UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of The Securities Exchange Act of 1934

Date of report (Date of earliest event reported): July 17, 2024

Biora Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39334**	**27-3950390**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4330 La Jolla Village Drive, Suite 300
San Diego, California **92122**
(Address of principal executive offices) **(Zip Code)**

Registrant's telephone number, including area code: (833) 727-2841

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	BIOR	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure

On July 18, 2024, Biora Therapeutics, Inc. (the "Company") issued a press release announcing supplemental data from its Phase 1 clinical trial of BT-600.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein. The exhibit furnished under Item 7.01 of this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Item 8.01 Other Events

On July 17, 2024, the Company held a conference call with members of its Clinical Advisory Board to present the additional data and made available an updated corporate presentation on the Company's website.

A copy of the corporate presentation is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

On July 18, 2024, the Company announced the following supplemental data from its clinical trial of BT-600, an orally-administered drug-device combination in development for the potential treatment of patients with ulcerative colitis that leverages the Company's ingestible NaviCap™ device to deliver a proprietary liquid formulation of tofacitinib directly to the colon:

Summary of Key BT-600 Phase 1 Trial Results

Results from the Phase 1 clinical trial demonstrate a pharmacokinetic profile consistent with drug delivery and absorption in the colon for both single and multiple ascending dose ("SAD/MAD") cohorts.

- First evidence of systemic absorption of tofacitinib was at six hours, consistent with colonic (vs. upper gastrointestinal) delivery. Maximal levels in the trial occurred at eight to ten hours vs. 30 minutes for conventional oral tofacitinib in other trials.
- Maximal systemic drug exposure was three to four times lower than that seen with conventional oral tofacitinib in other trials, demonstrating the NaviCap platform's ability to deliver locally to the colon and limit systemic drug exposure.

The distribution of colon tissue exposure suggests that pan-colonic delivery of tofacitinib was achieved.

- Sites in the distal colon were biopsied, following delivery of tofacitinib in the proximal colon.
- Biopsy results provided evidence of drug exposure extending to the distal colon, at common sites of disease.
- Modeling projects tissue levels at or above the estimated IC90 through at least 16 hours after dosing.
- Post-retrieval device analysis further confirmed that NaviCap devices accurately delivered drug in the colon, with no early release, and with >95% of devices detecting colon entry.

NaviCap devices were well tolerated by participants in both the SAD and MAD cohorts.

- All adverse events were mild and consistent with those expected in a healthy population.
- 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.

Tissue biopsies were performed to assess drug concentration in colonic tissues at 24 hours after dosing during the Phase 1 trial in healthy participants. Mean tissue concentrations for the splenic flexure, descending colon, and sigmoid colon were above the established IC50 for the JAK-STAT pathway, and a strong correlation was shown between tissue and corresponding plasma levels. The plasma/tissue correlation was used to model tissue levels at earlier time points, with the model projecting tissue levels above the IC90 through at least 16 hours after dosing with BT-600.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits*.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated July 18, 2024
99.2	Corporate Presentation (July 17, 2024)
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Biora Therapeutics, Inc.

Date: July 18, 2024

By: /s/ Eric d'Esparbes
Name: Eric d'Esparbes
Title: Chief Financial Officer

Biora Therapeutics Announces Supplemental Data from Phase 1 Clinical Trial of BT-600 as Presented at KOL Event

Pharmacokinetic and tissue data confirm NaviCap platform delivers topically through the entire colon, with lower systemic concentrations, as desired

Data modeling suggests tofacitinib tissue concentrations greater than IC90 through at least 16 hours after dosing

SAN DIEGO, July 18, 2024 – Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company reimagining therapeutic delivery, presented supplemental data from the Phase 1 trial of BT-600 during the company's virtual KOL event on Wednesday, July 17, 2024. BT-600, an orally administered drug-device combination, is in development for the treatment of patients with ulcerative colitis (UC). BT-600 leverages Biora's ingestible NaviCap™ device to deliver a proprietary liquid formulation of tofacitinib directly to the colon.

"We are excited by the colon tissue drug exposure we are seeing in this trial," said Ariella Kelman, MD, Chief Medical Officer of Biora Therapeutics. "We observed levels above the IC50 at 24 hours and five half-lives after dosing, despite extensive pre-procedure colon prep. We know higher tissue levels are associated with better responses to tofacitinib in UC, and our model projects tissue levels well above IC90 through at least 16 hours post dose. This is especially notable since we studied daily doses of 5 mg and 10 mg in this trial, which are 50–75% lower than approved doses for conventional tofacitinib. We also observed lower systemic concentrations, which may be associated with reduced toxicity risks."

Tissue biopsies were performed to assess drug concentration in colonic tissues at 24 hours after dosing during the Phase 1 trial in healthy participants. Mean tissue concentrations for the splenic flexure, descending colon, and sigmoid colon were above the established IC50 for the JAK-STAT pathway, and a strong correlation was shown between tissue and corresponding plasma levels. The plasma/tissue correlation was used to model tissue levels at earlier time points, with the model projecting tissue levels above the IC90 through at least 16 hours after BT-600 5 mg or 10 mg doses.

"The results of this trial confirm that BT-600 can deliver drug topically throughout the length of the colon and could achieve both of our pharmacokinetic goals: higher tissue exposure and lower systemic concentrations. This certainly gives us confidence as we move into our planned clinical trial in UC patients," continued Dr. Kelman.

"There is an urgent need to break the therapeutic ceiling of 20–30% remission rates over placebo in UC," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "We plan to break through by changing the way gastrointestinal diseases are treated with our NaviCap platform, which can reliably deliver to specific locations within the GI tract. The clinical trial results for our current program, BT-600, demonstrate its potential and also provide proof of concept for the NaviCap platform's ability to deliver other molecules and drug classes in UC and beyond."

Biora's virtual KOL event on July 17 featured Bruce Sands, MD, MS (Icahn School of Medicine at Mount Sinai) and Brian Feagan, MD, FRCPC (Schulich School of Medicine & Dentistry at the University of Western Ontario), who discussed the unmet need and current treatment landscape for patients with UC, as well as the value of colonic drug delivery for improving efficacy. A replay of the live event can be accessed on the company's website.

SUMMARY OF KEY BT-600 PHASE 1 TRIAL RESULTS

Results from the Phase 1 clinical trial demonstrate a pharmacokinetic (PK) profile consistent with drug delivery and absorption in the colon for both single and multiple ascending dose (SAD/MAD) cohorts:

- First evidence of systemic absorption of tofacitinib was at six hours, consistent with colonic (vs. upper gastrointestinal) delivery. Maximal levels in the trial occurred at eight to ten hours vs. 30 minutes for conventional oral tofacitinib in other trials.
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NaviCap devices were well tolerated by participants in both the SAD and MAD cohorts:

- All AEs were mild and consistent with those expected in a healthy population.
- No evidence of device or drug colon toxicity; colon tissue histology was within normal limits.
- There were no notable changes or differences in safety laboratory parameters between groups.

About BT-600

BT-600 is a drug/device combination of Biora's NaviCap™ ingestible drug delivery device with a proprietary liquid formulation of tofacitinib, for the potential treatment of moderate to severe ulcerative colitis. The NaviCap device is orally administered and has been designed for anatomically targeted therapeutic delivery directly to the colon in this application.

About the NaviCap™ Targeted Oral Delivery Platform

Biora's NaviCap targeted oral therapeutics platform utilizes a novel approach that could improve patient outcomes by enabling delivery of therapeutics directly to the site of disease, increasing therapeutic activity in tissue while reducing systemic uptake. For the 1.8 million patients in the United States who suffer from inflammatory bowel disease (IBD), existing therapeutics offer less than ideal efficacy, likely because of the challenges with safely achieving sufficient drug activity in the affected tissues. Research has shown that targeted delivery of therapeutics has the potential to improve patient outcomes in IBD.

The NaviCap platform uses an ingestible device designed for targeted delivery of therapeutics to improve treatment of ulcerative colitis. Once swallowed, Biora's GItrac™ autolocation technology enables the device to autonomously identify targeted locations in the GI tract and release a therapeutic dose of up to 500µl. Studies of the NaviCap device in healthy volunteers and patients with ulcerative colitis demonstrated successful delivery to the colon regardless of variable GI conditions, in both fasted and fed states.

About Ulcerative Colitis

Ulcerative colitis (UC) is a type of IBD that causes chronic inflammation and damage to the colon. Common symptoms include abdominal pain, increased bowel movements, stool urgency, and rectal bleeding. Despite the availability of advanced treatments for UC, including biologics, immunomodulators, and targeted synthetic small molecules, only about 40% of patients achieve clinical remission in induction trials. Surgical intervention is needed in approximately 20% of UC patients, with up to 10% of patients requiring surgical removal of the colon. About 1.5 million people are affected with UC in the United States alone, and ~40,000 new cases are diagnosed each year.

About Biora Therapeutics

Biora Therapeutics is reimagining therapeutic delivery. By creating innovative smart pills designed for targeted drug delivery to the GI tract, and systemic, needle-free delivery of biotherapeutics, the company is developing therapies to improve patients' lives.

Biora is focused on development of two therapeutics platforms: the NaviCap™ targeted oral delivery platform, designed to improve outcomes for patients with inflammatory bowel disease through treatment at the site of disease in the gastrointestinal tract, and the BioJet™ systemic oral delivery platform, designed to replace injection for better management of chronic diseases through needle-free, oral delivery of large molecules.

For more information, visit bioratherapeutics.com or follow the company on LinkedIn or X.

Safe Harbor Statement or Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this press release, including statements concerning the progress and future expectations and goals of our research and development, preclinical and clinical trial activities, including those involving BT-600 and our NaviCap platform and model projections, and partnering and collaboration efforts with third parties, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "envision," "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "anticipate," "forward," "believe," "design," "estimate," "predict," "projects," "projecting," "potential," "plan," "goal(s)," "target," or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements reflect our plans, estimates, and expectations, as of the date of this press release. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ

materially from the forward-looking statements expressed or implied in this press release. Such risks, uncertainties, and other factors include, among others, our ability to innovate in the field of therapeutics, our ability to make future FDA filings and initiate and execute clinical trials on expected timelines or at all, our ability to obtain and maintain regulatory approval or clearance of our products on expected timelines or at all, our plans to research, develop, and commercialize new products, the unpredictable relationship between preclinical study results and clinical study results, our expectations regarding allowed patents or intended grants to result in issued or granted patents, our expectations regarding opportunities with current or future pharmaceutical collaborators or partners, our ability to raise sufficient capital to achieve our business objectives, our ability to maintain our listing on the Nasdaq Global Market, and those risks described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission (SEC) and other subsequent documents, including Quarterly Reports on Form 10-Q, that we file with the SEC.

Biora Therapeutics expressly disclaims any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

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Exhibit 99.2

BIORA™ Therapeutics

Reimagining therapeutic delivery

UNMET NEEDS IN ULCERATIVE COLITIS

BT-600 PHASE 1 TRIAL RESULTS

July 17, 2024

FORWARD-LOOKING STATEMENTS

This presentation contains "forward-looking statements" within the meaning of the federal securities laws, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical fact included in this presentation, including statements concerning our plans, objectives, goals, strategies, future events, plans or intentions relating to product candidates, estimates of market size, the anticipated timing, design and conduct of our planned pre-clinical and clinical trials, including with respect to BT-600 and our NaviCap platform and model projections, the anticipated timing for pre-clinical and clinical data, the development of our product candidates, the potential clinical benefits of our product candidates, including efficacy and safety benefits, the potential benefits of strategic partnerships and licensing arrangements and our intent to enter into any strategic partnerships or licensing arrangements, the timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated product development efforts, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "envision," "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "projects," "projecting," "potential," "plan," goal(s)," or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this presentation, including competition from third parties with respect to our product candidates; risks related to the supply and manufacturing of and complexity of components in our devices; whether we will be able to develop our precision medicine products, and, if developed, that such product candidates will be authorized for marketing by regulatory authorities, or will be commercially successful; risks related to our continued listing on the Nasdaq Global Market; and those described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, and elsewhere in such filing and in other subsequent disclosure documents, including our Quarterly Reports on Form 10-Q, filed with the U.S. Securities and Exchange Commission.

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.

Industry and Market Data: We obtained the industry, market, and competitive position data used throughout this presentation from our own internal estimates and research, as well as from industry and general publications, and research, surveys, and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of the industry and market, which we believe to be reasonable. In addition, while we believe the industry, market, and competitive position data included in this prospectus is reliable and based on reasonable assumptions, we have not independently verified any third-party information, and all such data involve risks and uncertainties and are subject to change based on various factors. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

BIORA Therapeutics

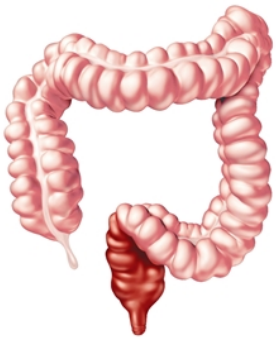
UNMET NEEDS IN ULCERATIVE COLITIS

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

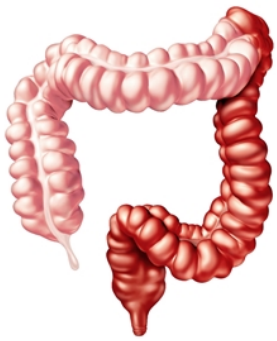
E1: PROCTITIS



SYMPTOMS
Rectal bleeding, tenesmus, urgency

30–60% of patients

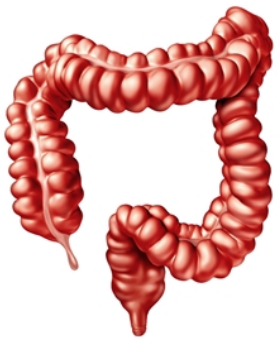
E2: DISTAL COLITIS



SYMPTOMS
E1 plus diarrhea, abdominal cramping

16–45% of patients

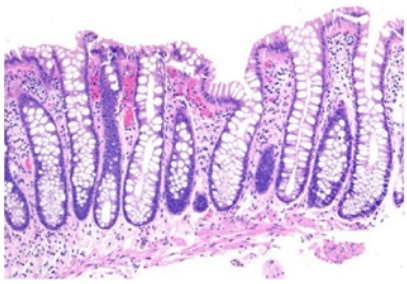
E1: PANCOLITIS



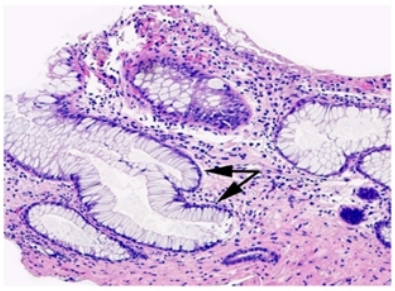
SYMPTOMS
E2 plus constitutional symptoms (fatigue, fever)

15–35% of patients

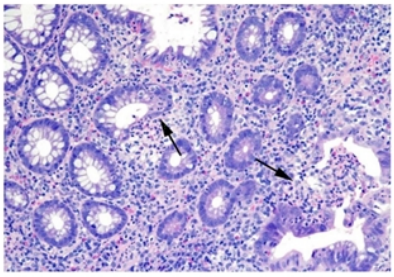
UC histology findings



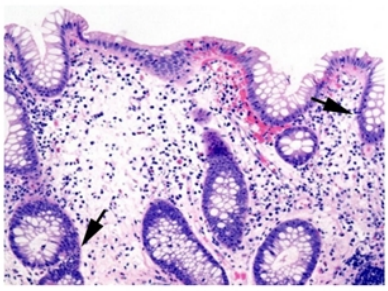
Normal colon



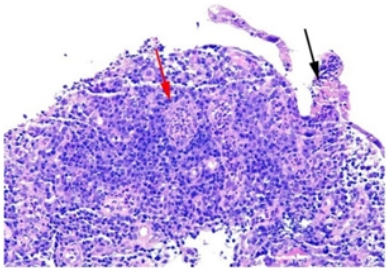
Inactive chronic colitis
crypt branching and dilation (arrows)



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



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



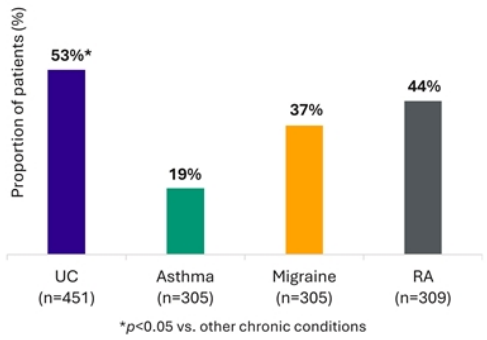
Severely active chronic colitis
loss of crypts and thin epithelium (black arrow) and dense lymphoplasmacytic and neutrophilic infiltrate

Images courtesy of Dr. Mabel Ko

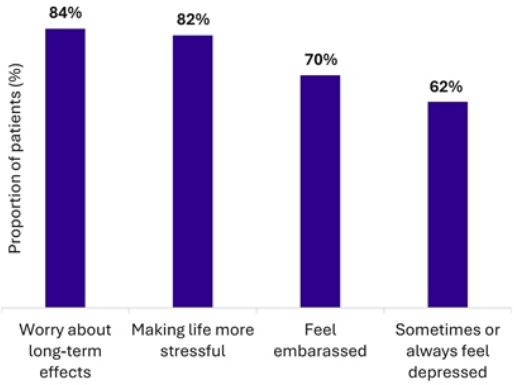
UC has high impact on patient lives

≈1.5 million patients with UC in the United States

PATIENTS WHO FELT THEIR CONDITION WAS CONTROLLING THEIR LIVES



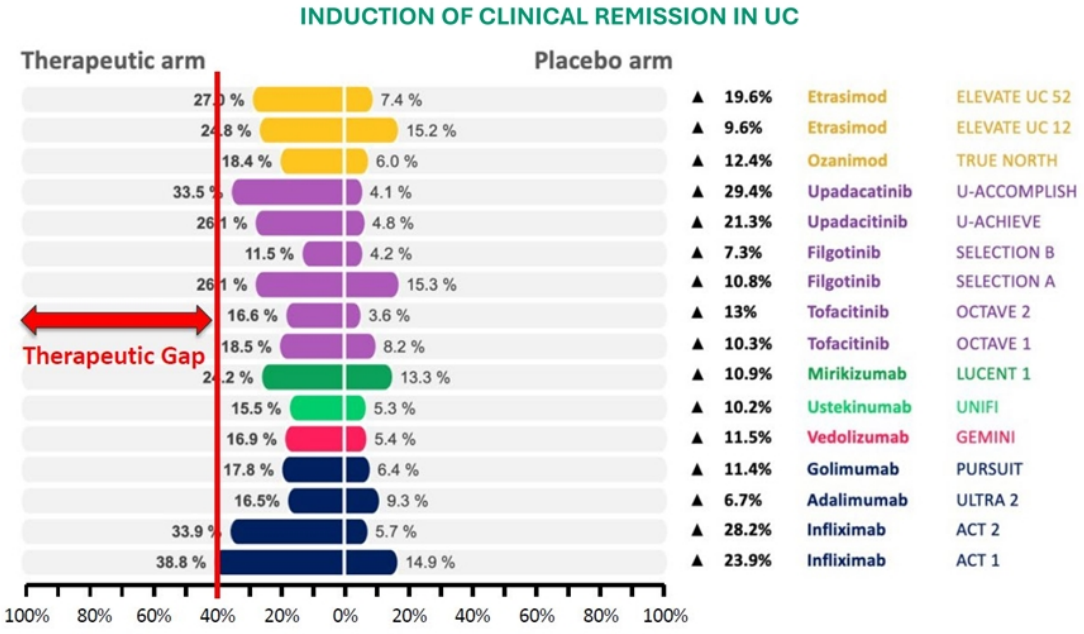
PSYCHOLOGICAL IMPACT OF UC



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



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

UNMET NEED IN ULCERATIVE COLITIS

Anatomically targeted, topical delivery could improve efficacy and patient outcomes

THERAPEUTIC CHALLENGES	POTENTIAL SOLUTION
1 Difficulty of achieving sufficient drug activity at site of disease	Localized delivery could increase drug activity at the site of disease, which is correlated with improved outcomes[1]
2 Systemic toxicity issues may limit daily dosage of UC drugs	Reduced systemic uptake is designed to reduce toxicity and adverse events
3 Combination therapy is limited by toxicity	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.

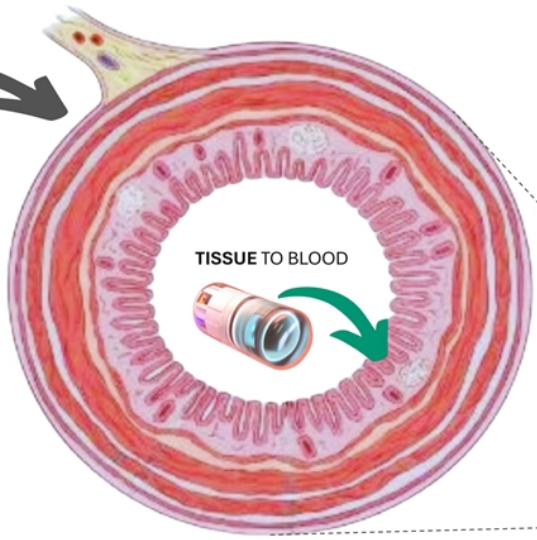
NAVICAP™ TARGETED ORAL DELIVERY

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

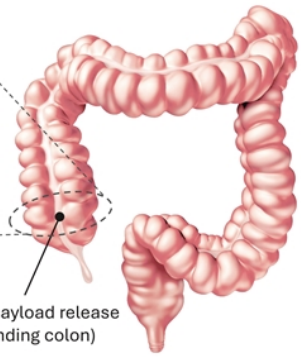


colon, cross section

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)

BIORA™ Therapeutics

BT-600 PHASE 1 CLINICAL TRIAL IN HEALTHY PARTICIPANTS

Ariella Kelman, MD
Chief Medical Officer
Biora Therapeutics

NAVICAP™ TARGETED ORAL DELIVERY PLATFORM

Needle-free, oral drug delivery to the colon

ORAL ADMINISTRATION

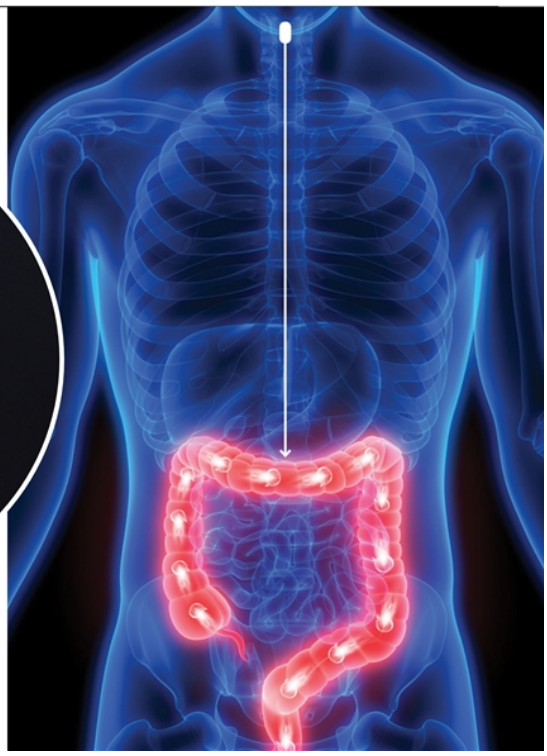
Convenient oral capsule the size of a fish-oil pill

AUTONOMOUS LOCATION

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

TARGETED DRUG DELIVERY

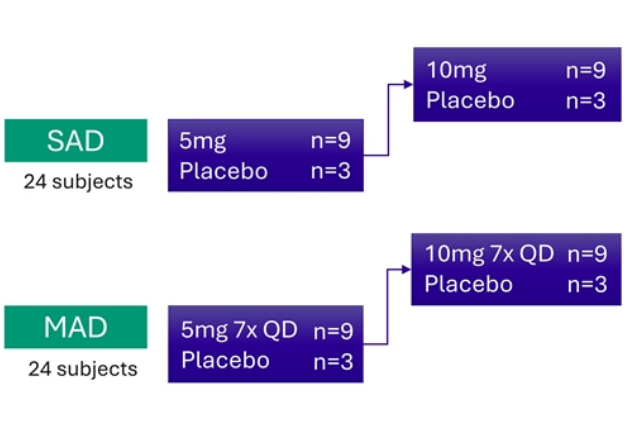
Method designed to coat the length of the colon with liquid formulation, minimizing systemic uptake

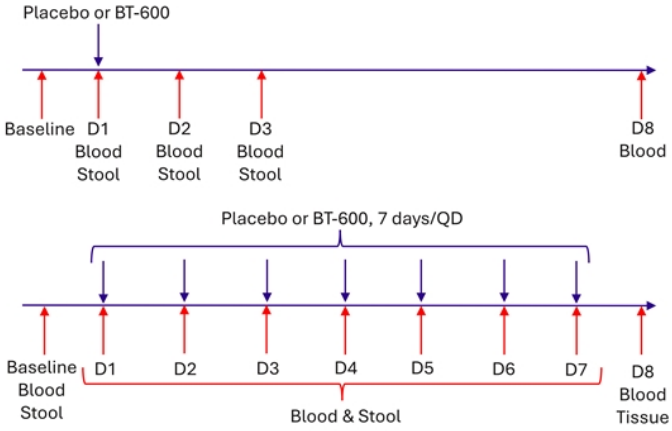


1. Lee SN, Razag G, Stork C, et al. Potential effects of food on a novel Drug Delivery System (DDS) to deliver therapeutic compound into the colon. Poster presented at: *Crohn's & Colitis Congress*, January 19-21, 2023, Denver, CO.

PHASE 1 CLINICAL TRIAL DESIGN

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

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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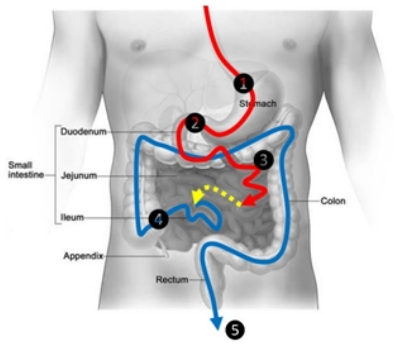
PHASE 1 NAVICAP DEVICE PERFORMANCE

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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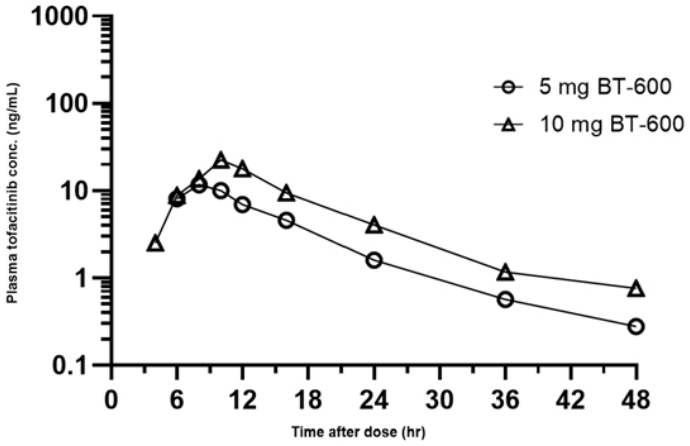
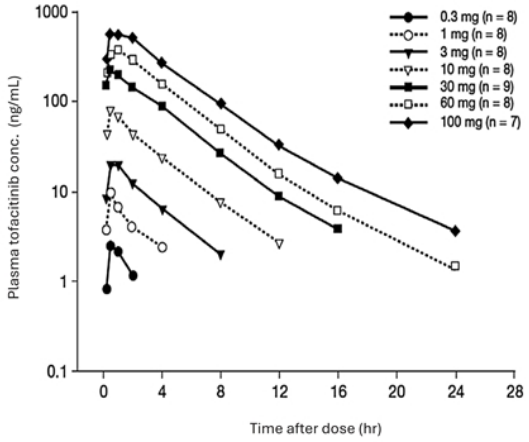
PHASE 1 SAD: PK RESULTS

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.

PHASE 1 MAD: PK RESULTS

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.

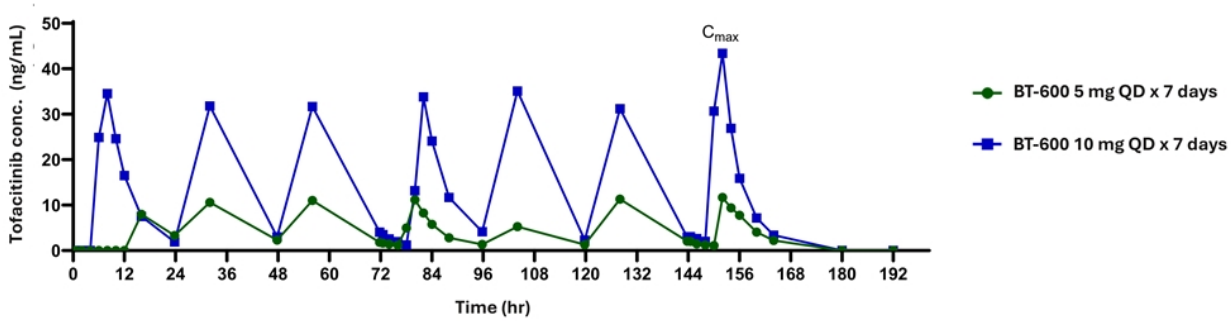
NOTE: These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

PHASE 1 MAD: PK RESULTS

Consistent PK profile with repeat dosing

Characteristic, single-subject concentration time curve

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

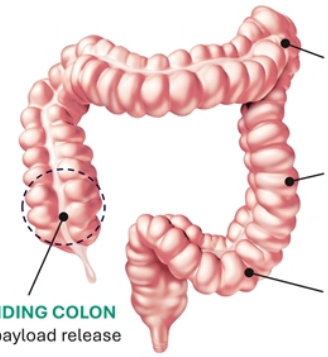


1. Phase 1 clinical trial data on file, Biora Therapeutics, Inc.

PHASE 1 MAD: BT-600

Evidence of drug delivery across all distal biopsy sites

BIOPSY SITES



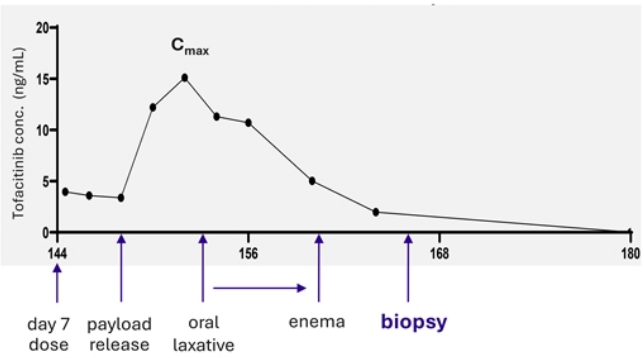
SPLENIC FLEXURE
tofacitinib present in
15/18 biopsies

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)

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

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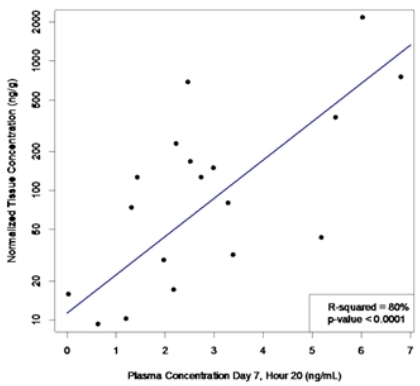
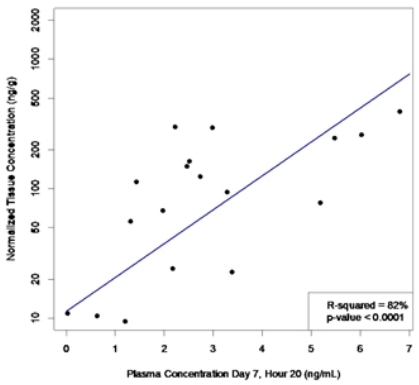
PHASE 1 MAD: COLON TISSUE EXPOSURE

Good correlation between tissue and plasma levels

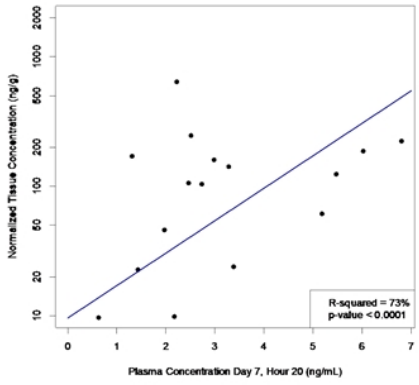
SPLENIC FLEXURE



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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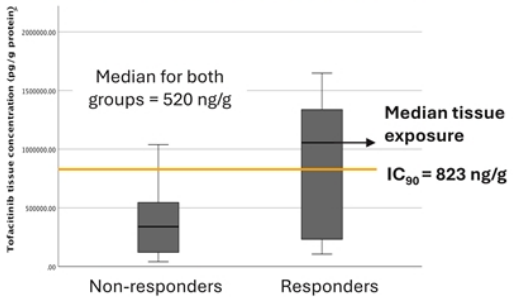
PHASE 1 MAD: COLON TISSUE EXPOSURE

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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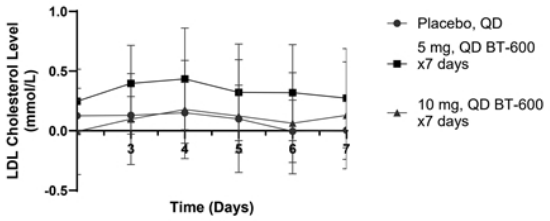
PHASE 1: SAFETY PARAMETERS

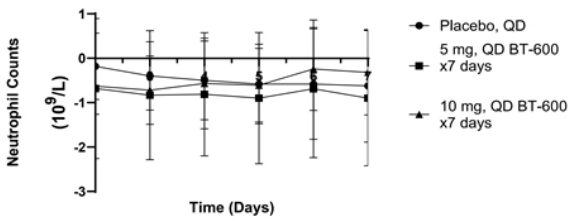
BT-600 was well tolerated

- 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.

BIORA Therapeutics

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

CONSIDERATIONS FOR COLONIC DELIVERY IN UC

Brian Feagan, MD, FRCPC
Professor of Medicine
Schulich School of Medicine & Dentistry
University of Western Ontario

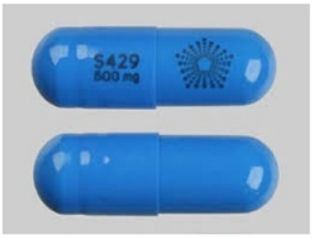
Gastroenterologist
London Health Sciences Centre, Ontario

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

Challenges with existing colonic delivery

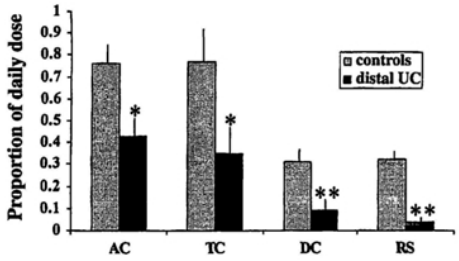
RECTAL PREPARATIONS

- 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]

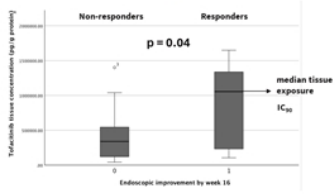


UC: 91% (proximal) vs. 9% (distal)

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)

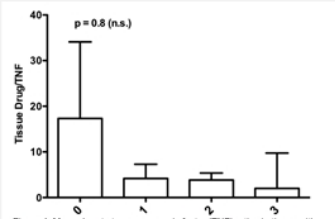
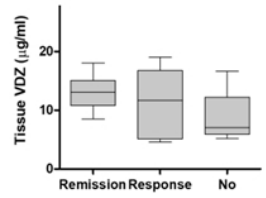


Figure 4: Mean drug to tumour necrosis factor (TNF) ratios in tissue with none, mild, moderate and severe inflammation (n.s., not significant).

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

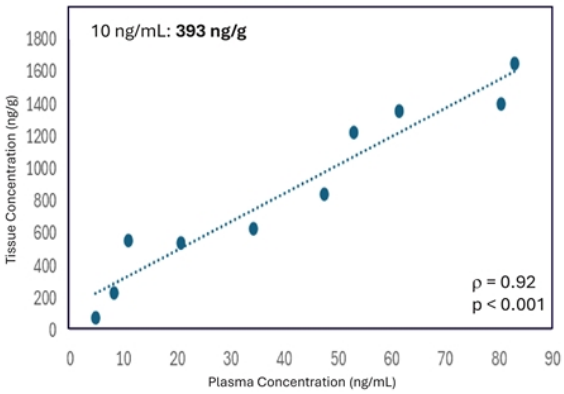
- Patients with endoscopic remission or response had significantly higher tissue drug levels (p=0.04)
- Authors suggest targeting vedolizumab tissue levels to optimize Tx in patients with no or loss of response

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

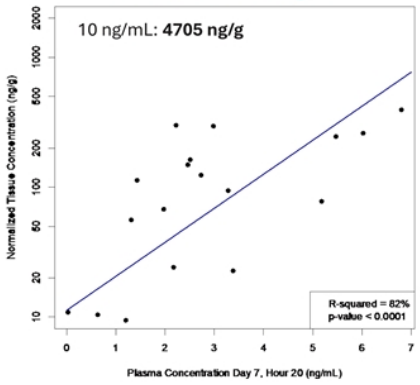
PHASE 1 MAD: COLON TISSUE EXPOSURE

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

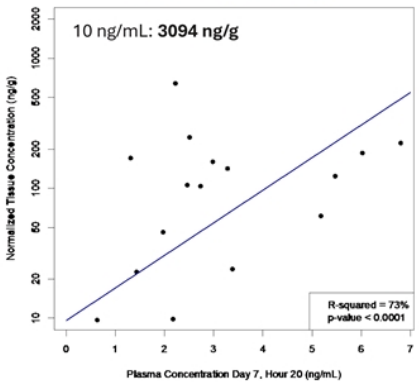
CONVENTIONAL TOFACITINIB 10 MG BID[1]



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**


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


BIORA™
Therapeutics