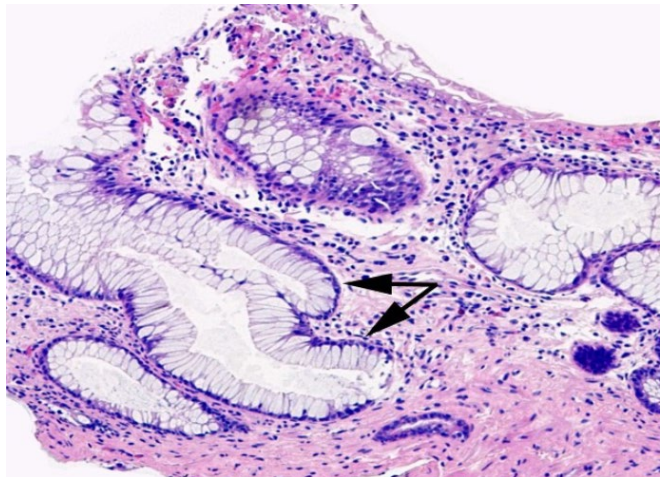
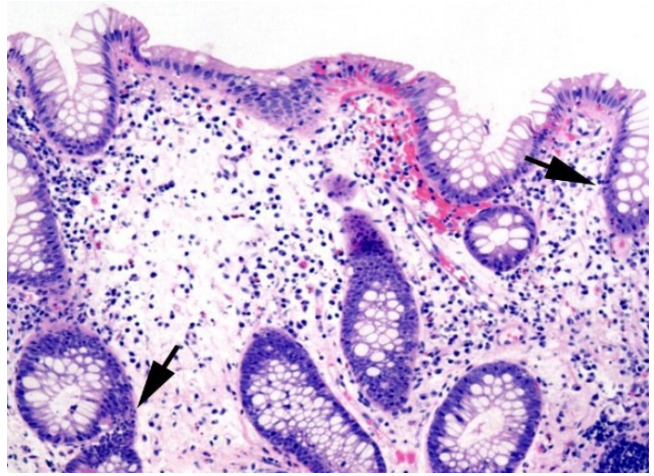
UC histology findings



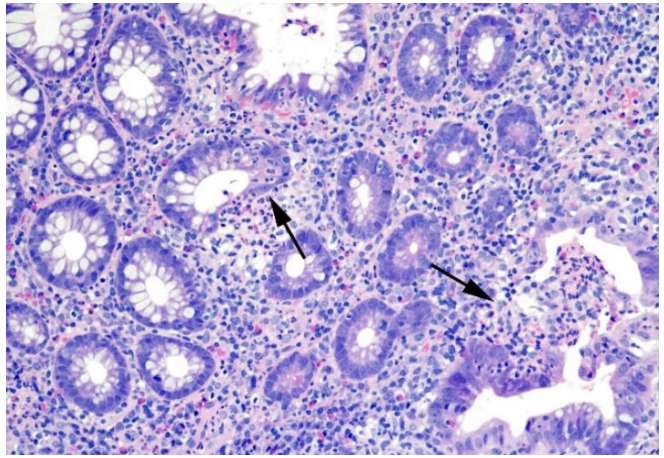
Normal colon



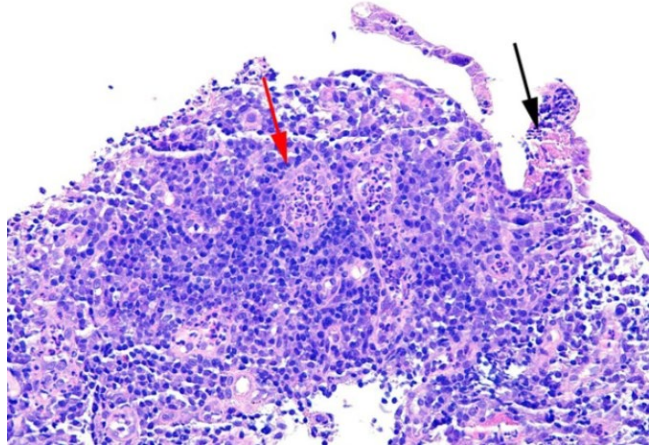
Inactive chronic colitis
crypt branching and dilation (arrows)



Mildly active chronic colitis
neutrophilic infiltrate in lamina propria and epithelium (arrows)



Moderately active chronic colitis
neutrophilic and lymphoplasmacytic infiltrate with cryptitis/crypt abscesses (arrows)



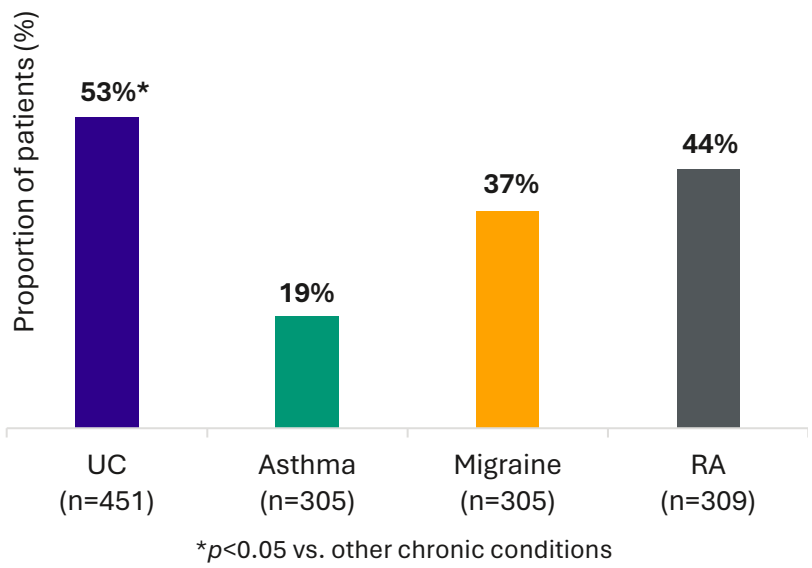
Severely active chronic colitis
loss of crypts and thin epithelium (black arrow) and dense lymphoplasmacytic and neutrophilic infiltrate

Images courtesy of Dr. Mabel Ko

UC has high impact on patient lives

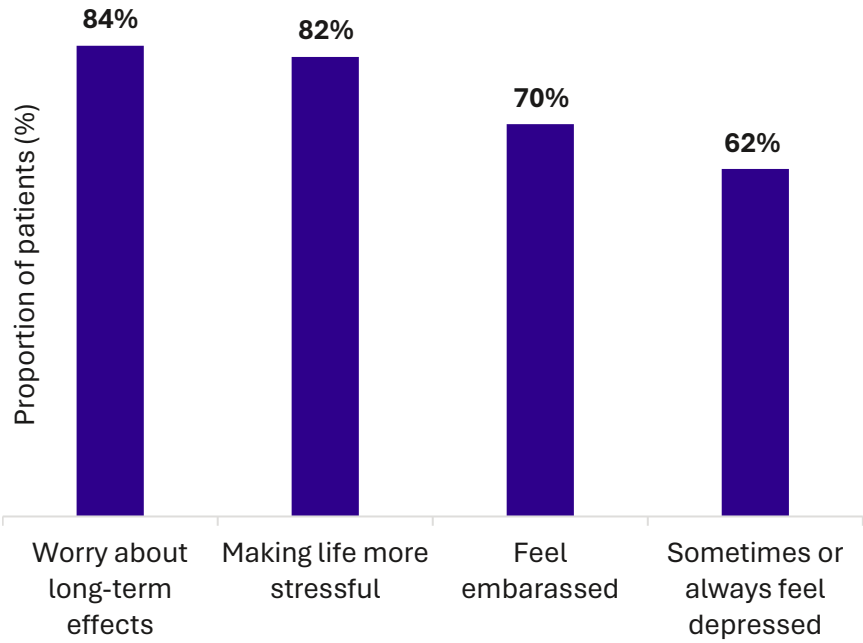
≈1.5 million patients with UC in the United States

PATIENTS WHO FELT THEIR CONDITION WAS CONTROLLING THEIR LIVES



*$p<0.05$ vs. other chronic conditions

PSYCHOLOGICAL IMPACT OF UC

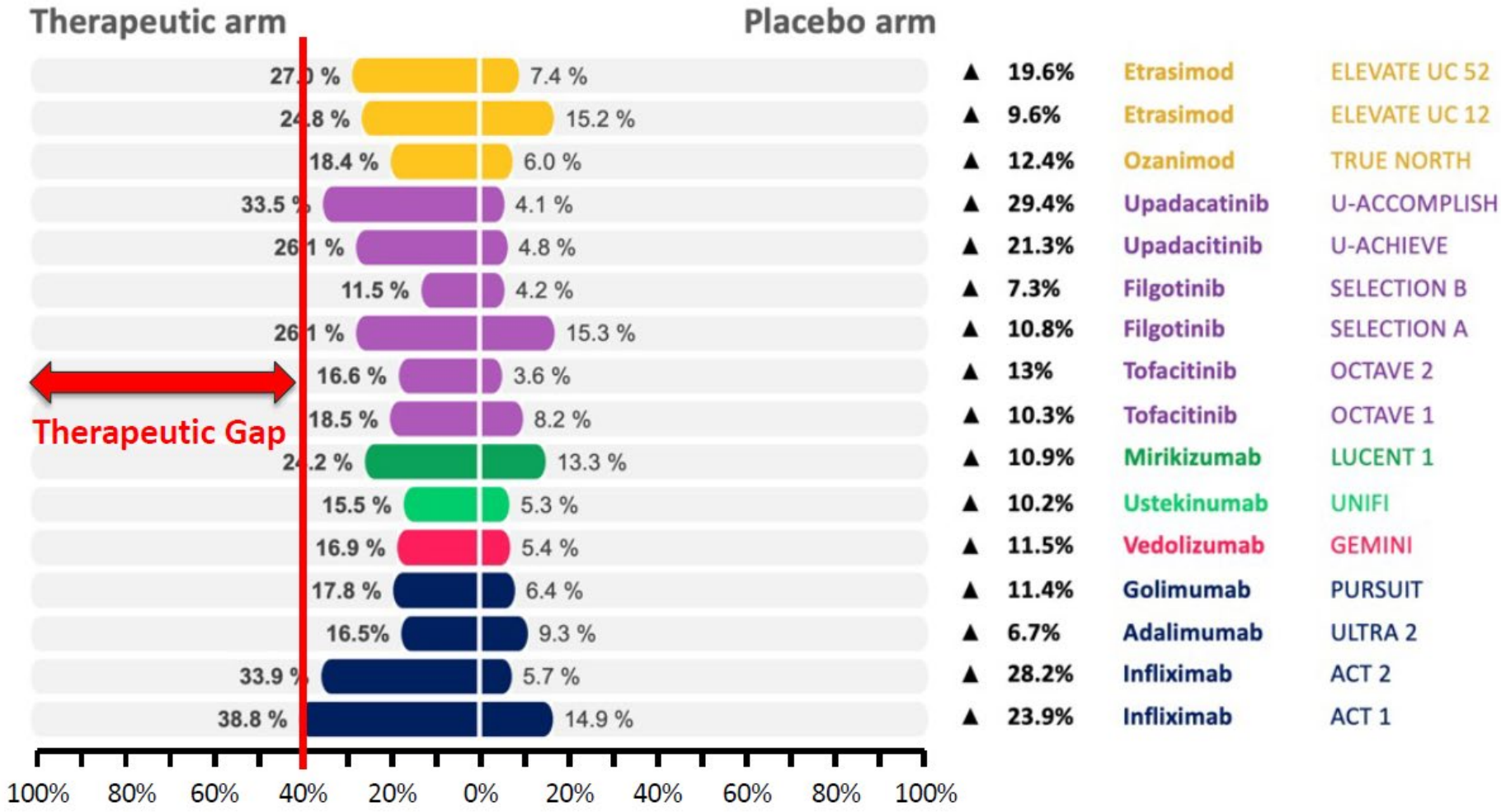


Internet survey designed to address a variety of disease impact indices

1. Rubin DT, Dubinsky MC, Panaccione R, et al. The impact of ulcerative colitis on patients' lives compared to other chronic diseases: a patient survey. *Dig Dis Sci*. 2010;55(4):1044-1052. doi:10.1007/s10620-009-0953-7

Therapeutic gap in UC

INDUCTION OF CLINICAL REMISSION IN UC



1. Alsoud D, Verstockt B, Fiocchi C, Vermeire S. Breaking the therapeutic ceiling in drug development in ulcerative colitis. *Lancet Gastroenterol Hepatol*. 2021;6(7):589-595. doi:10.1016/S2468-1253(21)00065-0

Anatomically targeted, topical delivery could improve efficacy and patient outcomes

THERAPEUTIC CHALLENGES

1. Difficulty of achieving sufficient drug activity at site of disease
2. Systemic toxicity issues may limit daily dosage of UC drugs
3. Combination therapy is limited by toxicity

POTENTIAL SOLUTION

- Localized delivery could increase drug activity at the site of disease, which is correlated with improved outcomes[1]
- Reduced systemic uptake is designed to reduce toxicity and adverse events
- Reduced toxicity could enable combination therapy[2]

1. Verstockt B, Alsoud D, van Oostrom J, et al. Tofacitinib tissue exposure correlates with endoscopic outcome. Poster presented at: *17th Congress of the European Crohn's and Colitis Organisation* (ECCO), February 18, 2022, virtual.
2. van Oostrom J, Verstockt B, Hanzel J, et al. Pharmacokinetic stratification of cytokine profiles during anti-TNF induction treatment in moderate-to-severe ulcerative colitis. Poster presented at: *17th Congress of the European Crohn's and Colitis Organisation* (ECCO), February 18, 2022, virtual.

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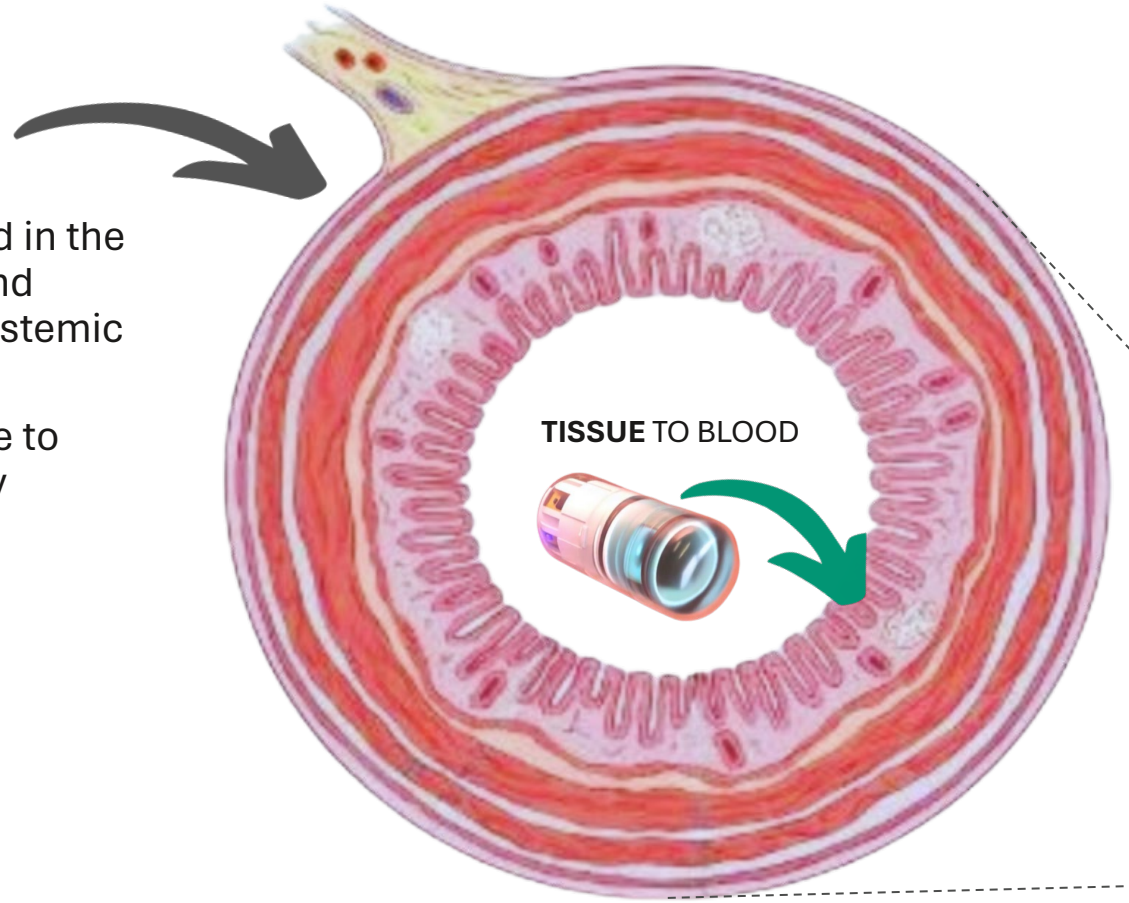
Anatomically targeted, topical drug delivery to the colon

CONVENTIONAL ORAL DELIVERY

BLOOD TO TISSUE

- Drug is absorbed in the upper GI tract and delivered into systemic circulation
- Dose limited due to systemic toxicity

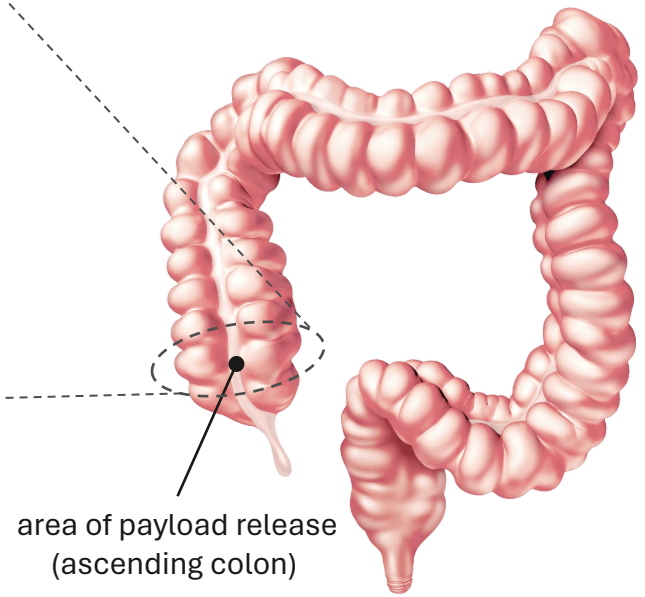


colon, cross section

NAVICAP DIRECT DELIVERY TO COLON

LUMEN TO TISSUE TO BLOOD

- Achieves tissue exposure through topical delivery to colon
- Lower drug levels in systemic circulation



area of payload release (ascending colon)

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BT-600 PHASE 1 CLINICAL TRIAL IN HEALTHY PARTICIPANTS

Ariella Kelman, MD

Chief Medical Officer
Biora Therapeutics

Needle-free, oral drug delivery to the colon

ORAL ADMINISTRATION

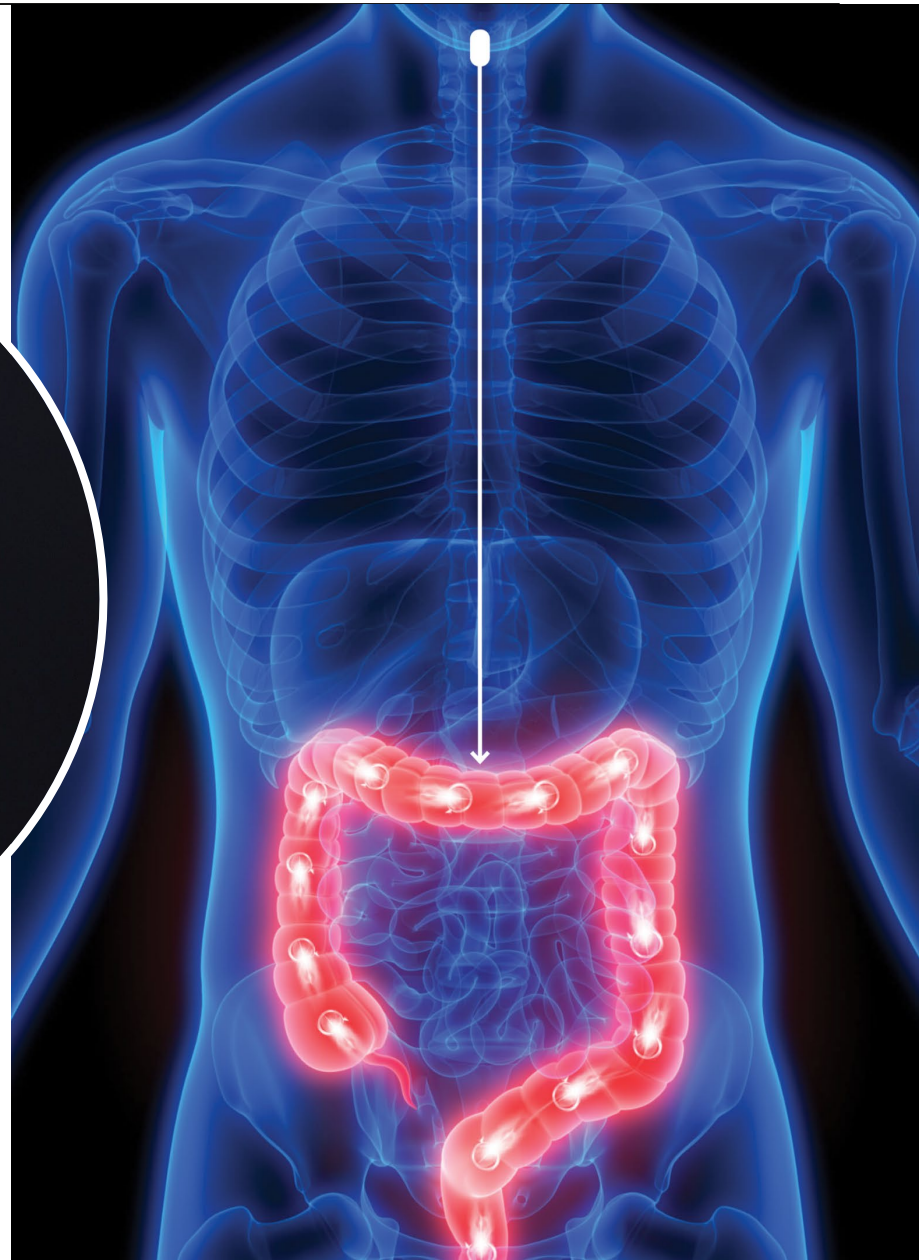
Convenient oral capsule the size of a fish-oil pill

AUTONOMOUS LOCATION

GITrac™ autolocation technology enables targeted delivery to the colon, regardless of fasted or fed state[1]

TARGETED DRUG DELIVERY

Method designed to coat the length of the colon with liquid formulation, minimizing systemic uptake



1. Lee SN, Razag G, Stork C, et al. Potential effects of food on a novel Drug Delivery System (DDS) to deliver therapeutic compound into the colon. Poster presented at: *Crohn's & Colitis Congress*, January 19-21, 2023, Denver, CO.

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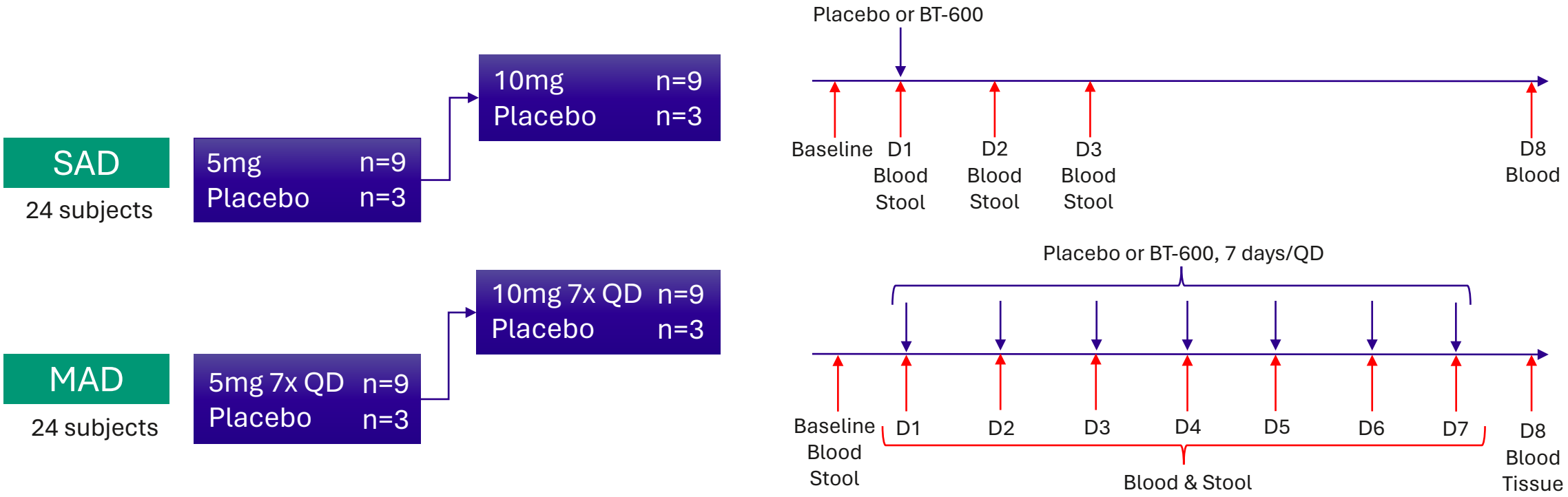
Evaluate safety and pharmacokinetics of BT-600 (NaviCap + tofacitinib proprietary liquid formulation) in healthy participants



PATIENT POPULATION	Total of 48 healthy participants (24 SAD and 24 MAD participants)
TRIAL DESIGN	Randomized, double-blind, placebo-controlled clinical trial to evaluate the safety, tolerability, and PK of SAD and MAD doses of BT-600 in healthy participants

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PHASE 1 SAD/MAD: TOPLINE RESULTS

All trial objectives met;
Precise drug delivery to the colon with limited systemic exposure

PLASMA PHARMACOKINETICS (PK)	**Achieved PK profile consistent with drug delivery in the colon**	• Tofacitinib first detected in blood at ≈6 hours, consistent with colonic delivery • Maximal blood levels were 3–4x lower than seen with Xeljanz[1] • Demonstrated ability to deliver tofacitinib to the colon with lower systemic levels than seen with conventional oral delivery in both SAD/MAD cohorts[1]
COLON TISSUE EXPOSURE	**Pan-colonic drug delivery**	• After delivery to the proximal colon, tofacitinib was detected across multiple biopsy sites in the distal colon • Delivery and distribution of tissue exposure consistent with delivery to the entire colon • Modeling projects tissue levels at or above the estimated IC90 across all three biopsy sites through at least 16 hours
DEVICE FUNCTION	**Accurately delivered to the colon**	• >95% of devices successfully detected colon entry
SAFETY & TOLERABILITY	**Showed safety of daily administration**	• BT-600 was well tolerated by participants in SAD and MAD cohorts

Phase 1 clinical trial data on file, Biora Therapeutics, Inc.

1. These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

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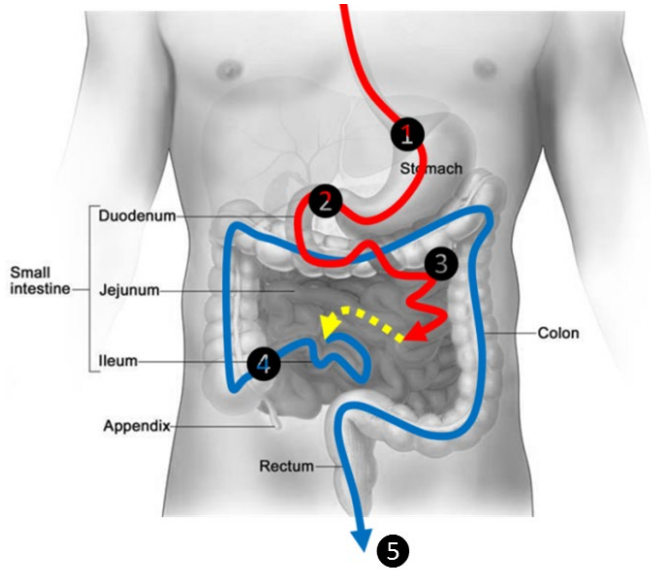
PHASE 1 NAVICAP DEVICE PERFORMANCE

Consistent drug release in the colon, bypassing the upper GI tract

- >95% of devices successfully detected colon entry
- No early drug release before colon entry
- Tight correlation between software device function and PK results
- Data consistent with those previously observed in human device function studies[1]

SOFTWARE ANALYSIS OF POST-DOSE RETRIEVED NAVICAP DEVICES

	SAD	MAD
Devices identified colon entry S4 call	24/24 (100%)	156/162 (96%)
Mean time of colon entry, hours post dose (SD)	5.6 (2.1)	6.6 (3.2)
Mean T_{first}, hours post dose (SD)	6.9 (2.6)	6.9 (2.0)



Phase 1 clinical trial data on file, Biora Therapeutics, Inc.

1. Lee SN, Razag G, Kelly C, et al. Results of human device function studies for the NaviCap™ Targeted Oral Delivery Platform in healthy volunteers and patients with UC. Poster presented at: Digestive Disease Week, May 18 – 21, 2024, Washington DC.

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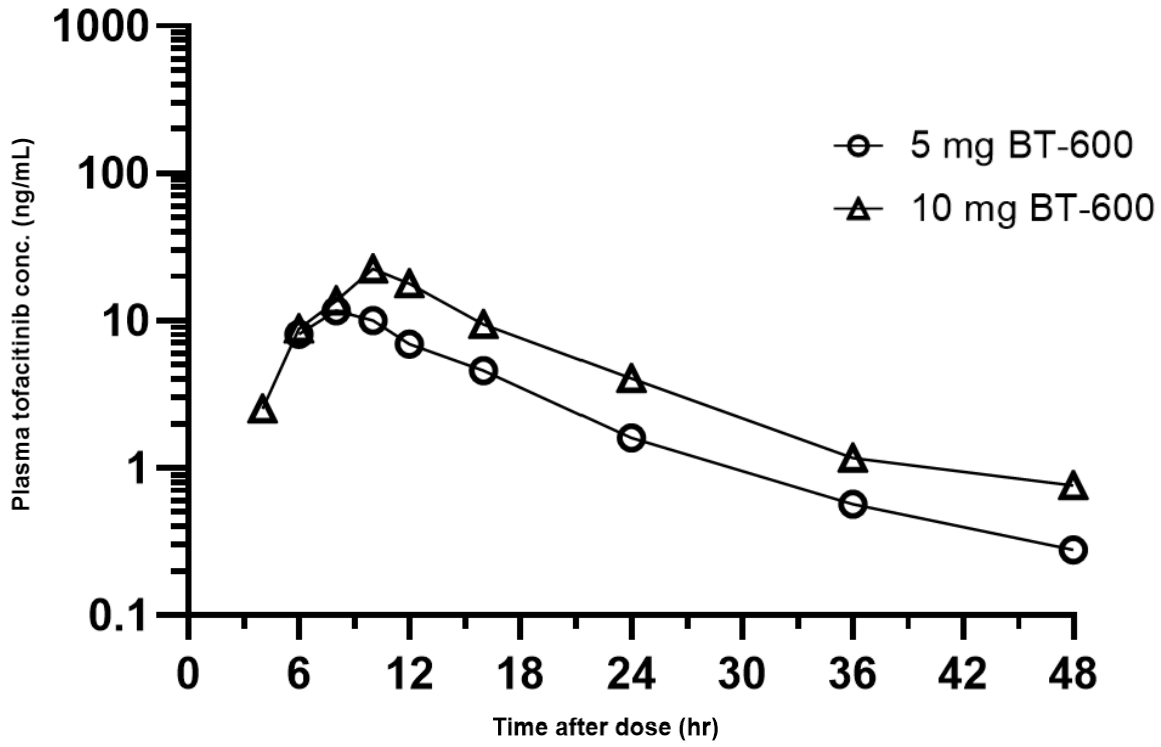
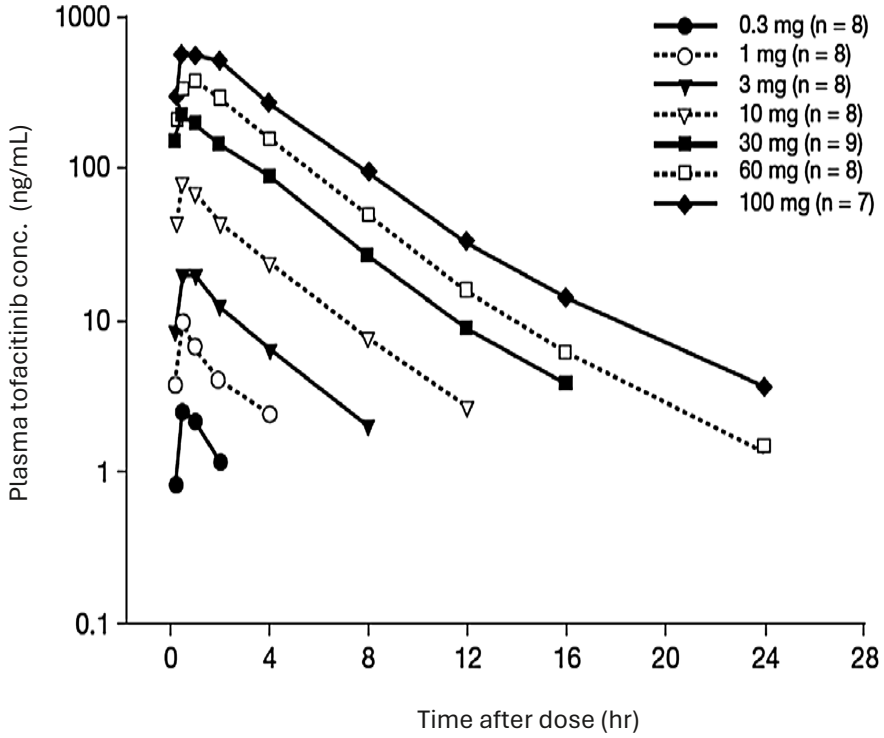
PK profile confirms lower systemic levels with 3–4x lower Cmax than Xeljanz

BT-600: MEAN PLASMA DRUG CONCENTRATION FOLLOWING ADMINISTRATION OF SINGLE ORAL DOSES[1]



XELJANZ: MEAN PLASMA DRUG CONCENTRATION FOLLOWING ADMINISTRATION OF SINGLE ORAL DOSES[2]



1. Phase 1 clinical trial data on file, Biora Therapeutics, Inc.
2. Krishnaswami S, Boy M, Chow V, Chan G. Safety, tolerability, and pharmacokinetics of single oral doses of tofacitinib, a Janus kinase inhibitor, in healthy volunteers. *Clin Pharmacol Drug Dev*. 2015;4(2):83-88. doi:10.1002/cpdd.171

NOTE: These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

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MAD PK confirms colonic delivery and low systemic exposure

PK Parameters†	BT-600 Multiple Oral Dosing[1] (n=9)				XELJANZ	
	DAY 1		DAY 7			
Dosing Regimen	**5 mg Once Daily**	**10 mg Once Daily**	**5 mg Once Daily**	**10 mg Once Daily**	**5 mg Twice Daily[2]**	**10 mg Single Dose[3]**
T_{first} hours	6 (4–16)	8 (4–10)	N/A	N/A	NR	NR
T_{max} hours	10 (4–10)	8 (4–12)	10 (6–12)	8 (6–10)‡	1.0 (0.5–14.0)	0.5 (0.25–1.0)
C_{max} ng/mL	11.3 (97)	24.2 (27)	11.3 (39)	16.3 (77)	42.7 (26)	88 (10.2)
AUC_{0-24} ng.hr/ml	92.8 (61)	194.0 (21)	115.8 (33)	140.5 (91)	263.4 (15)	283 (80)

† Values for T_{first} and T_{max} represent median (range). Values for C_{max} and AUC_{0-24} represent geometric mean (CV), except Xeljanz single-dose results which represent arithmetic mean (SD).
‡ T_{max} range excludes one device that did not release payload.

1. Phase 1 clinical trial data on file, Biora Therapeutics, Inc.
2. Pfizer, Inc. Xeljanz (tofacitinib) USPI. https://labeling.pfizer.com/showlabeling.aspx?id=959 Revised May 2024. Accessed June 18, 2024.
3. Krishnaswami S, Boy M, Chow V, Chan G. Safety, tolerability, and pharmacokinetics of single oral doses of tofacitinib, a Janus kinase inhibitor, in healthy volunteers. *Clin Pharmacol Drug Dev*. 2015;4(2):83-88.
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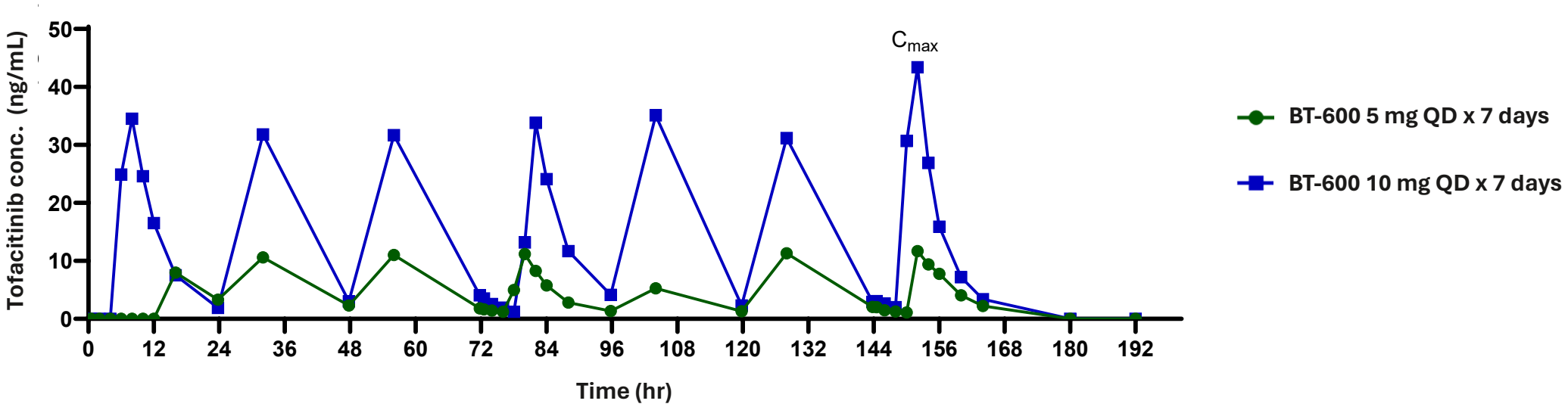
Consistent PK profile with repeat dosing

Characteristic, single-subject concentration time curve

- Dose dependent, low systemic exposure
- Consistent with colonic delivery



1. Phase 1 clinical trial data on file, Biora Therapeutics, Inc.

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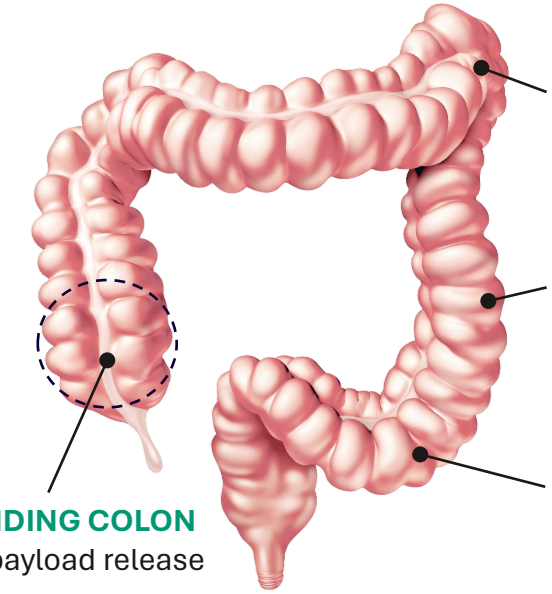
Evidence of drug delivery across all distal biopsy sites

BIOPSY SITES



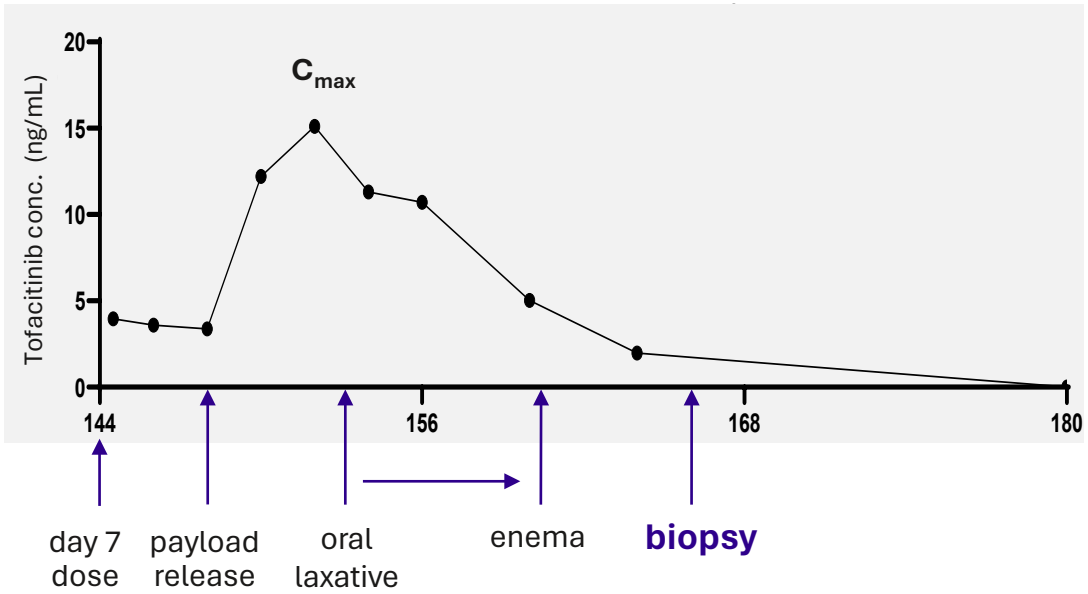
SPLENIC FLEXURE
tofacitinib present in
15/18 biopsies

DESCENDING COLON
tofacitinib present in
15/18 biopsies

SIGMOID COLON
tofacitinib present in
14/18 biopsies

ASCENDING COLON
area of payload release

PLASMA CONCENTRATION PROFILE FOR FINAL DOSE (DAY 7)



- Drug measured in tissue across distal colon sites (following proximal payload delivery) consistent with pan-colonic delivery
- Colon tissue absorption demonstrated despite:
  - Long dose-to-biopsy latency at ≈24 hours (and five half-lives) since final dose
  - Pre-procedural bowel prep with oral and rectal laxatives
  - Healthy participants (vs. UC patients who may have enhanced colonic absorption during active disease)

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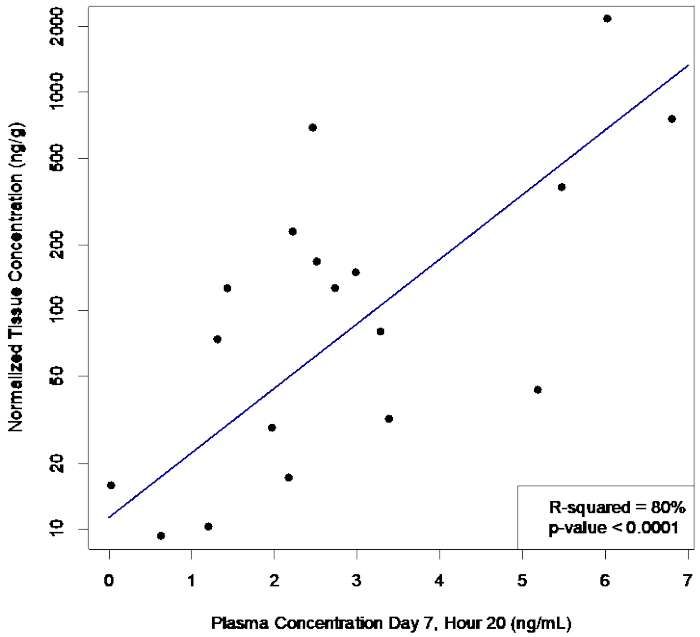
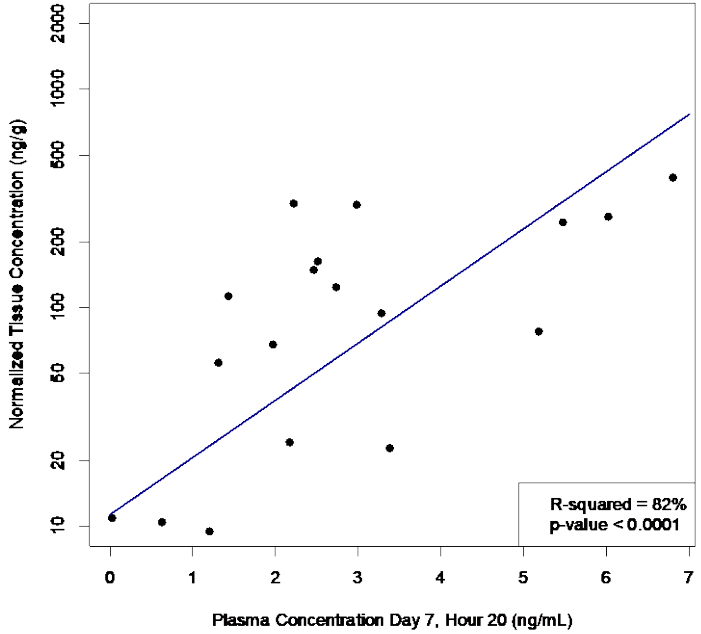
PHASE 1 MAD: COLON TISSUE EXPOSURE

Good correlation between tissue and plasma levels

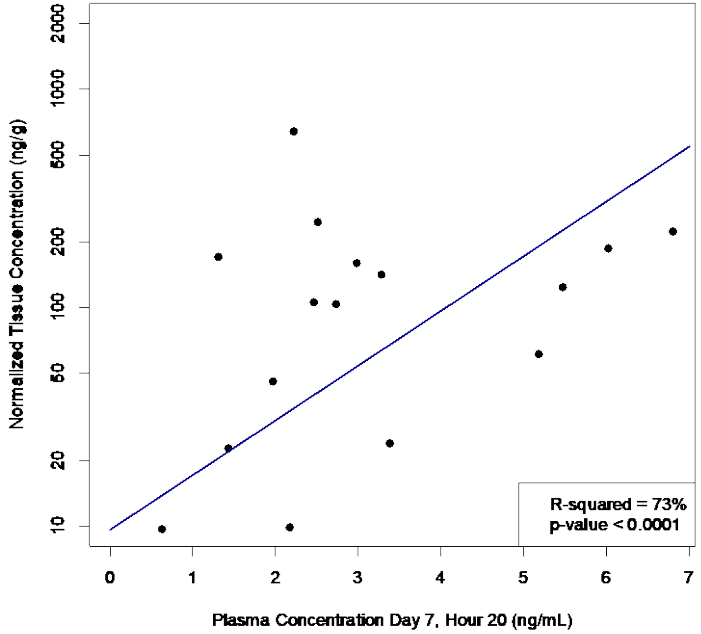
SPLENIC FLEXURE



DESCENDING COLON



SIGMOID COLON



- Plasma levels determined at 20 hours after final dose, while tissue biopsies were obtained at 24 ±2 hours after final dose
- Mean tissue concentrations above IC50 across all 3 biopsy sites at ≈24 hours (5 half lives) post dose
- Correlation between plasma and tissue levels was used to model tissue levels at earlier time points

Phase 1 clinical trial data on file, Biora Therapeutics, Inc.

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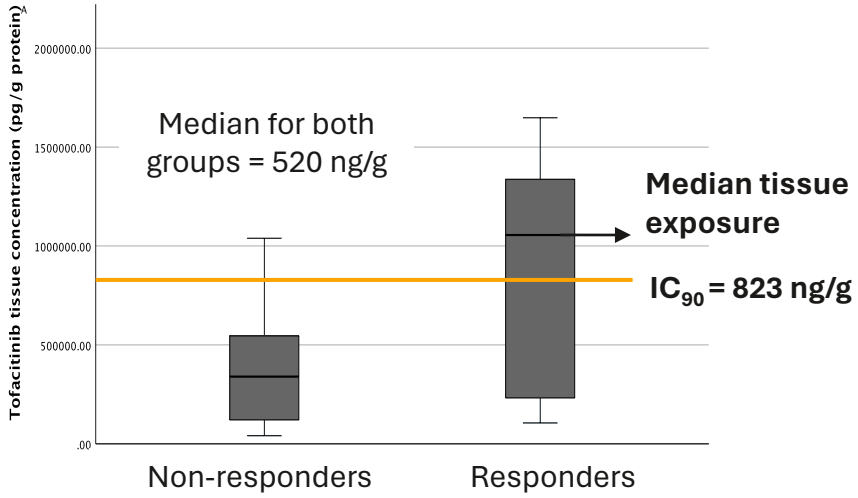
PHASE 1 MAD: COLON TISSUE EXPOSURE

Projected tofacitinib levels above IC90 through at least 16 hours

CONVENTIONAL ORAL TOFACITINIB CONCENTRATIONS (DOSE 10MG BID)[1]



Endoscopic improvement by week 16, **P=0.04** for group comparison

NAVICAP-DELIVERED TOFACITINIB CONCENTRATIONS (BT-600 5MG QD AND 10 MG QD)[2]

Hours Post Last Dose	Plasma Concentration ng/mL	Colon Tissue Concentration†		
		Splenic Flexure ng/g	Descending Colon ng/g	Sigmoid Colon ng/g
22–26 hours tissue 20 hours plasma (measured, n=15)	3.0	**338** (28, 649)	**159** (96, 223)	**161** (72, 251)
16 hours projected‡	10	Range **3,000 – 10,000** ng/g		

† Values represent mean (95% confidence interval)

‡ Predicted tissue levels geometric means based on plasma drug level at 16 hours after device ingestion

- Tofacitinib tissue concentrations shown to correlate with endoscopic response, with responders having a median tissue concentration above the estimated IC90
- Projected tofacitinib levels above IC90 through at least 16 hours, with measured levels above IC50 at 24 hours post dose
- NaviCap delivery predicted to enable tissue concentrations associated with improved efficacy with lower systemic exposure

1. Verstockt B, Alsoud D, van Oostrom J, et al. Tofacitinib tissue exposure correlates with endoscopic outcome. Poster presented at: *17th Congress of the European Crohn's and Colitis Organisation* (ECCO), February 18, 2022, virtual.
2. Phase 1 clinical trial data on file, Biora Therapeutics, Inc.

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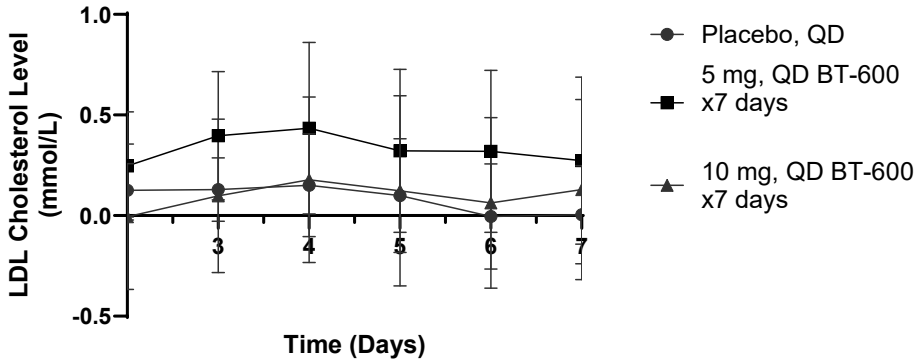
PHASE 1: SAFETY PARAMETERS

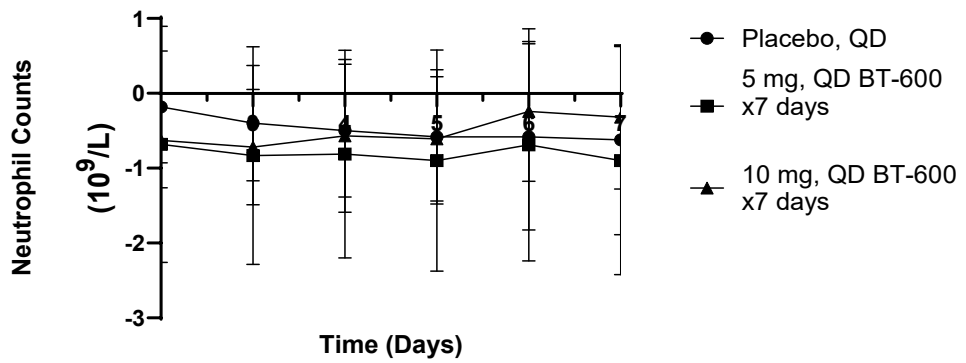
BT-600 was well tolerated

- All AEs were mild and consistent with those expected in healthy population (headache, constipation)
- No evidence of device or drug colon toxicity; colon tissue histology within normal limits
- No notable changes or differences in safety laboratory parameters between groups

LDL CHOLESTEROL
MEAN CHANGES FROM BASELINE (MAD)



NEUTROPHILS
MEAN CHANGES FROM BASELINE (MAD)



Phase 1 clinical trial data on file, Biora Therapeutics, Inc.

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BT-600 IN ULCERATIVE COLITIS

Phase 1 trial results support clinical development plan

PHASE 1

Purpose
Provide evidence of NaviCap colonic delivery of a therapeutic

Population
48 healthy participants

Design
Single-center SAD/MAD trial

Endpoints
- Safety & tolerability
- PK/PD
- Device function

COMPLETE

PHASE 1b

Purpose
Confirm PK profile in UC patients; inform Ph2 dose selection

Population
≈15 UC patients

Design
Single-center trial

Endpoints
- Safety & tolerability
- PK/PD
- Device function

PLANNED START: Q4 2024

DURATION: 6 MO

PHASE 2

Purpose
Proof of concept: efficacy of tofacitinib delivered via NaviCap

Population
≈150 UC patients

Design
Global multicenter induction efficacy trial

Endpoints
- Clinical and endoscopic response
- Mucosal healing
- PROs
- Biomarkers

PLANNED START: Q4 2025

DURATION: TBD

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CONSIDERATIONS FOR COLONIC DELIVERY IN UC

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University of Western Ontario

Gastroenterologist
London Health Sciences Centre, Ontario

Sr. Scientific Director
Alimentiv, Inc.

Topical treatments can be effective in UC, but challenging to deliver

Previous approaches to topical treatment include enemas, rectal foams, suppositories, and oral delayed-release preparations

- 5-Aminosalicylates, corticosteroid preparations in mild to moderate disease
- Calcineurin inhibitor enemas and suppositories in severe refractory disease

Inability to sufficiently reach colon tissue may limit efficacy of systemic treatments

- Doses needed to achieve sufficient colon tissue exposure are limited by toxicity risks
- Precise topical delivery could result in improved tissue exposure with lower systemic absorption

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Challenges with existing colonic delivery

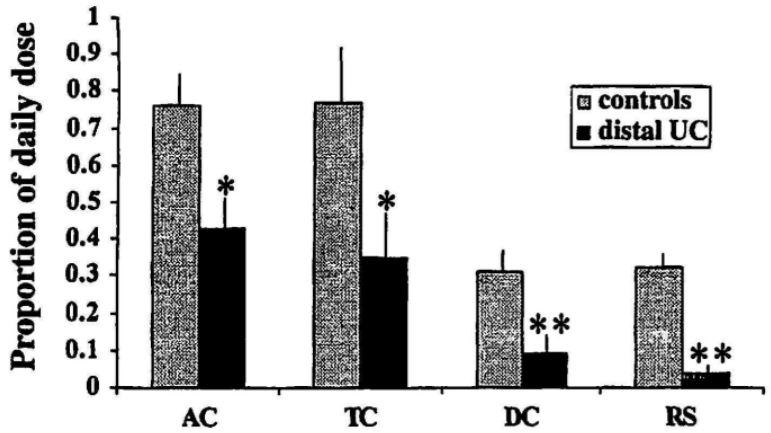
RECTAL PREPARATIONS

- Associated with poor retention
- Cannot reach proximal colon
- Can be embarrassing for patients

EXISTING COLONIC DELIVERY ORAL CAPSULES

- pH-sensitive polymers, enzyme sensitive systems
- Highly variable delivery in colon, often disintegrate in upper GI tract or are retrieved intact[1]
- Limited drug exposure in the distal colon, especially in UC[2]
  - Often require solid-dose formulations which need solubilization in the colon, limiting uptake
  - Reliant on variable GI conditions including pH, motility, water content, and bacterial enzymes

COLONIC DELIVERY ORAL FORMULATIONS SHOW POOR COLONIC DISTRIBUTION IN UC PATIENTS[2]

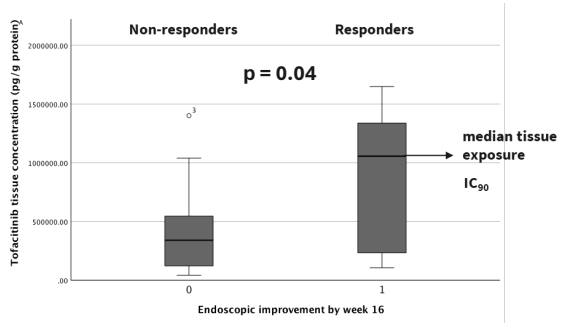


UC: 91% (proximal) vs. 9% (distal)

Healthy: 69% (proximal) vs. 31% (distal)

1. Ibekwe, V.C., Fadda, H.M., McConnell, E.L. *et al.* Interplay Between Intestinal pH, Transit Time and Feed Status on the *In Vivo* Performance of pH Responsive Ileo-Colonic Release Systems. *Pharm Res* 25, 1828–1835 (2008).
2. Hebden JM, Blackshaw PE, Perkins AC, Wilson CG, Spiller RC. Limited exposure of the healthy distal colon to orally-dosed formulation is further exaggerated in active left-sided ulcerative colitis. *Aliment Pharmacol Ther*. 2000 Feb;14(2):155-61.

Colon tissue drug exposure and activity correlates with endoscopic outcomes



TOFACITINIB TISSUE EXPOSURE HIGHER IN RESPONDERS[1]

30 UC patients with active endoscopic disease Tx with XELJANZ (tofacitinib) and prospectively monitored

- Higher tofacitinib tissue exposure was associated with endoscopic improvement by week 16 (*p*=0.04)

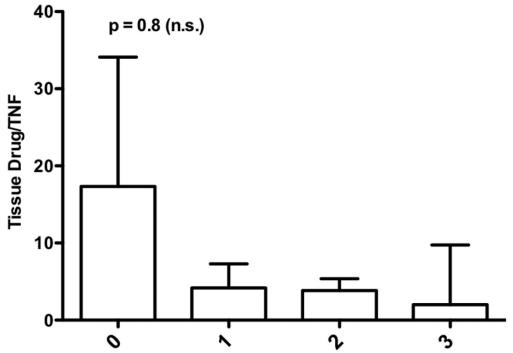
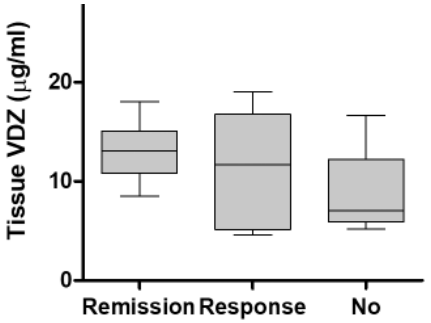


Figure 4: Mean drug to tumour necrosis factor (TNF) ratios in tissue with none, mild, moderate and severe inflammation (n.s., not significant).

ANTI-TNF TISSUE EXPOSURE HIGHER IN ENDOSCOPIC RESPONDERS[2]

30 UC patients on active maintenance therapy with REMICADE (infliximab) or HUMIRA (adalimumab) with tissue < blood and endoscopic assessment

- While there was a correlation between serum and tissue drug levels, areas of tissue with active inflammation acted as a sink for the anti-TNF antibody
- The ratio of anti-TNF to TNF cytokine levels was higher in patients in endoscopic remission



VEDOLIZUMAB TISSUE EXPOSURE HIGHER IN ENDOSCOPIC RESPONDERS[3]

37 IBD patients with active endoscopic disease Tx with ENTYVIO (vedolizumab) and prospectively monitored

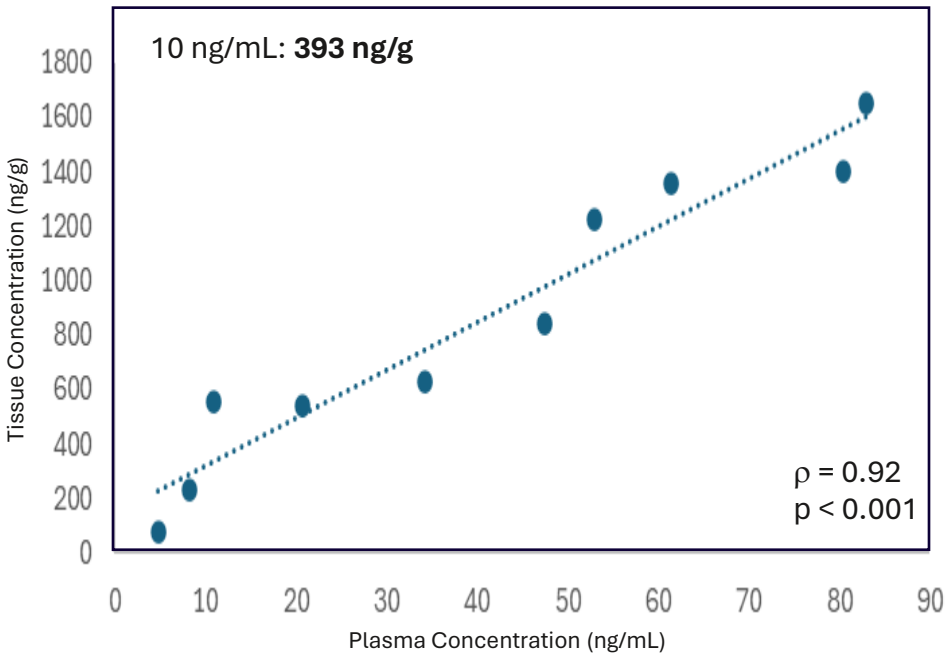
- Patients with endoscopic remission or response had significantly higher tissue drug levels (p=0.04)
- Authors suggest targeting vedolizumab tissue levels to optimize Tx in patients with no or loss of response

1. Verstockt B, Alsoud D, van Oostrom J, et al. Tofacitinib tissue exposure correlates with endoscopic outcome. Poster presented at: *17th Congress of the European Crohn's and Colitis Organisation* (ECCO), February 18, 2022, virtual.
2. Yarur AJ, Jain A, Sussman DA, et al. The association of tissue anti-TNF drug levels with serological and endoscopic disease activity in inflammatory bowel disease: the ATLAS study. *Gut*. 2016;65(2):249-255. doi:10.1136/gutjnl-2014-308099
3. Pauwels RWM, Proietti E, van der Woude CJ, et al. Vedolizumab Tissue Concentration Correlates to Mucosal Inflammation and Objective Treatment Response in Inflammatory Bowel Disease. *Inflamm Bowel Dis*. 2021;27(11):1813-1820. doi:10.1093/ibd/izab053

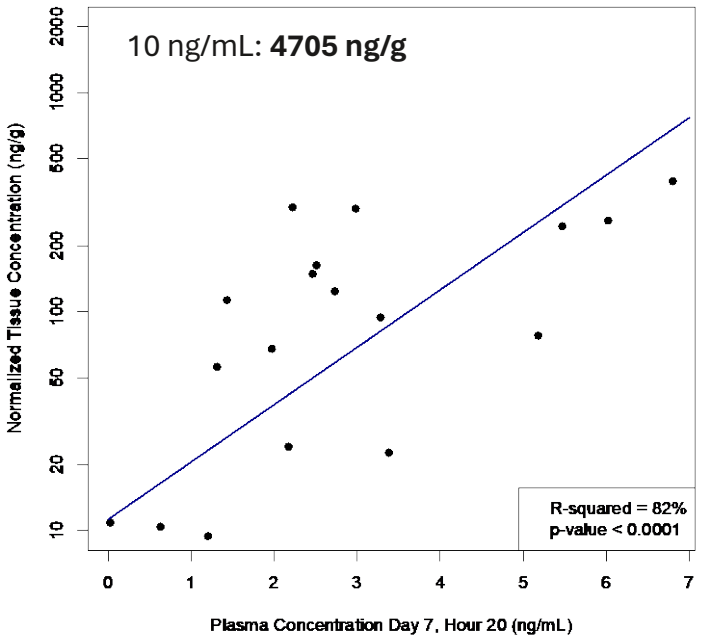
PHASE 1 MAD: COLON TISSUE EXPOSURE

NaviCap colonic delivery achieves higher tissue to plasma concentration ratio at lower dose

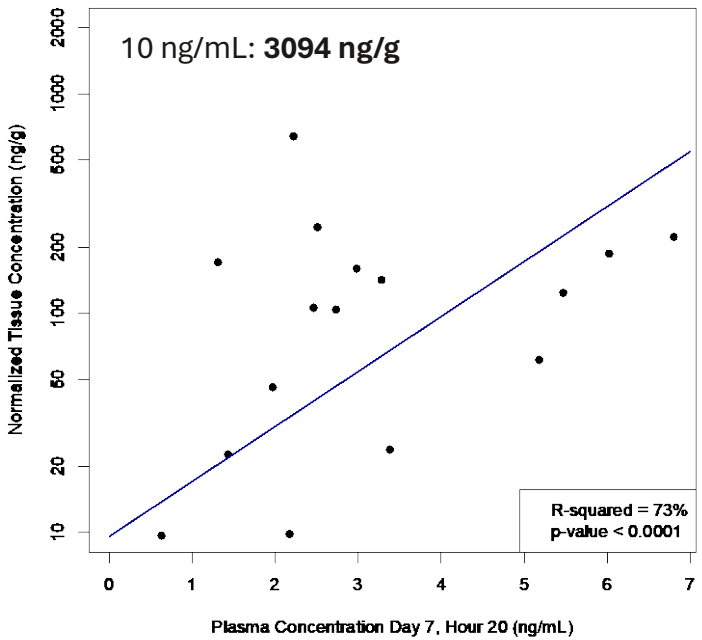
CONVENTIONAL TOFACITINIB 10 MG BID[1]



BT-600 DESCENDING COLON 5 MG AND 10 MG QD[2]



BT-600 SIGMOID COLON 5 MG AND 10 MG QD[2]



- Correlation between plasma and tissue levels was used to model tissue levels at earlier time points
- NaviCap colonic delivery achieves higher tissue to plasma concentration ratio at lower dose
  - Potential for improved efficacy with tissue exposure above IC90, with lower systemic absorption

1. Verstockt B., et al., . Tofacitinib tissue exposure correlates with endoscopic outcome. Poster presented at: Digestive Disease Week, May 21, 2022, virtual.
2. Phase 1 clinical trial data on file, Biora Therapeutics, Inc.

Key goals for successful topical colonic delivery

1. CONSISTENT PHARMACOKINETICS	Colonic delivery regardless of GI motility, which can vary between patients and across disease activity	✓ **Demonstrated in BT-600 Phase 1 trial and in NaviCap scintigraphy device function studies**
2. PRECISION RELEASE	Reliable delivery in the colon, rather than the upper GI tract	✓ **No early releases in BT-600 Phase 1 trial**
3. TISSUE EXPOSURE	Tissue exposure along the length of the colon	✓ **Demonstrated in BT-600 Phase 1 trial and in NaviCap scintigraphy device function studies**

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NAVIcap™

TARGETED ORAL DELIVERY

The NaviCap platform accurately delivers drug to colon

- Could achieve desired tissue exposure while decreasing undesired systemic exposure
- Could deliver better than current 20–30% efficacy rates while also enabling combination therapies
- NaviCap platform could be used for multiple drugs and drug classes

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