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 facts 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 clinical trials, the anticipated timing for 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 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.

WHAT WE DO

Developing innovative oral biotherapeutics for gastrointestinal health and beyond

TARGETED THERAPEUTICS

Targeted delivery of therapeutics to the site of disease in the gastrointestinal tract could improve outcomes for patients with IBD.

DDS
Targeted Drug Delivery System

PGN-600	PGN-001
Tofacitinib + DDS	Adalimumab variant + DDS

SYSTEMIC THERAPEUTICS

Capsule technology designed for systemic delivery of biotherapeutics, replacing injection with needle-free, oral delivery technology.

OBDS
Systemic Oral Biotherapeutics Delivery System

PGN-OB1	PGN-OB2
Adalimumab variant + OBDS	GLP-1 agonist + OBDS

Ionis Pharma	Large Pharma 1	Large Pharma 2
Antisense therapy + OBDS	Undisclosed drug + OBDS	Undisclosed drug + OBDS

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THERAPEUTICS PIPELINE

PROGRAM		INDICATION	DESIGN/FEASIBILITY	PRECLINICAL	CLINICAL
TARGETED THERAPEUTICS	DDS	IBD	Targeted Therapeutics Device		
	PGN-600	Ulcerative Colitis	Tofacitinib + Device		
	PGN-001	Ulcerative Colitis	Adalimumab variant + Device		
SYSTEMIC THERAPEUTICS	OBDS	–	Systemic Therapeutics Device		
	PGN-OB1	Autoimmune	Adalimumab variant + Device		
	PGN-OB2	Diabetes	GLP-1 agonist + Device		
	–	Undisclosed	Antisense Therapy + Device	in partnership with IONIS	
	–	Undisclosed	Undisclosed Drug + Device	in partnership with LARGE PHARMA 1	
	–	Undisclosed	Undisclosed Drug + Device	in partnership with LARGE PHARMA 2	

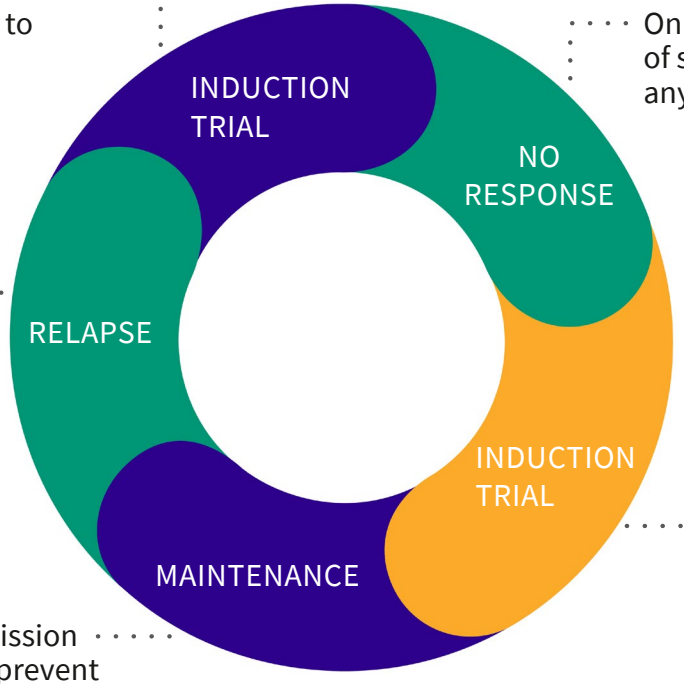
TARGETED THERAPEUTICS

ULCERATIVE COLITIS: THE TREATMENT GAP

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

UC TREATMENT CYCLE

Treatment begins with induction: 2-3 months of drug therapy to reach therapeutic levels



Only 15% of patients achieve remission of symptoms following induction with any drug therapy[1,2]

60% of patients who achieve short-term remission relapse within 12 months[2]

Patient undergoes induction (2-3 months) with a different drug.

Efficacy rate decreases with successive rounds of therapy[1]

Patients who achieve remission continue drug therapy to prevent relapse

TREATMENT OBJECTIVE

- The goal is deep remission: a combination of symptom remission and endoscopic healing

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[3]

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.

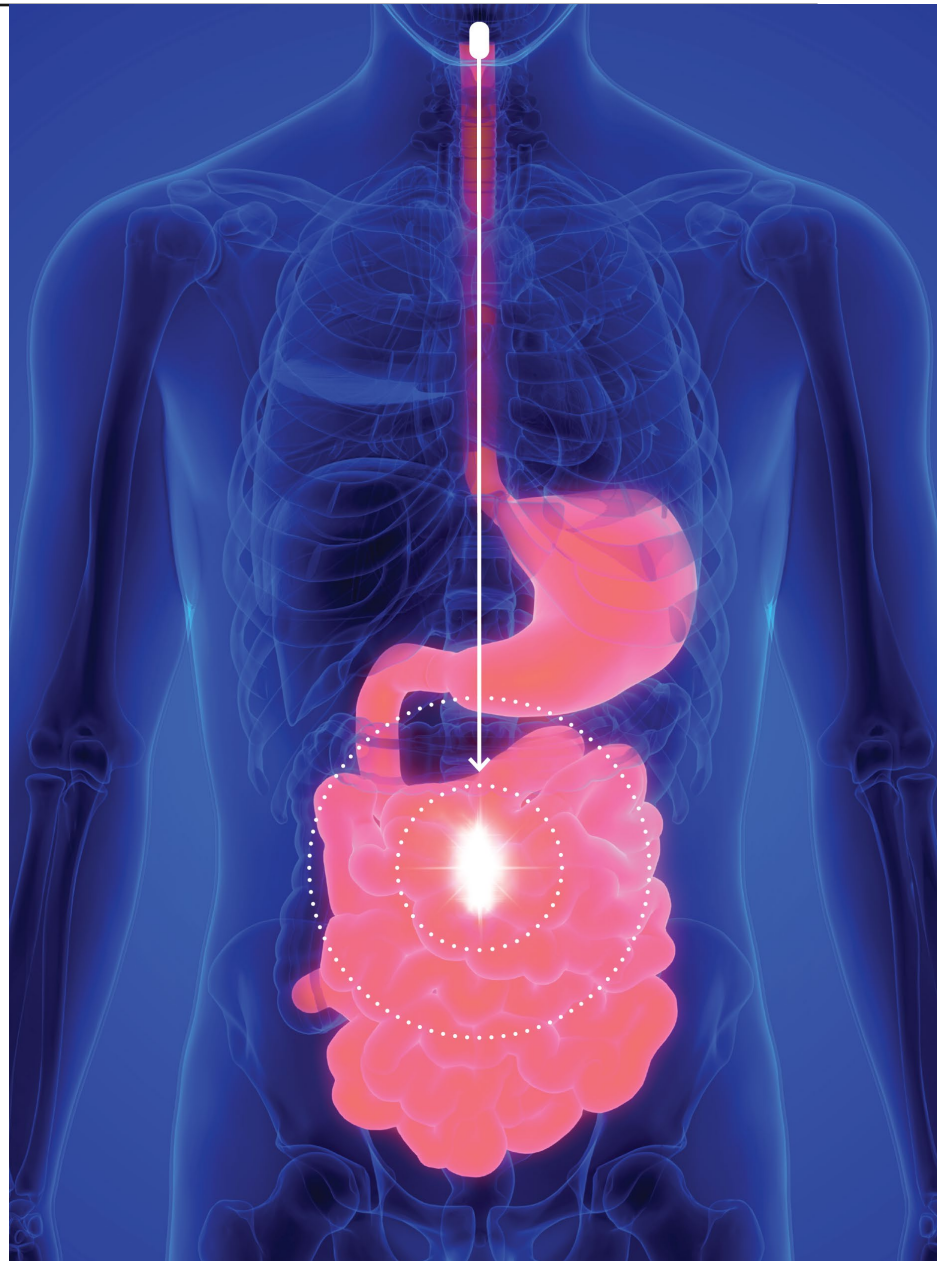
TARGETED THERAPEUTICS: A POTENTIAL SOLUTION FOR UNMET NEED IN UC

CURRENT THERAPEUTIC CHALLENGES FOR UC

1. UC drugs have systemic toxicity issues that may limit daily dosage
2. Achieving sufficient drug levels at the site of disease is difficult with systemic delivery.
3. Only 1 in 4 UC patient achieves short-term response[2]
4. UC has multiple pathways,[3] but current protocols target single pathways due to toxicity concerns

TARGETED THERAPEUTIC DELIVERY: POTENTIAL SOLUTIONS

- Reduced systemic uptake should reduce toxicity and adverse events
- Increased drug levels in tissue are correlated with improved endoscopic outcomes[1]
- Targeted delivery could enable rapid induction, which should improve patient response
- Targeted delivery could enable combination therapy to target multiple inflammatory pathways simultaneously[3]



1. 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.
2. 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
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.

OUR IBD SOLUTION: TARGETED THERAPEUTICS

Targeted drug 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

watch activation video

Research in partnership with: CROHN'S & COLITIS FOUNDATION

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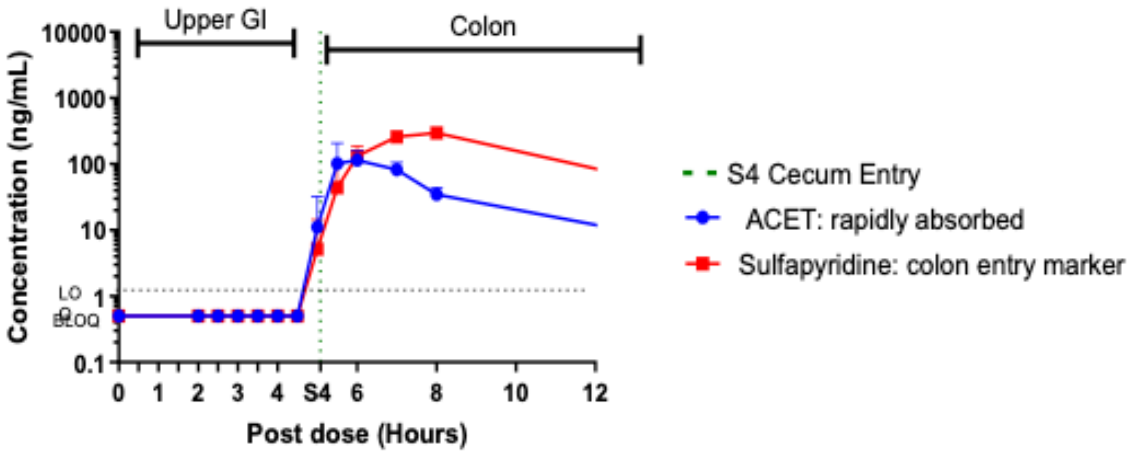
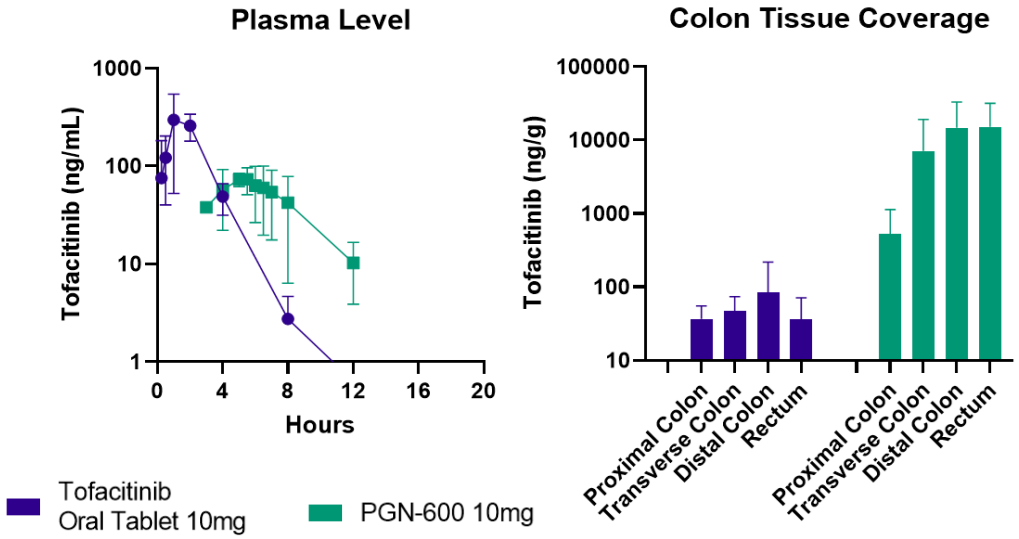
TARGETED THERAPEUTICS: PRECLINICAL RESULTS

ACCURATE DELIVERY TO THE COLON



BETTER PK EFFECT & COVERAGE



Pharmacokinetic data from two marker drugs administered in canine model indicated:

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

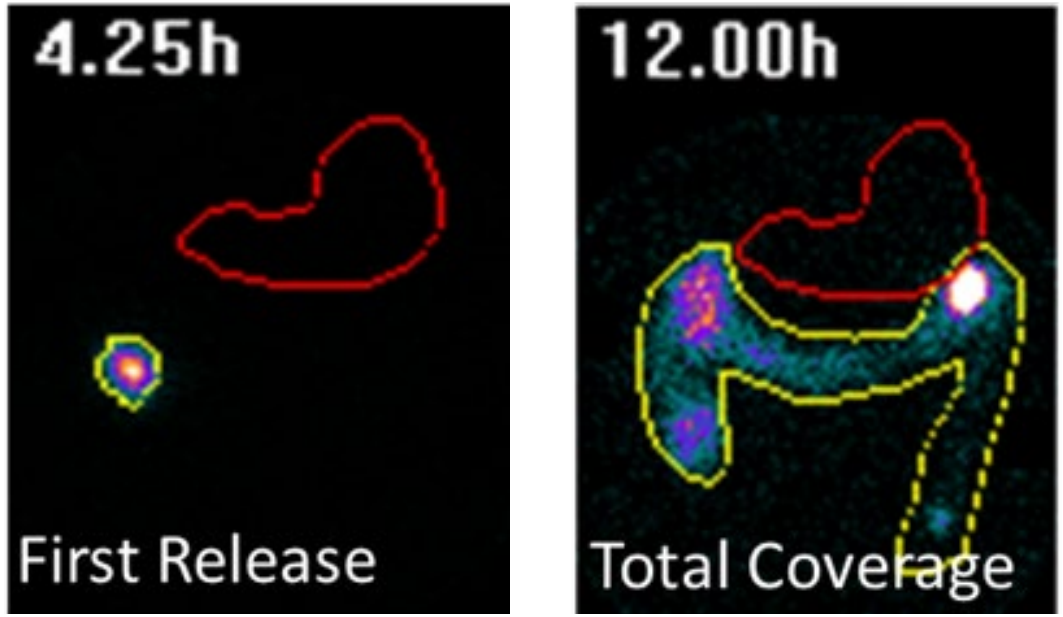
Standard oral dose vs. PGN-600 (tofacitinib delivered via DDS capsule) in canine model demonstrated:

- Reduced drug levels in blood vs. standard oral dose
- Tissue drug levels at least 25x higher along the length of the colon vs. standard oral dose

TARGETED THERAPEUTICS: CLINICAL DEVICE PERFORMANCE

Accurate localization and delivery demonstrated in humans

DEVICE LOCALIZATION AND DELIVERY TO COLON



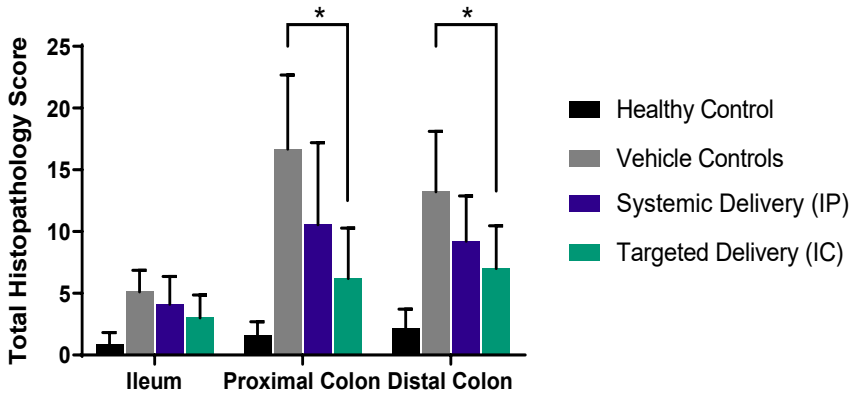
Successful clinical device validation for localization and delivery function using scintigraphic imaging:

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

TARGETED DELIVERY: SUPERIOR PHARMACODYNAMICS IN MULTIPLE MOLECULES

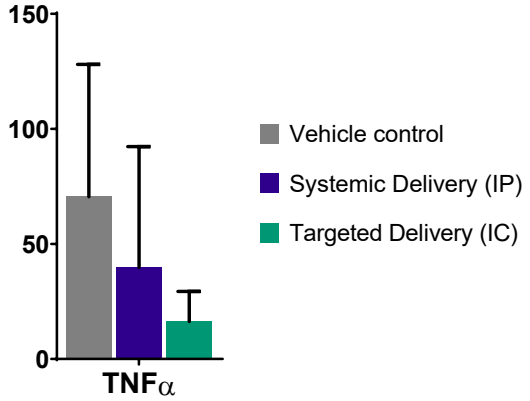
Anti-TNFα in animal models

IMPROVED HISTOPATHOLOGY SCORE



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

REDUCED INFLAMMATORY CYTOKINES



REDUCED T-CELL COUNTS

T-Cell Immunohistochemistry (CD4+)

Systemic Delivery (IP) of anti-TNFα to Proximal Colon

Targeted Delivery (IC) of anti-TNFα to Proximal Colon

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

- Significantly improved histopathology score vs. systemic delivery
- Significantly reduced inflammatory cytokines vs. systemic delivery
- T-cell counts reduced in proximal colon (decrease in inflammation) vs. systemic delivery

TARGETED THERAPEUTICS CLINICAL PLAN

FUNCTION STUDIES	TOX STUDY	PHASE 1 CLINICAL STUDIES	PHASE 1B/2A CLINICAL STUDIES

PM-601 Device Function Study in Normal Healthy Volunteers
• Device was well tolerated
• Achieved pan-colon distribution of payload
• Accurately identified entry into the colon (10/12); no early deployment
 	
PM-602 Device Function Study in Patients with Active Ulcerative Colitis
• Recruiting
	PGN-600 Tox GLP
	• Up to 30 animals in three groups:
	  • Oral pill
	  • Device only (10 mg)
	  • Device + drug (25 mg)
	• 8 weeks/QD
		PGN-600 Phase 1 SAD/MAD Study to Evaluate Safety, Tolerability, and PK/PD in Normal Healthy Volunteers
		• 48 total subjects (24 SAD / 24 MAD)
		• 8 days
			PGN-600 Safety and Efficacy in Subjects with Moderate to Severe Ulcerative Colitis Who Have Been Previously Exposed to TNF Antagonist

OBJECTIVES • Scintigraphy confirmation of device location, drug release, and colon coverage	**OBJECTIVES** • Confirmation of device location, drug release, and colon coverage **Previous Tox Study (2021)** • 7 days/QD in canines • No safety signals were observed	**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

SYSTEMIC THERAPEUTICS

NEEDLE AVERSION LEADS TO POOR PATIENT ADHERENCE

Patients prefer oral delivery of medication

20% of adults avoid medical treatment due to fear of needles[1]

42% of patients fail to maintain injectable treatment due to needle aversion[3]

among diabetes patients initiating treatment with injectable GLP-1 agonist

88% of patients prefer a daily oral capsule to bi-weekly injection[3]

among rheumatoid arthritis patients undergoing anti-TNFa therapy

1. Wright S, Yelland M, Heathcote K, Ng SK, Wright G. Fear of needles--nature and prevalence in general practice. Aust Fam Physician. 2009;38(3):172-176.
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
3. Frost & Sullivan research commissioned by Rani Therapeutics Holdings, Inc. https://ir.ranitherapeutics.com/static-files/b1f080bf-a860-4136-87cb-d6f7c49c1502

SYSTEMIC THERAPEUTICS DELIVERY SYSTEM

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

RESEARCH PARTNERSHIPS

- Large Pharma 1
- Large Pharma 2
- IONIS

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

watch activation video

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SYSTEMIC THERAPEUTICS: PRECISION DELIVERY

Preclinical studies demonstrate precise and reliable release of payload

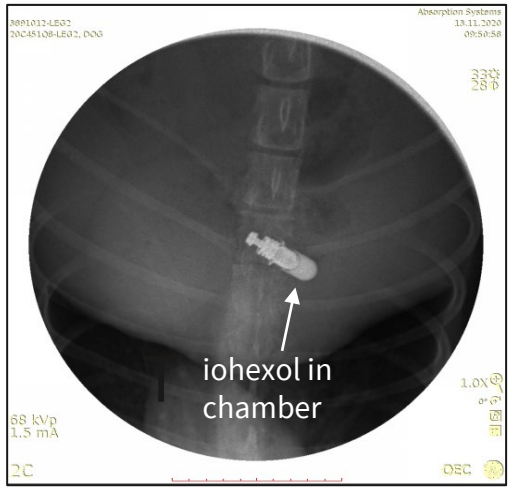
STUDY DESIGN

- Capsule loaded with a radio-opaque marker (iohexal)
- Two different enteric triggers evaluated
- Sequential imaging as the capsule transits through the GI tract in canines

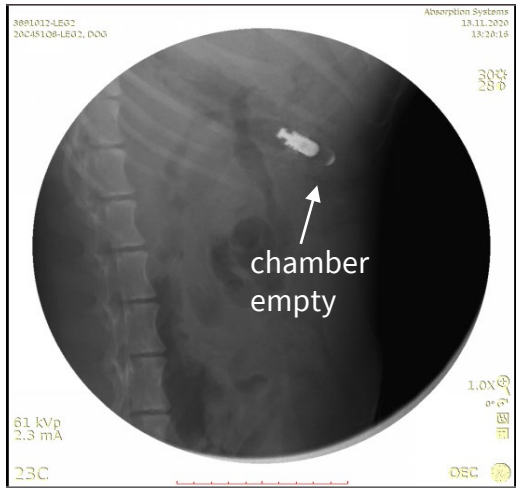
RESULTS

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

ACCURATE DELIVERY IN SMALL INTESTINE



Immediately after dosing in the stomach

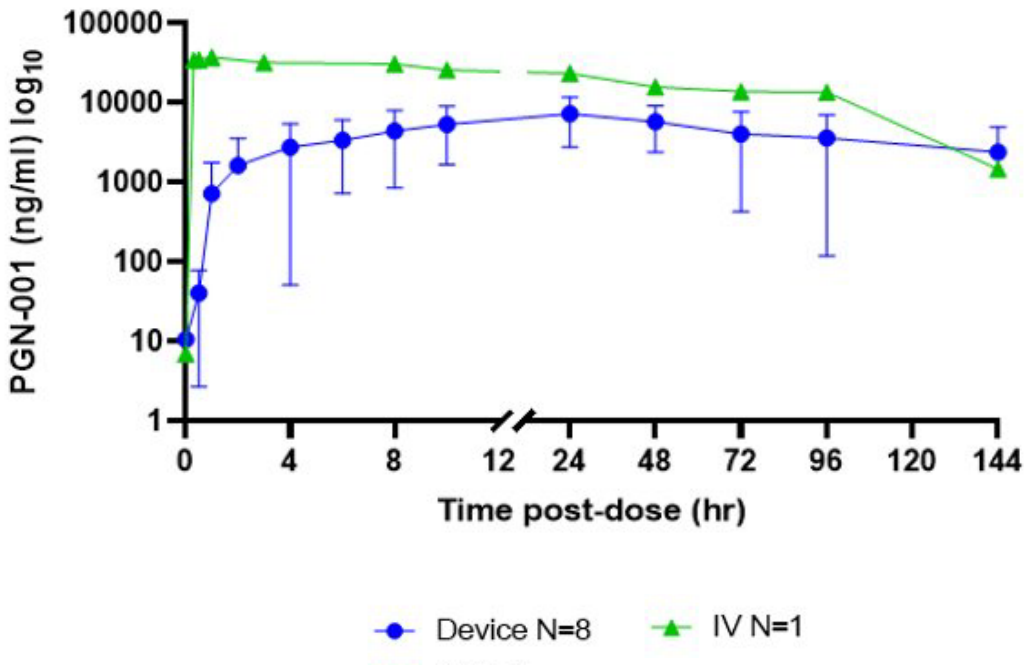


After deployment in the small intestine

EXCELLENT SYSTEMIC UPTAKE FOR ORALLY DELIVERED LARGE MOLECULES

Demonstrated up to 67% bioavailability for monoclonal antibodies

BIOAVAILABILITY COMPARABLE TO IV ADMINISTRATION

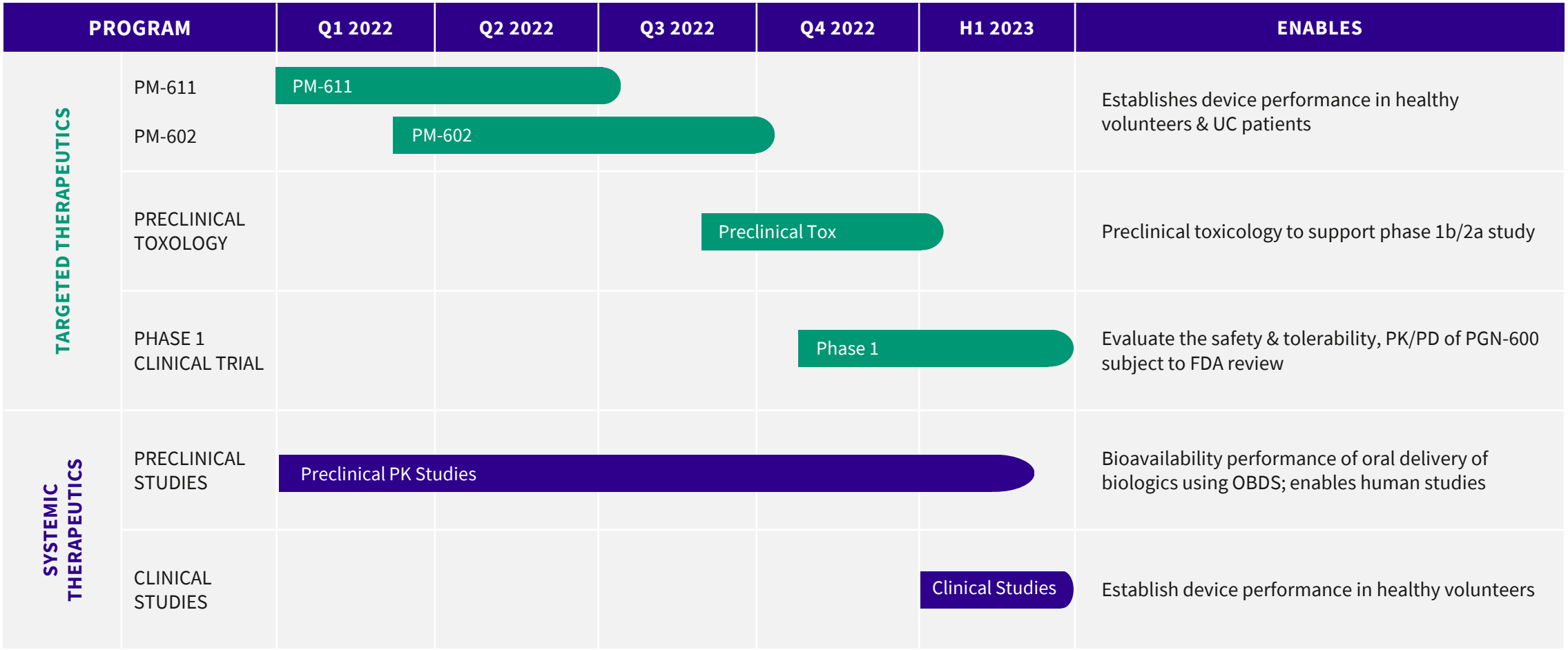


- Multiple studies in swine model with endoscopically placed, autonomous device compared to IV administration
- Achieved up to 67% bioavailability for a variant of adalimumab[1]
- Most recent study had an average of 22% bioavailability in animals where drug was detected in blood[1]
  - For comparison, commercially available oral large molecules achieve bioavailability of 1% or less

1. Biora Therapeutics internal data

TIMELINE

DEVELOPMENT TIMELINE

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