

VISCERA LABS

June 2026



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Viscera Labs is developing a novel formulation of colestevlam (VL-001) for the treatment of bile acid diarrhea (BAD)

2.2 million people with types 2 and 3 BAD in the US

There is no approved treatment

BAD is managed by functional gastroenterologists

Focused promotional effort

Gastroenterologists prescribe colestevlam off-label to treat BAD

Customer familiarity with the agent

The tolerability and dosing of the current formulations of bile acid sequestrants can be limiting

Need for a bile acid sequestrant that targets the terminal ileum

VL-001 may have utility in glycemic control, statin-intolerant hypercholesterolemia and pruritus associated with cholestatic liver disease

Expands the clinical utility of VL-001

A Unique Market Opportunity by Managing Risk

Regulatory

Although no product for BAD is yet approved by FDA:

- Viscera will leverage the development efforts of competing assets via a 505b2 pathway
- Viscera Labs has been granted a pre-IND meeting in June 2026

Clinical

While VL-001 has yet to be evaluated in humans:

- VL-001 has shown efficacy in pre-clinical models
- The current formulation of colesevelam has demonstrated efficacy in the treatment of BAD

Commercial

VL-001 will compete with generic colesevelam, however:

- VL-001 is designed to be more efficacious and tolerable due its targeted delivery
- Initial HCP reactions to the program have been positive

The Viscera Labs management team has decades of experience in all aspects of the pharmaceutical industry



JP Benya
President & CEO



Steve Petruccelli
EVP, Secretary



Lisa Pedicone, PhD
VP, Chief Scientific Officer



Paul Ursino
VP, Chief
Development Officer

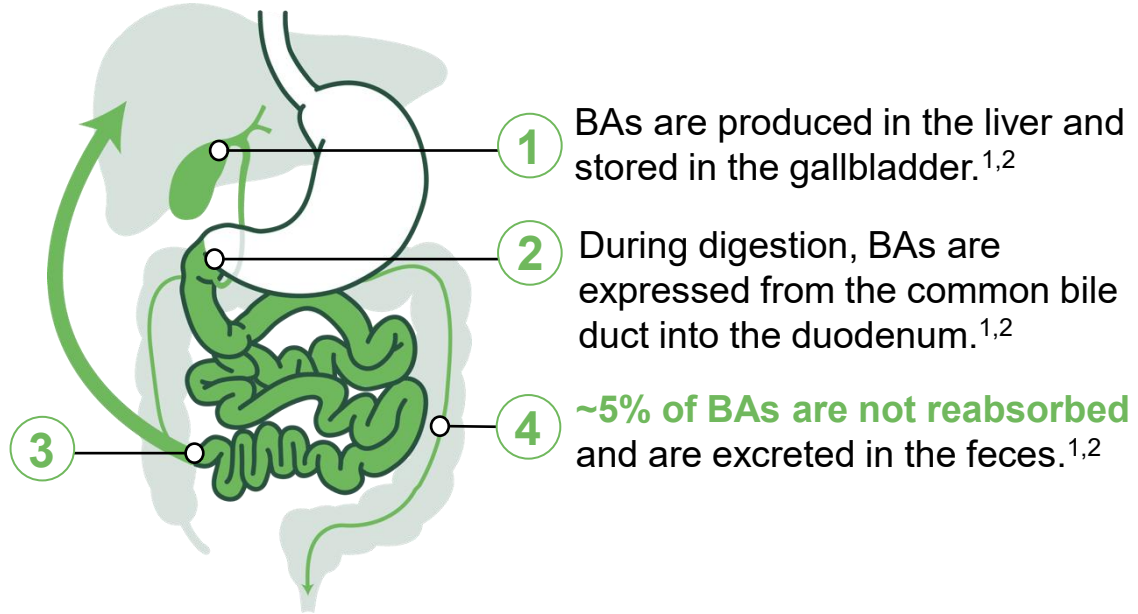


Catherine Coffey Ross
VP, Corporate Development



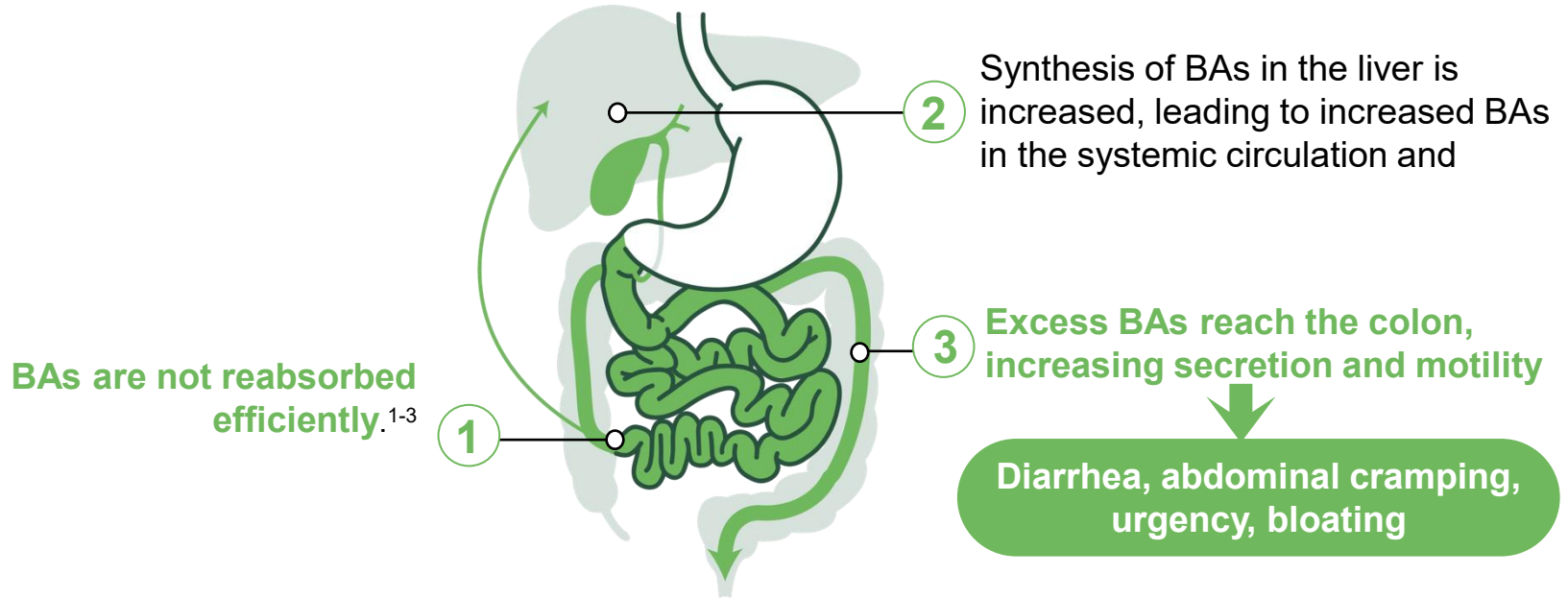
The bile acid (BA) pool remains constant in healthy persons

After traveling through the small intestine and aiding in digestion, **~95% of BAs are reabsorbed from the terminal ileum** and recycled back to the liver.¹⁻³



1. Farrugia A, Arasaradnam R. *Frontline Gastroenterol.* 2021;12:500-507. 2. Marasco G et al. *J Clin Med.* 2022;11:3102.
3. Camilleri M, Nurko S. *Neurogastroenterol Motil.* 2022;34:e14287.

In BAD, excess BAs reach the colon and cause diarrhea



1. Farrugia A, Arasaradnam R. *Frontline Gastroenterol.* 2021;12:500-507. 2. Marasco G et al. *J Clin Med.* 2022;11:3102.
3. Camilleri M, Nurko S. *Neurogastroenterol Motil.* 2022;34:e14287.

BAD has substantial negative impact on patients' lives

>90% of patients were **nervous leaving home** and were often or sometimes **embarrassed** by symptoms.¹

40% of patients experienced **extreme tiredness**.¹

30% of patients reported **frequent work absences** because of their symptoms.¹



NEARLY **50%** of patients **worried about losing bowel control** quite a bit or a great deal.²

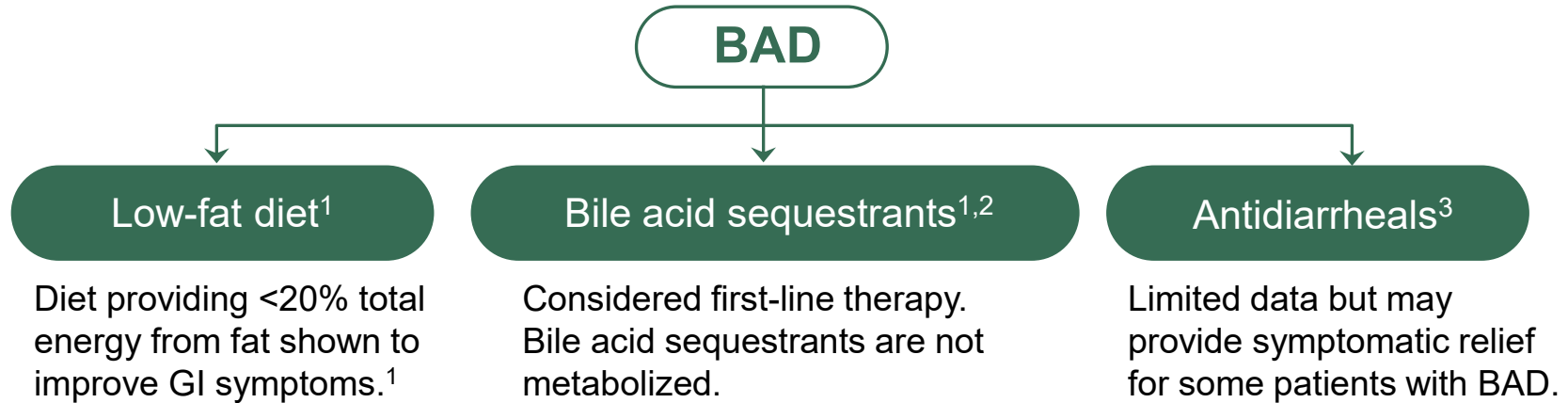
75% of patients considered **proximity to a toilet** moderately to extremely important.²

Data from 100 patients with BAD responding to an online survey from BAM Support UK.²

Data from an observational study of 44 patients at Mayo Clinic in Rochester, Minnesota, with Rome III-diagnosed IBS-D and BAD.²

1. Bannaga A et al. *BMJ Open Gastroenterol.* 2017;19;4(1): 2. BouSaba J et al. *Clin Gastroenterol Hepatol.* 2022;20:2083-2090.

Treatment options for BAD are limited



There are no FDA approved treatments for BAD.

1. Watson L et al. *Clin Med*. 2015;15(6):536-540. 2. Camilleri M, Nurko S. *Neurogastroenterol Motil*. 2022;34:e14287.
3. Mottacki N et al. *Aliment Pharmacol Ther*. 2016;43:884-898.

BA sequestrants bind BAs in the small intestine and reduce their delivery to the colon¹

Mechanism of BA sequestrants in BAD



Cholestyramine • Most studied of the
(Questran[®], generic)² BA sequestrants for BAD³



Colestipol
(Colestid[®], generic)² • Few data in BAD³



Colesevelam
(Welchol[®], generic)² • Stronger binding affinity for BA
than cholestyramine and binds a
broader spectrum of BAs⁴
• Better tolerated than
cholestyramine and colestipol⁴

1. Camilleri M, Nurko S. *Neurogastroenterol Motil.* 2022;34:e14287. 2. NIH. Accessed April 13, 2023. dailymed.nlm.nih.gov.
3. Wilcox C et al. *Aliment Pharmacol Ther.* 2014;39:923-939. 4. Borup C et al. *Lancet Gastroenterol Hepatol.* 2023;8u:321-331

Many patients do not tolerate current formulations of BA sequestrants



Poor tolerability

UP TO **70%** patients discontinue BA sequestrants due to AEs, usually nausea.¹

Poor palatability

due to the taste and/or texture often limit compliance^{1,2}

POTENTIAL FOR **Drug-drug interactions**

must be considered in patients taking multiple medications^{2,3}

1. Vijayvargiya P et al. *Clin Gastroenterol Hepatol*. 2020;18(13):2962-2970. 2. Appleby RN et al. *United European Gastroenterol J*. 2017;5(3):380-388. 3. Wilcox C et al. *Aliment Pharmacol Ther*. 2014;39:923-939.

Colesevelam tolerability

Study	Population	N ^a	Key findings
Borup 2023 ¹	BAD	41 ^b	<ul style="list-style-type: none"> • AE rates among colesevelam-treated patients (n=22) vs placebo-treated patients (n=19): bloating (41% vs 21%), stomach-ache (23% vs 21%), nausea (18% vs 5%) • No patients discontinued due to AEs
Beigel 2014 ²	BAM-associated diarrhea and CD	34	<ul style="list-style-type: none"> • 1/19 (5.3%) colesevelam-exposed patients discontinued due to constipation compared with 2/15 (13.3%) in placebo-exposed patients
Odunsi-Shiyunbade 2010 ³	IBS-D	24	<ul style="list-style-type: none"> • AE rates among colesevelam-treated patients (n=12) vs placebo-treated patients (n=12): headache (40% vs 33%), flatulence (24% vs 8%), nausea (17% vs 24%), lower abdominal cramps (17% vs 0%) • No patients discontinued due to AEs
Welchol PI ⁴	T2DM	1128	<ul style="list-style-type: none"> • 6.7% colesevelam-treated patients (n=566) discontinued treatment due to AEs (mostly GI effects such as abdominal pain and constipation) compared with 3.2% of placebo-treated patients (n=562)

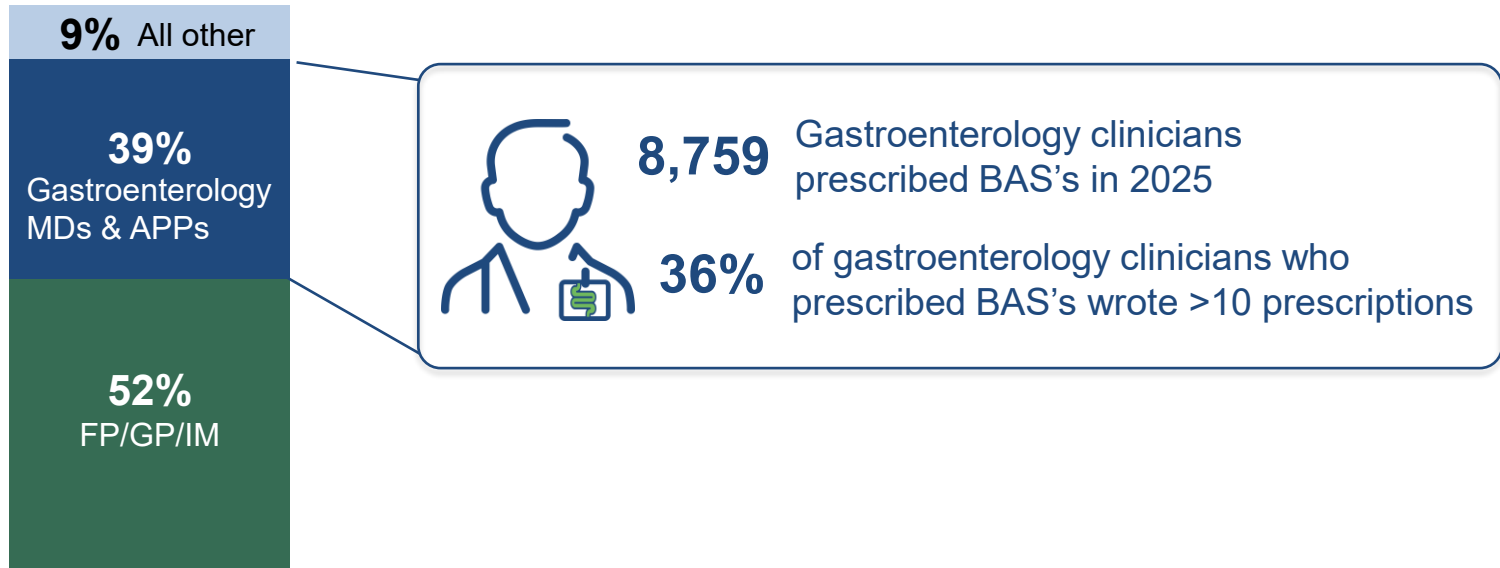
^a All randomized patients; ^bPrimary outcome population.

1. Borup C et al. *Lancet Gastroenterol Hepatol.* 2023;8:321-331. 2. Beigel F et al. *J Crohn's Colitis.* 2014;8:1471-1479.

3. Odunsi-Shiyunbade ST et al. *Clin Gastroenterol Hepatol.* 2010;8:159-165. 4. Welchol (colesevelam)[prescribing information]. Cosette Pharmaceuticals, Inc.; South Plainfield, NJ; 2022.

Gastroenterologists are currently prescribing bile acid sequestrants

BAS prescribing in 2025



Data are from healthcare providers who prescribed >10 prescriptions in 2025.
FP, family practice; GP, general practitioner; IM, internal medicine.
Definitive Healthcare, 2025.

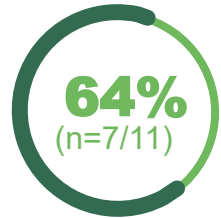
Current prescribing practices in BAD



of physicians reported being very or extremely comfortable treating BAD.



of patients are being prescribed a BA sequestrant.



of physicians consider drug-drug interactions the primary limitation of available therapies for BAD.

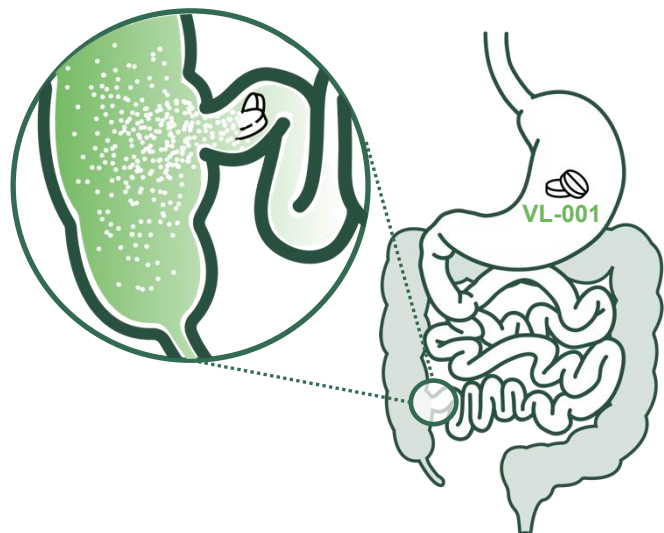


64%
(n=7/11) of physicians **use colestevlam frequently** to treat BAD.

60%
(n=6/10) of physicians who use colestevlam were **very or extremely satisfied** with it, citing dosing and efficacy as its greatest benefits.

Note: Data from survey conducted in November 2020 by Gi Health Foundation in 9 community gastroenterologists, 1 academic hepatologist, and 1 community geriatric physician.
Data on file. Viscera Labs.

VL-001 is designed to target colestevlam release in the terminal ileum



Potential advantages of VL-001 over current colestevlam formulations^{2,3}

- Improved tolerability (i.e., nausea)
- Fewer drug-drug interactions (e.g., oral contraceptives)
- Improved efficacy due to targeted sequestration of bile acids
- Lower drug burden, lower pill count, and smaller tablet size

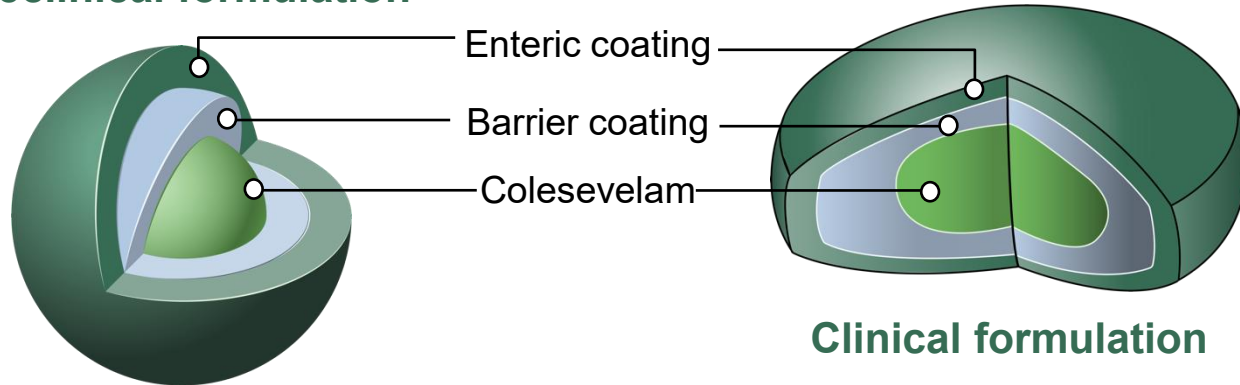
VL-001 is an extended-release formulation designed to pass through the upper GI tract and release colestevlam in the terminal ileum.¹

1. Data on file. Viscera Labs. 2. Appleby RN et al. *United European Gastroenterol J.* 2017;5(3):380-388. 3. Vijayvargiya P et al. *Clin Gastroenterol Hepatol.* 2020;18(13):2962-2970.

The VL-001 formulation leverages several barriers to ensure delivery of the colesevelam at the terminal ileum

Delayed release colesevelam with an enteric coating over a barrier coating, both using GRAS excipients, that resists prolonged contact with acidic gastric fluids and releases at neutral pH

Preclinical formulation



A series of three non-GLP in vivo pharmacology studies were conducted to evaluate the bile acid sequestration effects of colesevelam and VL-001



Study 1:

A model establishment study evaluating the effect of reference colesevelam on fecal bile acid excretion



Study 2:

A comparative study assessing the effect of VL-001 and reference colesevelam on fecal bile acid excretion.

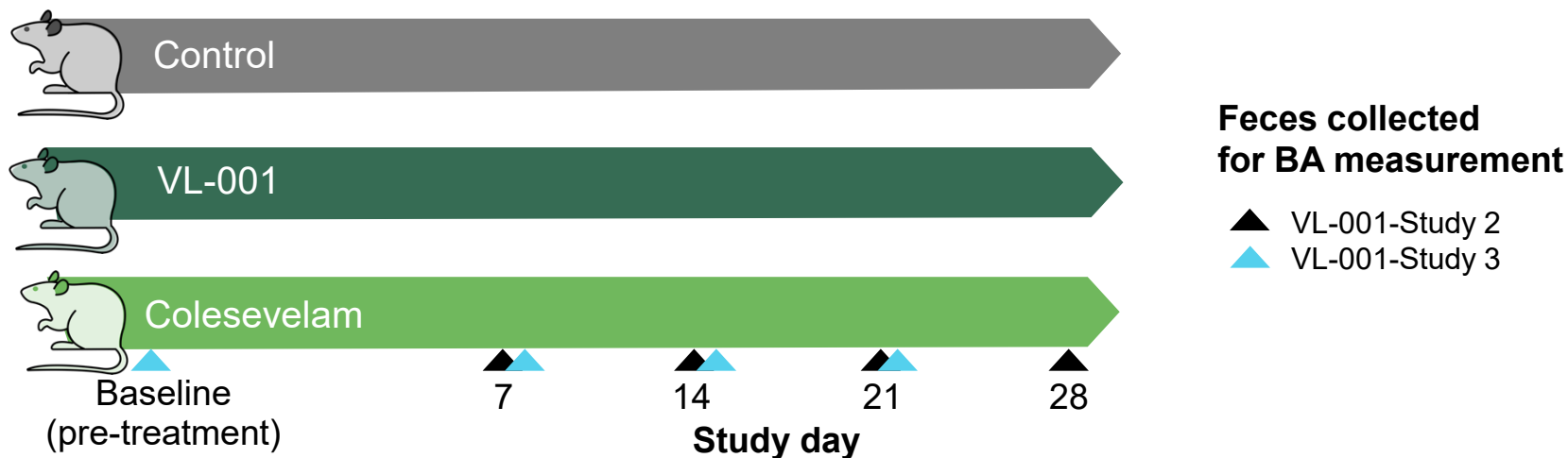


Study 3:

A confirmatory comparative study to confirm Study 2 assessing the effect of VL-001 and reference colesevelam on fecal bile acid excretion with incorporation of baseline (Day 0) measurements

All studies utilized dietary administration of test and reference materials, with fecal bile acid levels measured as the primary pharmacodynamic endpoint.

VL-001-Study 2 and Study 3 assessed the bile acid sequestrant effects of VL-001

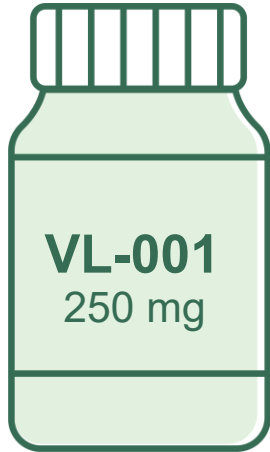


BA, bile acid.

Studies conducted in C57Black 6 mice by Vipragen Biosciences, Karnataka, India. November 2022 . Data on file. Viscera Labs.

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VL-001 CMC progress



9,000
TABLETS

of VL-001 250mg were manufactured in December 2022 by Cipro Pharmaceuticals, India.

New tablets will be manufactured to complete the phase 1b trial and will also be put on stability.

Stability assessment is complete; 36-month data is nominal

Agents for BAD Being Evaluated by Corporate Sponsors Have Not Progressed

Agent	Mechanism	Development phase			
		1	2	3	4
Eluxadoline (Viberzi® , Allergan) ^{1,2}	Mixed μ - and κ -opioid receptor agonist and δ -antagonist	[Progress bar from phase 1 to phase 4]			Last updated 5/2021
A3384 (Albireo) ^{1,3,a}	Colonic-release cholestyramine	[Progress bar from phase 1 to phase 2]		Last updated 4/2024	
Aldafermin (NGM Biopharmaceuticals) ^{1,4}	FGF-19 analogue	[Progress bar from phase 1 to phase 2]		Last updated 10/2023	
LJN452 (Novartis) ^{1,5,a}	FXR agonist	[Progress bar from phase 1 to phase 2]		Last updated 1/2021	

FGF, fibroblast growth factor; FXR, farnesoid X.

^aDevelopment status uncertain.

1. Clinicaltrials.gov. Accessed Jan 24, 2025. Search: “Bile Acid Diarrhea”, “Bile Acid Malabsorption”. <https://www.clinicaltrials.gov>. 2. Vijayvargiya P et al. *Dig Dis Sci.* 2022;67(8):3911-3921. 3. Appleby RN et al. *United European Gastroenterol J.* 2017;5(3):380-388. 4. BouSaba J et al. *Gastroenterology.* 2023 Apr 19:S0016-5085(23)0062102. Online ahead of print. 5. Camilleri M et al. *Aliment Pharmacol Ther.* 2020;52(5):808-820.

Commercialization

- Comprehensive market research and market shaping begins 4Q'29 ahead of 3Q'30 launch
- 35 field representatives (Sales, MSL, etc.) will call on decile 4-10 GIs and APPs
- Leverage relationship with GIHF (www.gihealthfoundation.org) and GHAPP (www.ghapp.org) to raise awareness about BAD and to promote VL-001

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THANK YOU !

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