BIORA™ Therapeutics

CORPORATE PRESENTATION

November 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.

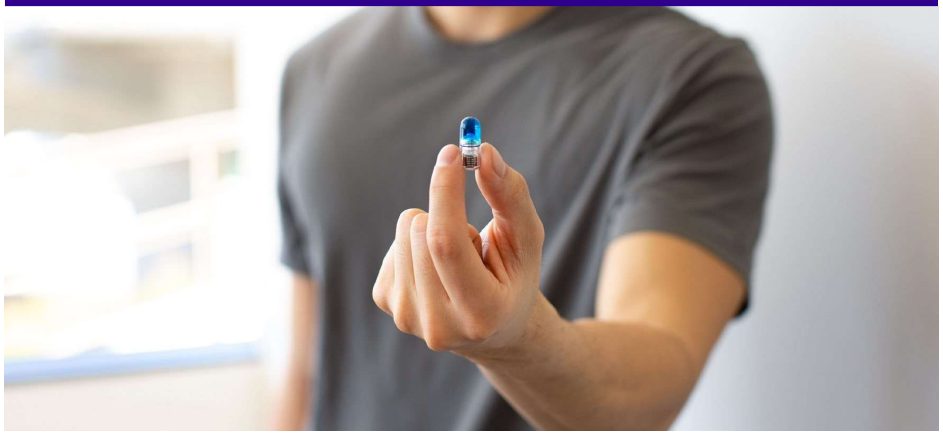
BIORA™ Therapeutics

ISO 13485 CERTIFIED

BIO*jet*™

SYSTEMIC ORAL DELIVERY

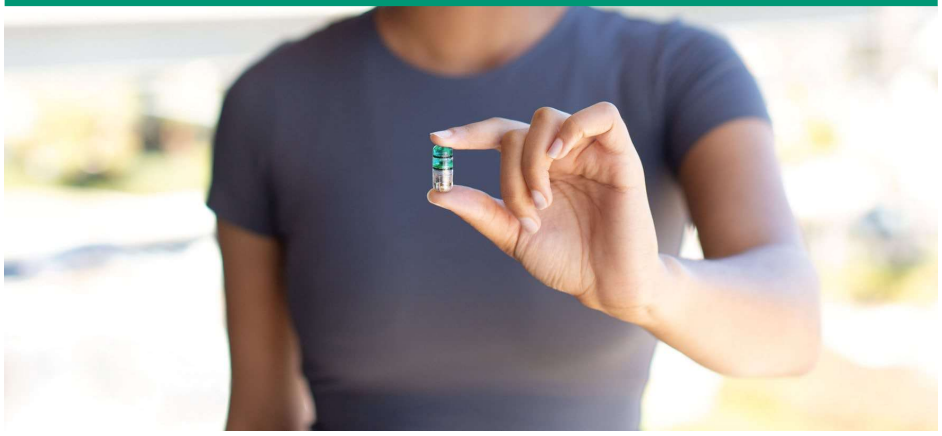
Needle-free delivery of middle-to-large molecule therapeutics designed to replace injection



NAVI*cap*™

TARGETED ORAL DELIVERY

Treatment at the site of disease in the colon could improve outcomes for people with IBD




NAVIcap™
TARGETED ORAL DELIVERY

CLINICAL TRIAL RESULTS

NAVIcap™

Successfully developed platform through four human device function studies and a Phase 1 clinical trial

Q4 2022 – PM 601	Q4 2022 – PM 602	Q1 2023 – PM 611	Q2 2023 – PM 603	Q3 2024 – BT-600
DEVICE FUNCTION STUDY **Healthy Participants Fasted State**	DEVICE FUNCTION STUDY **Active UC Patients**	DEVICE FUNCTION STUDY **Healthy Participants Fasted & Fed**	DEVICE FUNCTION STUDY **Healthy Participants Fasted State**	PHASE 1 SAD/MAD CLINICAL TRIAL **Healthy Participants Fasted State**
• *n*=12 • Achieved distribution of payload across the entire colon[1]	• *n*=7 • 100% of devices performed as intended[1]	• *n*=39 • 97.4% of devices activated payload release function[1]	• *n*=16 • 94% of devices performed as intended[1]	• *n*=48 • >95% device performance[2]
HEALTHY PARTICIPANTS ✓	**ACTIVE UC PATIENTS** ✓	**FUNCTION w/wo FOOD** ✓	**PHASE 1-READY DEVICE** ✓	**PHASE 1 SAD/MAD** ✓

- *Over 800 NaviCap devices have been assessed in animals and over 320 in humans*
- *IND clearance by the FDA followed by a US-based Phase 1 clinical trial*

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.
2. Feagan B, Razag, G, Lee SN, et al. Single ascending dose results from a Phase 1 clinical trial of BT-600, a combination product of the NaviCap targeted oral delivery platform and tofacitinib. Poster presented at *American College of Gastroenterology Annual Scientific Meeting*, October 25 – 30, 2024, Philadelphia, Pennsylvania.

BIORA Therapeutics

BT-600 PHASE 1 TRIAL IN HEALTHY PARTICIPANTS

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

Feagan B, Razag, G, Lee SN, et al. Single ascending dose results from a Phase 1 clinical trial of BT-600, a combination product of the NaviCap targeted oral delivery platform and tofacitinib. Poster presented at *American College of Gastroenterology Annual Scientific Meeting*, October 25 – 30, 2024, Philadelphia, Pennsylvania.

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.

BT-600 PHASE 1 TRIAL IN HEALTHY PARTICIPANTS

Evidence of localized drug delivery and uptake across all distal biopsy sites

NAVIcap™

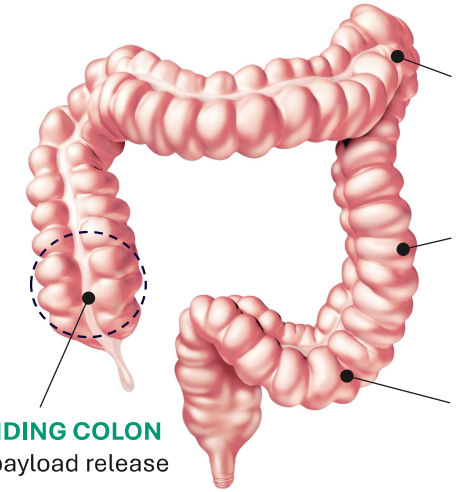
NAVICAP-DELIVERED TOFACITINIB BT-600 5 MG and 10 MG QD[2]

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		

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

† 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

BIOPSY SITES



SPLENIC FLEXURE
tofacitinib present in **15/18 biopsies**

DESCENDING COLON
tofacitinib present in **15/18 biopsies**

ASCENDING COLON
area of payload release

SIGMOID COLON
tofacitinib present in **14/18 biopsies**

PRESIDENTIAL POSTER AWARD
American College of Gastroenterology
Annual Scientific Meeting
Oct 25–30, 2024

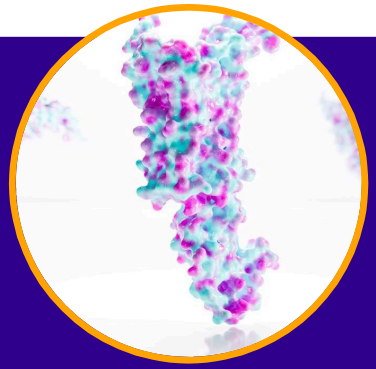
Feagan B, Razag, G, Lee SN, et al. Single ascending dose results from a Phase 1 clinical trial of BT-600, a combination product of the NaviCap targeted oral delivery platform and tofacitinib. Poster presented at *American College of Gastroenterology Annual Scientific Meeting*, October 25–30, 2024, Philadelphia, Pennsylvania.

BIORA Therapeutics

BIO*jet*™

SYSTEMIC ORAL DELIVERY

Challenges of oral delivery for injectable macromolecules



PROTECTION

- Middle-to-large (macro) molecules need protection to survive GI tract environment

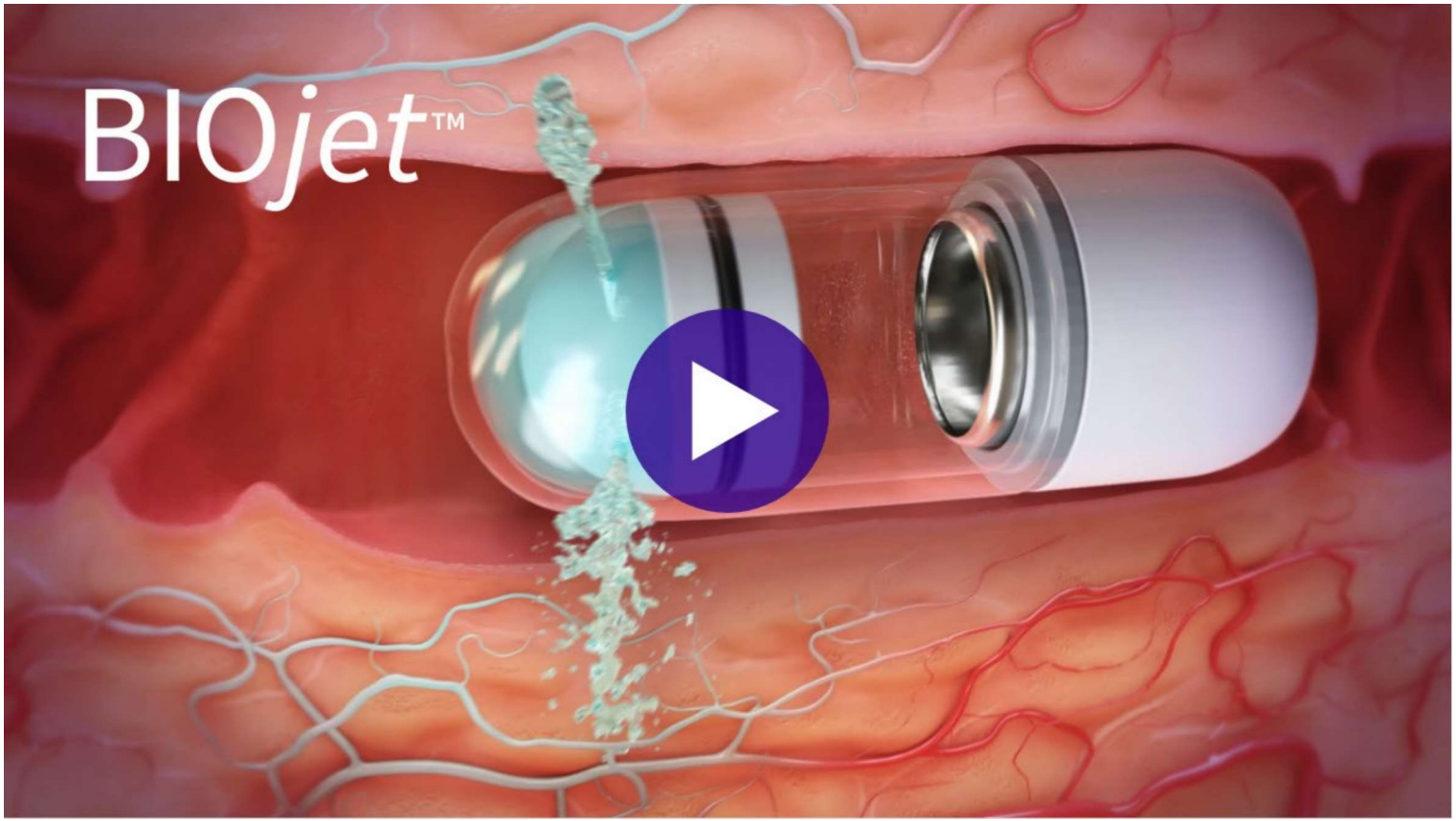
BIOAVAILABILITY

- Limited effectiveness of existing technologies:
  - Permeation enhancers
  - Nanoparticles
- ~1% bioavailability for current oral peptide formulations

EASE OF ADOPTION

- Ease of administration
- No reformulation
- Automated manufacturing

Swallowable autoinjector uses liquid jet injection to deliver drug into the submucosa of the small intestine



SCAN ME

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

30+ in vivo studies proved bioavailability via liquid jet injection across multiple molecules

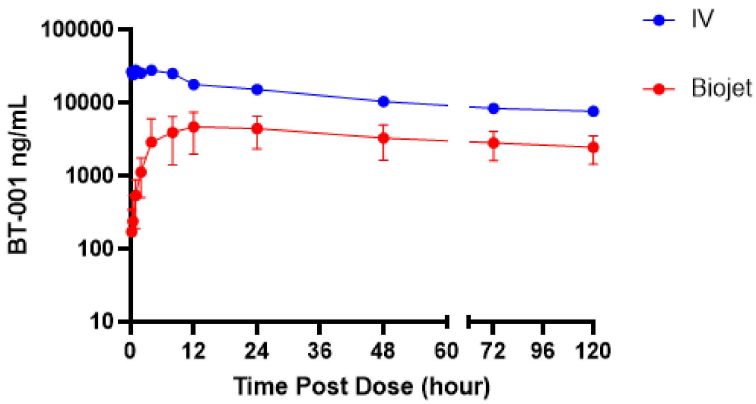
BIOJET DELIVERY IN SWINE MODEL

with endoscopically placed & autonomously triggered 000 device

MOLECULE TYPE	DRUG	ORAL BIOAVAILABILITY[1]
ANTIBODY	adalimumab (monoclonal antibody)	**>30%** mean oral bioavailability **vs. IV control** Equates to 60–80% vs. subQ
PEPTIDE	semaglutide (GLP-1 receptor agonist)	
OLIGONUCLEOTIDE	undisclosed antisense oligonucleotides	

BIOJET-DELIVERED ADALIMUMAB

Plasma PK vs. IV



RESEARCH COLLABORATIONS

- Five pharma collaborators tested peptides, antibodies and ASOs

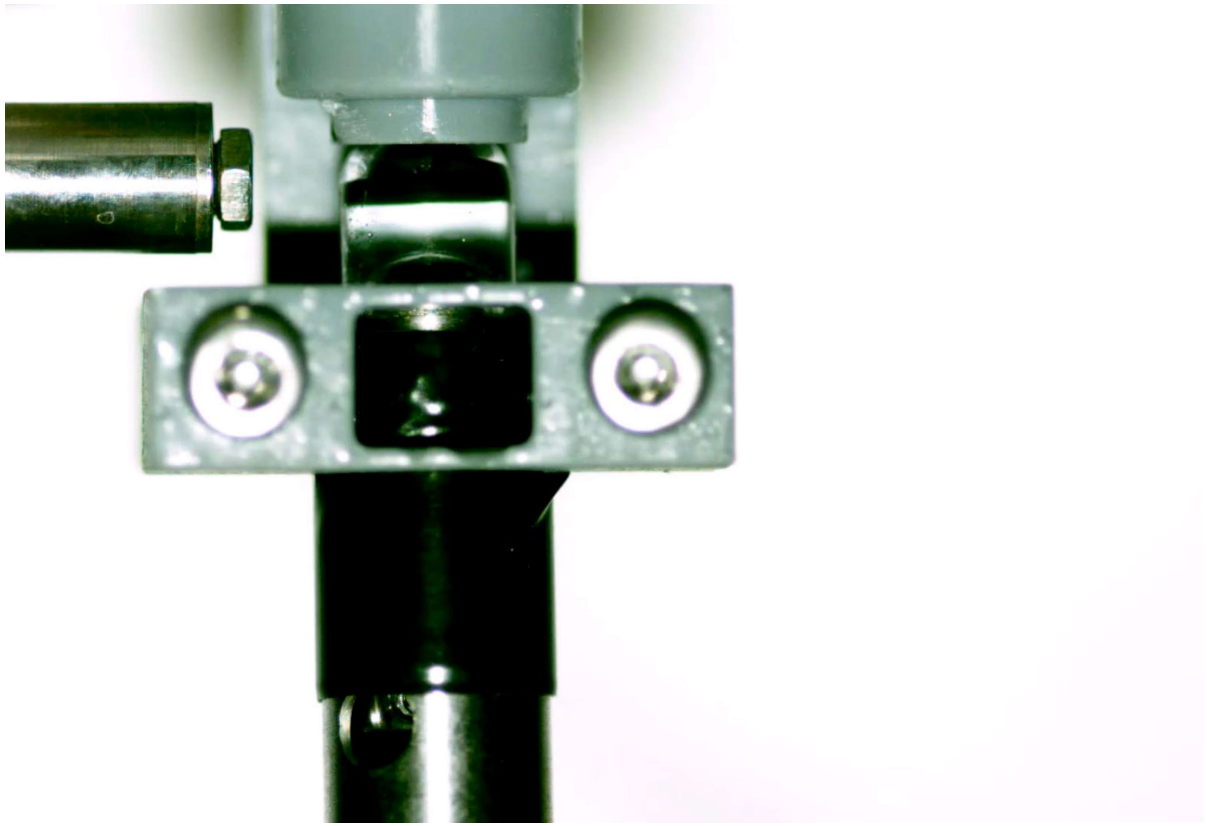
AstraZeneca IONIS ***Pharma 3**** ***Pharma 4**** ***Pharma 5****

1. Biora Therapeutics data on file

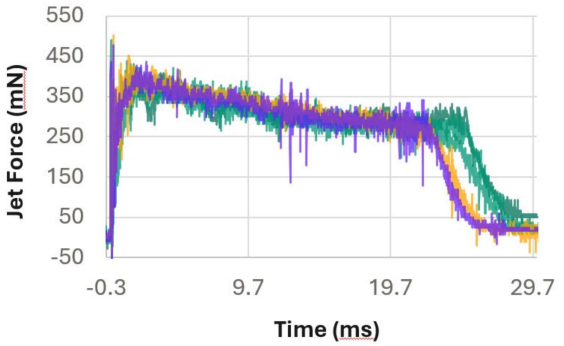
*undisclosed pharma collaborators

BIORA Therapeutics

Benchtop testing of liquid jet injection technology



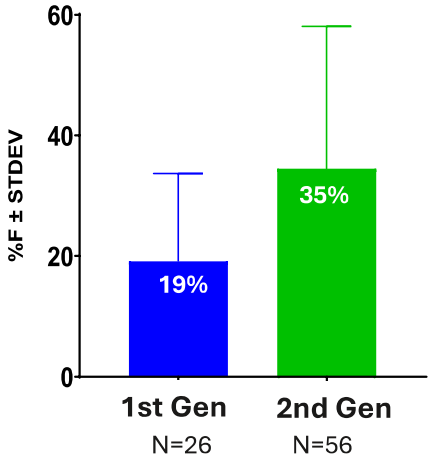
- Jet force rig test fixture developed to evaluate function and measure jet parameters
- A force sensor (left side) is used for liquid jet assessment and characterization
- When trigger degrades, the device actuates, driving the piston into the drug reservoir, which drives payload out through nozzles as a liquid jet



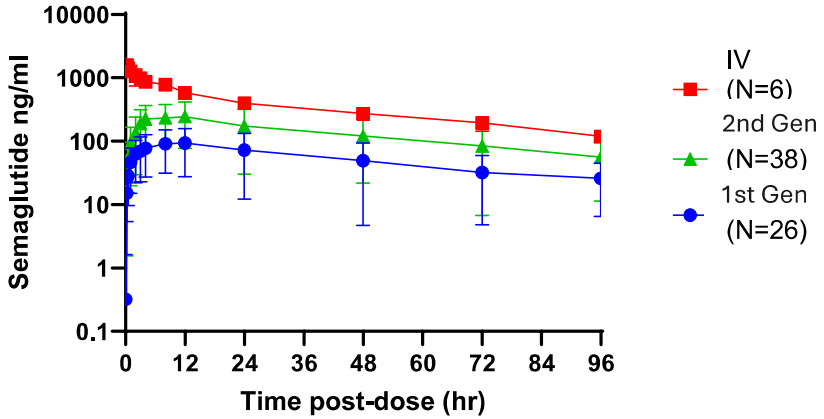
View video: https://biora.wistia.com/medias/48bbq4jvt4

Achieved 35% mean bioavailability of peptides

BIOJET-DELIVERED PEPTIDES
Mean F% vs. IV*



BIOJET-DELIVERED SEMAGLUTIDE
Plasma PK vs. IV*



ACROSS 10 STUDIES OF INTRADUODENALLY PLACED DEVICES IN PORCINE MODEL:

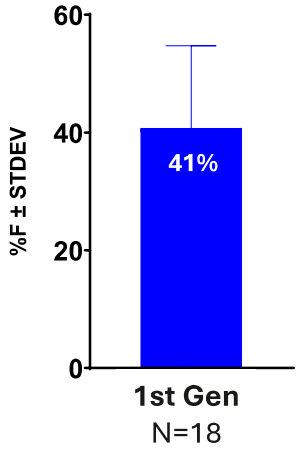
- 35% mean bioavailability (compared to IV; 60–80% vs. SC) was achieved with 2nd generation 000 devices (*n*=56, CV=69%)
- Combined internal and collaborator study data for 3 peptides of similar sizes

(*) Data from animals with detected drug in blood. Biora Therapeutics data on file

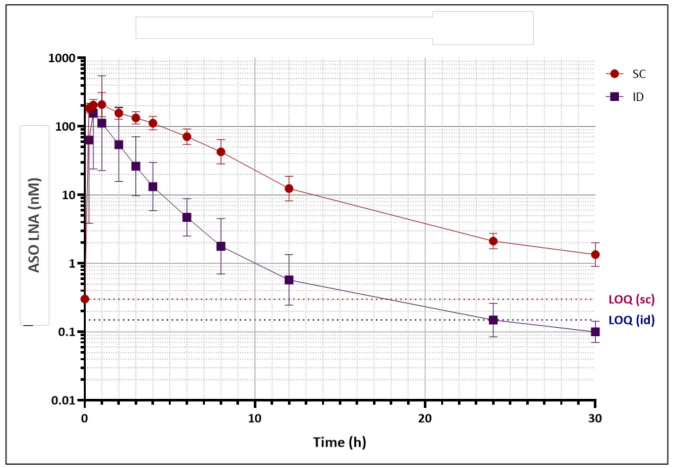
Achieved 41% mean bioavailability of antisense oligonucleotides (ASOs)

BIOjet™

BIOJET-DELIVERED ASOs
Mean F% vs. SC*



BIOJET-DELIVERED ASOs
Plasma PK vs. SC*



Data shown as geometric mean with geometric SD; Values below LOQ are set as LOQ/2

ACROSS 2 STUDIES OF INTRADUODENALLY PLACED DEVICES IN PORCINE MODEL:

- 41% mean bioavailability (compared to **SC**) was achieved with baseline-configured 000 devices (*n*=18, CV=34%)
- For molecules targeting the liver, oral dosing could improve delivery through the first-pass hepatic effect
  - Tissue bioavailability was assessed for an ASO with 44% in liver and 49% in kidney vs SC

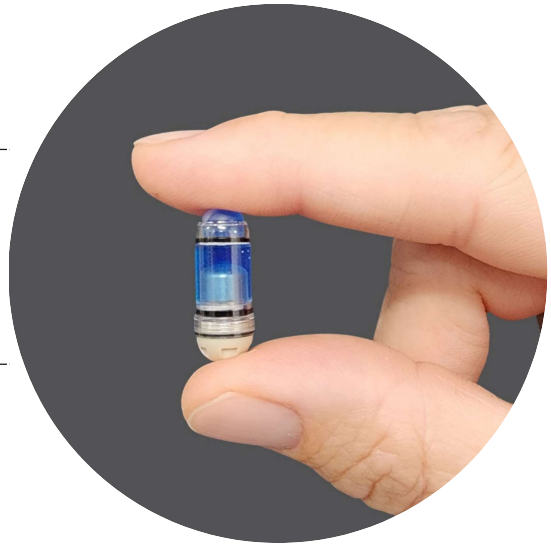
(*) Data from animals with detected drug in blood. Biora Therapeutics data on file

BIORA Therapeutics

00-size clinical device available by year-end

BIOjet™

DESIRED BY PATIENTS AND PHARMA	• Reduced size from 000 to 00 for ease of swallowing, while slightly increasing payload capacity • Improves on 000 device with simplified triggering mechanism • Designed for automated manufacture, fill, and sterilization
BUILDING ON PREVIOUS SUCCESS WITH 000-SIZE DEVICE	• Advanced engineering modeling enabled rapid development of proof-of-concept 00 device • Benchtop assessments have correlated with *in vivo* results
EXPANDED CURRENT COLLABORATIONS TO INCLUDE *IN VIVO* TESTING OF 00-SIZE DEVICE	• Successfully tested autonomous delivery of radioactive tracer in canine model • Canine studies with drug payload currently underway • PK studies in primate model in Q4 2024 • Full assessment and feasibility with molecules from multiple collaborators in Q1 2025



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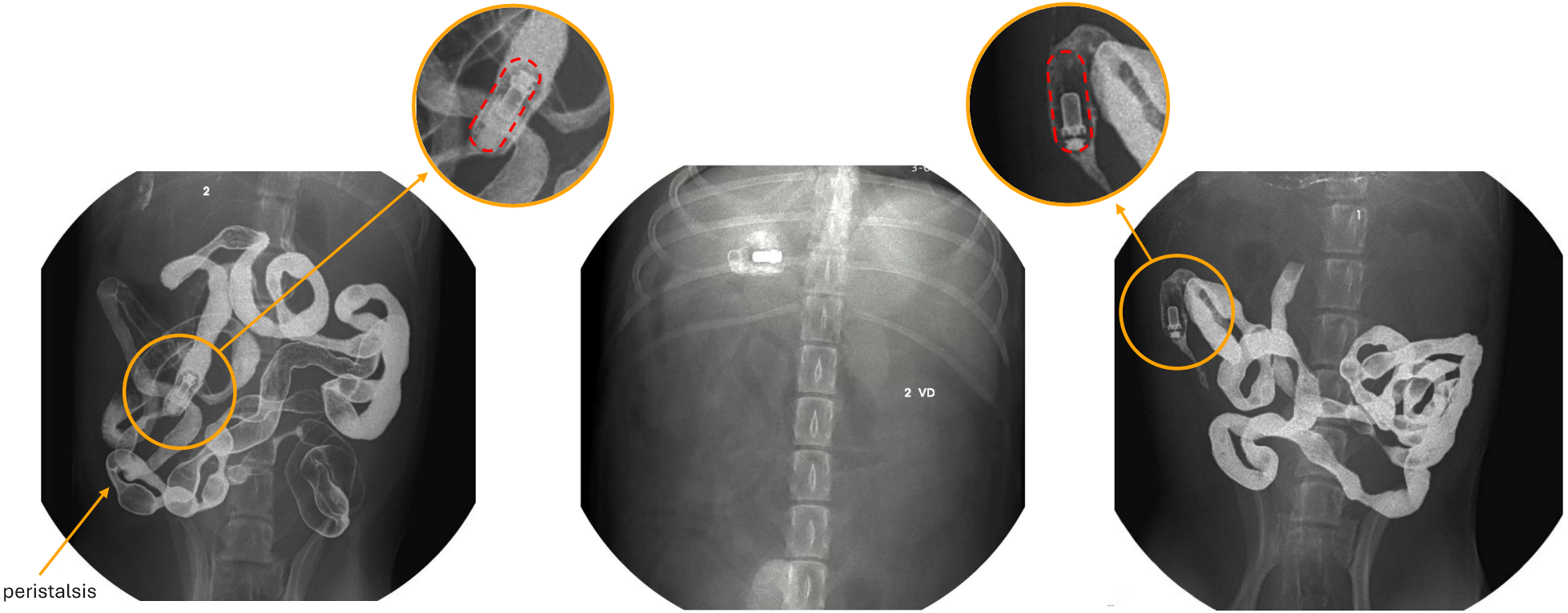
Canine studies with contrast agent payload confirm fully autonomous actuation of 00-size BioJet device



BEFORE DEPLOYMENT

120 minutes post dose

DURING ACTUATION (VIDEO)

Using underpowered device to avoid injecting contrast agent

AFTER DEPLOYMENT

180 minutes post dose

BIORA Therapeutics

Planned preclinical studies on the path to clinical 00 device

BIOjet™

	Q4 2024			Q1 2025		
CANINE Device Function	✓ Trigger function imaging	✓ Drug delivery device function	Drug delivery device function	Collaborator B molecule study		
PORCINE Bioavailability			Device Bioavailability Testing	Collaborator A molecule study	Collaborator B molecule study	Collaborator C molecule study
PRIMATE Device Function & Bioavailability			First Non-Human Primate (NHP) Study	Confirmatory NHP Study	Collaborator A molecule study	Collaborator B molecule study

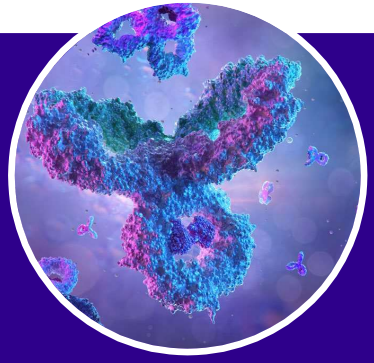
BIORA Therapeutics

Needle-free, oral delivery of injectable macromolecules

BIOjet™
SYSTEMIC ORAL DELIVERY

CATEGORY-LEADING ORAL BIOAVAILABILITY

- **~30% bioavailability** vs. IV across molecule classes (equates to 60–80% vs. subQ)
- High bioavailability enables lower API volumes



BROAD APPLICABILITY

- Largest payload of any ingestible injectable: >300 µl capacity enables **>50 mg doses**
- Designed for automated manufacturing using **existing liquid formulations**

NOVEL DRUG DELIVERY TECHNOLOGY

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

BIORA Therapeutics

APPENDIX

INTELLECTUAL PROPERTY

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

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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.
14. **Single ascending dose results from a Phase 1 clinical trial of BT-600, a combination product of the NaviCap targeted oral delivery platform and tofacitinib.** Poster presented at ACG 2024.

see bioratherapeutics.com/publications

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.

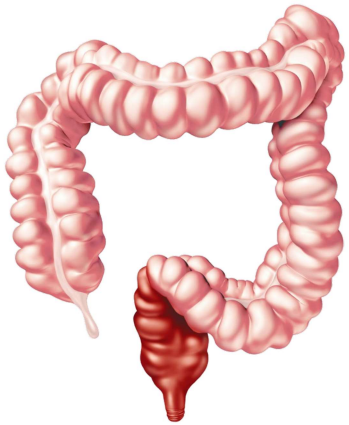
see bioratherapeutics.com/publications

ADDITIONAL NAVICAP SLIDES

CLINICAL PRESENTATION

Ulcerative colitis: a disease of the colonic tissue

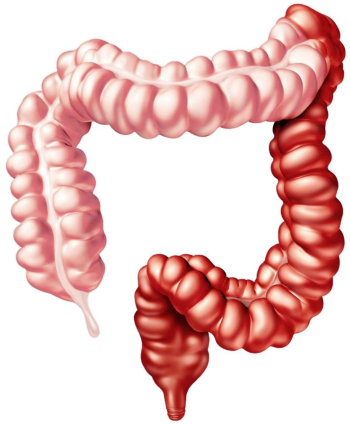
E1: PROCTITIS



SYMPTOMS
Rectal bleeding, tenesmus, urgency

30–60% of patients

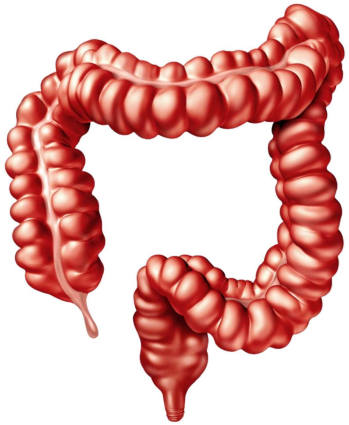
E2: DISTAL COLITIS



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

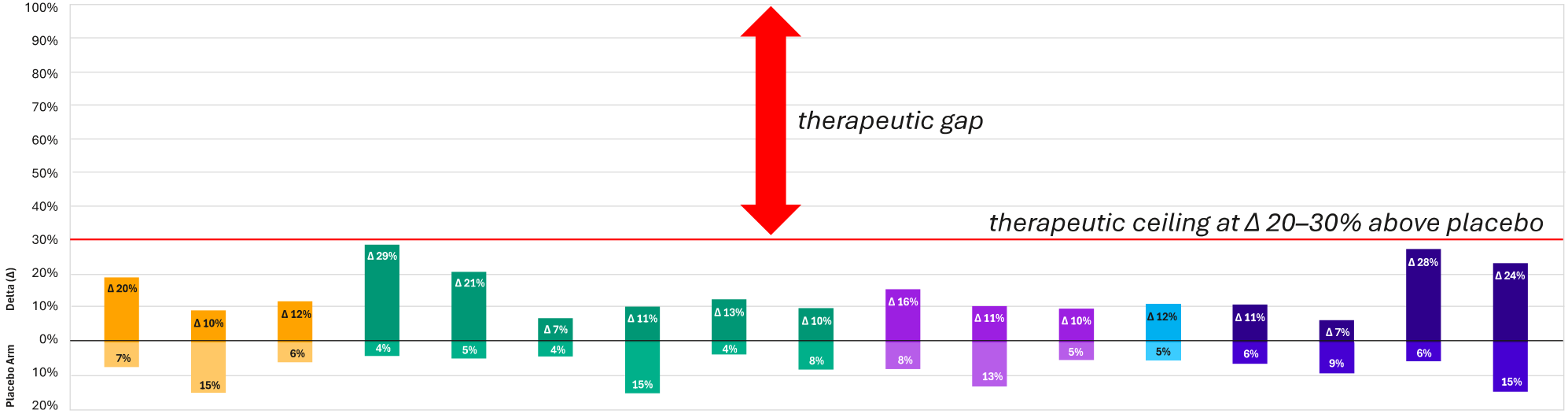
- Inflammatory bowel disease (IBD) includes Crohn's disease and ulcerative colitis (UC)
- UC causes inflammation and damage to the mucosal and submucosal layers of the colon
- About 1 million people in the U.S. are affected with UC, and ~40,000 cases are diagnosed each year[1]

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.

UNMET NEED

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.

BIORA Therapeutics

References: UC clinical trials

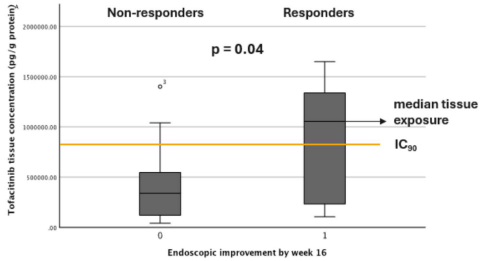
INDUCTION OF CLINICAL REMISSION IN UC

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.

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)

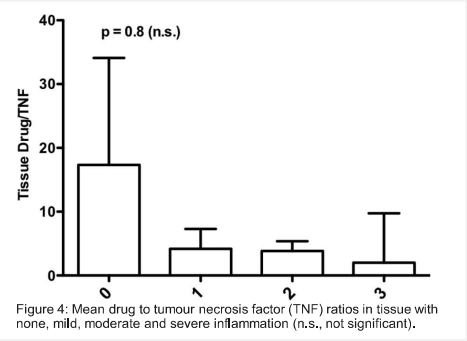
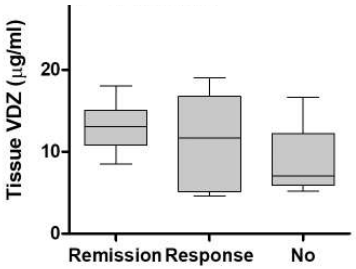


Figure 4: Mean drug to tumour necrosis factor (TNF) ratios in tissue with none, mild, moderate and severe inflammation (n.s., not significant).

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

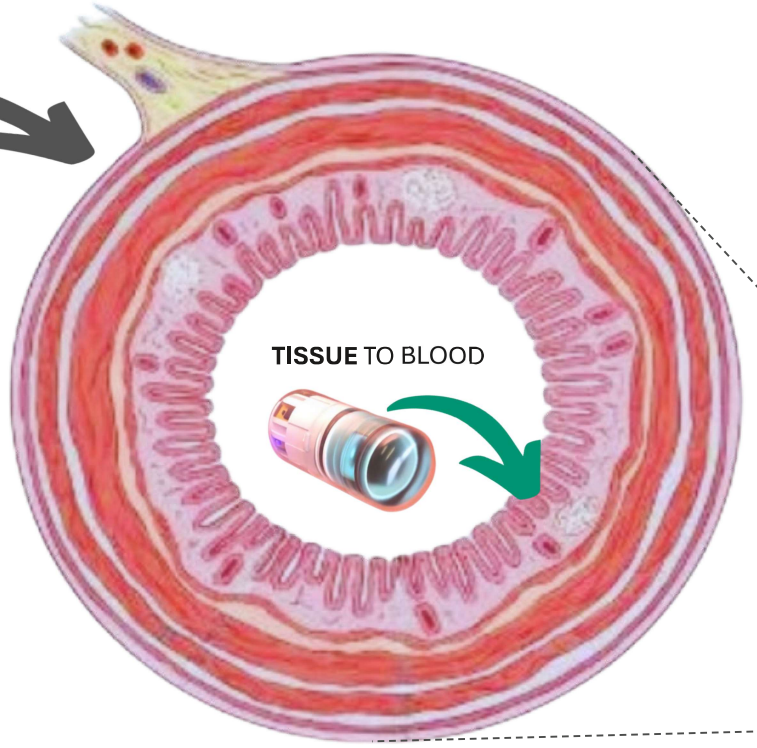
Anatomically targeted, topical drug delivery to the colon for treatment of UC

NAVIcap™

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

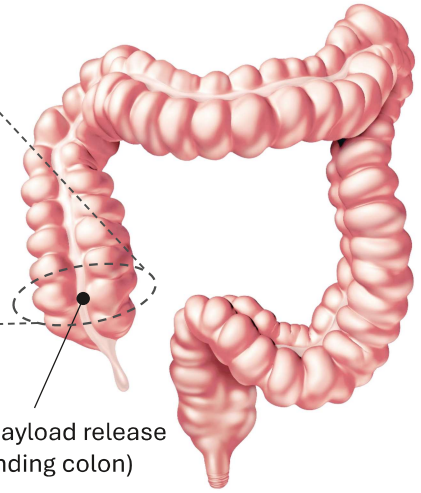


colon, cross section

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)

OUR SOLUTION

Localized delivery to the colon 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

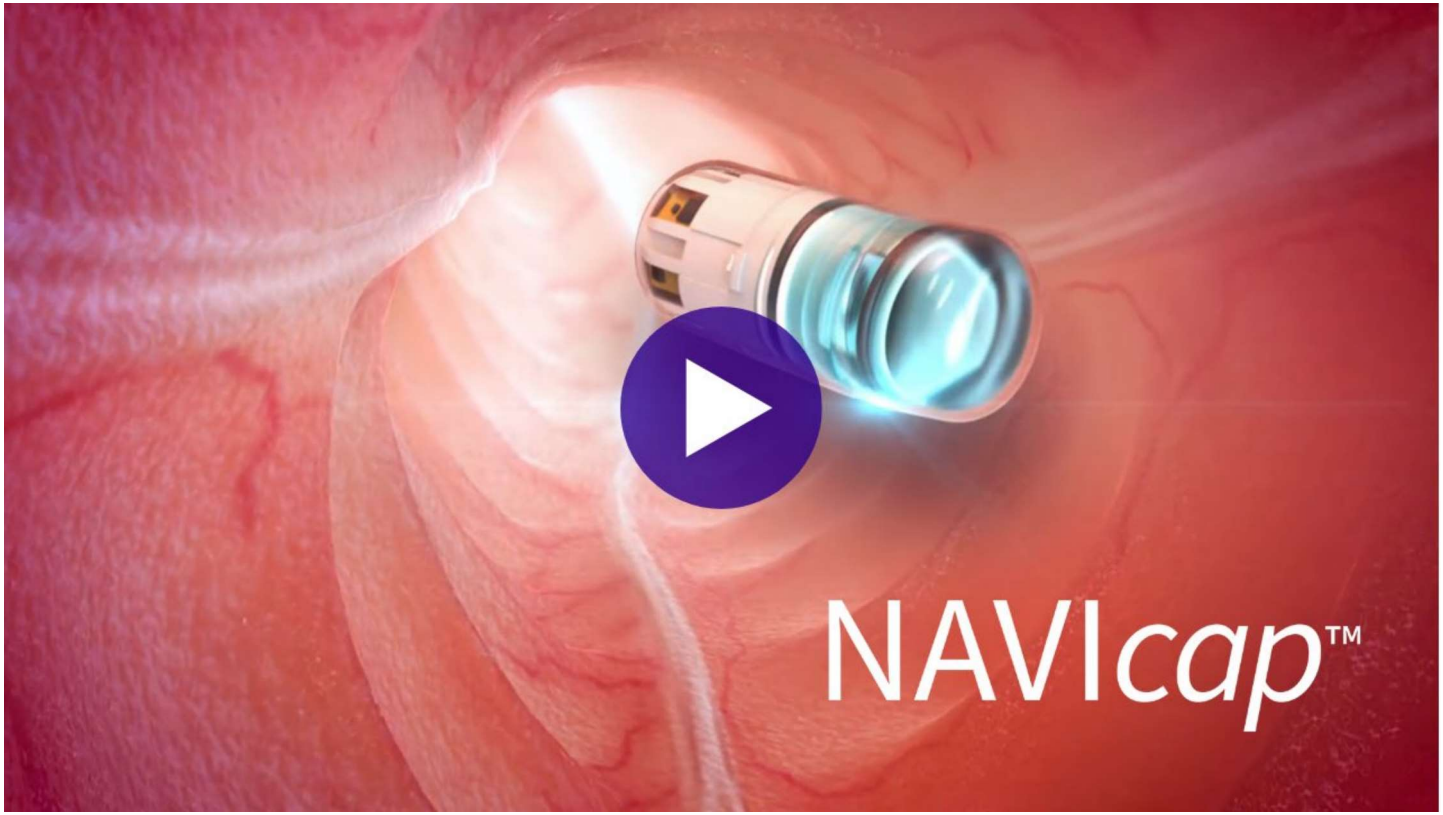
POTENTIAL SOLUTION

- 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.

Autonomous localization and drug delivery to the colon



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

ORAL ADMINISTRATION

Swallowable capsule the size of a fish-oil pill

ANATOMICALLY TARGETED DRUG DELIVERY

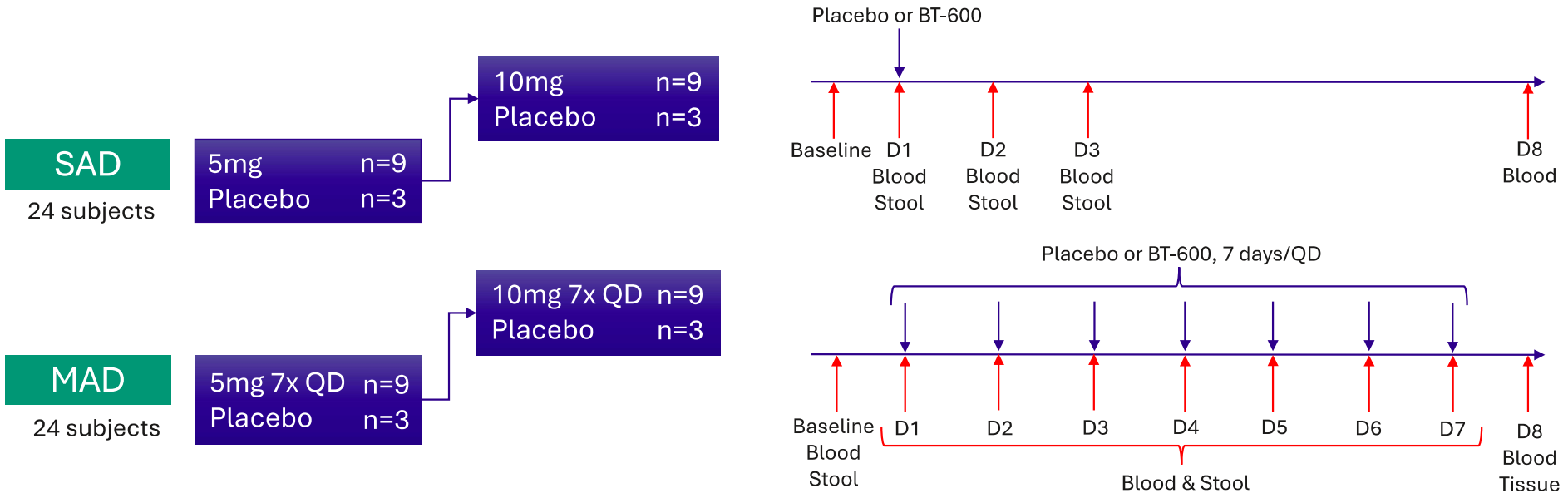
Designed to coat the length of the colon with liquid formulation, act at the site of disease, and minimize systemic uptake

AUTONOMOUS LOCATION

Uses GITrac™ optical location technology to track its location and deliver to the targeted location

PHASE 1 CLINICAL TRIAL DESIGN

Evaluate safety and pharmacokinetics of BT-600 in healthy participants

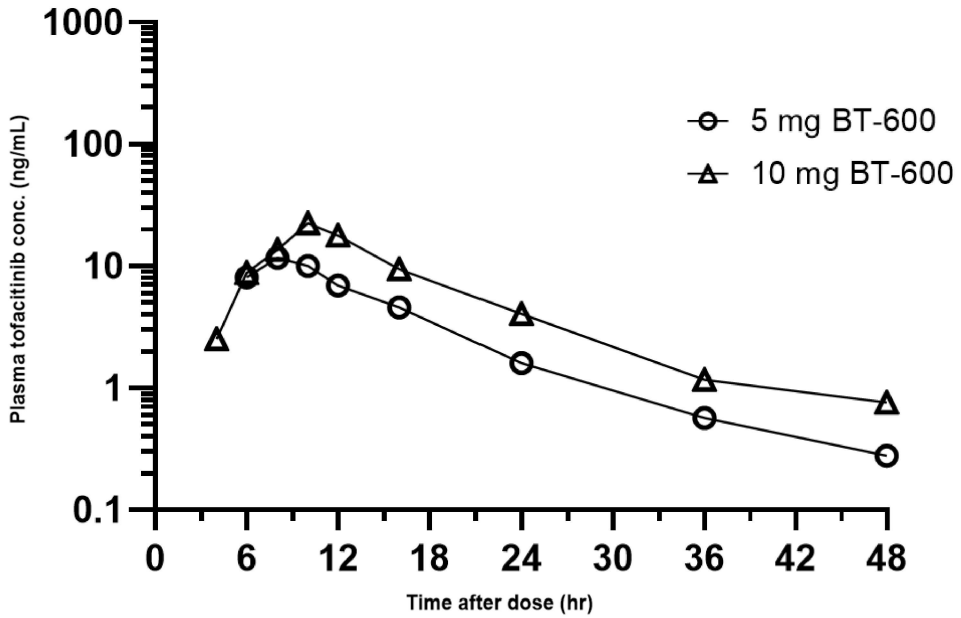


PATIENT POPULATION	Total of 48 healthy participants (24 SAD and 24 MAD participants)
TRIAL DESIGN	Randomized, double-blind, placebo-controlled clinical trial to evaluate the safety, tolerability, and PK of SAD and MAD doses of BT-600 in healthy participants

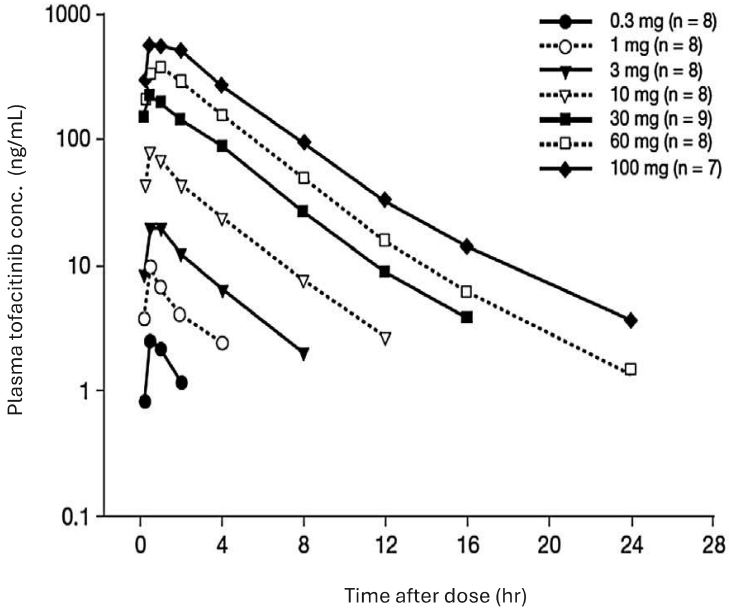
PHASE 1 SAD: PK RESULTS

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.

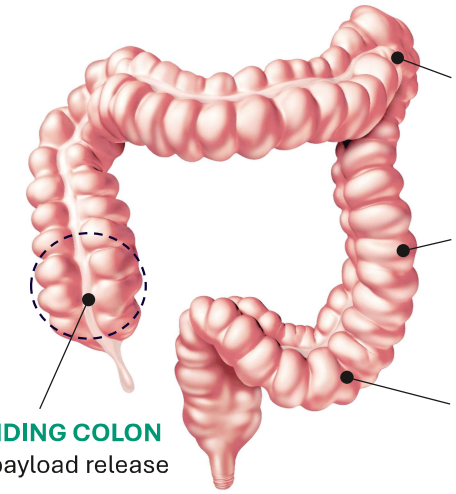
1. Phase 1 clinical trial data on file, Biora Therapeutics, Inc.
2. Pfizer, Inc. Xeljanz (tofacitinib) USPI. https://labeling.pfizer.com/showlabeling.aspx?id=959 Revised May 2024. Accessed June 18, 2024.
3. Krishnaswami S, Boy M, Chow V, Chan G. Safety, tolerability, and pharmacokinetics of single oral 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: BT-600

Evidence of drug delivery across all distal biopsy sites

BIOPSY SITES



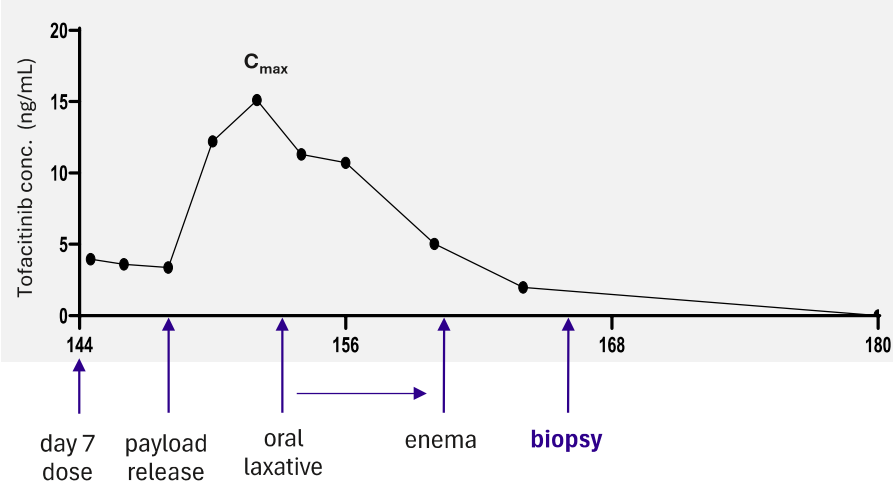
SPLENIC FLEXURE
tofacitinib present in
15/18 biopsies

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 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

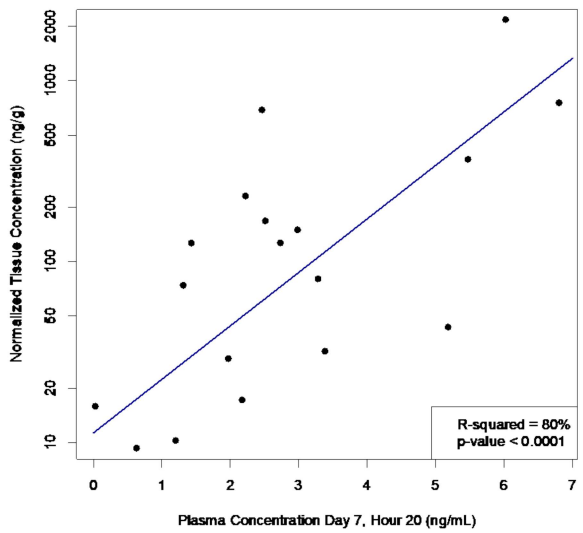
Phase 1 clinical trial data on file, Biora Therapeutics, Inc.

BIORA Therapeutics

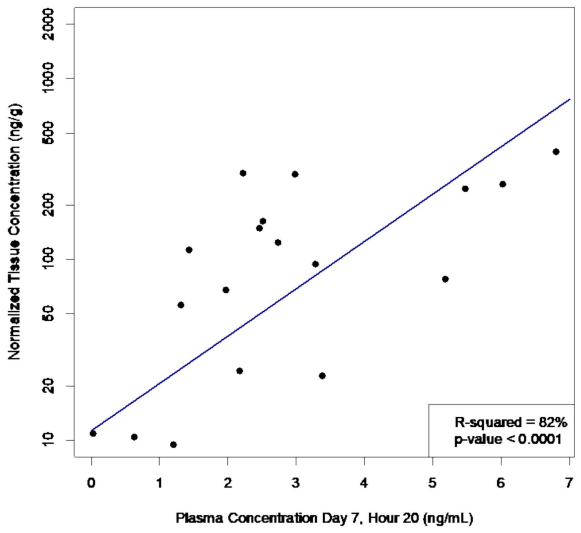
PHASE 1 MAD: COLON TISSUE EXPOSURE

Good correlation between tissue and plasma levels

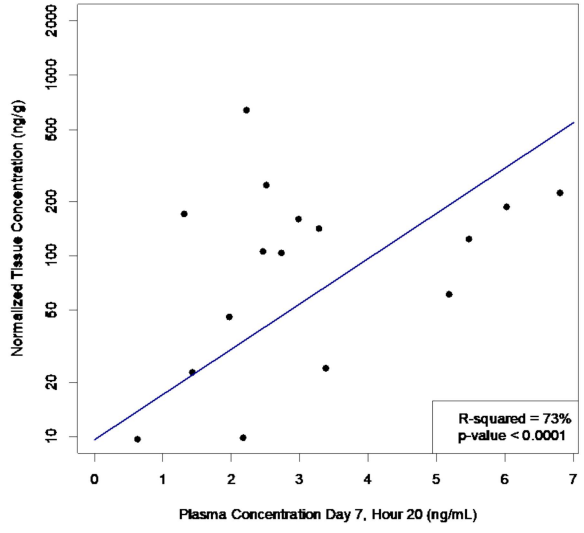
SPLENIC FLEXURE



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

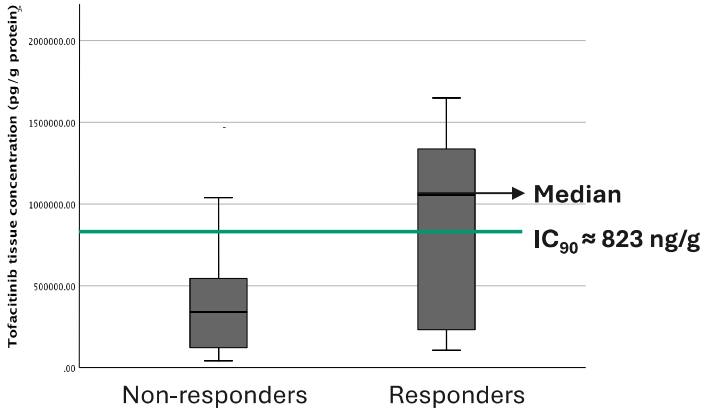
Phase 1 clinical trial data on file, Biora Therapeutics, Inc.

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

- Tofacitinib tissue concentrations shown to correlate with endoscopic response
- Responders had median tissue concentration above the estimated IC90

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

- 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.

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.

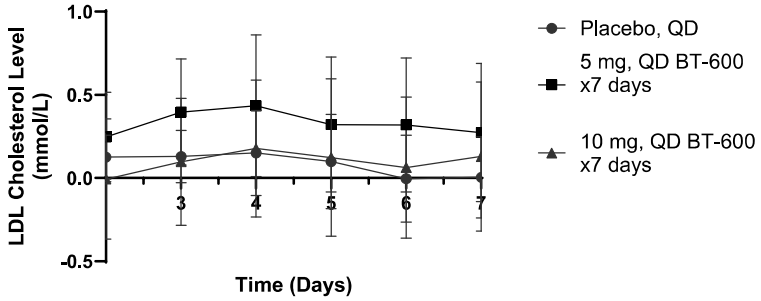
BIORA Therapeutics

PHASE 1: SAFETY PARAMETERS

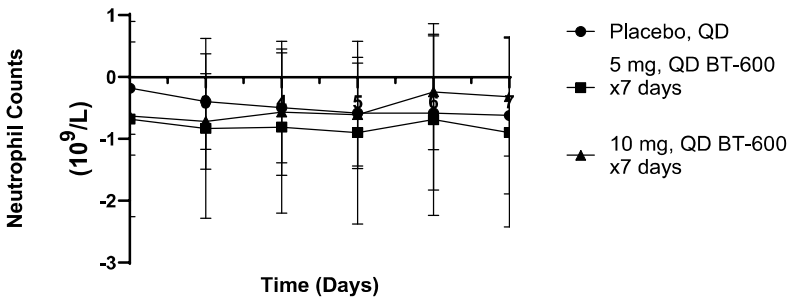
BT-600 was well tolerated

- 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)



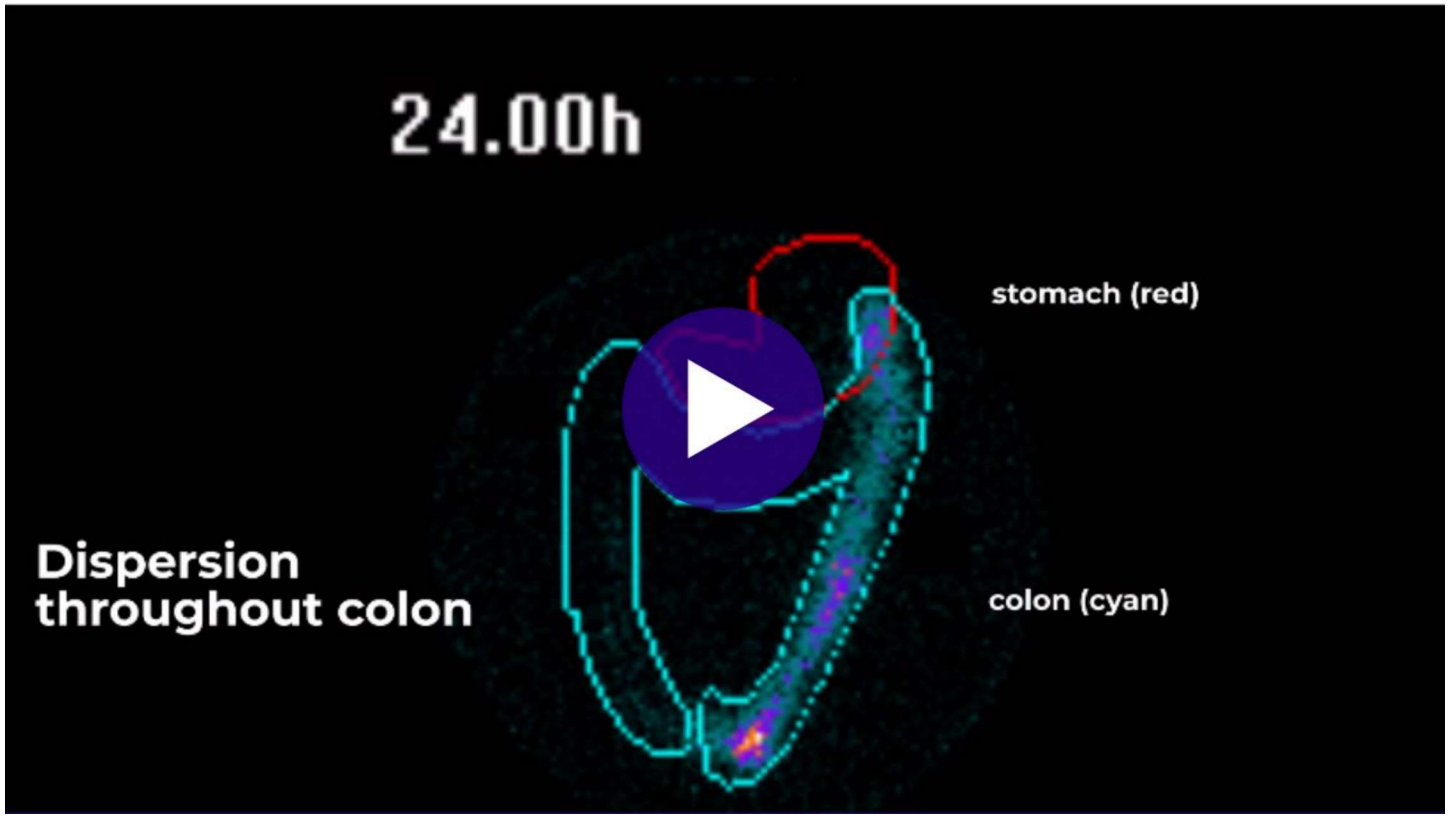
NEUTROPHILS
MEAN CHANGES FROM BASELINE (MAD)



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

DEVICE FUNCTION STUDIES (WITHOUT DRUG)

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 IN ULCERATIVE COLITIS

Phase 1 trial results support clinical development plan

NAVIcap™

PHASE 1

Purpose
Provide evidence of colonic delivery of a therapeutic (tofacitinib)

Population
48 healthy participants

Design
Single-center SAD/MAD trial

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

✓ **COMPLETE**

✓ **ALL OBJECTIVES MET**

PHASE 2

Purpose
Proof of concept: efficacy of tofacitinib delivered via NaviCap device

Population
≈150 UC patients

Design
Global multicenter induction efficacy trial

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

OBTAINING REGULATORY FEEDBACK FOR PLANNED PHASE 2 TRIAL

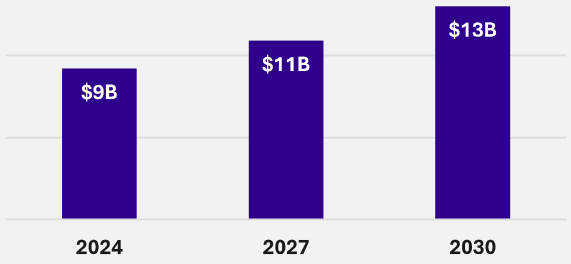
BIORA Therapeutics

UC MARKET SIZE AND SHARE

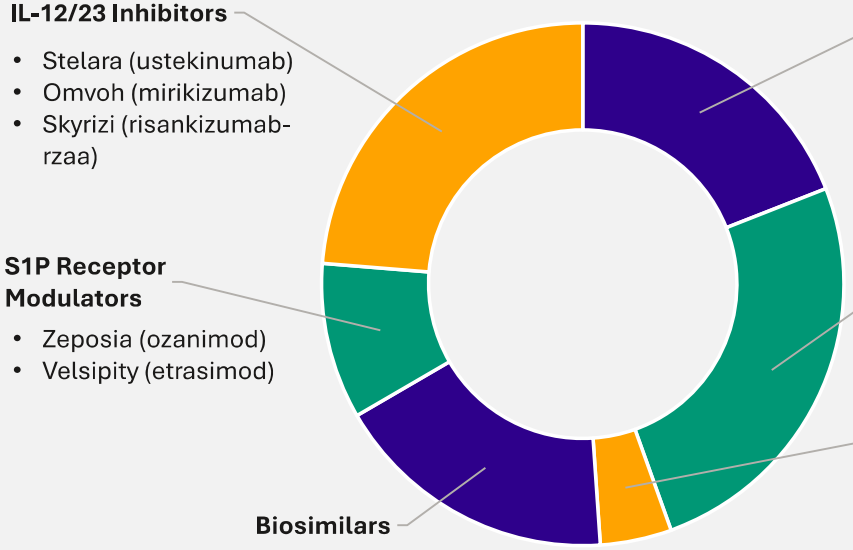
NaviCap could optimize delivery of IBD therapies

- 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]



*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.
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