BIORA™ Therapeutics

Reimagining therapeutic delivery

CORPORATE PRESENTATION

August 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

Innovating smart pill technologies to deliver the right dose to the right place, safely.

BIORA™ Therapeutics

NAVIcap™

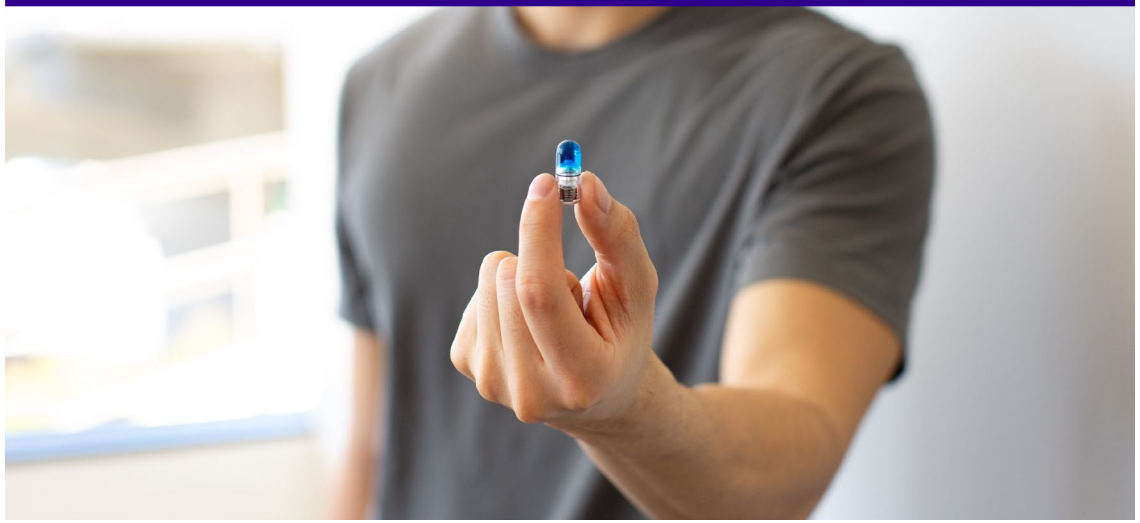
TARGETED ORAL DELIVERY

Treatment at the site of disease in the GI tract could improve outcomes for patients with inflammatory bowel disease

BIOjet™

SYSTEMIC ORAL DELIVERY

Needle-free, oral delivery of large molecules designed to replace injection for better management of chronic diseases



THERAPEUTIC PIPELINE

NAVICAP™ PROGRAMS	DRUG	DESIGN/FEASIBILITY	PRECLINICAL	CLINICAL
NaviCap™ Targeted Oral Delivery Platform	--			
BT-600 in ulcerative colitis	tofacitinib*			
BT-001 in ulcerative colitis	adalimumab variant*			

BIOJET™ PROGRAMS	DRUG	DESIGN/FEASIBILITY	PRECLINICAL	CLINICAL
BioJet™ Systemic Oral Delivery Platform	--			
AstraZeneca collaboration	undisclosed			
Ionis collaboration	antisense oligonucleotide			
Multiple pharma collaborations	undisclosed			

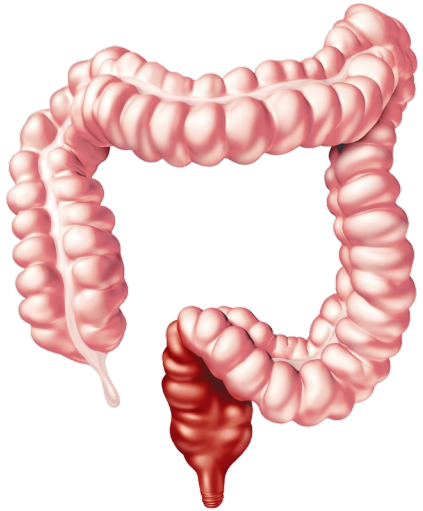
*Biora's own molecules

NAVIcap™

TARGETED ORAL DELIVERY

Ulcerative colitis: a disease of the colonic tissue

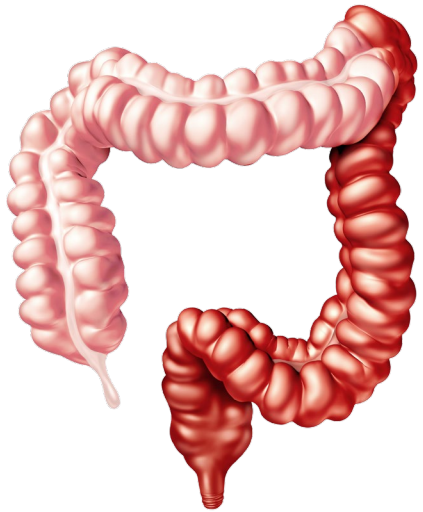
E1: PROCTITIS



SYMPTOMS
Rectal bleeding, tenesmus, urgency

30–60% of patients

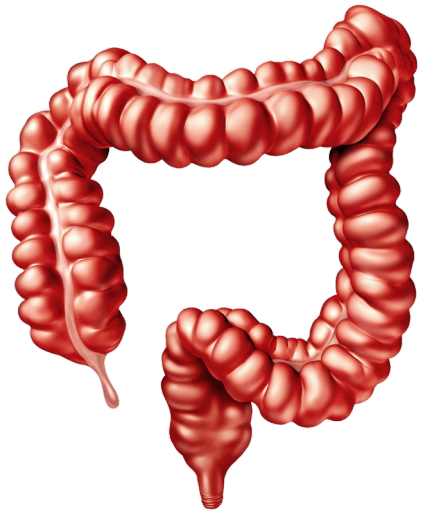
E2: DISTAL COLITIS



SYMPTOMS
E1 plus diarrhea, abdominal cramping

16–45% of patients

E3: PANCOLITIS



SYMPTOMS
E2 plus constitutional symptoms (fatigue, fever)

15–35% of patients

- Ulcerative colitis (UC) is localized and primarily confined to the colon

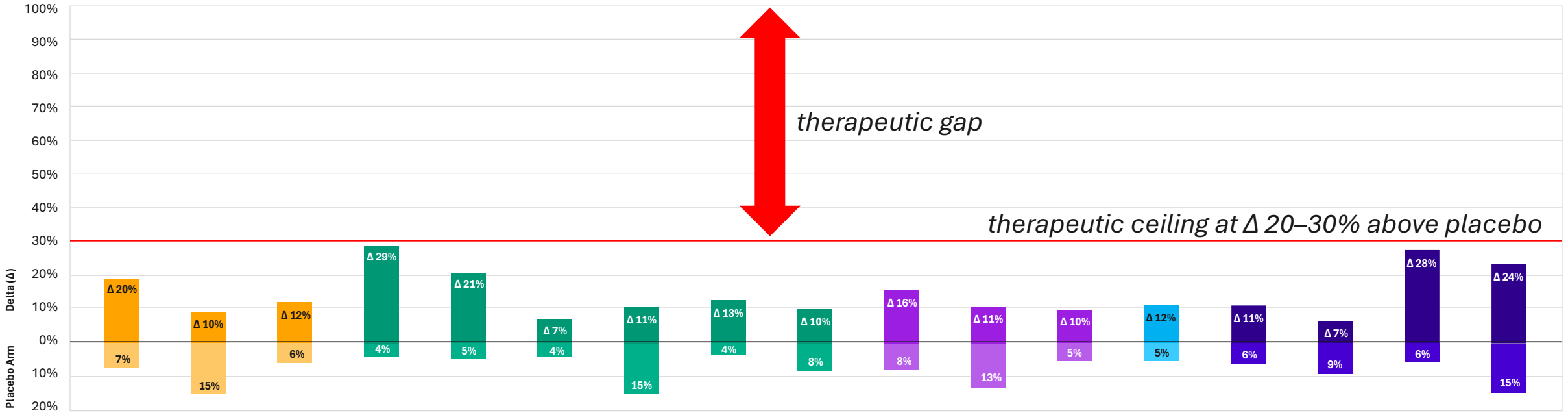
ABOUT UC

- Inflammatory bowel disease (IBD) includes Crohn's disease and ulcerative colitis (UC)
- UC causes inflammation and damage to the mucosal and submucosal layers of the colon
- About 1 million people in the U.S. are affected with UC, and ~40,000 cases are diagnosed each year[1]

1. Shivashankar R, Tremaine WJ, Harmsen WS, Loftus EV Jr. Incidence and Prevalence of Crohn's Disease and Ulcerative Colitis in Olmsted County, Minnesota From 1970 Through 2010. *Clin Gastroenterol Hepatol*. 2017;15(6):857-863.

The therapeutic ceiling in UC

INDUCTION OF CLINICAL REMISSION IN UC[1]



	S1P RECEPTOR MODULATORS			JAK INHIBITORS						IL-12/23 INHIBITORS			INTEGRIN INHIBITOR	TNF INHIBITORS			
	etrasimod	etrasimod	ozanimod	upadacitinib	upadacitinib	filgotinib*	filgotinib*	tofacitinib	tofacitinib	risankizumab-rzaa	mirikizumab	ustekinumab	vedolizumab	golimumab	adalimumab	infliximab	infliximab
	ELEVATE UC 52	ELEVATE UC 12	TRUE NORTH	U-ACCOMPLISH	U-ACHIEVE	SELECTION B	SELECTION A	OCTAVE 2	OCTAVE 1	INSPIRE	LUCENT 1	UNIFI	GEMINI	PURSUIT	ULTRA 2	ACT 2	ACT 1
Therapeutic Arm	27%	25%	18%	34%	26%	12%	26%	17%	19%	24%	24%	16%	17%	18%	17%	34%	39%
Placebo Arm	7%	15%	6%	4%	5%	4%	15%	4%	8%	8%	13%	5%	5%	6%	9%	6%	15%
Delta (Δ)	20%	10%	12%	29%	21%	7%	11%	13%	10%	16%	11%	10%	12%	11%	7%	28%	24%

*Filgotinib is not approved for use in the U.S.

1. See appendix for references.

Colon-targeted, topical delivery to improve UC 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]

With support from:

CROHN'S & COLITIS FOUNDATION

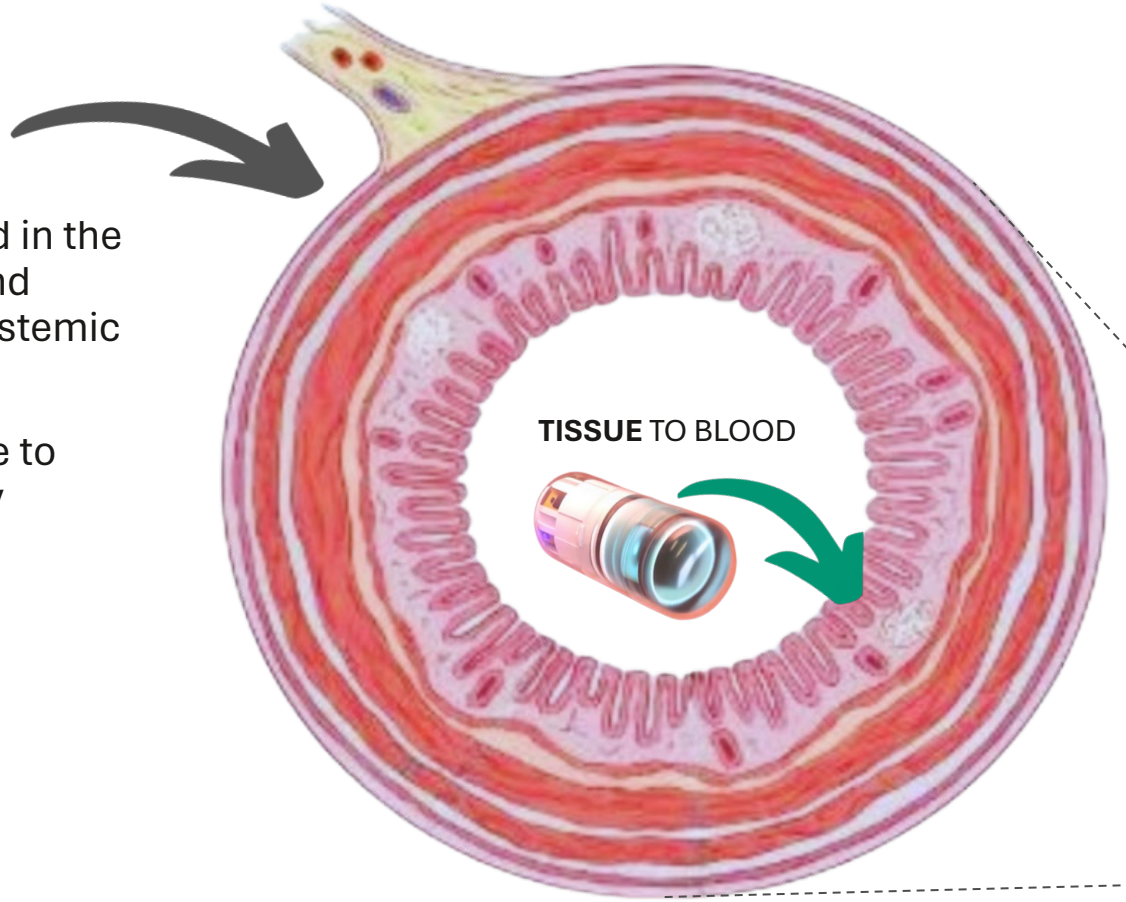
1. Verstockt B, Alsoud D, van Oostrom J, et al. Tofacitinib tissue exposure correlates with endoscopic outcome. Poster presented at: *17th Congress of the European Crohn's and Colitis Organisation* (ECCO), February 18, 2022, virtual.
2. van Oostrom J, Verstockt B, Hanzel J, et al. Pharmacokinetic stratification 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.

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

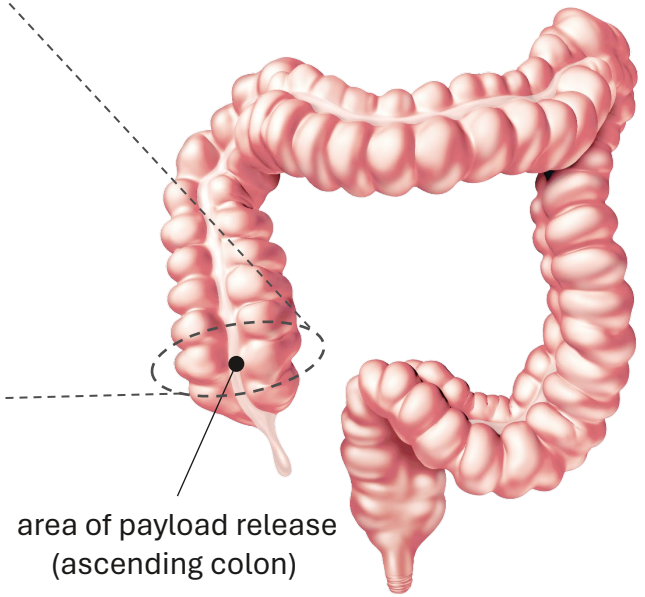


colon, cross section

NAVICAP DIRECT DELIVERY TO COLON

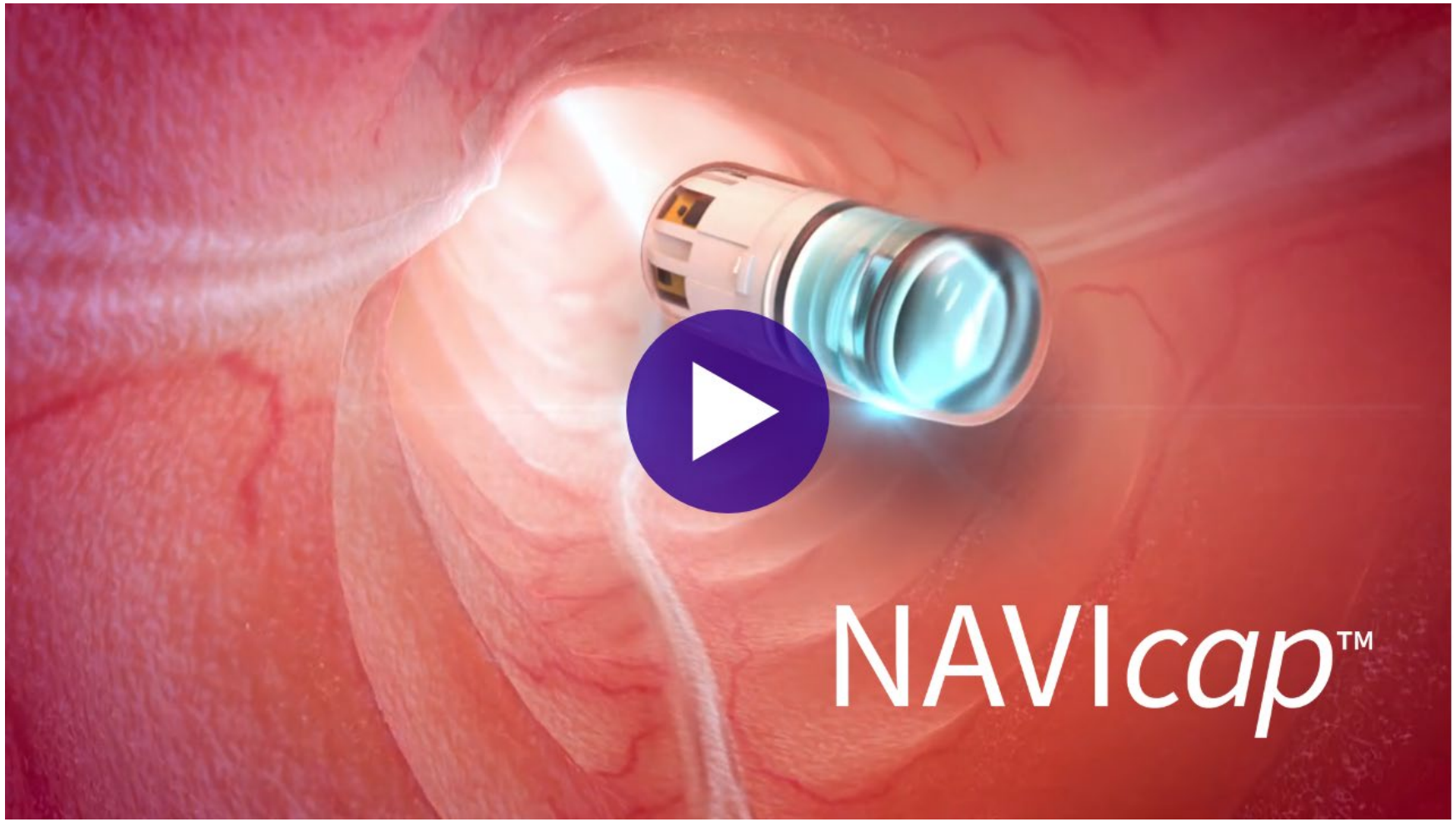
LUMEN TO TISSUE TO BLOOD

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



area of payload release (ascending colon)

Autonomous localization and drug delivery to the colon



https://biora.wistia.com/medias/r65935rbqs

ORAL ADMINISTRATION

Convenient oral capsule the size of a fish-oil pill

AUTONOMOUS LOCATION

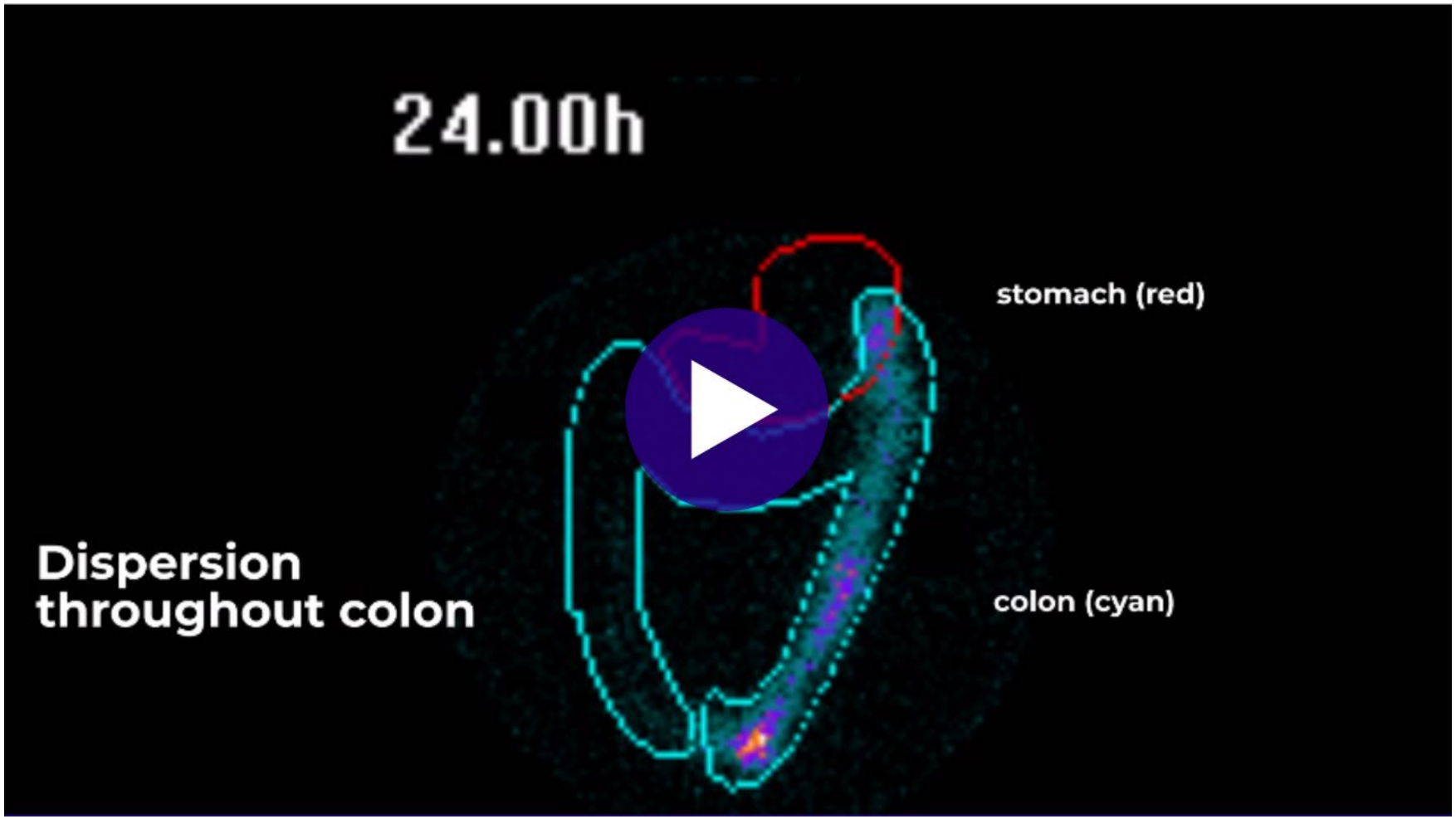
GITrac™ autolocation technology enables localized delivery to the colon, regardless of fasted or fed state[1]

ANATOMICALLY TARGETED DRUG DELIVERY

Designed to coat the length of the colon with liquid formulation, act at the site of disease and minimize 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.

Delivery throughout the entire colon



https://www.bioratherapeutics.com/pipeline/targeted-therapeutics#scintigraphy

PAN-COLONIC DELIVERY

Scintigraphic imaging of NaviCap delivery in a healthy participant

CONSISTENT PERFORMANCE

Across four separate clinical device function studies in both healthy participants and UC patients

The NaviCap device performed as designed in both fed and fasted states

BT-600 PHASE 1 CLINICAL TRIAL IN HEALTHY PARTICIPANTS

PHASE 1 SAD/MAD: TOPLINE RESULTS

NAVIcap™

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.

BIORA™ Therapeutics

PHASE 1 NAVICAP DEVICE PERFORMANCE

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

SOFTWARE ANALYSIS OF POST-DOSE RETRIEVED NAVICAP DEVICES

	Phase 1 SAD	Phase 1 MAD
Devices identified colon entry	24/24 (100%)	156/162 (96%)
Mean time of colon entry hours post dose (SD)	5.6 (2.1)	6.6 (3.2)
Mean time of first drug concentration in plasma (T_{first}) hours post dose (SD)	6.9 (2.6)	6.9 (2.0)

- >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 (table below)

PREVIOUS NAVICAP CLINICAL DEVICE FUNCTION STUDIES (WITHOUT DRUG)[1]

	PM-601 (2022) Scintigraphy Study	**PM-602** (2022) Scintigraphy Study	**BT-603** (2023) Scintigraphy Study	**PM-611** (2023) Fasted & Fed Study
Study participants	healthy participants	active UC patients	healthy participants	healthy participants
Devices identified colon entry	10/12 (83%)	7/7 (100%)	15/16 (94%)	39/39 (100%)
Payload delivery	8/12 (67%)	7/7 (100%)	15/16 (94%)	38/39 (97%)*

* Value reflects payload activation based on analysis of retrieved devices. Scintigraphic imaging was not performed as part of this study.

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.

BIORA™ Therapeutics

MAD PK confirms colonic delivery and low systemic exposure

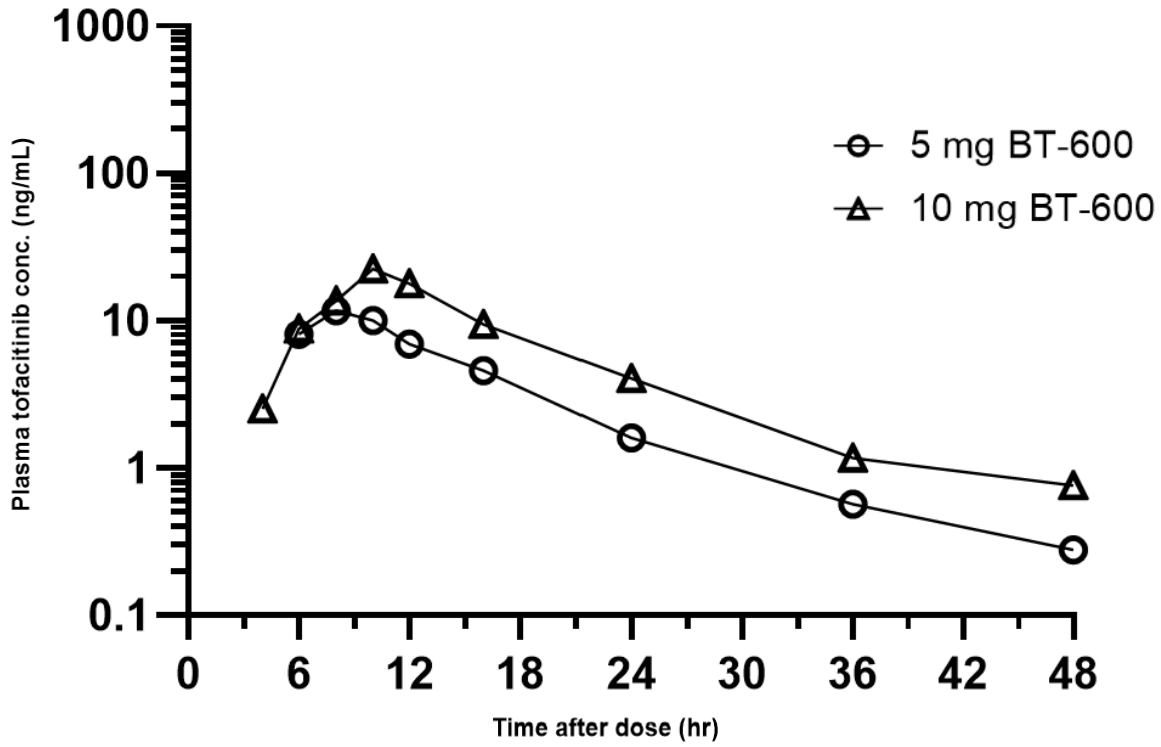
PK Parameters†	BT-600 Multiple Oral Dosing[1] (n=9)				XELJANZ	
	DAY 1		DAY 7			
Dosing Regimen	**5 mg Once Daily**	**10 mg Once Daily**	**5 mg Once Daily**	**10 mg Once Daily**	**5 mg Twice Daily[2]**	**10 mg Single Dose[3]**
T_{first} hours	6 (4–16)	8 (4–10)	N/A	N/A	NR	NR
T_{max} hours	10 (4–10)	8 (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.

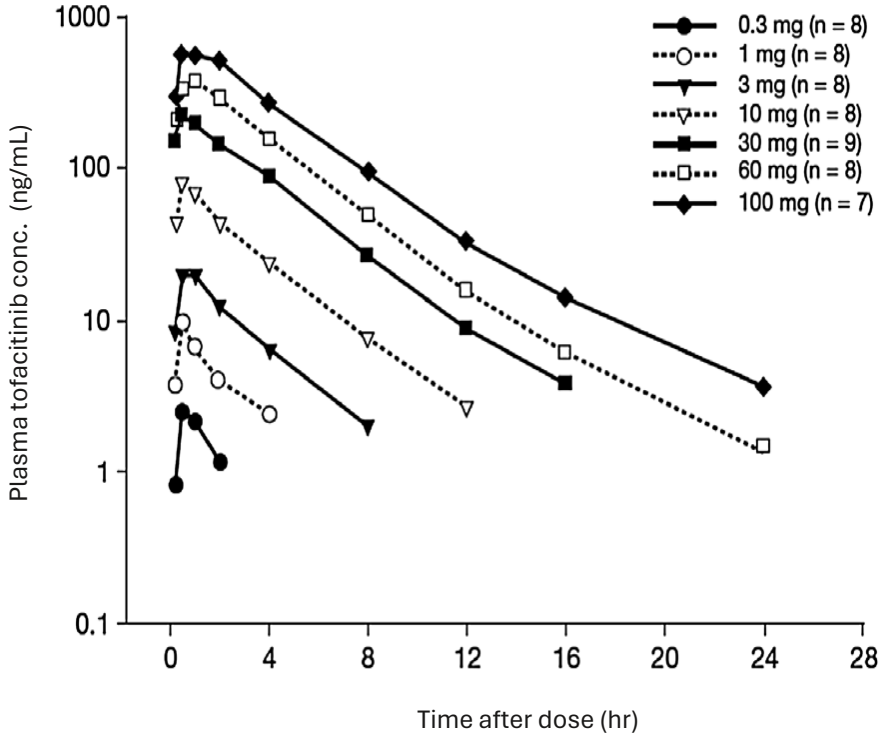
1. Phase 1 clinical trial data on file, Biora Therapeutics, Inc.
2. Pfizer, Inc. Xeljanz (tofacitinib) USPI. https://labeling.pfizer.com/showlabeling.aspx?id=959 Revised May 2024. Accessed June 18, 2024.
3. Krishnaswami S, Boy M, Chow V, Chan G. Safety, tolerability, and pharmacokinetics of single oral 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.

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]

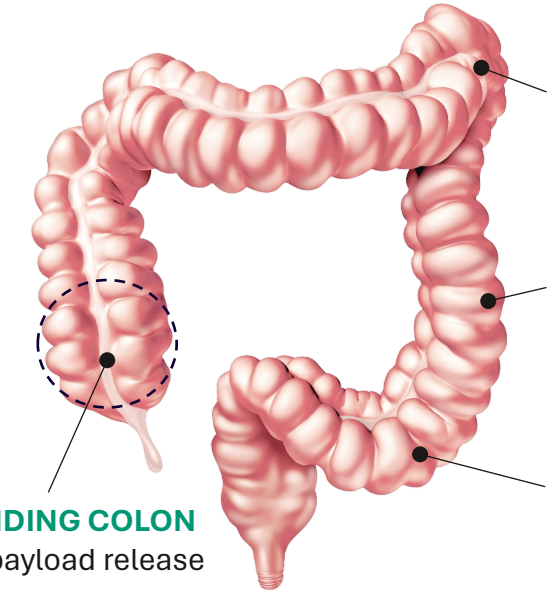


1. Phase 1 clinical trial data on file, Biora Therapeutics, Inc.
2. Krishnaswami S, Boy M, Chow V, Chan G. Safety, tolerability, and pharmacokinetics of single oral doses of tofacitinib, a Janus kinase inhibitor, in healthy volunteers. *Clin Pharmacol Drug Dev*. 2015;4(2):83-88. doi:10.1002/cpdd.171

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.

Evidence of drug delivery across all distal biopsy sites

BIOPSY SITES



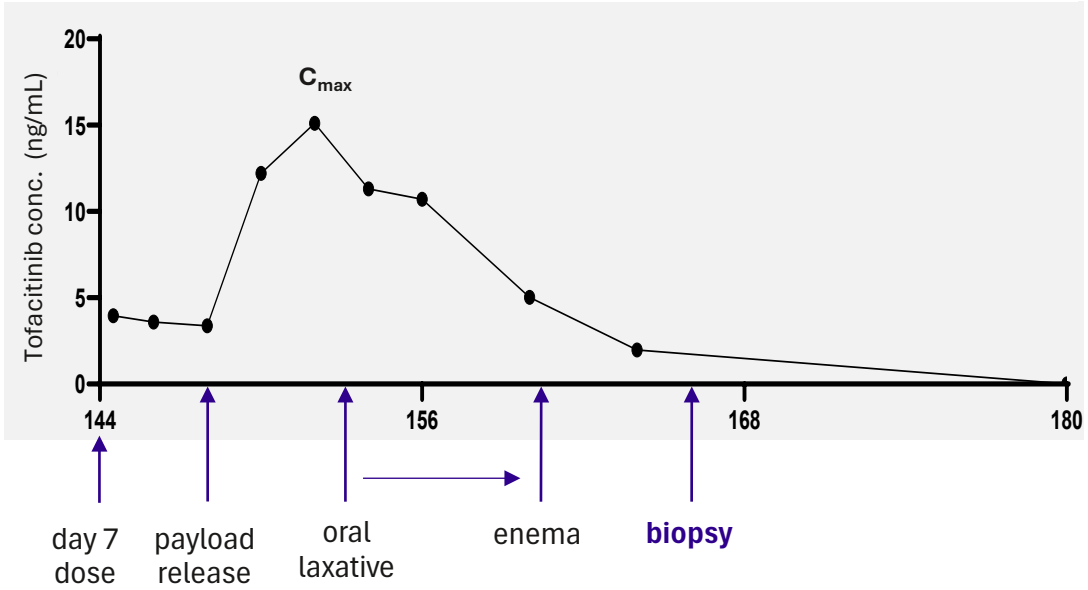
SPLENIC FLEXURE
tofacitinib present in
15/18 biopsies

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 delivery in proximal colon) consistent with pan-colonic delivery

Colon tissue absorption demonstrated despite:

- Dose-to-biopsy latency of ~24 hours (approx. five half-lives)
- Pre-procedural bowel prep with oral and rectal laxatives

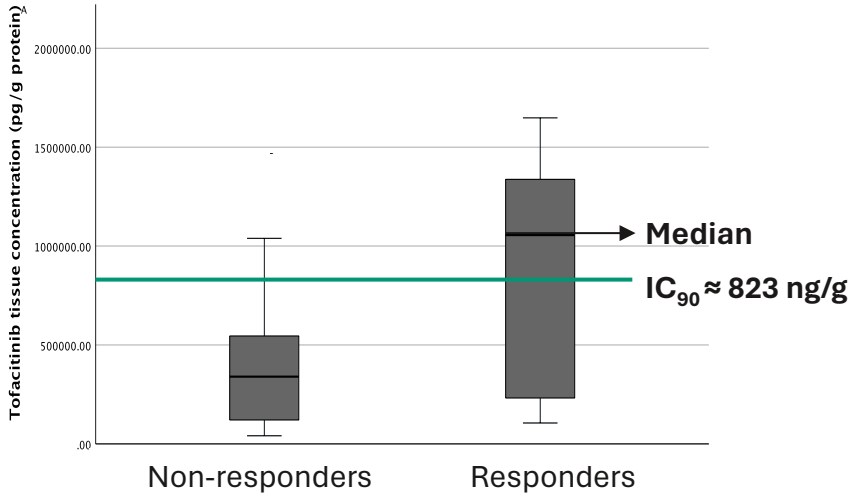
Phase 1 clinical trial data on file, Biora Therapeutics, Inc.

BIORA Therapeutics

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 comparison group

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

Hours Post Last Dose	Plasma Concentration ng/mL	Colon Tissue Concentration (mean, 95% CI)		
		Splenic Flexure ng/g	Descending Colon ng/g	Sigmoid Colon ng/g
24 hours 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		

† Tissue concentration measured at 22–26 hours post dose; plasma concentration measured at 20 hours post dose;
‡ 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
- Responders had median tissue concentration above the estimated IC90

- Measured tofacitinib levels **above IC50 at 24 hours** post dose
- Projected levels **above IC90 through at least 16 hours** post dose

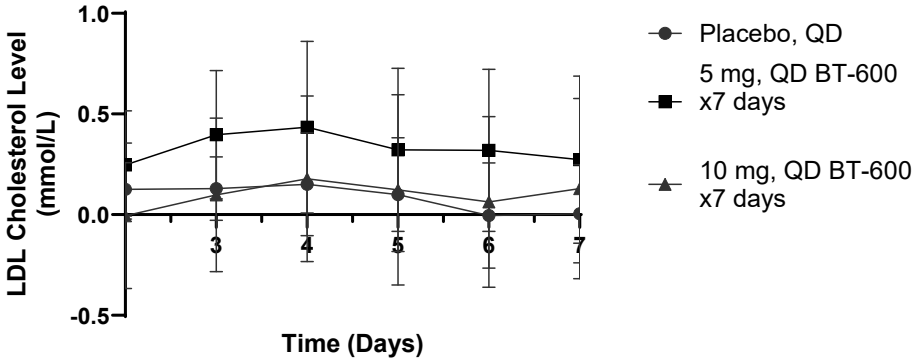
1. Verstockt B, Alsoud D, van Oostrom J, et al. Tofacitinib tissue exposure correlates with endoscopic outcome. Poster presented at: *17th Congress of the European Crohn's and Colitis Organisation* (ECCO), February 18, 2022, virtual.
2. Phase 1 clinical trial data on file, Biora Therapeutics, Inc.

PHASE 1: SAFETY PARAMETERS

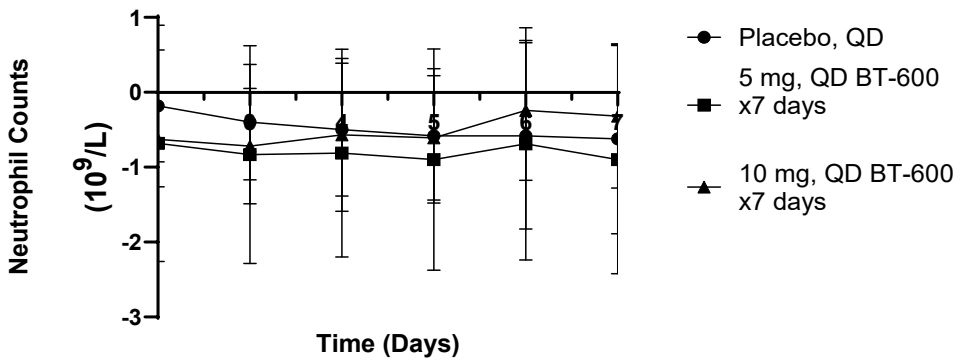
BT-600 was well tolerated

- No serious adverse events; all AEs were consistent with those expected in healthy population (e.g. 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.

Phase 1 trial results support clinical development plan

NAVIcap™

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

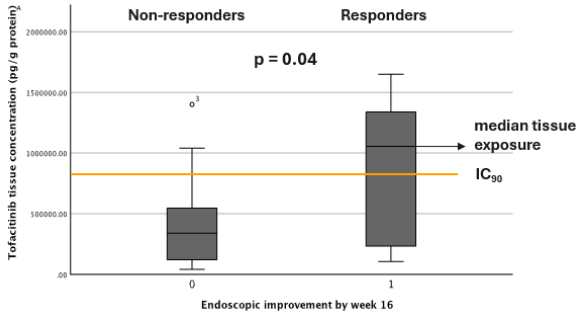
Endpoints
- Clinical and endoscopic response
- Mucosal healing
- PROs
- Biomarkers

PLANNED START: Q4 2025

DURATION: TBD

BIORA™ Therapeutics

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)

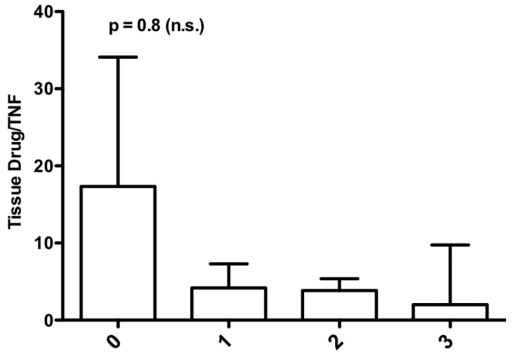
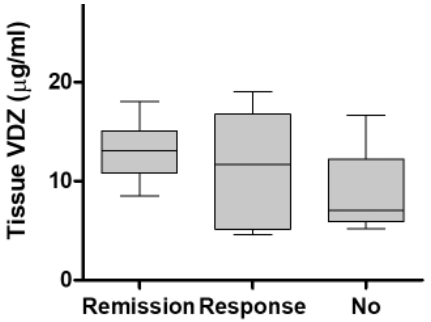


Figure 4: Mean drug to tumour necrosis factor (TNF) ratios in tissue with none, mild, moderate and severe inflammation (n.s., not significant).

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 therapy in patients with no or loss of response

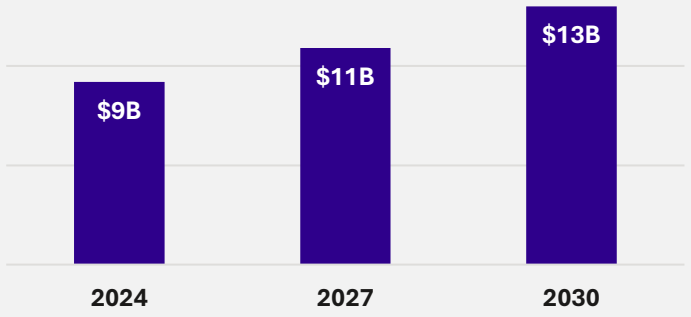
1. Verstockt B, Alsoud D, van Oostrom J, et al. Tofacitinib tissue exposure correlates with endoscopic outcome. Poster presented at: *17th Congress of the European Crohn's and Colitis Organisation* (ECCO), February 18, 2022, virtual.
2. Yarur AJ, Jain A, Sussman DA, et al. The association of tissue anti-TNF 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

NaviCap could optimize delivery of IBD therapies

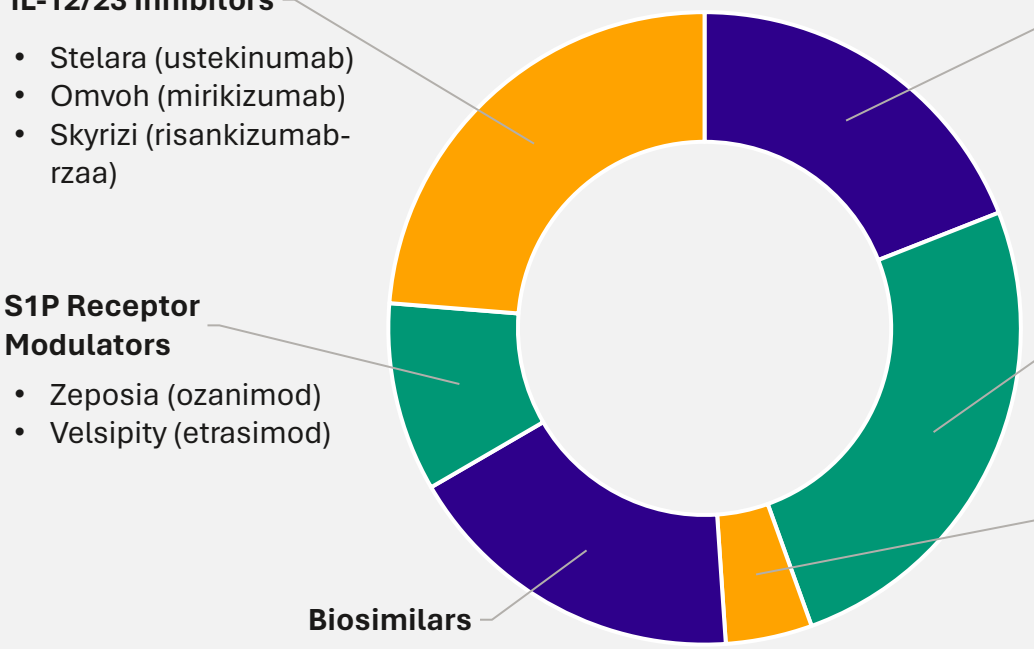
NAVIcap™

- Across established UC therapies, drug activity at the site of disease is known to correlate with better outcomes:
  - JAK inhibitors[1]
  - TNF inhibitors[2]
  - Integrin inhibitors[3]
- NaviCap could optimize therapeutic classes by enabling drugs to reach and act in the colon for better outcomes in UC and beyond

UC THERAPEUTICS GLOBAL SALES[4]



UC ADVANCED THERAPEUTICS FORECASTED GLOBAL MARKET SHARE BY DRUG CLASS[5]



IL-12/23 Inhibitors
- Stelara (ustekinumab)
- Omvoh (mirikizumab)
- Skyrizi (risankizumab-rzaa)

TNF Inhibitors
- Humira (adalimumab)
- Remicade (infliximab)
- Simponi (golimumab)

S1P Receptor Modulators
- Zeposia (ozanimod)
- Velsipity (etrasimod)

Integrin Inhibitors
- Entyvio (vedolizumab)

JAK Inhibitors
- Xeljanz (tofacitinib)
- Rinvoq (upadacitinib)
- Jyseleca (filgotinib)*

Biosimilars

*Filgotinib is not approved for use in the U.S.

1. Verstockt B, Alsoud D, van Oostrom J, et al. 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
4. GlobalData, Ulcerative Colitis: Global Drug Forecast and Market Analysis to 2029 (2020), based on 6.0% CAGR
5. GlobalData, Ulcerative Colitis: Global Drug Forecast and Market Analysis to 2029 (2020), based on forecasted 2029 global sales

BIORA™ Therapeutics

BIO*jet*™

SYSTEMIC ORAL DELIVERY

CASE STUDY

Unmet need in peptide delivery for treatment of diabetes

38% of people with diabetes discontinue injectable medications due to injection concerns[1,2]

42% of patients fail to maintain diabetes treatment due to injection concerns when using an injectable GLP-1 agonist[2]

71% higher discontinuation rate for diabetes patients initiating treatment with an injectable GLP-1 agonist vs. those starting oral therapy[2]

1. Palanca A, Ampudia-Blasco FJ, Calderón JM, et al. Real-World Evaluation of GLP-1 Receptor Agonist Therapy Persistence, Adherence and Therapeutic Inertia Among Obese Adults with Type 2 Diabetes. *Diabetes Ther*. 2023;14(4):723-736. doi:10.1007/s13300-023-01382-9
2. Spain CV, Wright JJ, Hahn RM, Wivel A, Martin AA. Self-reported Barriers to Adherence and Persistence to Treatment With Injectable Medications for Type 2 Diabetes. *Clin Ther*. 2016;38(7):1653-1664.e1. doi:10.1016/j.clinthera.2016.05.009

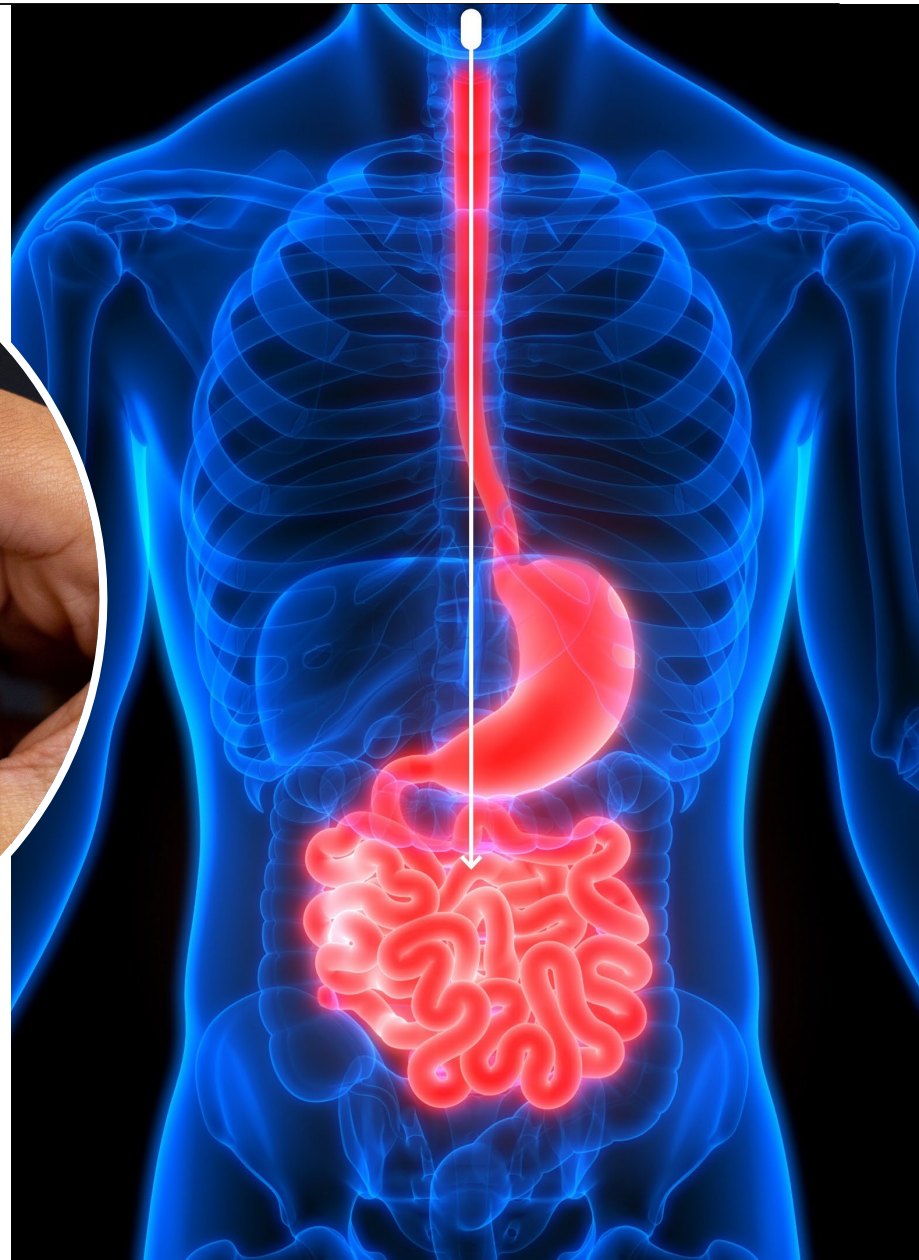
Needle-free, oral delivery to small intestine

PRECISE DELIVERY

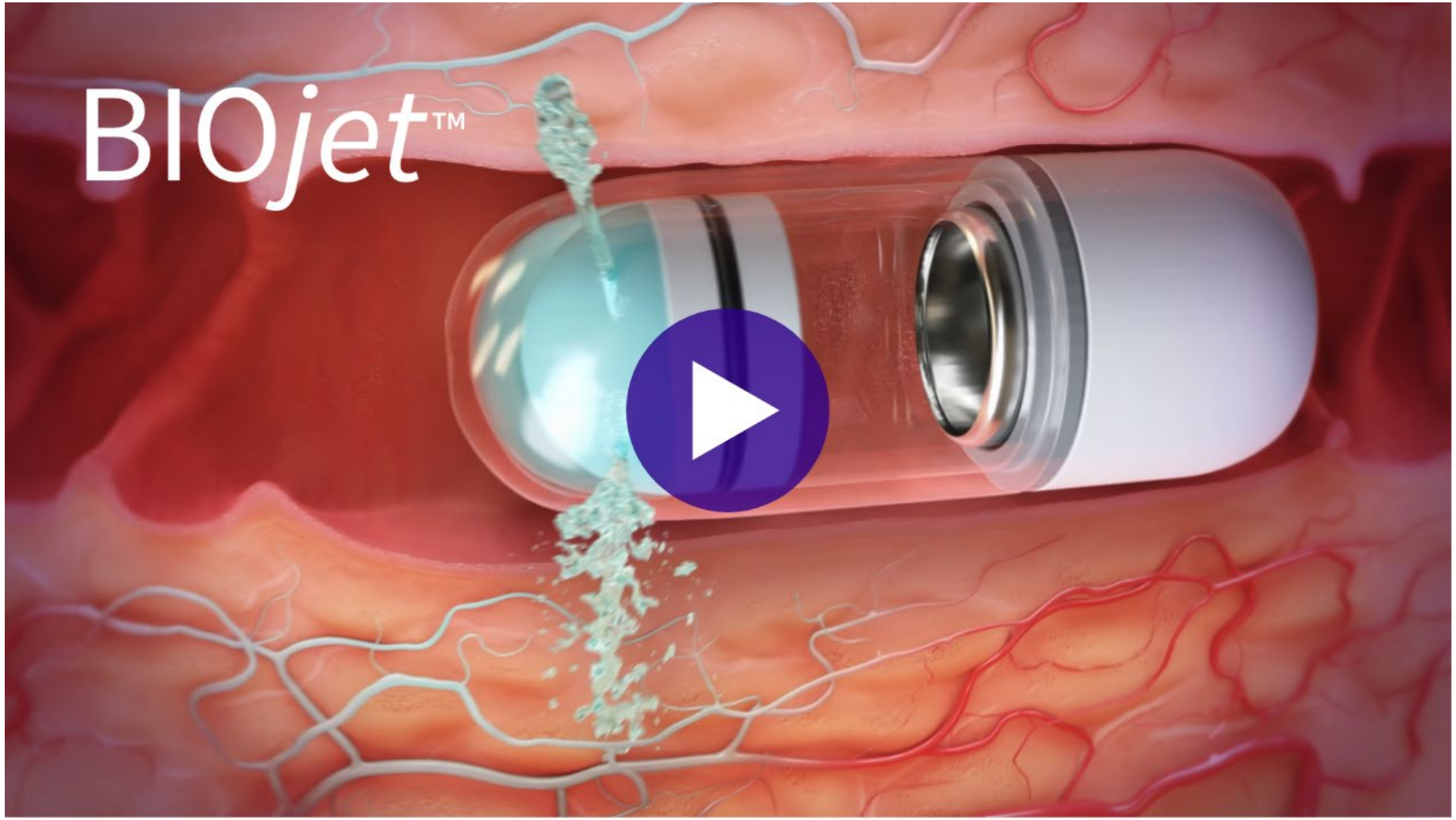
- Enteric trigger for precise timing of drug delivery to the small intestine
- Potential to enable liver-targeted delivery

UNIQUE SOLUTION

- Uses existing liquid formulations, without complex reformulation
- Deliver large payloads in the multi-milligram range



Liquid jet delivery to the small intestine



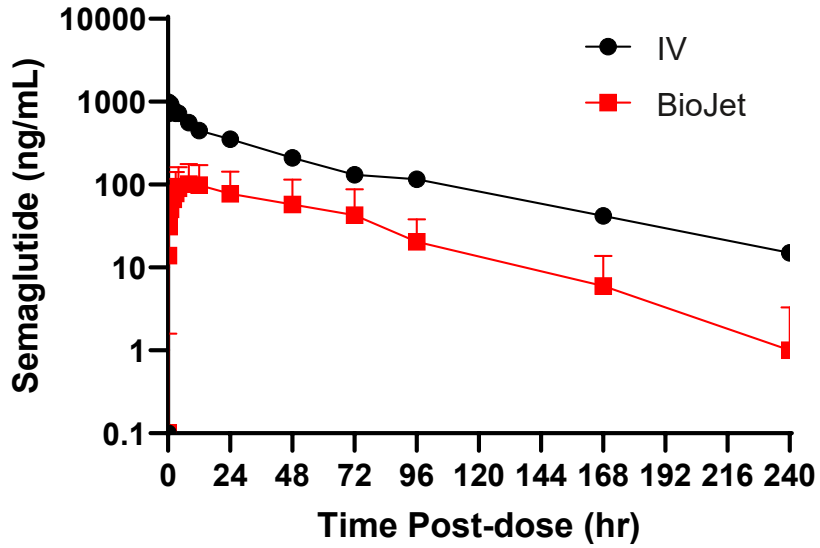
SCAN ME

https://biora.wistia.com/medias/embr15eh3a

BioJet™ oral delivery pharmacokinetics across multiple molecules

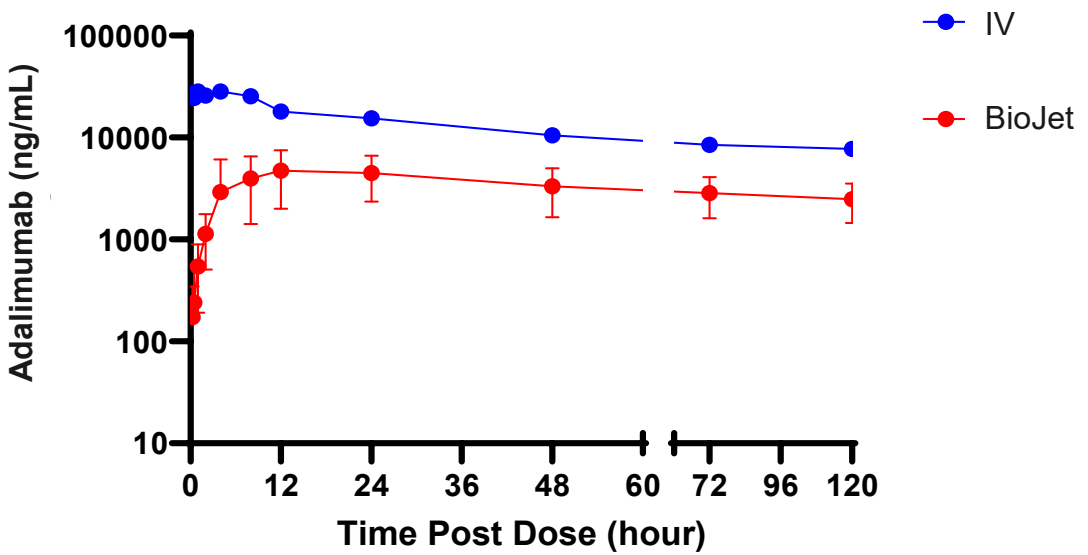
BIOjet™

SEMAGLUTIDE SYSTEMIC EXPOSURE BIOJET VS. IV ADMINISTRATION



Oral bioavailability mean: ***36%*** *(n=55; SD ~25%)*[1]

ADALIMUMAB SYSTEMIC EXPOSURE BIOJET VS. IV ADMINISTRATION



Oral bioavailability mean ***>30%***[1]

- Consistent across multiple studies in porcine model.
- Detectable drug levels up to ten days post-dosing. No significant clinical signs observed up to ten days.

1. Biora Therapeutics, Inc. Data on file. Average bioavailability calculation is based on animals with drug in blood across studies using multiple device configurations.

BIORA Therapeutics

Demonstrated high bioavailability across multiple molecules

BIOjet™

Preclinical studies in swine model with endoscopically placed and autonomously triggered BioJet device

MOLECULE TYPE	DRUG	ORAL BIOAVAILABILITY
ANTIBODY	adalimumab (monoclonal antibody)	**over 40%** mean oral bioavailability vs. IV control demonstrated across all three biomolecule types[1]
PEPTIDE	semaglutide (GLP-1 receptor agonist)	
OLIGONUCLEOTIDE	undisclosed antisense oligonucleotides	

RESEARCH COLLABORATIONS

AstraZeneca

IONIS

multiple undisclosed pharma collaborators

1. Biora Therapeutics data on file

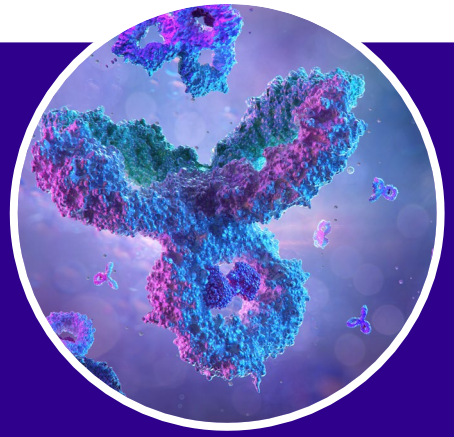
BIORA Therapeutics

Needle-free, liquid jet delivery of biomolecules

BIOjet™
SYSTEMIC ORAL DELIVERY

CATEGORY-LEADING BIOAVAILABILITY

- Liquid jet delivery to the small intestine designed to **maximize systemic uptake**
- Enables **liver-targeted delivery** of large molecules



BROAD APPLICABILITY

- **Platform technology** proven to deliver multiple molecule classes
- Delivers large payload at **multi-milligram doses**
- Leverages **liquid formulation** without complex reformulation

NOVEL DRUG DELIVERY TECHNOLOGY

- Possesses **comprehensive patent protection**
- Provides opportunity to **extend drug exclusivity**

BIORA™ Therapeutics

Innovating smart pill technologies to deliver the right dose to the right place, safely.

BIORA™ Therapeutics

NAVIcap™

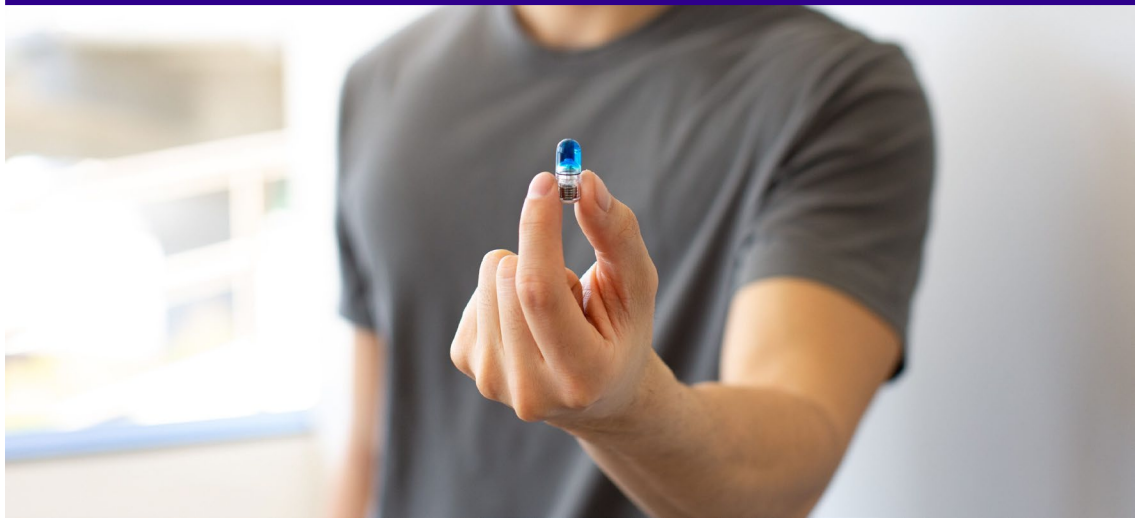
TARGETED ORAL DELIVERY

- Phase 1 clinical trial successful
- Moving to Phase 1B in patients with UC

BIOjet™

SYSTEMIC ORAL DELIVERY

- Tested in animals with multiple molecule classes, including peptides, ASOs, antibodies
- Progressing toward partnerships



APPENDIX

References: UC clinical trials

INDUCTION OF CLINICAL REMISSION IN UC

S1P RECEPTOR MODULATORS			JAK INHIBITORS						IL-12/23 INHIBITORS			INTEGRIN INHIBITOR	TNF INHIBITORS			
etrasimod[1]	etrasimod[1]	ozanimod[2]	upadacitinib[3]	upadacitinib[3]	filgotinib[4]	filgotinib[4]	tofacitinib[5]	tofacitinib[5]	risankizumab-rzaa[6]	mirikizumab[7]	ustekinumab[8]	vedolizumab[9]	golimumab[10]	adalimumab[11]	infliximab[12]	infliximab[12]
ELEVATE UC 52	ELEVATE UC 12	TRUE NORTH	U-ACCOMPLISH	U-ACHIEVE	SELECTION B	SELECTION A	OCTAVE 2	OCTAVE 1	INSPIRE	LUCENT 1	UNIFI	GEMINI	PURSUIT	ULTRA 2	ACT 2	ACT 1

1. Sandborn WJ, Vermeire S, Peyrin-Biroulet L, et al. Etrasimod as induction and maintenance therapy for ulcerative colitis (ELEVATE): two randomised, double-blind, placebo-controlled, phase 3 studies. *Lancet*. 2023;401(10383):1159-1171.
2. Sandborn WJ, Feagan BG, D'Haens G, et al. Ozanimod as Induction and Maintenance Therapy for Ulcerative Colitis. *N Engl J Med*. 2021;385(14):1280-1291.
3. Danese S, Vermeire S, Zhou W, et al. Upadacitinib as induction and maintenance therapy for moderately to severely active ulcerative colitis: results from three phase 3, multicentre, double-blind, randomised trials. *Lancet*. 2022;399(10341):2113-2128.
4. Feagan BG, Danese S, Loftus EV Jr, et al. Filgotinib as induction and maintenance therapy for ulcerative colitis (SELECTION): a phase 2b/3 double-blind, randomised, placebo-controlled trial. *Lancet*. 2021;397(10292):2372-2384.
5. Sandborn WJ, Su C, Sands BE, et al. Tofacitinib as induction and maintenance therapy for ulcerative colitis. *N Engl J Med* 2017; 376: 1723–36.
6. Data on file, AbbVie Inc. ABVRRTI78474. https://www.skyrizihcp.com/gastroenterology/ulcerative-colitis
7. Sands BE, Feagan BG, Hunter Gibble T, et al. Mirikizumab Improves Quality of Life in Patients With Moderately-to-Severely Active Ulcerative Colitis: Results From the Phase 3 LUCENT-1 Induction and LUCENT-2 Maintenance Studies. *Crohns Colitis 360* 2023; 5(4), otad070.
8. Sands BE, Sandborn WJ, Panaccione R, et al. Ustekinumab as induction and maintenance therapy for ulcerative colitis. *N Engl J Med* 2019; 381: 1201–14.
9. Feagan BG, Rutgeerts P, Sands BE, et al. Vedolizumab as induction and maintenance therapy for ulcerative colitis. *N Engl J Med* 2013; 369: 699–710.
10. Sandborn WJ, Feagan BG, Marano C, et al. Subcutaneous golimumab induces clinical response and remission in patients with moderate-to-severe ulcerative colitis. *Gastroenterology* 2014; 146: 85–95.
11. Sandborn WJ, van Assche G, Reinisch W, et al. Adalimumab induces and maintains clinical remission in patients with moderate-to-severe ulcerative colitis. *Gastroenterology* 2012; 142: 257–65.
12. Rutgeerts P, Sandborn WJ, Feagan BG, et al. Infliximab for induction and maintenance therapy for ulcerative colitis. *N Engl J Med* 2005; 353: 2462–76.

NOTE: Filgotinib is not approved for use in the U.S.

Diverse patent portfolio with 73 distinct patent families

Approximately 190 granted patents and 136 pending applications
in major countries and regions around the world

NaviCap™ Platform

30 patent families covering:

- Device designs, materials, components, and manufacturing
- Localization in the GI tract
- Dosing and PK/PD profiles
- Liquid drug formulations
- IBD-specific drug combinations

BioJet™ Platform

7 patent families covering:

- Device designs, materials, components, and manufacturing
- GI-specific trigger compositions
- Dosing and PK/PD profiles
- Jet parameters
- GI delivery by drug class and drug size

Other Device & Diagnostic IP

36 patent families covering:

- Ingestible devices for GI sampling and diagnostics
- GI sample preservation
- GI analyte detection & quantification
- Diagnostic biomarkers & assays

BIORA™ Therapeutics

PUBLICATIONS

NaviCap™ targeted oral delivery platform

1. **Development of targeted therapeutic antibodies for the treatment of inflammatory bowel disease: A proof of concept**. Poster presented at DDW 2019.
2. **A comparison of systemic versus targeted anti-TNFα antibody in treatment of colitis induced by adoptive transfer of CD44-/CD62L+ T-cells into RAG2-/- mice recipients**. Presented at DDW 2019.
3. **Targeted delivery of soluble tofacitinib citrate to the site of inflammation to improve efficacy and safety**. Poster presented at DDW 2021.
4. **Development of a novel drug delivery system for treatment of Ulcerative Colitis**. Poster resented at DDW 2021.
5. **Development of a Novel Drug Delivery System to Deliver Drugs Directly to the Colonic Mucosa, Resulting in Improved Efficacy and Reduced Systemic Exposure for the Treatment of Ulcerative Colitis**. *Crohn's & Colitis 360*. 2021, 3, 1–5.
6. **Tofacitinib tissue exposure correlates with endoscopic outcome**. Oral presentation at DDW 2022 and BWG. Poster presented at ECCO 2022.
7. **Pharmacokinetic stratification of cytokine profiles during anti-TNF induction treatment in moderate-to-severe UC**. Poster presented at ECCO 2022 and DDW 2022.
8. **Pilot study to assess pharmacokinetic and pharmacodynamic markers following enema-dosing with adalimumab in patients with active ulcerative colitis.** Poster presented at ACG 2022.
9. **A scintigraphic study to evaluate the safety, tolerability, and functionality of a Drug Delivery System (DDS) device in healthy volunteers in fasted state.** Poster presented at ACG 2022.
10. **A scintigraphic study to evaluate the localization and delivery function of a Drug Delivery System (DDS) device in patients with active ulcerative colitis (UC) in fasted state.** Poster presented at ACG 2022.
11. **Development of a novel Drug Delivery System (DDS) to deliver drugs directly to the colonic mucosa to improve efficacy and reduce systemic exposure for the treatment of ulcerative colitis (UC)**. Poster presented at Crohn’s & Colitis Congress 2023.
12. **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 2023.
13. **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 2024.

see bioratherapeutics.com/publications

BioJet™ systemic oral delivery platform

1. **Development of *ex-vivo* and *in-vivo* models to assess the performance of an oral biotherapeutic delivery system (OBDS) capsule**. Poster presented at the *Controlled Release Society Annual Meeting*, July 13-14, 2022 and at the *American College of Gastroenterology Annual Scientific Meeting*, October 21-26, 2022.

2. **Assessing the performance of an oral biotherapeutic delivery system (OBDS) using intra-duodenal endoscopy delivery in *Yucatan* minipigs**. Poster presented at the *Controlled Release Society Annual Meeting*, July 13-14, 2022 and at the *American College of Gastroenterology Annual Scientific Meeting*, October 21-26, 2022.

3. **Development of preclinical models to assess the performance of the oral biotherapeutic delivery system (OBDS) capsule.** Poster presented at the *Parenteral Drug Association Universe of Pre-Filled Syringes and Injection Devices Conference*, October 18-19, 2022.

4. **Evaluation of the pharmacokinetics of glucagon-like-peptide-1 (GLP-1) receptor agonist delivered through the BioJet™ oral biotherapeutic delivery platform in a porcine model.** Poster presented at the *American Diabetes Association 83rd Scientific Sessions*, June 23-26, 2023.

5. **Evaluation of the pharmacokinetics of glucagon-like-peptide-1 (GLP-1) receptor agonist delivered through the BioJet™ oral biotherapeutic delivery platform in a porcine model: an update.** Poster presented at the *59th Annual Meeting of the European Association for the Study of Diabetes*, October 2-6, 2023.

6. **Empowering Peptide Self Administration with Needle-Free Smart Capsules.** Oral presentation at the *Next-Gen Peptide Formulation & Delivery Summit*, June 19, 2024.

see bioratherapeutics.com/publications


BIORA™
Therapeutics