

THARIMMUNE

Unlocking Immunology for a Better Tomorrow

+

**Intract
Pharma** 

**Announce Letter of Intent to
Combine Companies**

September 30, 2024

Nasdaq: THAR | www.tharimmune.com

Intract Pharma, Ltd. | www.intractpharma.com



Forward Looking Statements

Certain statements in this presentation are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, contained in this press release, including statements regarding Tharimmune's or Intract's future financial or operating performance, the timing and design of Tharimmune's future Phase 2 trial, Tharimmune's and Intract's expectations with respect to the Merger, including the timing of entering into a definitive agreement, the timing of closing thereof, the pro forma ownership of the combined company, anticipated financing plans, the combined company's strategy, future operations, future financial position, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "depends," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "target," "should," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such forward-looking statements are based on the beliefs of management, as well as assumptions made by, and information currently available to, Tharimmune and Intract's management. Tharimmune may not actually achieve the plans, intentions, or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements. Factors that may cause such differences, include, but are not limited to, those discussed under Risk Factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2023 and other periodic reports filed by Tharimmune from time to time with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent Tharimmune's and Intract's views as of the date of this release. Subsequent events and developments may cause Tharimmune's views to change; however, Tharimmune does not undertake and specifically disclaims any obligation to update or revise any forward-looking statements to reflect new information, future events or circumstances or to reflect the occurrences of unanticipated events, except as may be required by applicable law. These forward-looking statements should not be relied upon as representing Tharimmune's views as of any date subsequent to the date of this release.

Tharimmune (Nasdaq: THAR) + Intract Pharma (UK) Transaction Summary



Deal Terms

- THAR signs non-binding LOI to acquire all outstanding shares of privately held Intract Pharma
- THAR remains in US (Bridgewater, NJ) and continues to trade on Nasdaq (THAR)
- Intract becomes wholly-owned subsidiary in UK (London)



Ownership

- THAR shareholders own 51% of the combined company
- Intract shareholders own 49% of the combined company



Use of Capital

- THAR: cash-on-hand as of 6/30 (~\$8 m); continue to develop TH104 + TH023)
- Intract: continue to develop high-value oral biologics platform technology and progress on pharma collaborations

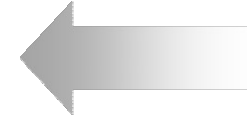


Leadership Team

- Management: Randy Milby (CEO); Thomas Hess (CFO) Vipul Yadav (President & CSO); Sireesh Appajosyula (COO); Nir Barak (CMA)
- Board : Leonard Mazur (Independent); Kelly Anderson (Independent); Lynn Bui (independent) Randy Milby (Chairman); Sireesh Appajosyula; Vipul Yadav

A Transformative Combination Creates Best-in-Class Immunometabolic Company

THARIMMUNE



NASDAQ-listed biotech company focused on immunology & oncology

Synergy of clinical assets and follow-on oral biologics/peptide platform

Private biotech company with oral biologic & peptide expertise

Phase 2 asset with near-term readouts with registrational trial potential in 2026

Diverse & differentiated portfolio across immuno-metabolic conditions

Best-in-class high-growth oral large molecule R & D (autoimmune mAbs & GLP-1s)

Opportunity for higher returns with expanded clinical indications

Strengthened regulatory, clinical, and drug development execution

Cost-efficiencies through shared & operational resources

Increased opportunities for funding and strategic alliances for clinical stage assets

Unlocks shareholder value through expanded pipeline and platform synergies

Potential for delivery platform licensing and partnership opportunities

Expanded Leadership with Deep Pharmaceutical Experience

Executive Team



Randy Milby, RPh, MBA
Chief Executive Officer



Sireesh Appajosyula, PharmD
Chief Operating Officer



Thomas Hess, CPA
Chief Financial Officer



Nir Barak, MD
Chief Medical Advisor



Vipul Yadav, PhD
President & Chief Scientific Officer



Expanded Board

Leonard Mazur
Independent Director



Kelly Anderson
Independent Director



Lynne A Bui
Independent Director







Randy Milby
Chairman of the Board

Sireesh Appajosyula
Director

Vipul Yadav
Director

Synergy Through Clinical-Stage and Follow-On Oral Biologics Pipeline

Candidate	Indication(s)	Preclinical	Phase 1	Phase 2	Anticipated Milestones
TH104 <i>(nalmefene)</i> <i>Buccal Film</i>	Moderate-to-Severe Chronic Pruritis in Primary Biliary Cholangitis				2025: Ph2 Topline Readout
TH023 <i>(Oral anti-TNFα mAb)</i>	Multiple Autoimmune Indications				2H 2025: Ph1 Topline Readout
Oral mAb and GLP-1 Peptide Programs Several Ongoing Big Pharma/Biotech Partnerships Next Gen Platform Development	Autoimmune and Metabolic Indications				2H 2025: Lead candidate selection
Antibodies/Knob Domains/ADCs	PD-1/HER2/HER3 + Oncology & Metabolic Targets				2025: Lead selection + IND enabling studies

*pending discussions with FDA; †Partnered with Intract Pharma; Exclusive mAb supply by Celltrion Inc., Intract/Tharimmune has granted ROFR to Celltrion, Inc.

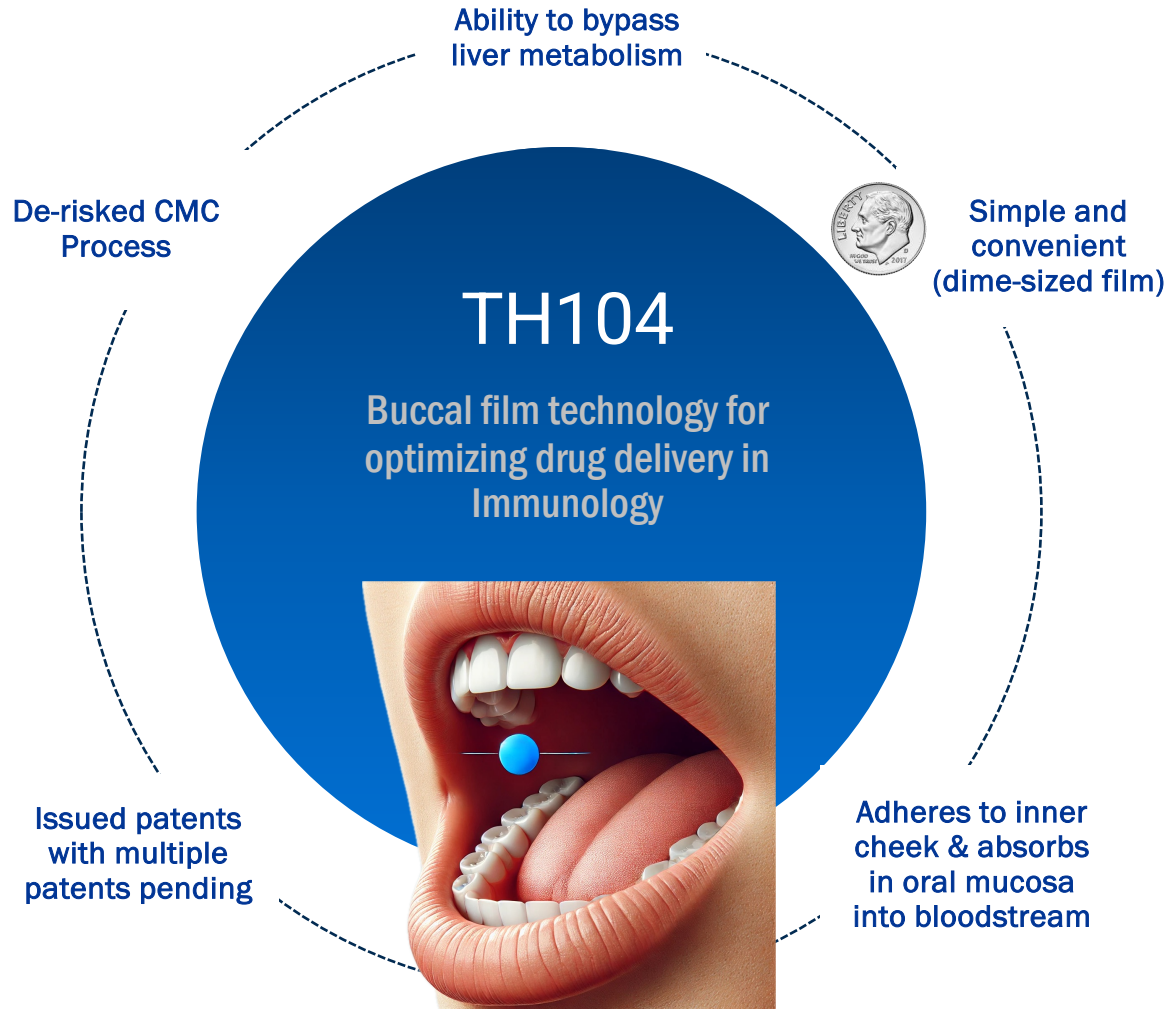

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Lead Candidate:

TH104



TH104: Proprietary Transmucosal Buccal Film Avoids First-Pass Liver Metabolism



Phase 1 study demonstrated TH104 oral film had comparable safety and tolerability to IV

Drug embedded on proprietary transmucosal film

- ✓ Once-Daily Dosing
- ✓ Rapid Onset
- ✓ High Absorption

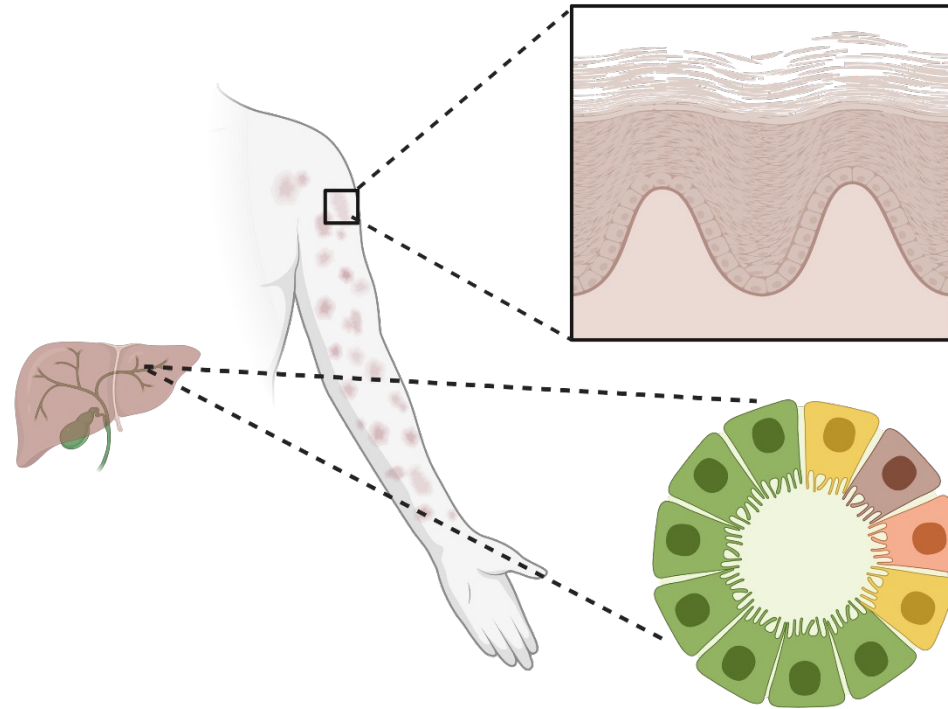
Designed to bypass liver
(no first-pass effect)

- ✓ Absorbs in oral mucosa & distributes to skin
- ✓ Designed for liver impaired conditions

High Unmet Need: Moderate-to-Severe Chronic Pruritus (debilitating itching) in PBC

In patient testimonials, PBC itch is described as “the worst, most unimaginable itch”, like bugs crawling under the skin”.

- PBC is an **orphan disease** in the USA and Europe, with 178k patients in US.
- Affects men & women (rate higher in women: ~ 1 in 1,000 > 40 years old)²
- **65% of patients** have “worse **nocturnal** pruritus” with 71% of patients stating a disturbance in their sleep³



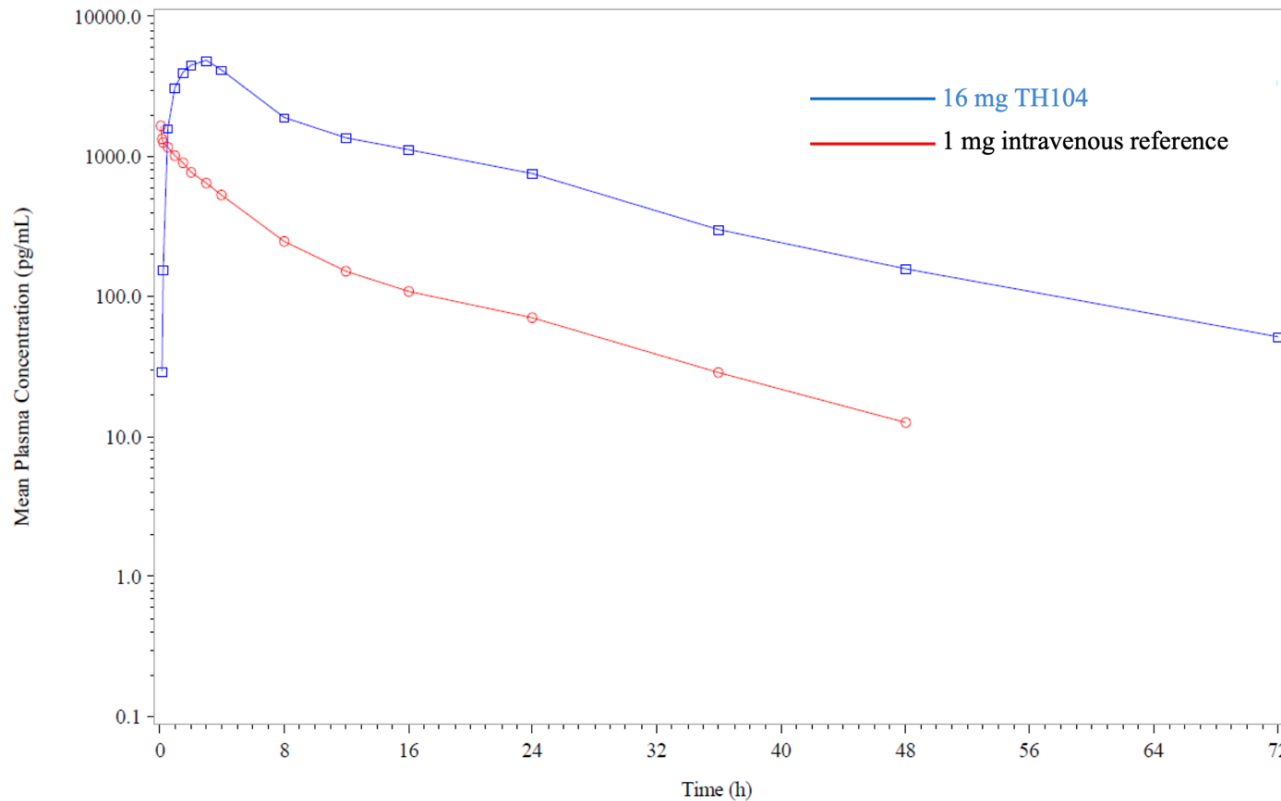
More than 70% of Primary Biliary Cholangitis (PBC) patients affected by pruritus¹

PBC is a chronic disease where **bile ducts in the liver** are eventually dysfunctional; the bile builds up and causes liver damage.⁴

1. Gungabissoon U, et al. BMJ Open Gastro 2022;9:e000857. doi:10.1136/bmjgast-2021-000857
2. <https://www.healthywomen.org/condition/primary-biliary-cholangitis-pbc>
3. Rische et. al. Itch in Primary Biliary Cholangitis: A Patients' Perspective Acta Derm Venereol 2008; 88: 34-37
4. <https://www.niddk.nih.gov/health-information/liver-disease/primary-biliary-cholangitis/definition-facts>

TH104 Demonstrated Favorable Pharmacokinetic Profile Compared to IV Dosing

Mean Concentration vs. Time Curve of Nalmefene (semilog plot)



Pharmacokinetic profile of oral transmucosal delivery of TH104 comparable to IV delivery

PK Profile:

- **Primary endpoint of the absolute bioavailability*: 0.459 (45.9%)**
- Median time to maximum concentration (C_{max}): 2.0 hours
- Mean half-life ($T_{1/2}$): 14 hours

AE Profile:

- Treatment emergent adverse events (TEAEs) reported in 8 subjects (40.0%) in TH104 group; 7 subjects (36.8%) in IV
- All reported TEAEs were considered mild in severity
- Most frequently reported TEAE in both groups was dizziness (4 TH104 group; 7 intravenous)
- TEAEs reported in at least 2 subjects in any treatment group were nausea (3 in each group) and somnolence (3 in each group).

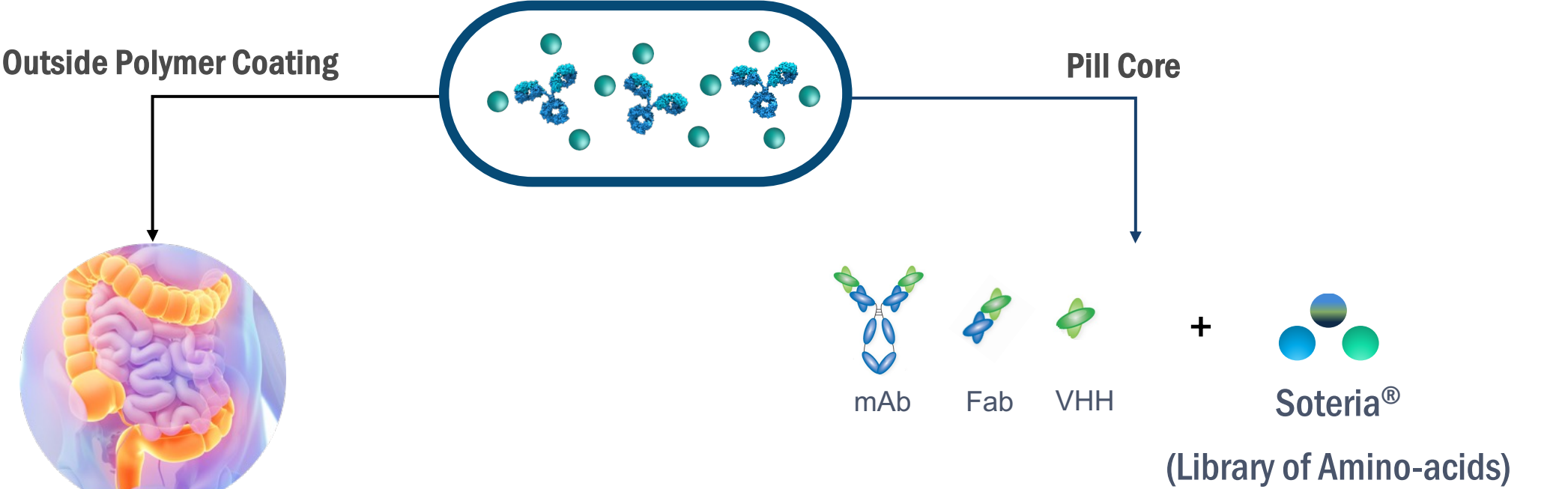
*fraction (or percentage) of the administered dose absorbed into the systemic circulation compared to an equivalent intravenous dose of nalmefene

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**Combination with Intract
Oral Biologics & Peptides**



Intract Utilizes Potential Best-in-Class Proprietary Oral Antibody Delivery Platform



Phloral®

Dual-Trigger Enteric Coating for Targeted Drug Delivery to Lower GI

Precision Drug Release in Ileum/Colon



TH023 utilizes approved monoclonal antibody infliximab sourced from Celltrion

(Library of Amino-acids)

Stabilizes antibody against proteases
Natural intestinal transcytosis via active and passive transport

Phloral®: Multiple Clinical Studies Executed Including a Commercial Product in UC



Inflammatory Bowel Disease

- ✓ EMA approved novel small molecule product (mesalamine) launched for first line treatment for UC in 2019.
- ✓ Passed Phase 3 trial in 817 UC patients¹.

Clostridium difficile infection

- ✓ Phloral® coated capsules used for FMT trial to test efficacy in 51 C.diff patients².
- ✓ Positive efficacy data shown with Phloral® capsules targeting FMT to the colon

Obesity/T2D

- ✓ Phloral® coated capsules of MCFA dosed to 20 subjects with a BMI of 30-40kg/m².
- ✓ Significant decrease in calorific intake and increase in PYY hormone was demonstrated³.

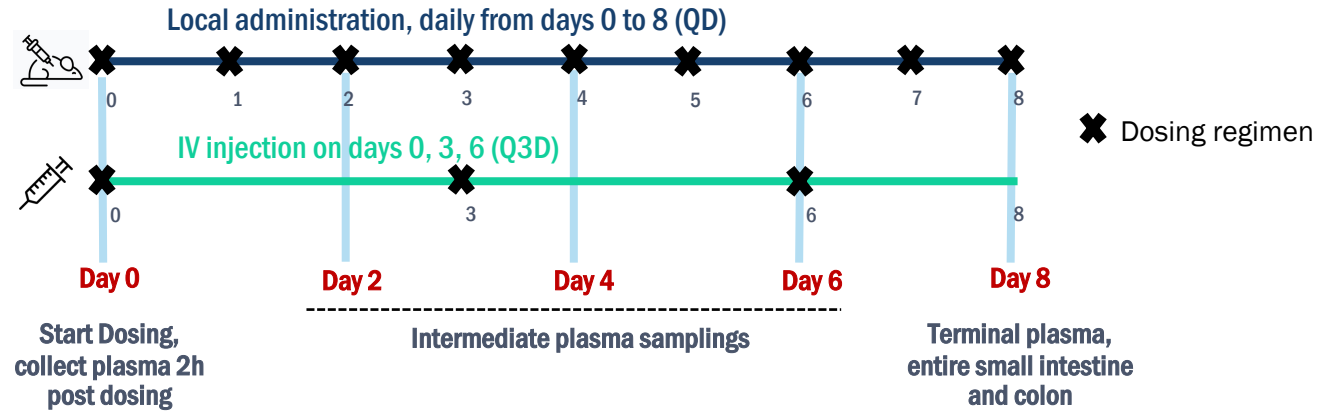
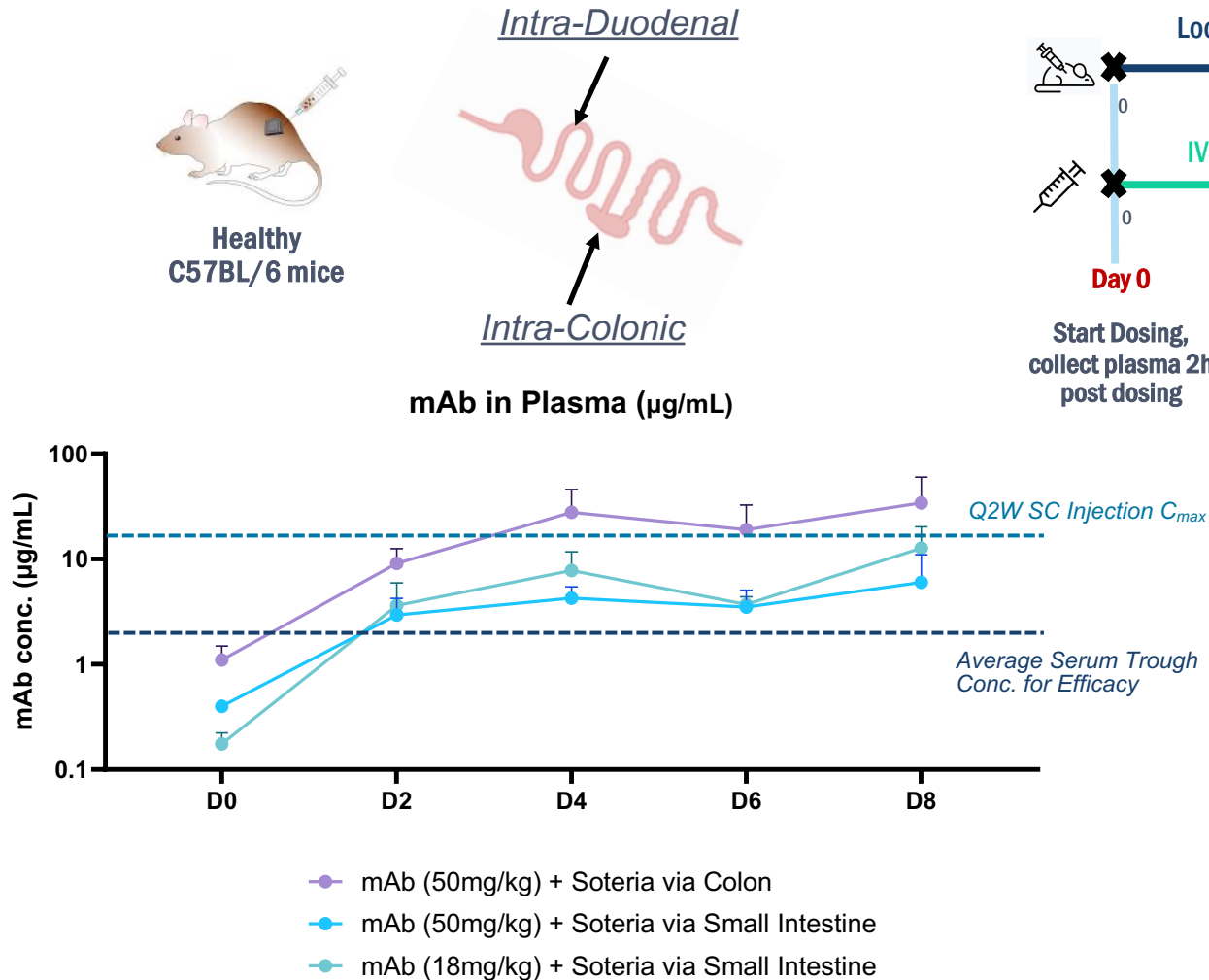
1. D'Haens et al., *Aliment Pharmacol Ther.* 2017;1-11

2. Allegretti et al., *Digestive Diseases and Sciences.* 2018.

3. Peiris et al., *Gut* 2021;0-1.

Soteria® Platform: mAb Serum Conc. Exceeds Trough and Matches SQ Injection Conc.

In-vivo PK in Healthy Mice Following QD Dosing for 1wk



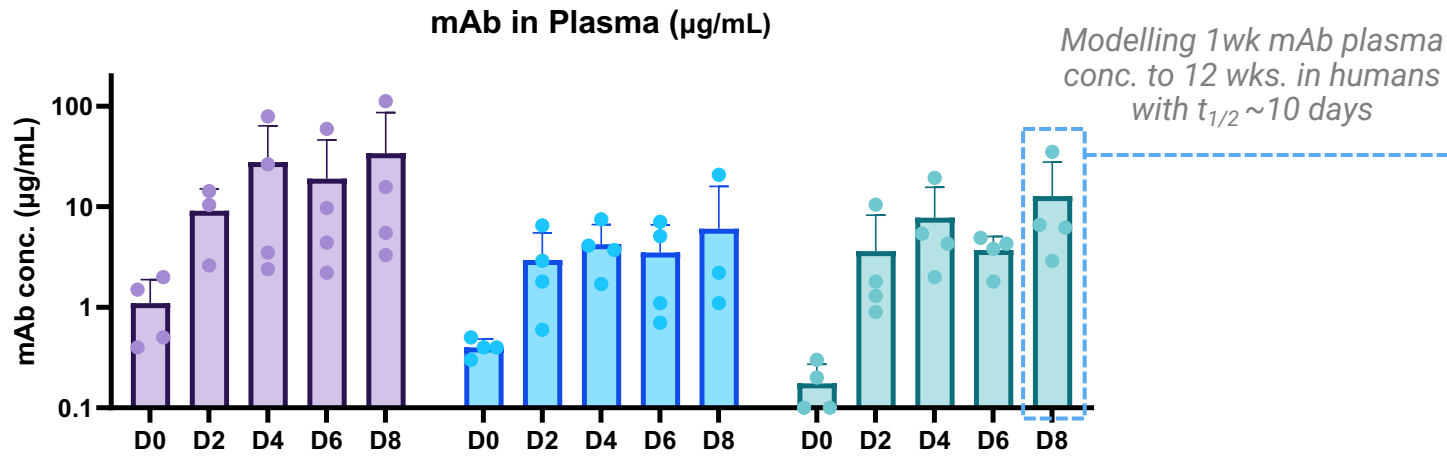
Colon targeting of mAb showed higher systemic conc. vs small intestine delivery, potentially due to better enzymatic stability and active transport receptor engagement

No dose effect observed between 50 and 18mg/kg, potentially due to intestinal epithelial transport saturation.

QD dosing of antibody enables build-up in plasma levels due to $t_{1/2}$ of ~3-4 days in mouse.

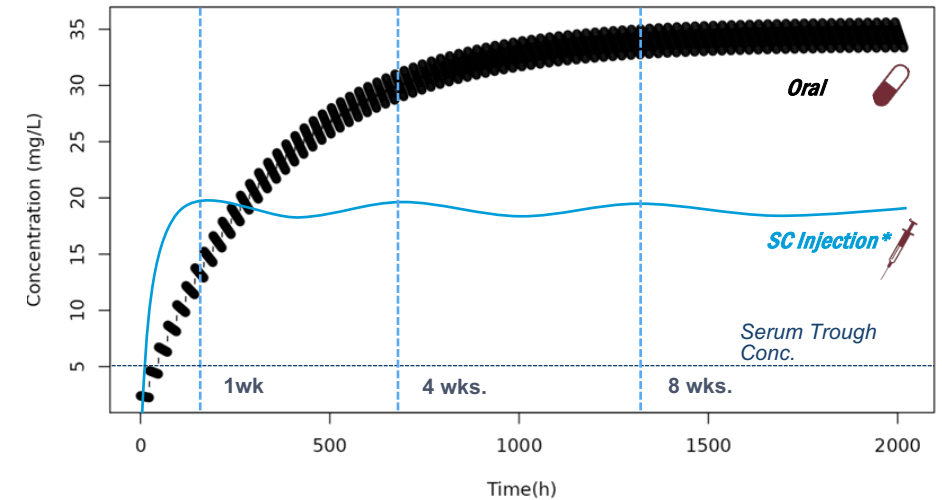
Soteria[®] Platform: Serum Conc. Can Exceed Injection Trough and Cmax with QD Dosing

PK Plot with Individual Mouse Data Points



- mAb (50mg/kg) + Soteria via Colon
- mAb (50mg/kg) + Soteria via Small Intestine
- mAb (18mg/kg) + Soteria via Small Intestine

The time course of concentrations

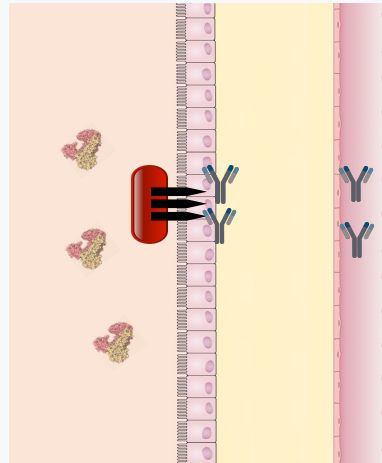
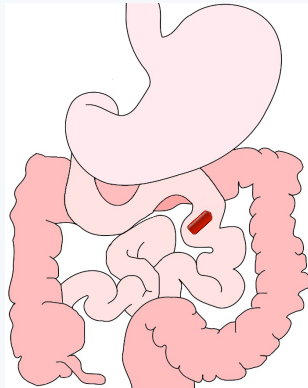


- All arms reached > therapeutic serum trough concentration for injectable mAbs in humans.
- When 1wk plasma conc. is modelled in humans with a $t_{1/2}$ of 10days, the mAb concentration surpasses Q2W 240mg SC injection PK profile.

*Schreiber et al., Gastroenterology, 2021; 160:2340-2353

Intract Platform Compared to Other Technologies in Development

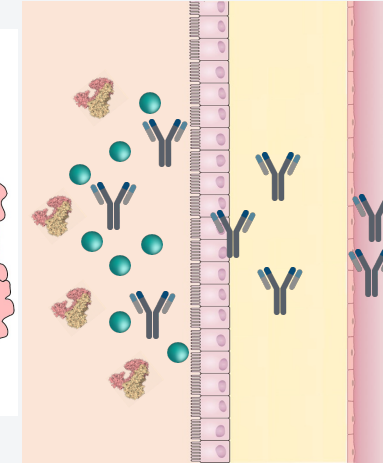
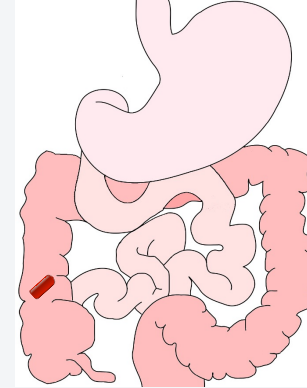
Orally Ingestible Devices



Drug Loaded Needles

- No enzyme protection if deployment fails
- CMC/COGS/Safety challenges
- Injection into tissue for systemic delivery hampered by deployment failures

Oral Antibody Platform Technology

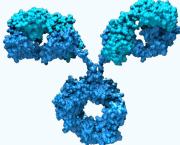

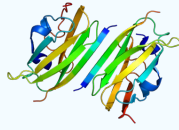


Enzyme Stabilizer + Amino Acids

- Enzyme protection for high local tissue exposure
- CMC/COGS
- Modest permeation enhancement

High Pharma Interest in Oral Therapies Against Traditional Injectables Biologics




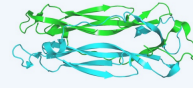
Target **$\alpha4\beta7$ integrin**

Indication(s) **IBD**




IL-23

IBD and Psoriasis

IL-17

Psoriasis








Small Molecules **\$2.4b Acquisition**



\$3.2b Acquisition

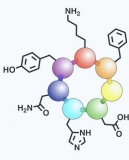





Cyclic Peptide **NASDAQ Listed**

Small Molecule **NASDAQ Listed**

Raised >\$450m

Cyclic Peptide **\$1b Licensing Deal**




Small Molecules **\$2.4b Acquisition**



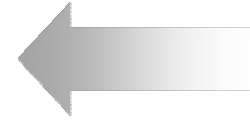



Cyclic Peptide **\$0.5b Licensing Deal**

C 4
X D

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