



**BIORA**<sup>™</sup>  
Therapeutics

*Reimagining  
therapeutic delivery*

**CORPORATE  
PRESENTATION**

June 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, 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 “may,” “might,” “will,” “objective,” “intend,” “should,” “could,” “can,” “would,” “expect,” “believe,” “design,” “estimate,” “predict,” “potential,” “plan” 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; 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.

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



# NAVicap™

TARGETED ORAL DELIVERY

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



# BIOjet™

SYSTEMIC ORAL DELIVERY

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



# THERAPEUTIC PIPELINE

	PROGRAM	INDICATION	DESIGN/FEASIBILITY	PRECLINICAL	CLINICAL
NAVICAP™ TARGETED DELIVERY	<b>NaviCap™</b> Targeted Oral Delivery Platform	--	[Progress bar: ~85%]		
	<b>BT-600</b> NaviCap + tofacitinib*	UC	[Progress bar: ~80%]		
	<b>BT-001</b> NaviCap + adalimumab variant*	UC	[Progress bar: ~45%]		
BIOJET™ SYSTEMIC ORAL DELIVERY	<b>BioJet™</b> Systemic Oral Delivery Platform	--	[Progress bar: ~75%]		
	<b>AstraZeneca Collaboration</b> BioJet + undisclosed drug	Undisclosed	[Progress bar: ~55%]		
	<b>Ionis Collaboration</b> BioJet + antisense therapy	Undisclosed	[Progress bar: ~55%]		
	<b>Large Pharma 2 Collaboration</b> BioJet + undisclosed drug	Undisclosed	[Progress bar: ~35%]		
	<b>Large Pharma 3 Collaboration</b> BioJet + undisclosed drug	Undisclosed	[Progress bar: ~35%]		
	<b>PLANNED FOR 2024</b>				
	<b>BT-200</b> BioJet + GLP-1 receptor agonist*	Demonstration Program	[Progress bar: ~55%]		
	<b>BT-002</b> BioJet + adalimumab variant*	Demonstration Program	[Progress bar: ~55%]		

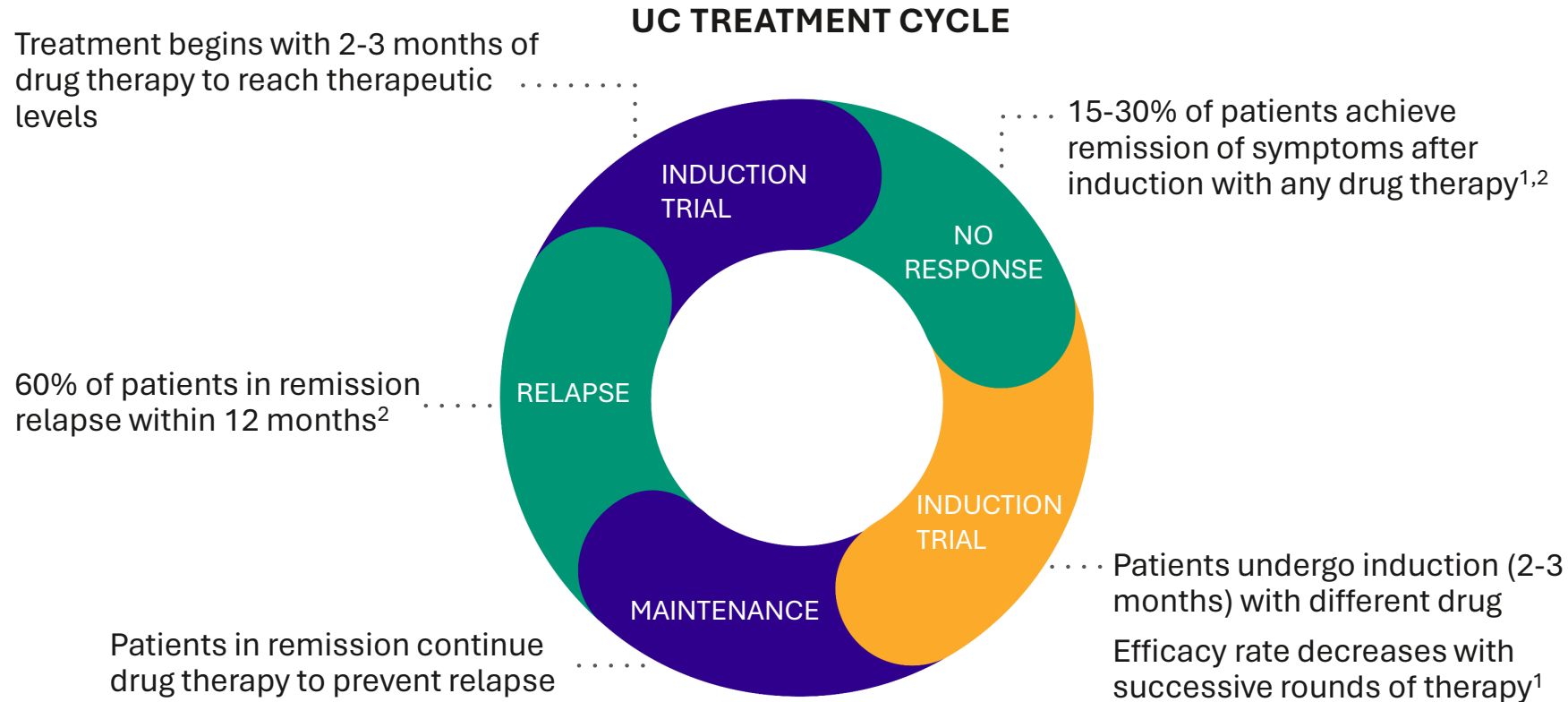
\*Biora's own molecules

NAVI*cap*<sup>TM</sup>

TARGETED ORAL DELIVERY

# ULCERATIVE COLITIS: THE TREATMENT GAP

*Despite therapeutics targeting different pathways, few patients achieve long-term remission*



## ABOUT ULCERATIVE COLITIS

- Inflammatory bowel disease (IBD) includes Crohn's disease and ulcerative colitis (UC)
- UC causes inflammation and damage to the large intestine
- About 1 million people in the U.S. are affected with UC, and ~40,000 cases are diagnosed each year<sup>3</sup>

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.

2. Hirten RP, Sands BE. New Therapeutics for Ulcerative Colitis. *Annu Rev Med.* 2021;72:199-213.

3. 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 IN ULCERATIVE COLITIS

## *Targeted delivery could enable rapid induction and improve patient response*

### THERAPEUTIC CHALLENGES

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

### POTENTIAL SOLUTION

- ▶ Targeted delivery could increase drug levels at the site of disease, which is correlated with improved outcomes<sup>1</sup>
- ▶ Reduced systemic uptake is designed to reduce toxicity and adverse events
- ▶ Reduced toxicity could enable combination therapy<sup>2</sup>

Development in partnership with:



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.](#)



## *Needle-free, oral drug delivery to the colon*

### ORAL ADMINISTRATION

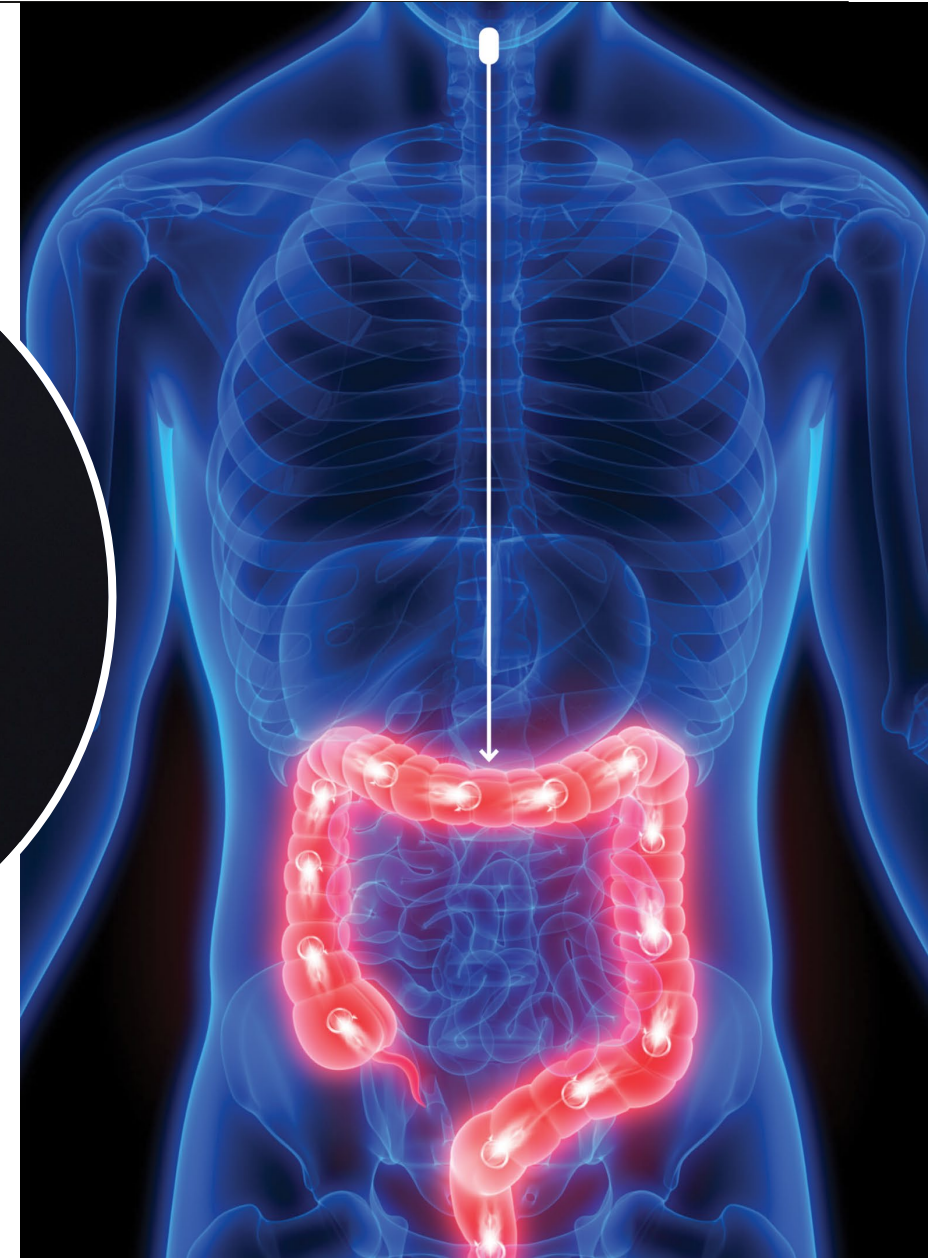
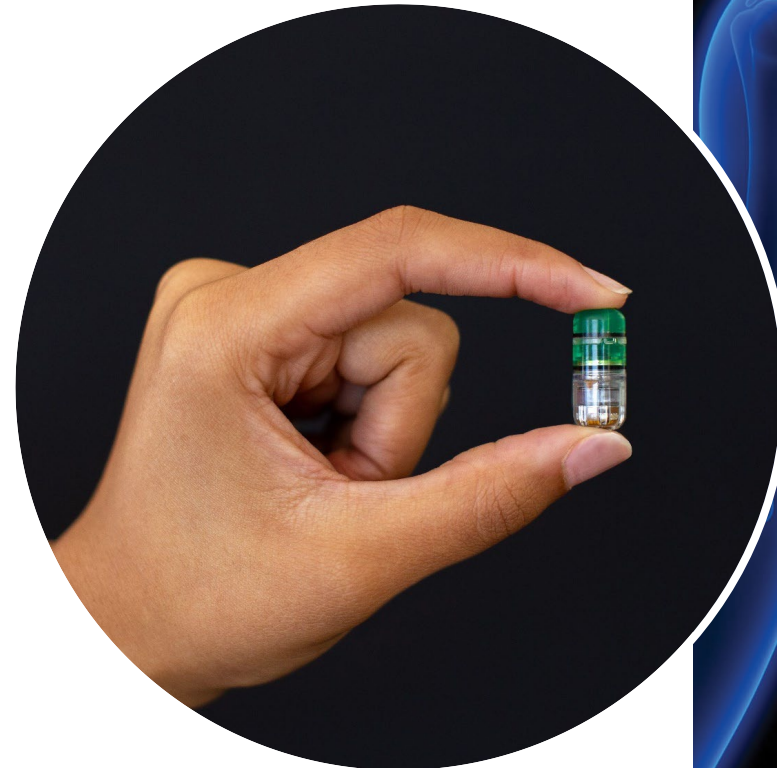
Convenient oral capsule the size of a fish-oil pill

### AUTONOMOUS LOCATION

GITrac™ autolocation technology enables targeted delivery to the colon, regardless of fasted or fed state<sup>1</sup>

### TARGETED DRUG DELIVERY

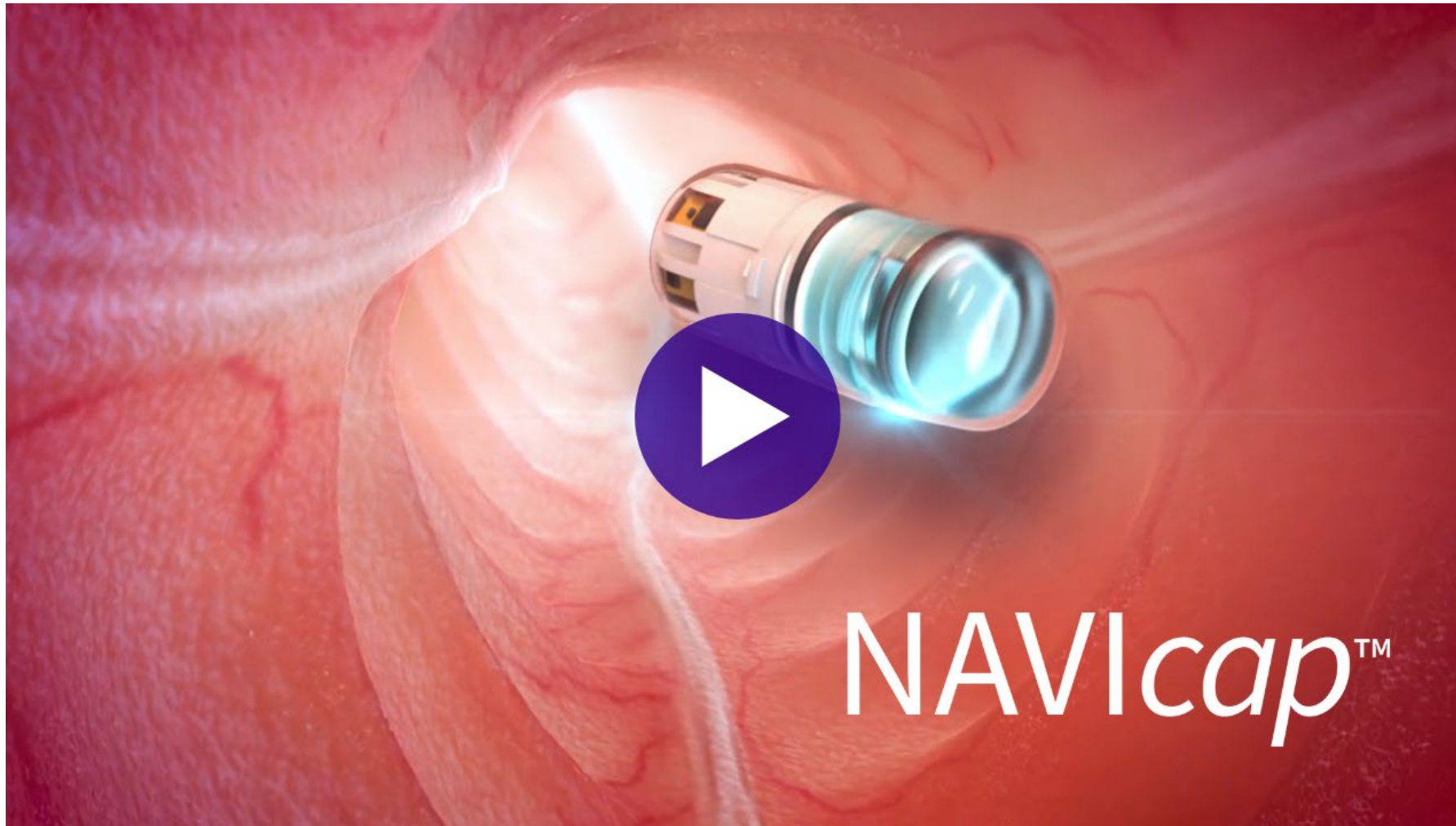
Method designed to coat the length of the colon with liquid formulation, minimizing systemic uptake



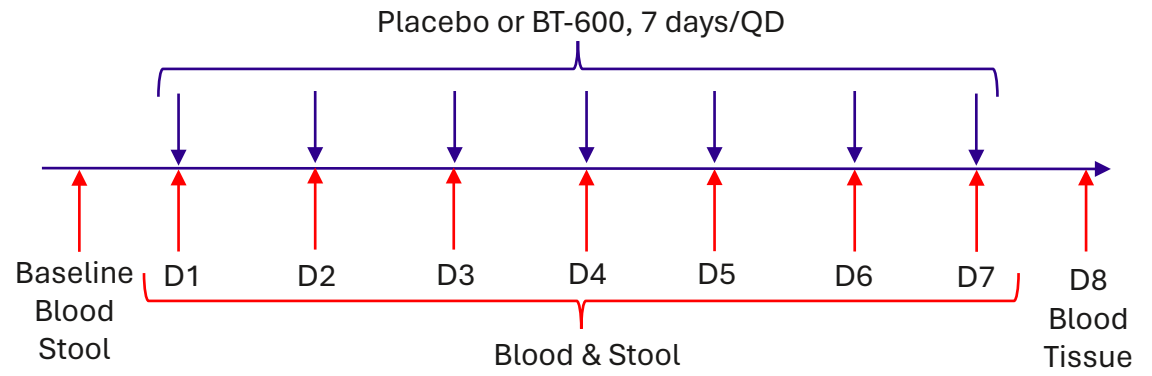
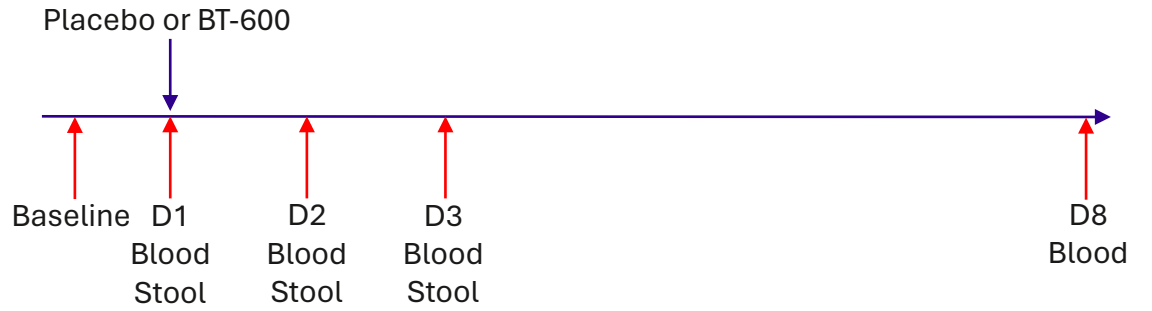
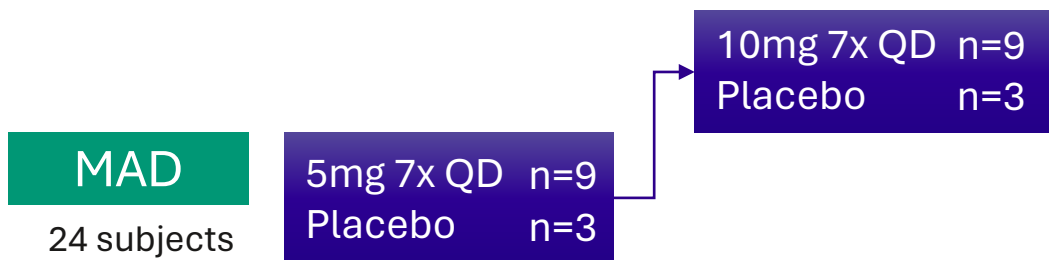
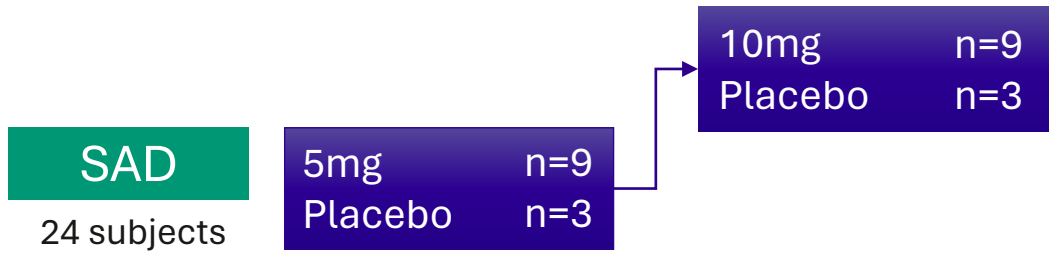
1. Lee SN, Razag G, Stork C, et al. Potential effects of food on a novel Drug Delivery System (DDS) to deliver therapeutic compound into the colon. Poster presented at: Crohn's & Colitis Congress, January 19-21, 2023, Denver, CO.



# *Autonomous location and delivery to the colon*



# Evaluate safety, tolerability, and pharmacokinetics of BT-600 in healthy participants



<b>PATIENT POPULATION</b>	Total of 48 healthy participants (24 SAD and 24 MAD participants)
<b>TRIAL DESIGN</b>	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

## *Successful device performance; all pharmacokinetic endpoints achieved*

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### SAFETY AND TOLERABILITY

#### **No safety signals were observed**

- NaviCap devices were well tolerated by healthy participants in the SAD cohort

### DEVICE FUNCTION

#### **Devices performed as intended**

- All participants receiving BT-600 showed systemic drug absorption, indicating that all NaviCap devices released and delivered drug as intended
- Tofacitinib was present in fecal samples of all subjects, further confirming drug delivery in the colon

### PLASMA PHARMACOKINETICS

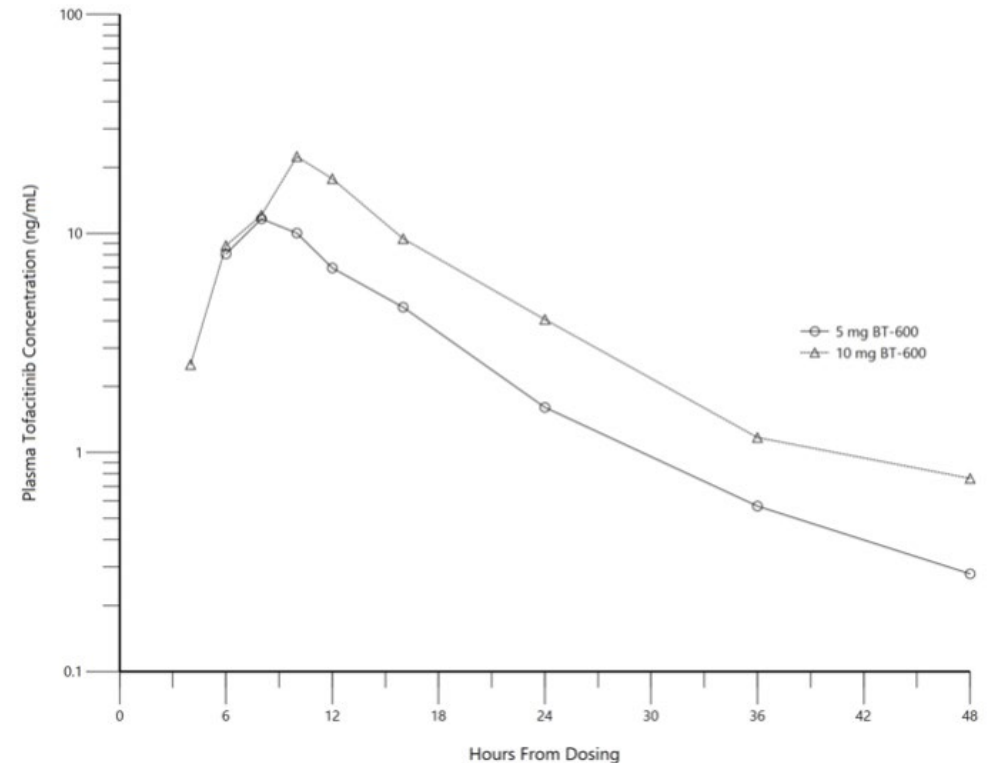
#### **Achieved PK profile suggesting drug delivery in the colon**

- The desired pharmacokinetic profile was achieved, indicating drug delivery and absorption in the colon instead of the upper GI tract
- Dose-proportional pharmacokinetics were observed, with consistently lower plasma drug concentrations with the 5 mg dose than with the 10 mg dose

*Pharmacokinetic profile consistent with anatomically targeted delivery in the colon*

- First evidence of systemic absorption at ~6 hours, consistent with colonic (vs. upper GI) delivery
  - $T_{max}$  8-10 hours (vs. 0.5 hours for conventional oral tofacitinib<sup>1</sup>)
- Colonic delivery associated with 3-4x lower systemic absorption
  - $C_{max}$  mean 26 ng/mL for BT-600 10 mg dose (vs. 88 ng/mL for conventional oral tofacitinib<sup>1</sup>)
- Consistently lower drug concentrations observed with 5 mg vs. 10 mg dose

**MEAN PLASMA TOFACITINIB CONCENTRATION FOLLOWING ADMINISTRATION OF A SINGLE ORAL DOSE OF 5 mg AND 10 mg BT-600**



1. 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

## Four successful studies in humans showing the NaviCap™ device was well tolerated and performed as intended

Q4 2022	Q4 2022	Q1 2023	Q2 2023
<b>PM-601 Device Function Study in Healthy Participants – Fasted State</b>	<b>PM-602 Device Function Study in Patients with Active UC</b>	<b>PM-611 Device Function Study in Healthy Participants – Fasted &amp; Fed</b>	<b>BT-603 Device Function Study in Healthy Participants – Fasted State</b>
<ul style="list-style-type: none"><li>83% of devices accurately identified entry into the colon (10/12)<sup>1</sup></li><li>Achieved distribution of payload across the entire colon<sup>1</sup></li><li>No early deployment before colon detection<sup>1</sup></li></ul>	<ul style="list-style-type: none"><li>100% of devices accurately identified entry into the colon, triggered release of a liquid payload, and achieved distribution across the entire colon (7/7)<sup>3</sup></li></ul>	<ul style="list-style-type: none"><li>100% of analyzed devices successfully identified entry to the colon and activated gas cells for delivery in all fasted/fed schedules (39/39)<sup>2</sup></li><li>97.4% of analyzed devices activated the payload release function (38/39)<sup>2</sup></li></ul>	<ul style="list-style-type: none"><li>94% of devices accurately identified entry into the colon, triggered release of a liquid payload, and achieved distribution across the entire colon (15/16)<sup>4</sup></li></ul>
<b>HEALTHY PARTICIPANTS</b>	<b>ACTIVE UC PATIENTS</b>	<b>FUNCTION WITH/WITHOUT FOOD</b>	<b>PHASE 1-READY DEVICE</b>

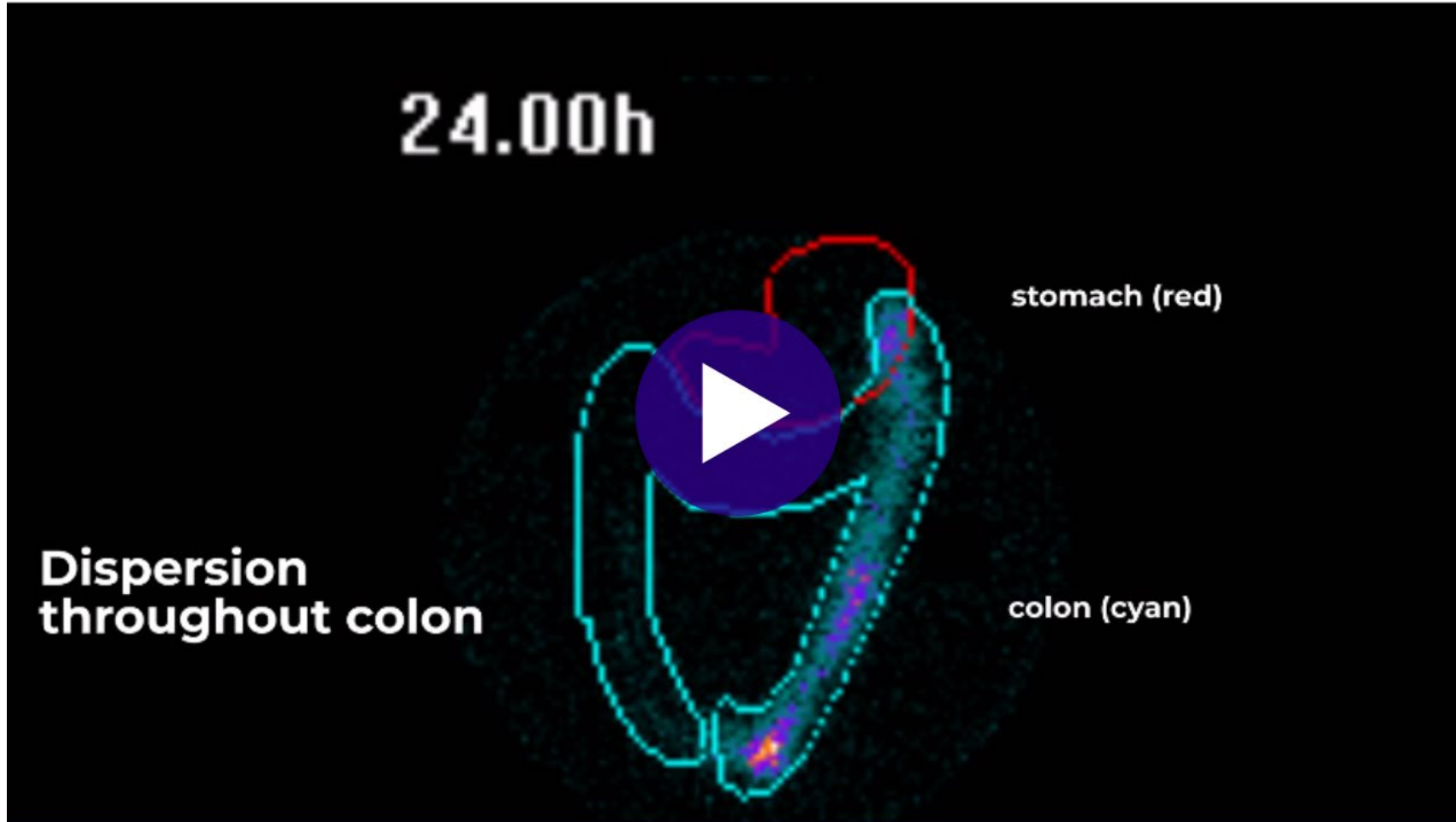
1. Lee SN, Sandefer E, Doll W, et al. A Scintigraphic Study to Evaluate the Safety, Tolerability, and Functionality of a Drug Delivery System (DDS) Device in Healthy Volunteers in Fasted State. Poster presented at: *American College of Gastroenterology Annual Scientific Meeting*, October 21-26, 2022, Charlotte, NC.

2. 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.

3. Martin K, Lee SN, Stork C, et al. 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: *American College of Gastroenterology Annual Scientific Meeting*, October 21-26, 2022, Charlotte, NC.

4. Biora Therapeutics internal data

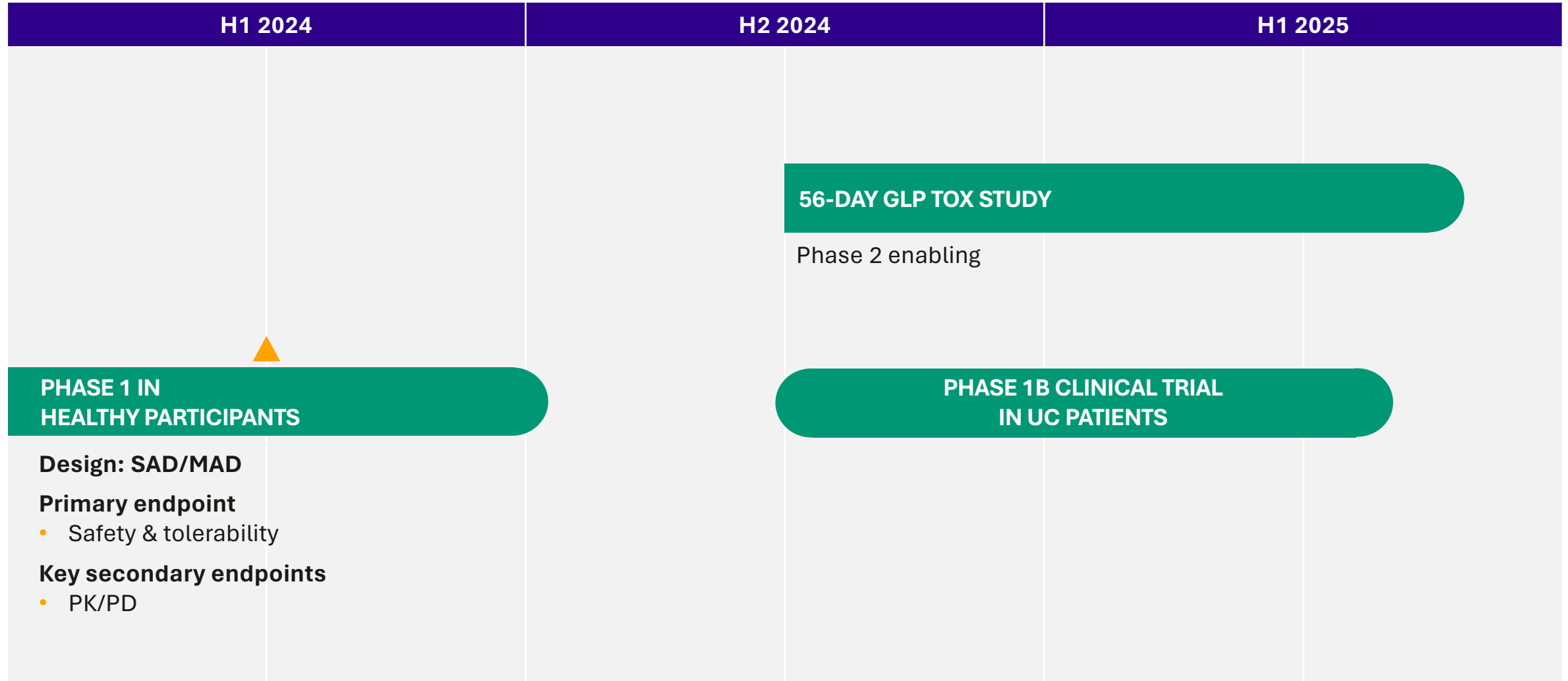
# *Scintigraphic imaging of NaviCap delivery in healthy participant*



Despite variability in the GI environment among participants, the NaviCap device has been observed to perform as designed across a range of expected differences in motility.



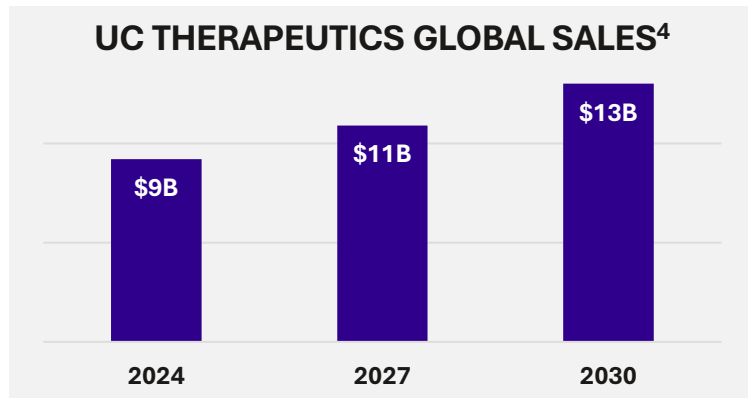
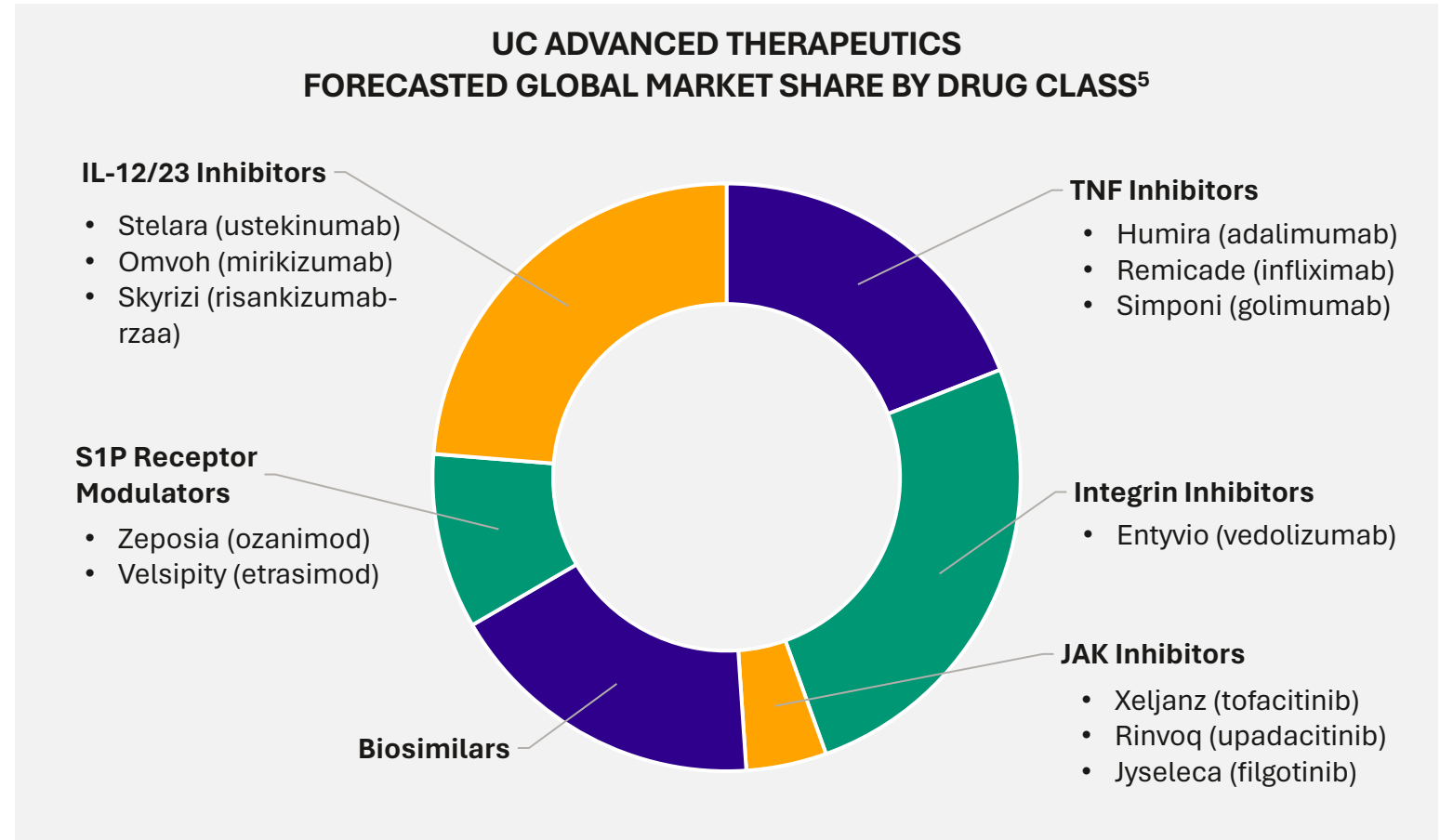
# Clinical Development Plan



▲ = INTERIM DATA

## *NaviCap could optimize delivery of IBD therapies, enabling drugs to act at site of disease and improve outcomes*

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



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



BIOjet™

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<sup>1,2</sup>

42%

of patients fail to maintain diabetes treatment due to injection concerns when using an injectable GLP-1 agonist<sup>2</sup>

71%

higher discontinuation rate for diabetes patients initiating treatment with an injectable GLP-1 agonist vs. those starting oral therapy<sup>2</sup>

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



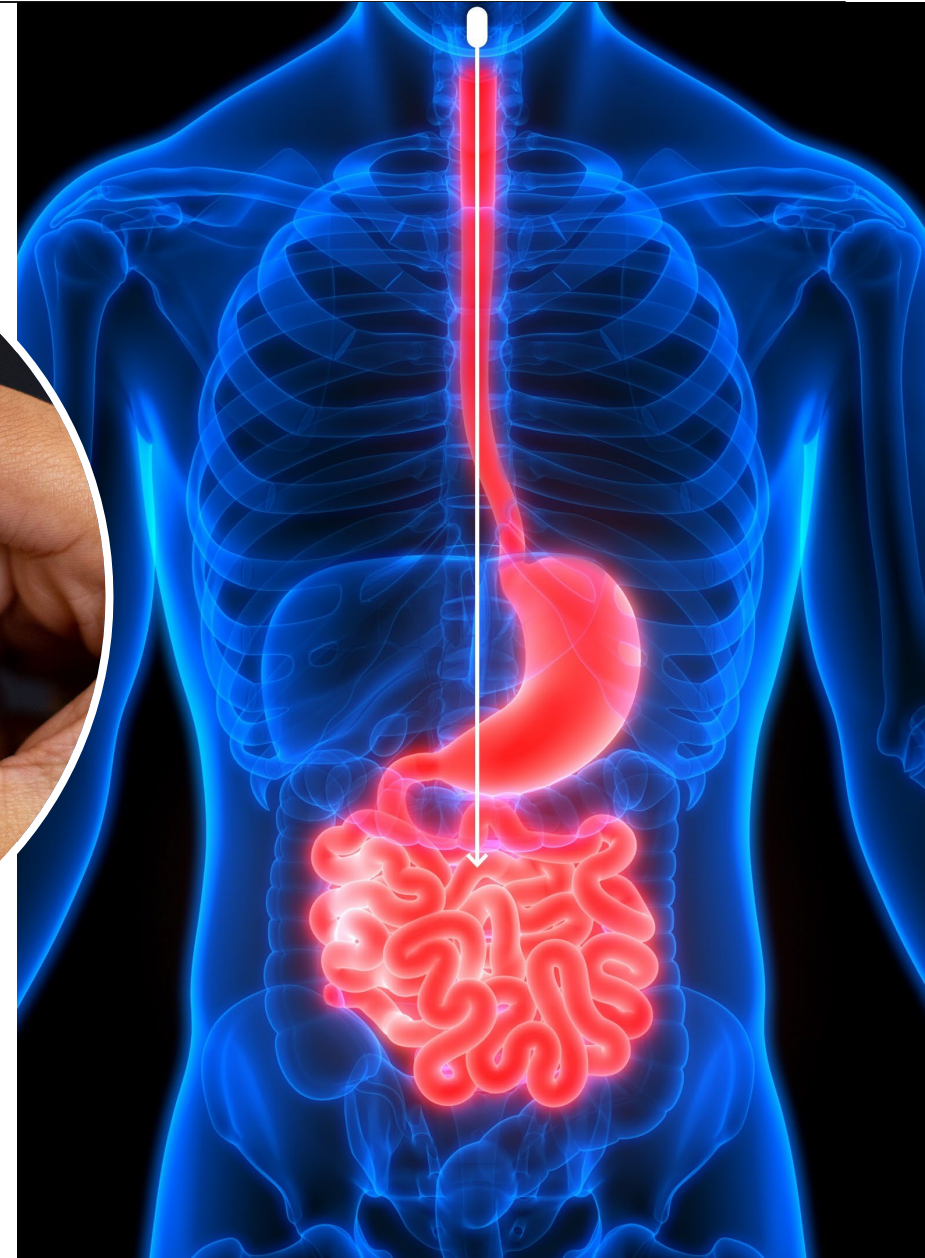
*Needle-free, oral delivery to small intestine*

**PRECISE DELIVERY**

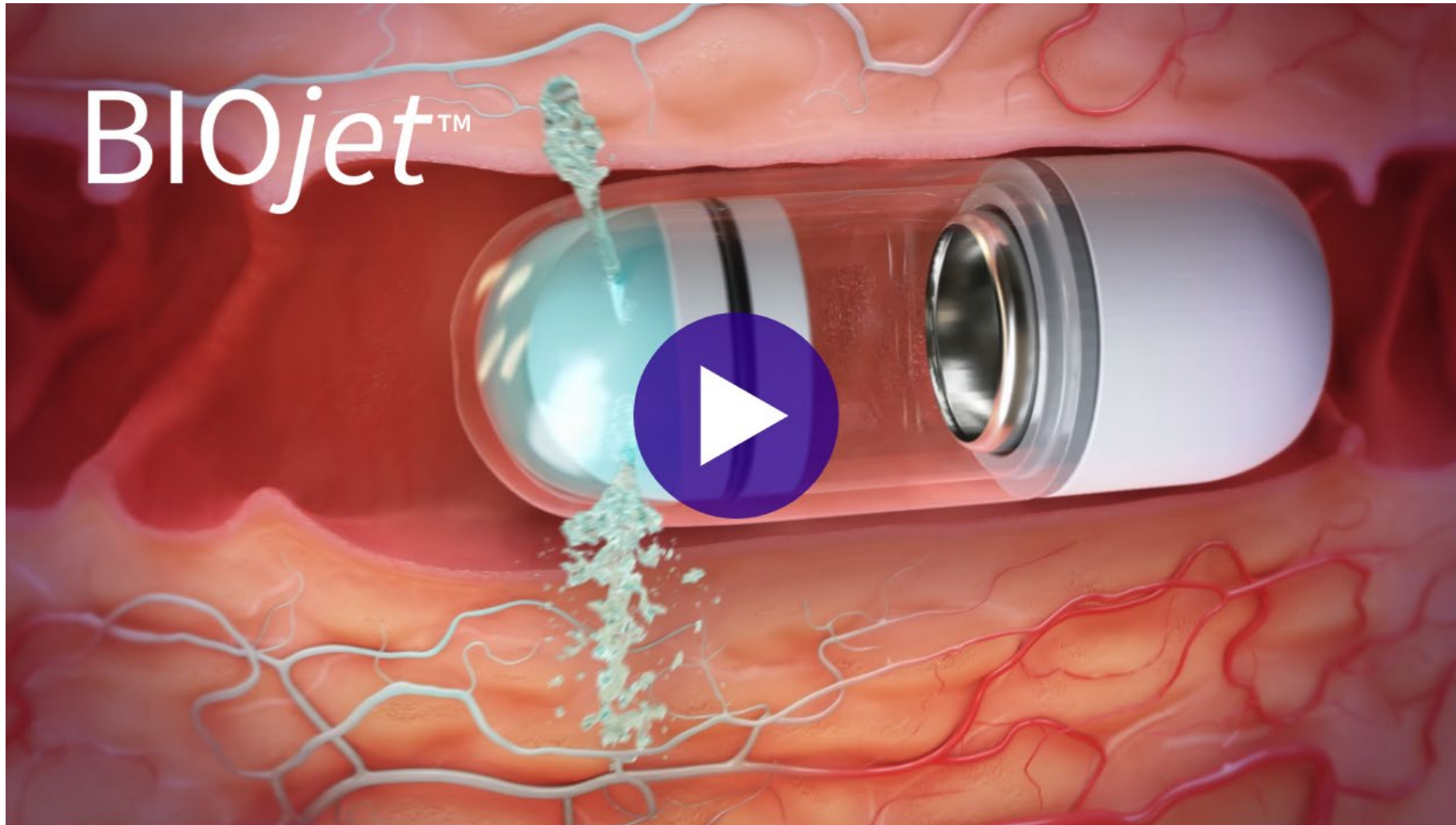
- Enteric trigger for precise timing of drug delivery to the small intestine
- Potential to enable liver-targeted delivery

**UNIQUE SOLUTION**

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



# Liquid jet delivery to the small intestine

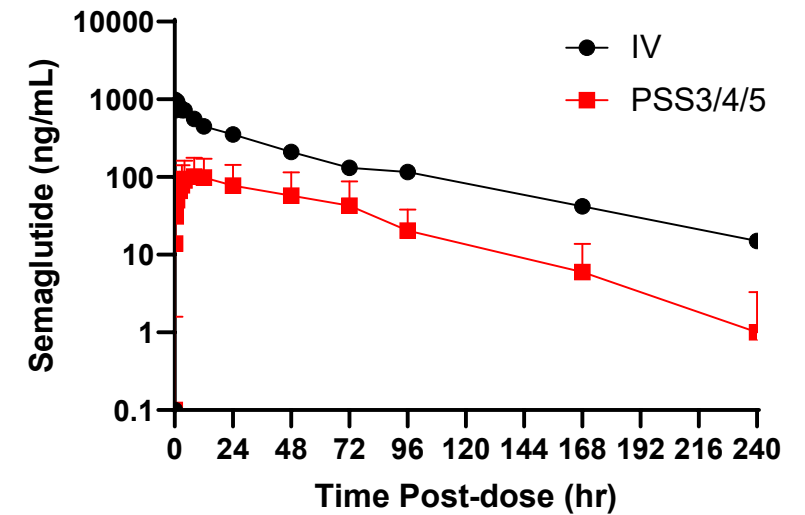


# Demonstrated bioavailability across multiple molecules

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

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

**SYSTEMIC EXPOSURE TO SEMAGLUTIDE FOLLOWING AUTONOMOUS TRIGGERING OF BIOJET DEVICE vs. IV CONTROLS**



## RESEARCH COLLABORATIONS



multiple undisclosed pharma collaborators

1. Biora Therapeutics data on file

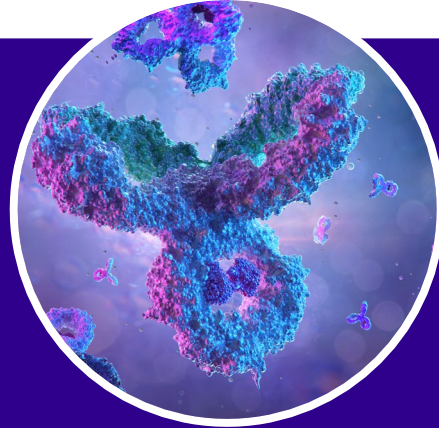
# Needle-free, liquid jet delivery of biomolecules

**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**

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



# NAVicap™

TARGETED ORAL DELIVERY

- Clinical trial completed
- Anticipating final SAD/MAD data in Q2



# BIOjet™

SYSTEMIC ORAL DELIVERY

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



# APPENDIX



## *Diverse patent portfolio with 73 distinct patent families*

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

### **NaviCap™ Platform**

#### ***30 patent families covering:***

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- 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:***

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- 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:***

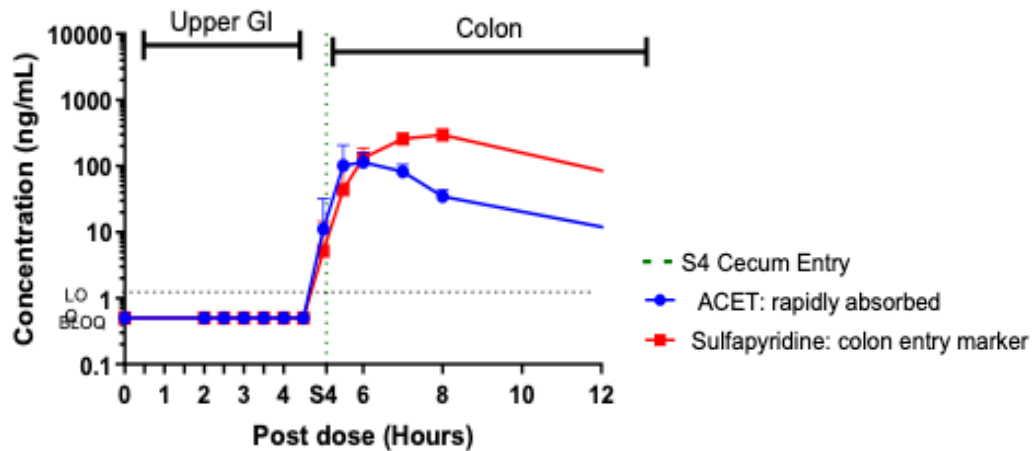
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- Ingestible devices for GI sampling and diagnostics
- GI sample preservation
- GI analyte detection & quantification
- Diagnostic biomarkers & assays

# Demonstrated accurate localization and delivery to colon

## ACCURATE DELIVERY TO COLON IN CANINES

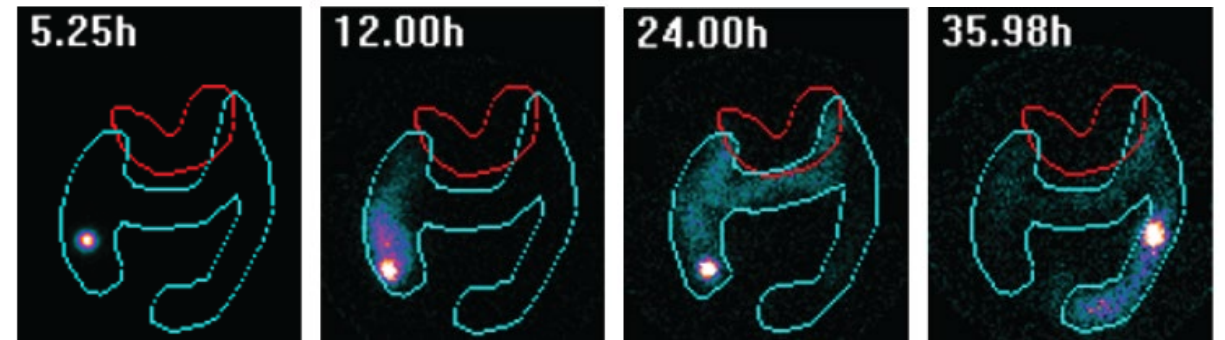
Pharmacokinetic data from two marker drugs administered in canine model



- Successful delivery to colon via device
- No early release of drug
- No drug absorption in upper GI tract

## ACCURATE LOCALIZATION AND DELIVERY TO HUMAN COLON

Clinical device validation for localization and delivery function using scintigraphic imaging in patients with active ulcerative colitis



- Achieved distribution across the entire colon

## *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-TNF $\alpha$  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 presented 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.

## *BioJet™ systemic oral delivery platform*

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- 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.



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