



Viscera Labs Announces FDA Grants Pre-IND Meeting for Lead Program

East Hanover, NJ – June 18, 2026 — Viscera Labs today announced that the U.S. Food and Drug Administration (FDA) has granted the company’s request for a Pre-Investigational New Drug (Pre-IND) meeting to discuss the development pathway for its lead therapeutic program, VL-001 for the treatment of bile acid diarrhea. There is currently no FDA approved medication to treat bile acid diarrhea.

The upcoming meeting will provide an opportunity for Viscera Labs to engage with the FDA on key elements of its pre-clinical development strategy, manufacturing plans, and proposed IND-enabling activities as the company explores a potential Phase 2 clinical trial.

“This is an important milestone for Viscera Labs and reflects the progress our team has made in advancing our lead program,” said JP Benya, Chief Executive Officer of Viscera Labs. “We look forward to constructive dialogue with the FDA as we work to bring VL-001 to patients suffering with bile acid diarrhea.”

Viscera Labs’ lead program is focused on addressing bile acid diarrhea (BAD), a chronic and often underdiagnosed gastrointestinal disorder associated with excess bile acids entering the colon and causing debilitating symptoms including urgent diarrhea, abdominal pain, bloating, and impaired quality of life. BAD is estimated to affect over 2.2 million patients in the United States including up to one-third of patients diagnosed with irritable bowel syndrome with diarrhea (IBS-D). Despite the significant patient burden, current treatment options remain limited and are frequently associated with poor tolerability and compliance, underscoring the need for more targeted and effective therapeutic approaches.

The pre-IND meeting is a formal regulatory interaction that enables sponsors to obtain FDA guidance before submitting an Investigational New Drug (IND) application. Feedback received during the meeting is expected to help inform the design and execution of the company’s development plans.

Viscera Labs continues to advance its proprietary platform focused on developing targeted therapies for serious diseases with high unmet need.

About Viscera Labs

Viscera Labs is an innovative pharmaceutical company focused on developing novel and cost-effective therapeutic agents for bile acid-mediated disorders.

About VL-001

VL-001 is a novel delayed-release formulation of colesevelam that is being developed for the treatment of bile acid diarrhea.

Forward-Looking Statements

This press release contains forward-looking statements regarding the future development, regulatory progress, and potential commercialization of Viscera Labs' product candidates. These statements are based on current expectations and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied, including risks related to regulatory interactions, clinical development, manufacturing, financing, and other factors. Viscera Labs undertakes no obligation to update forward-looking statements except as required by law.

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