



BIORA[™]
Therapeutics



**CORPORATE
PRESENTATION**

May 2022

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 preclinical and clinical trials, the anticipated timing for preclinical 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 difficulties in managing changes to our organization due to our strategic transformation; competition from third parties with respect to our product candidates; 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, 2021, 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.

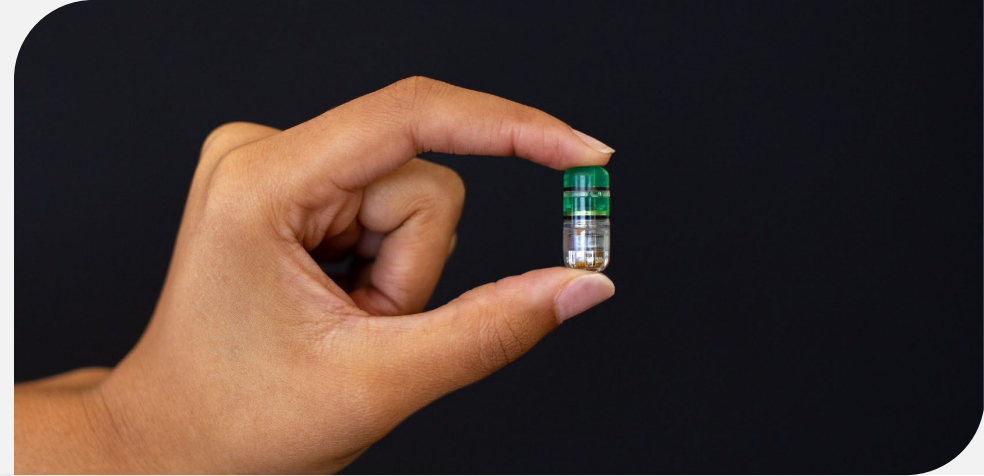
ABOUT BIORA THERAPEUTICS

Our mission is to reimagine therapeutics and their delivery

Innovating smart capsule technologies to deliver the right dose to the right place, safely

TARGETED ORAL DELIVERY OF BIOTHERAPEUTICS

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



SYSTEMIC ORAL DELIVERY OF BIOTHERAPEUTICS

Ingestible technology designed to enable needle-free, systemic delivery of large molecules for improved management of chronic diseases

PIPELINE

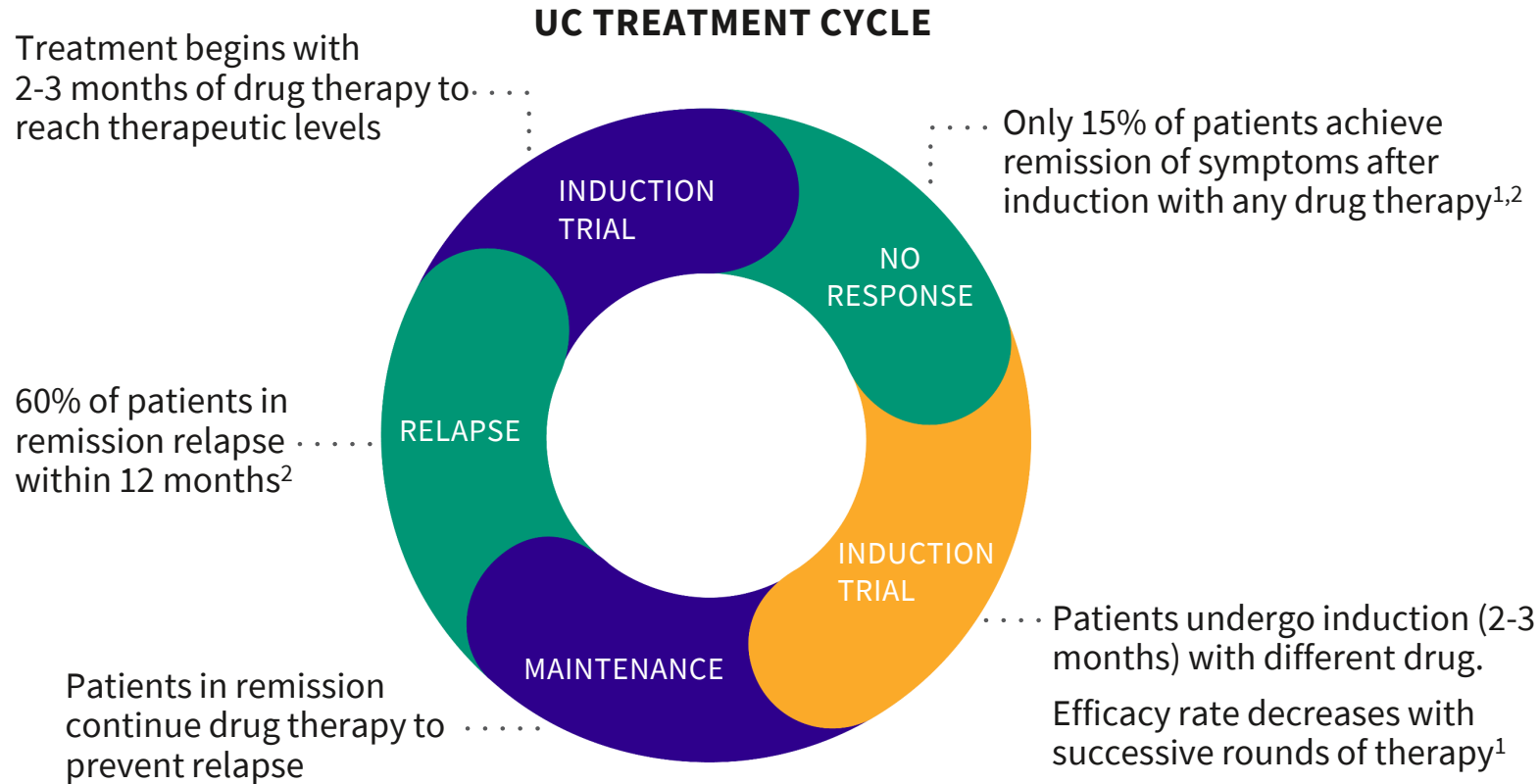
PROGRAM		INDICATION	DESIGN/FEASIBILITY	PRECLINICAL	CLINICAL
TARGETED THERAPEUTICS	DDS Device	IBD			
	PGN-600 Tofacitinib + Device	UC			
	PGN-001 Adalimumab + Device	UC			
SYSTEMIC THERAPEUTICS	OBDS Device	--			
	PGN-OB1 Adalimumab variant + Device	Autoimmune			
	PGN-OB2 GLP-1 agonist + Device	Diabetes			
	Ionis Collaboration Antisense therapy + Device	Undisclosed			
	Large Pharma 1 Collaboration Undisclosed drug + Device	Undisclosed			
	Large Pharma 2 Collaboration Undisclosed drug + Device	Undisclosed			
FUTURE	RSS Device	Precision GI sampling			



TARGETED THERAPEUTICS

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 year³

UC MARKET OPPORTUNITY

- Clinical landscape: >10 approved drugs for UC
- Market size: \$7+ billion

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.

4. Market size for 2020. <https://www.thebrainyinsights.com/report/ulcerative-colitis-drug-market-12521>

CURRENT THERAPEUTIC CHALLENGES FOR UC

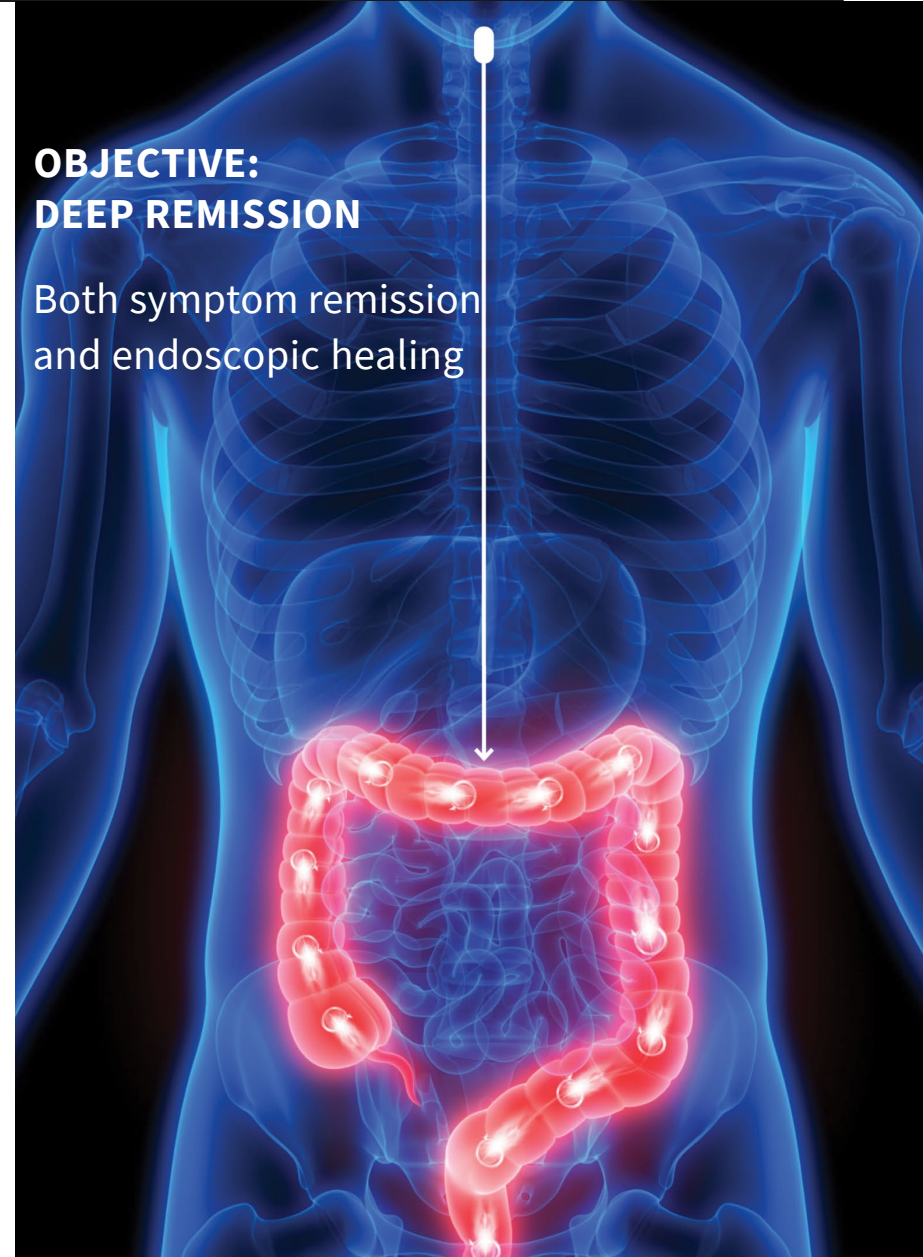
- 1 Only 1 in 4 UC patients achieve short-term response¹
- 2 Difficulty of achieving sufficient drug levels at site of disease
- 3 Systemic toxicity issues may limit daily dosage of UC drugs
- 4 Combination therapy is limited by toxicity

TARGETED THERAPEUTIC DELIVERY: POTENTIAL SOLUTIONS

- Targeted delivery could enable rapid induction and improve patient response
- Increased drug levels in tissue correlate with improved outcomes²
- Reduced systemic uptake is designed to reduce toxicity and adverse events
- Reduced systemic uptake could enable combination therapy³

OBJECTIVE: DEEP REMISSION

Both symptom remission and endoscopic healing



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

2. Verstockt B, Alsoud D, van Oostrom J, et al. Tofacitinib tissue exposure correlates with endoscopic outcome. Oral presentation at the 34th edition of the Belgian Week of Gastroenterology, February 9, 2022.

3. Van Oostrom J, Hanzel J, Verstockt B, et al. Pharmacokinetic stratification of cytokine profiles during anti-TNF induction treatment in moderate-to-severe ulcerative colitis. Poster presented at the 17th Congress of the European Crohn's and Colitis Organisation (ECCO); February 18, 2022.

Tissue drug concentration correlates with endoscopic outcomes in UC

30 consecutive UC patients with active endoscopic disease (Mayo endoscopic subscore 2-3) initiated treatment with tofacitinib and prospectively monitored

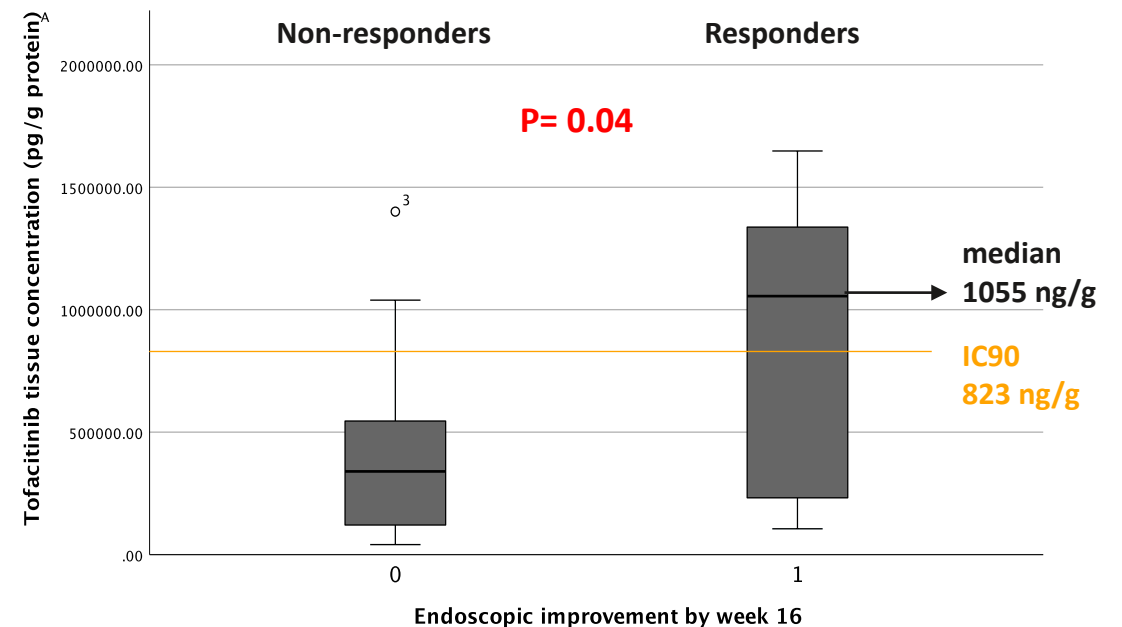
RESULTS

- Tofacitinib tissue exposure at the end of induction was associated with endoscopic improvement by week 16 (p=0.04).
- In responders (n=14), tofacitinib tissue exposure exceeded the IC90 (median tissue exposure 1,055ng/g; IC90 823ng/g).

Research presented at ECCO 2022 and DDW 2022 in collaboration with:



TOFACITINIB TISSUE EXPOSURE EXCEEDED IC90 (823ng/g) IN RESPONDERS



Targeted delivery to the GI tract designed to improve efficacy and safety

ADVANTAGES OF OUR APPROACH

- Targeted delivery designed to improve endoscopic outcomes by increasing drug levels at the site of disease
- Payload delivery method designed to minimize systemic uptake, potentially reducing adverse effects
- Reduced systemic toxicity could finally enable combination therapy



ORAL ADMINISTRATION

- Oral capsule approximately the size of a fish oil capsule for patient convenience

FLEXIBLE FORMULATION

- Delivers a payload of ~500µl liquid or solid formulation to the desired location

ACCURATE DELIVERY

- Proprietary autolocation in the GI tract for accurate drug delivery

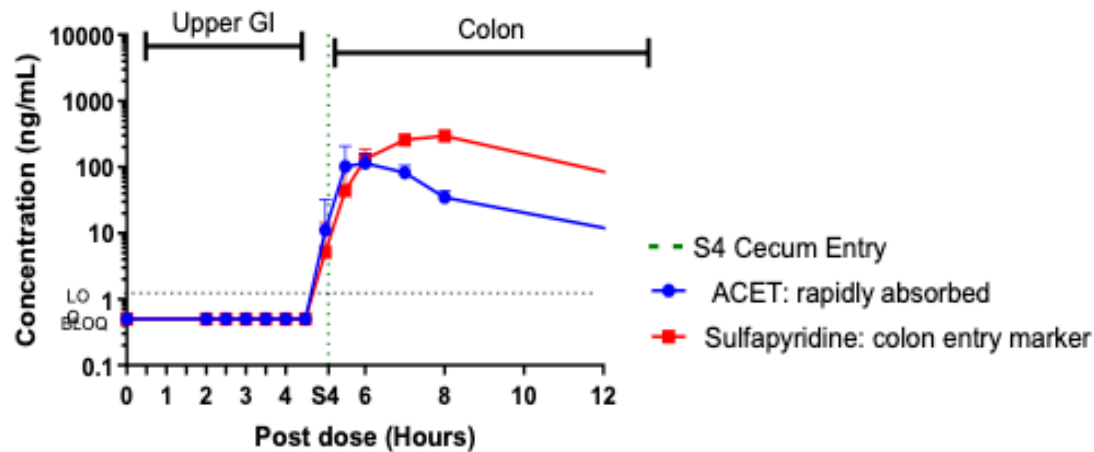
Research in
partnership with:



Demonstrated accurate localization and delivery to colon

ACCURATE DELIVERY TO COLON IN CANINES

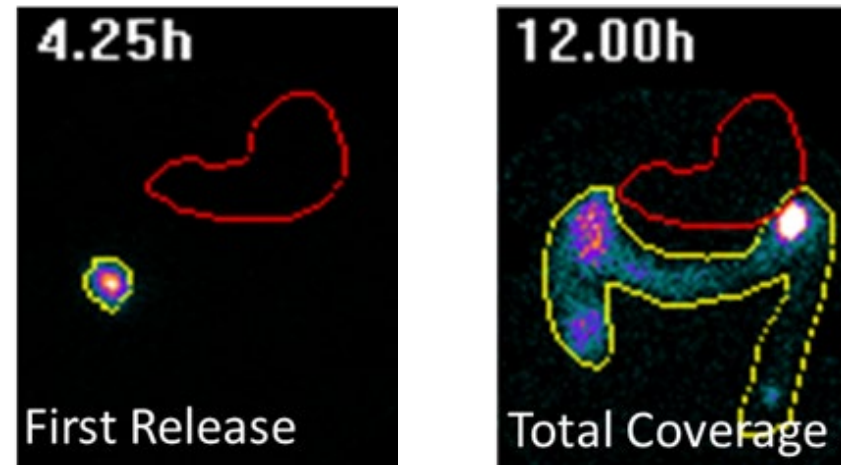
Pharmacokinetic data from two marker drugs administered in canine model



- Successful delivery to colon via DDS
- 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 normal, healthy volunteers



- Safety and tolerability in normal healthy volunteers; devices recovered intact
- 83% accuracy of localization function (10/12)
- No early release before colon detection

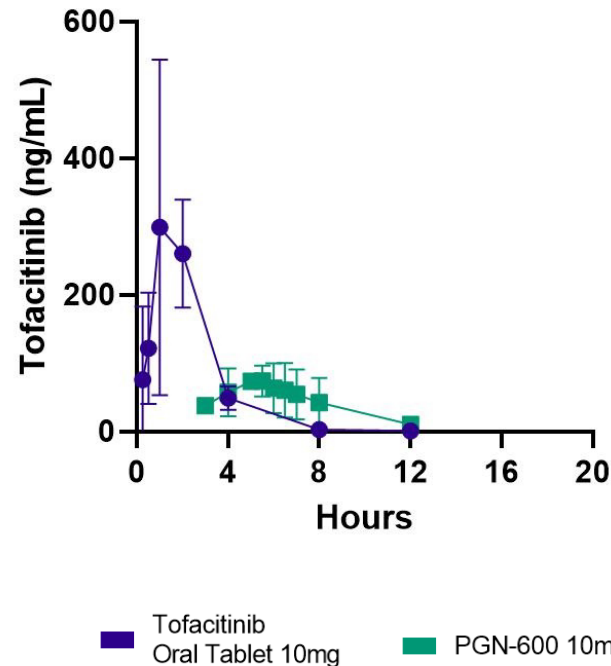
Reduced systemic uptake, better PK effect and coverage

PGN-600 (tofacitinib liquid formulation delivered via DDS capsule) vs. standard oral tablet in canine model

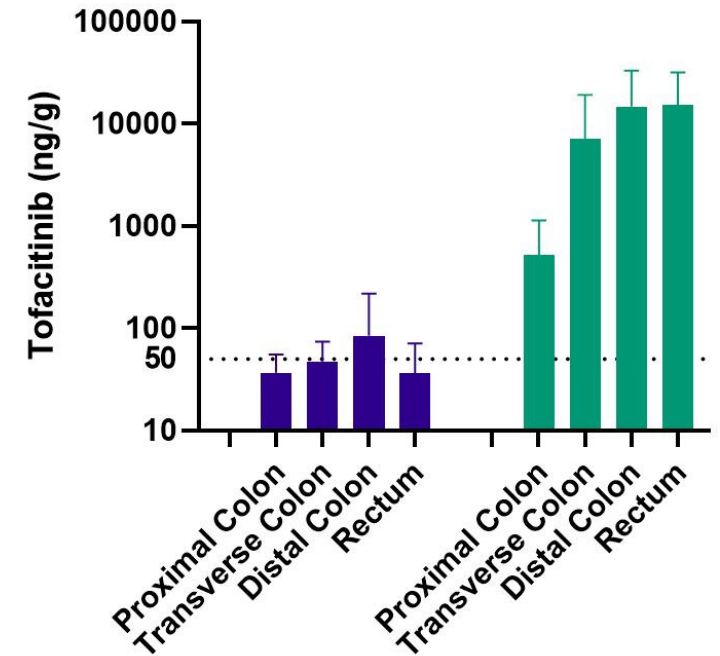
RESULTS

- Reduced drug levels in blood vs. standard oral tablet
- Tissue drug levels at average ~100X higher along the length of the colon vs. standard oral tablet

PLASMA LEVEL CMAX 5X LOWER



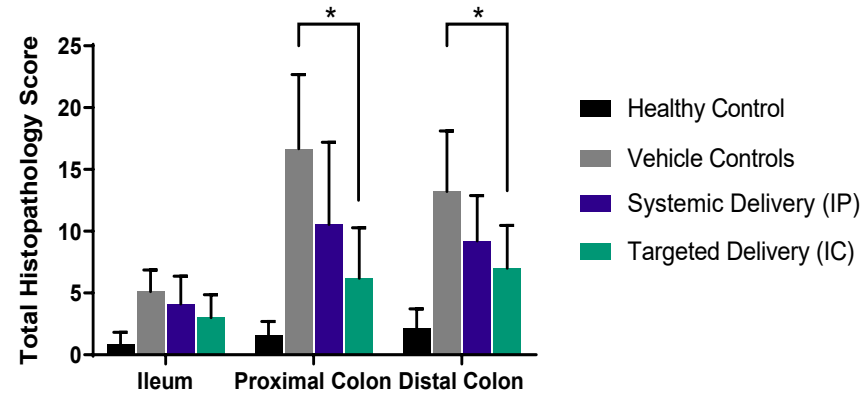
COLON TISSUE COVERAGE ~100X HIGHER



Targeted delivery of anti-TNF α has superior pharmacodynamics vs. systemic delivery

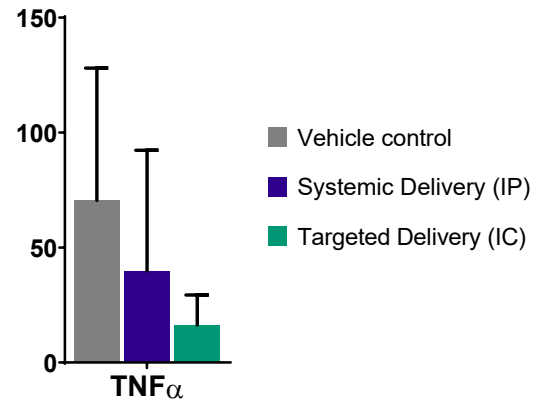
Systemic delivery via intraperitoneal injection (IP) vs. targeted intracecal delivery (IC) of anti-TNF α in mouse model of T-cell transfer colitis

IMPROVED HISTOPATHOLOGY SCORE

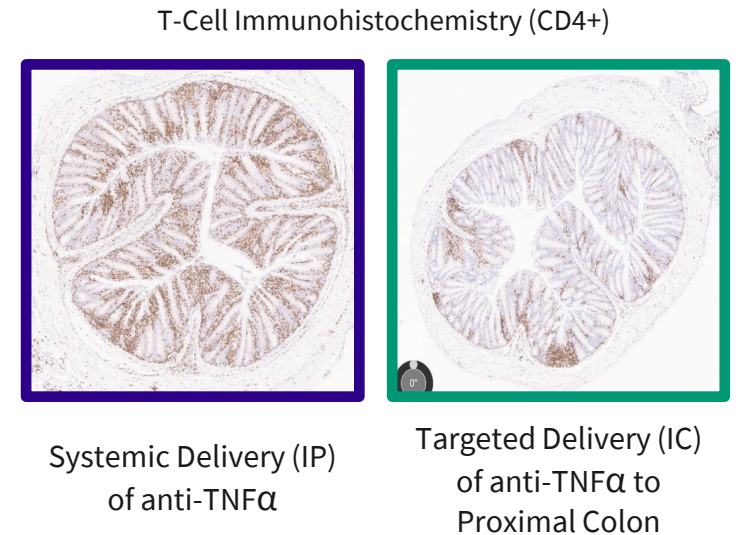


*Pair-wise comparisons by two-tailed Mann-Whitney U-Test; $p < 0.05$

REDUCED INFLAMMATORY CYTOKINES



REDUCED T-CELL COUNTS



DEVICE FUNCTION STUDIES		TOX STUDIES		PHASE 1 CLINICAL	PHASE 2A CLINICAL
PM-601 Device Function Study in Normal Healthy Volunteers <ul style="list-style-type: none"> 12 subjects Single administration Scintigraphic confirmation of colon entry and payload release 	PM-602 Device Function Study in Patients with Active Ulcerative Colitis <ul style="list-style-type: none"> Up to 12 subjects Single administration 	Previous Tox Study (2021) 7 days/QD in canines	Tox GLP Up to 30 animals in three groups: <ul style="list-style-type: none"> Oral pill Device only (10mg) Device + drug (25mg) 8 weeks/QD	Phase 1 SAD/MAD Study to Evaluate Safety, Tolerability, and PK/PD in Normal Healthy Volunteers <ul style="list-style-type: none"> 48 total subjects (24 SAD / 24 MAD) 8 days 	Safety and Efficacy in Subjects with Moderate to Severe Ulcerative Colitis Who Have Been Previously Exposed to TNF Antagonist
RESULTS Device was well tolerated Achieved pan-colon distribution of payload Accurately identified entry into the colon (10/12); no early deployment	OBJECTIVES Scintigraphy confirmation of device location, payload release, and colon coverage	RESULTS No safety signals were observed	OBJECTIVES Confirmation of device location, drug release, and colon coverage	OBJECTIVES Safety & tolerability of PGN-600 by assessing treatment-related AEs, ECGs, vital signs, and clinical laboratory values	OBJECTIVES Demonstrate safety & tolerability, PK/PD of PGN-600 in UC patients Estimate % of patients with clinical remission after 8 weeks treatment with PGN-600
CONCLUDED	RECRUITING	CONCLUDED	Q3 2022	Expect to initiate Q4 2022	Expect to initiate 2023



SYSTEMIC THERAPEUTICS

UNMET NEED

Needles are associated with poor disease management

38%

of diabetics miss 4+ injections per week.¹

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 therapy²

1. Frost & Sullivan research commissioned by Rani Therapeutics Holdings, Inc. <https://ir.ranitherapeutics.com/static-files/b1f080bf-a860-4136-87cb-d6f7c49c1502>

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 designed for optimal systemic uptake

ADVANTAGES OF SYSTEMIC ORAL BIOTHERAPEUTICS

- Needle-free, liquid jet administration to intestinal tissue for enhanced systemic uptake
- More frequent administration vs. injection may improve outcomes
- Versatile platform can deliver a range of large molecules, including:
 - Monoclonal antibodies
 - Peptides
 - Nucleic acids



LIQUID FORMULATION

- Delivers a payload of ~400µl liquid drug with little to no reformulation

PRECISE DELIVERY

- Enteric trigger for precise timing of drug delivery to the small intestine

NEEDLE-FREE ADMINISTRATION

- Capsule about the size of a multivitamin for pain-free oral administration

RESEARCH COLLABORATIONS

- Large Pharma 1
- Large Pharma 2



Precise and reliable release of payload in small intestine demonstrated in animal models

Capsule loaded with a radio-opaque marker (iohexol).
Sequential imaging as the capsule transits through
the GI tract in canines.

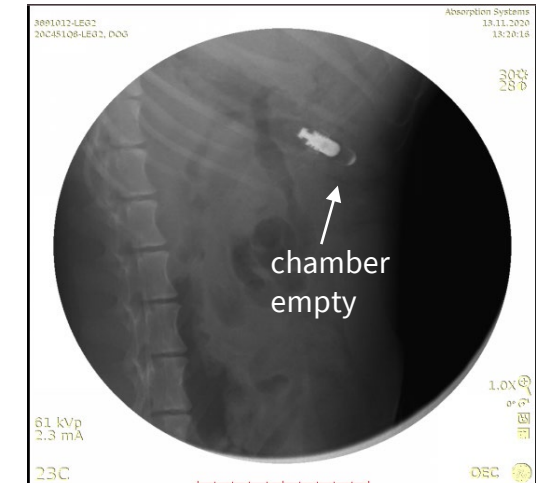
ACCURATE DELIVERY IN SMALL INTESTINE

RESULTS

- Reliable triggering and iohexal release
- Ability to optimize timing of trigger release
- No safety issues observed



Immediately after dosing
in the stomach



After deployment in
the small intestine

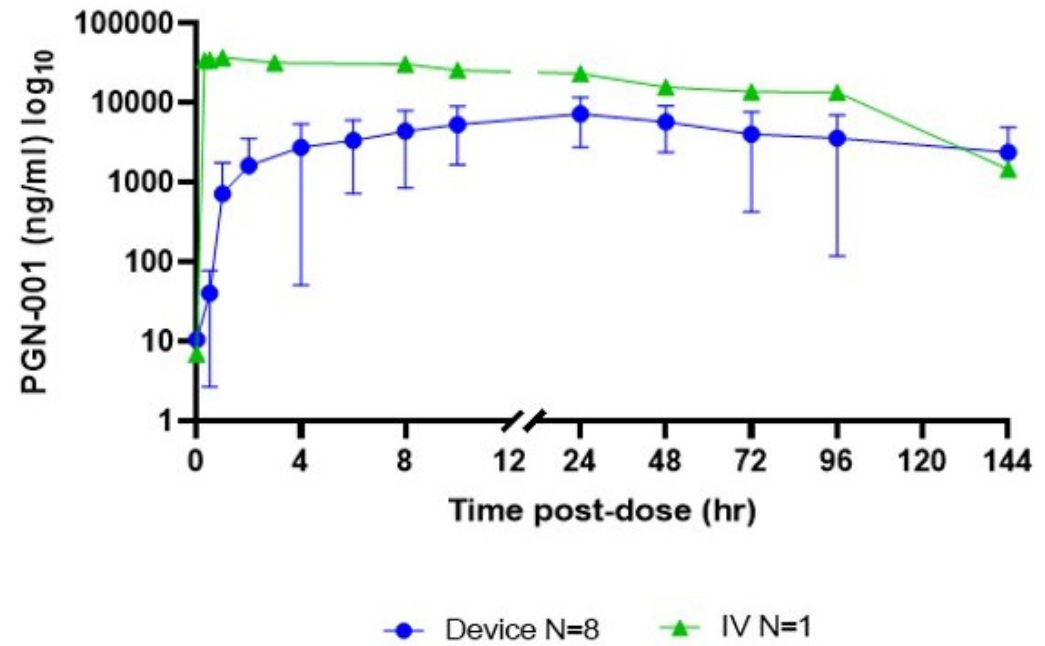
Excellent systemic uptake for orally delivered large molecules demonstrated in animal models

Multiple studies in swine model with endoscopically placed, autonomous device compared to IV administration

RESULTS

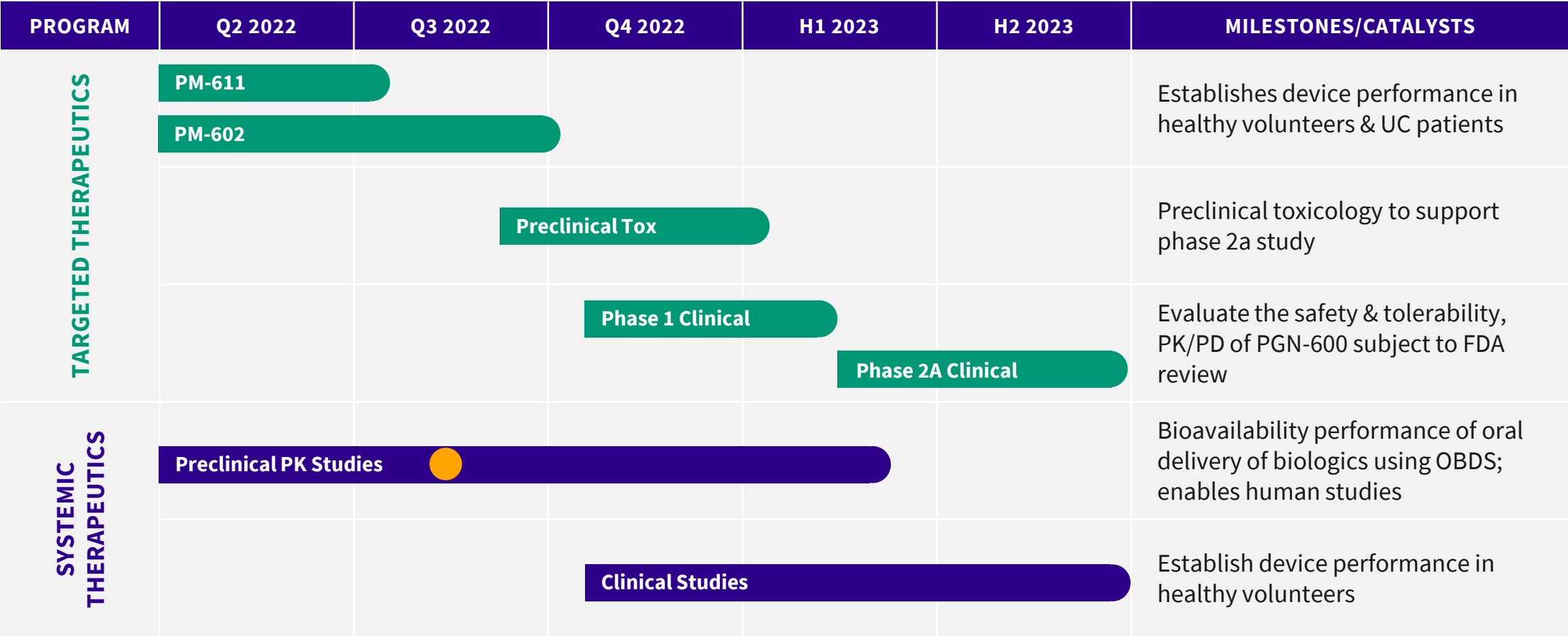
- Based on multiple studies, an average of ~22% bioavailability was observed in animals where the drug was detected in blood¹
- Achieved up to 67% bioavailability for a variant of adalimumab¹
 - *For comparison, commercially available oral large molecules achieve 1% or less bioavailability*
- No issues with safety or tolerability of the device

BIOAVAILABILITY COMPARABLE TO IV



1. Biora Therapeutics internal data

DEVELOPMENT TIMELINE



 DATA READOUT

APPENDIX

- **Development of targeted therapeutic antibodies for the treatment of inflammatory bowel disease: A proof of concept.** Presented at DDW 2019.
- **A comparison of systemic versus targeted anti-TNF α antibody in treatment of colitis induced by adoptive transfer of CD44-/CD62L+ T-cells into RAG2-/- mice recipients.** Presented at DDW 2019.
- **Development of a novel drug delivery system for treatment of Ulcerative Colitis.** Presented at DDW 2021.
- **Targeted delivery of soluble tofacitinib citrate to the site of inflammation to improve efficacy and safety.** Presented at DDW 2021.
- **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.
- **Tofacitinib tissue exposure correlates with endoscopic outcome.** Presented at ECCO 2022 and DDW 2022.
- **Pharmacokinetic stratification of cytokine profiles during anti-TNF induction treatment in moderate-to-severe UC.** Presented at ECCO 2022 and DDW 2022.

Diverse patent portfolio with 82 distinct patent families¹

DEVICES

37 patent families covering

- GI localization
- Targeted delivery to GI tract
- Jet delivery into GI tissue
- Device designs, materials, components & manufacturing
- GI sampling mechanisms

THERAPEUTICS

28 patent families covering

- Treatment via ingestible device
- GI delivery PK/PD profiles
- GI delivery dosing regimens
- GI delivery drug combinations
- Liquid drug formulations

SAMPLING & DIAGNOSTICS

17 patent families covering

- GI sample preservation
- GI analyte detection & quantification
- Complimentary diagnostic markers
- Protein and nucleic acid markers & assays

1. Approximately 170 issued patents and 170 pending applications in major jurisdictions around the world



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