

ALIGOS

THERAPEUTICS

ALG-055009: Phase 2a HERALD Topline Data

September 2024



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Our Portfolio of Potential Best-in-Class Drug Candidates Will Drive Value

ALG-055009 for MASH

- ✓ Phase 2a HERALD enrollment completed in May 2024
- ✓ Positive Phase 2a HERALD topline safety and MRI-PDF data readout ahead of schedule in Q3 2024

ALG-000184 for CHB

- ✓ Greater DNA suppression observed vs. NAs
- ✓ Phase 1b study is ongoing with interim data readouts at APASL, EASL
- ✓ Clear regulatory path forward for chronic suppressive therapy with superiority label with the FDA & CDE
- Additional interim data readouts expected at AASLD
- Receive approval from the National Medical Products Administration in China to begin Phase 1b exploratory combination study with Phase 1b exploratory combination study with Amoytop (Mipeginterferon alfa-2b)
- Phase 2 enabling activities ongoing; planned Phase 2 IND filing in Q1 2025

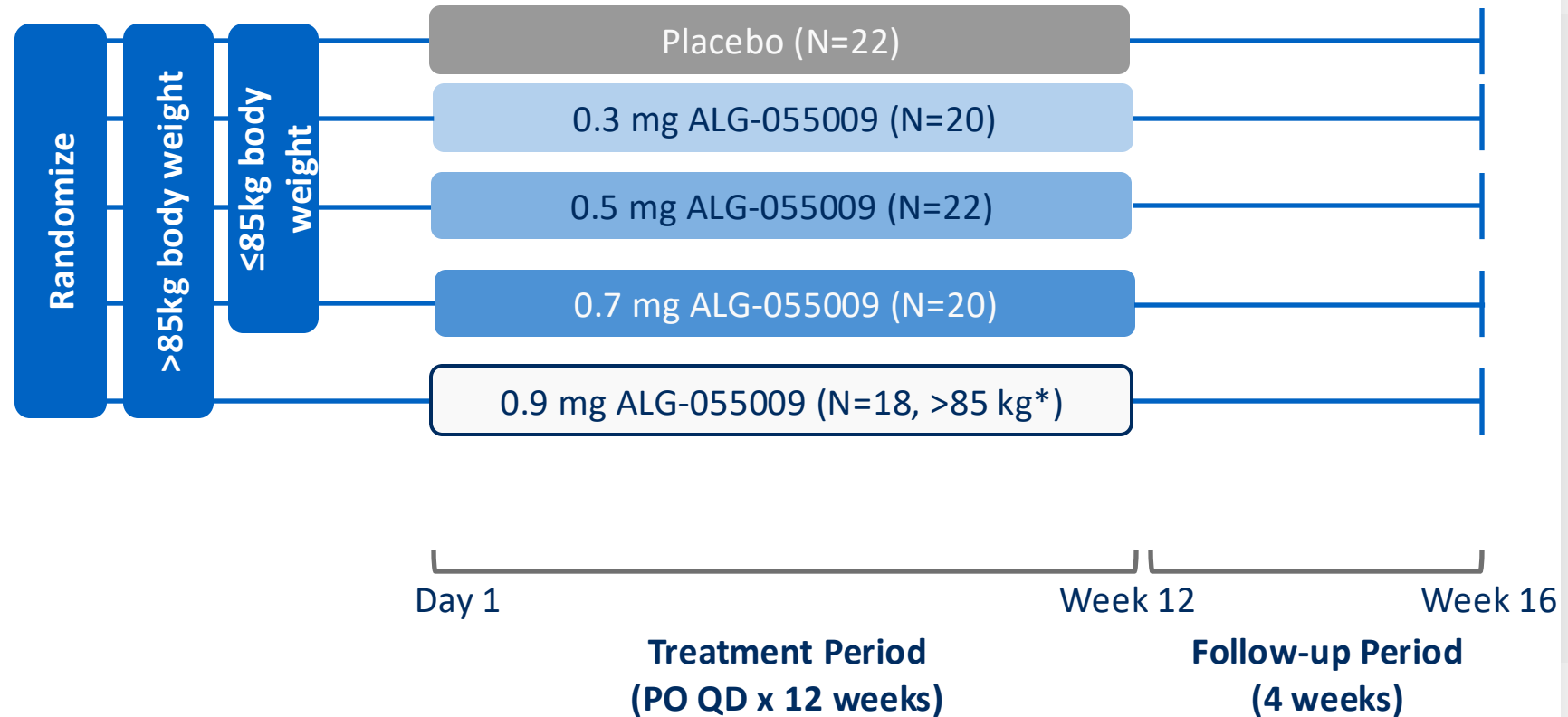
ALG-097558 for Pan-Coronavirus

- ✓ Phase 1 FIH topline data presented April 2024
- Phase 2 enabling activities (externally funded) ongoing
- ALG-097558 is expected to begin two clinical trials in Q4 2024
 - AGILE, a UK government supported organization, will sponsor and perform a study in high-risk COVID patients evaluating ALG-097558 as monotherapy or in combination with remdesivir
 - The NIAID will sponsor a clinical study in special populations (renal/hepatic impairment subjects) evaluating pharmacokinetic (PK) differences

ALG-055009

Phase 2a HERALD study design

- **Population:** 102 adult subjects with MASH and liver fibrosis (F1-F3)
- **Primary endpoint:** Relative change in liver fat content by MRI-PDFF at Week 12
- **Principal Investigator:** Dr. Rohit Loomba



NCT06342947.

HERALD: Baseline Characteristics Generally Balanced Across Arms

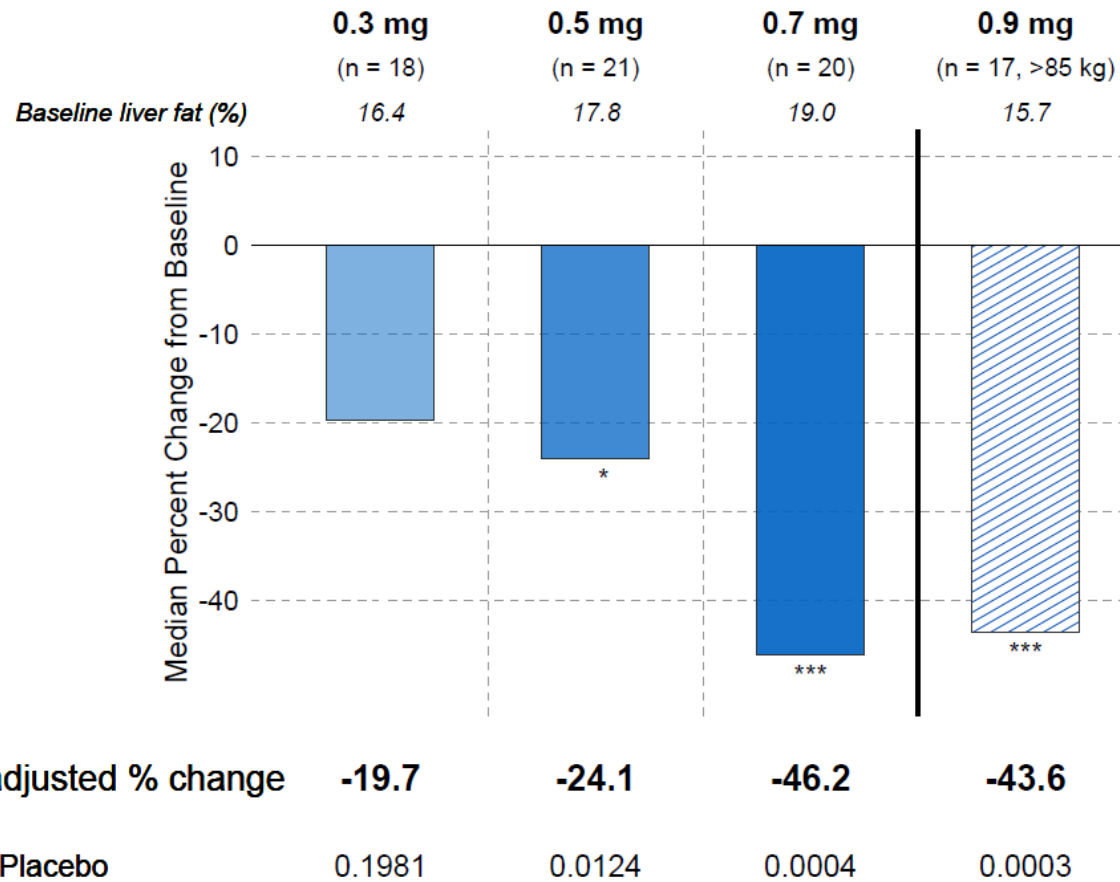
Consistent with today's at-risk MASH population

	Placebo (N=22)	ALG-055009			
		0.3 mg (N=20)	0.5 mg (N=22)	0.7 mg (N=20)	0.9 mg* (N=18, >85 kg)
Age, mean (years)	48.5	53.3	49.5	51.4	48.1
Female, n (%)	21 (95.5)	12 (60.0)	8 (36.4)	14 (70.0)	8 (44.4)
Hispanic, n (%)	13 (59.1)	9 (45.0)	8 (36.4)	8 (40.0)	9 (50.0)
BMI, mean (kg/m ²)	42.1	37.8	39.0	37.4	40.2
Weight, mean (kg)	109.1	107.0	115.2	106.4	116.5*
MRI-PDFF, mean (%)	18.6	18.2	17.9	19.4	19.0
Type 2 Diabetes, n (%)	11 (50.0)	9 (45.0)	10 (45.5)	10 (50.0)	7 (38.9)
GLP-1 Agonists, n (%)	4 (18.2)	3 (15.0)	6 (27.3)	5 (25.0)	1 (5.6)
Statins, n (%)	4 (18.2)	11 (55.0)	6 (27.3)	8 (40.0)	6 (33.3)
ALT, mean (U/L)	39.5	39.9	53.0	38.3	38.5

BMI = body mass index; ALT = alanine aminotransferase; GLP-1 = glucagon-like peptide-1; BW = body weight

HERALD: Primary Endpoint Achieved

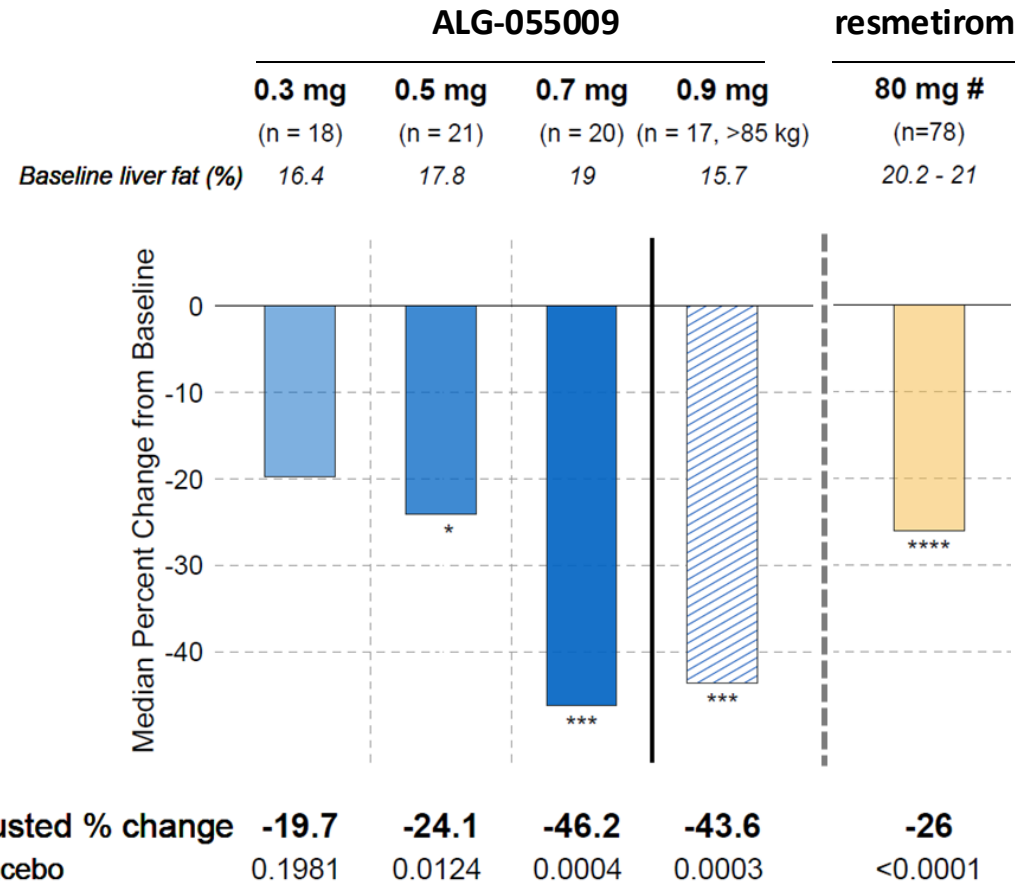
Placebo-adjusted median relative change in liver fat at Week 12



Note: Only subjects weighing >85 kg were enrolled in the 0.9 mg dose group, no body weight restrictions were implemented in other dose groups. Data from MRI-PDFF analysis dataset, defined as all randomized subjects who have MRI-PDFF measurements available at both baseline and Week 12; median % change in placebo was +7.2%; *p<0.05 ***p<0.001.

ALG-055009 Demonstrated Significant Improvements in Liver Fat

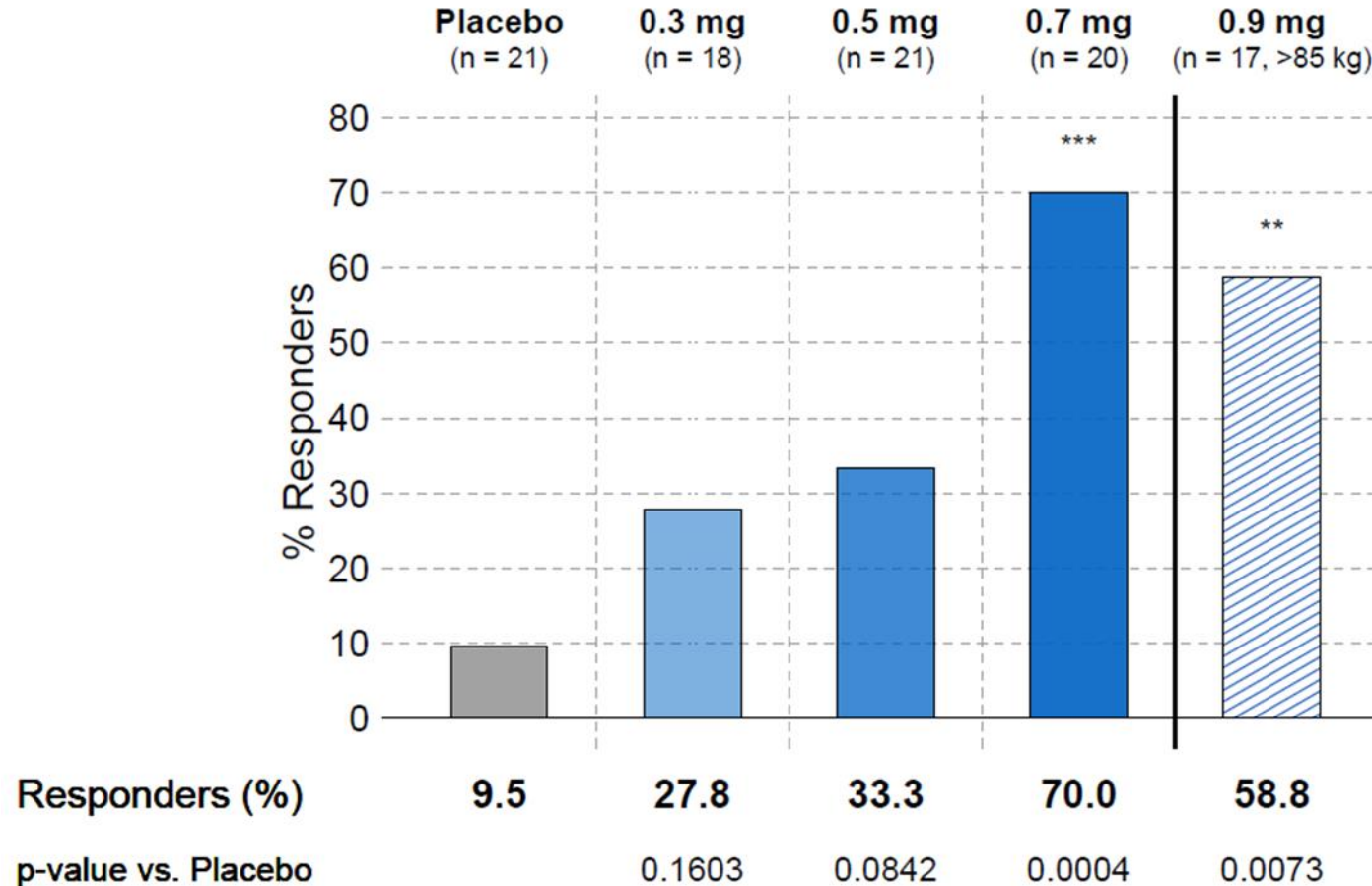
Placebo-adjusted median relative percent change in liver fat at Week 12[^]



[^]Includes publicly reported data from the placebo-controlled Phase 2 trial of Resmetirom in a similar patient population conducted with different protocols at different sites and at different times from HERALD. No head-to-head clinical trials have been conducted. Resmetirom data: Figure 2 of Harrison et al. Lancet 2019: 2012-24. There are differences in study protocols, conditions, patient populations and reporting standards. Caution should be exercised when comparing data across trials. HERALD: only subjects weighing >85 kg were enrolled in the 0.9 mg dose group; no body weight restrictions were implemented in other dose groups. # ± 20 mg possible dose adjustment at Week 4. *p<0.05 ***p<0.001 ****p<0.0001.

HERALD: Significant MRI-PDFF Response Rates at Week 12

Up to 70% of patients achieved $\geq 30\%$ relative reduction in liver fat

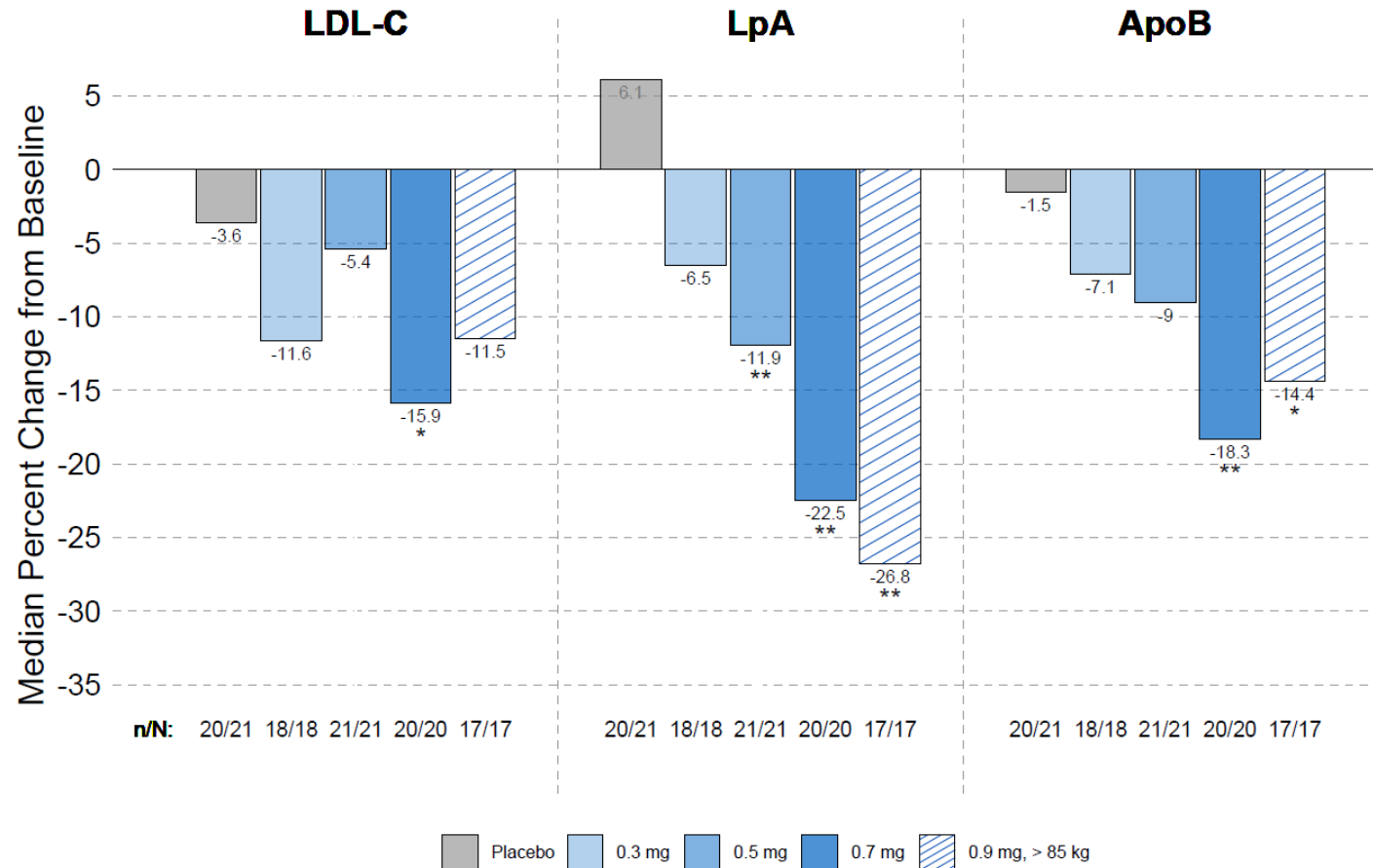


1. Loomba et al. Hepatology (2021). **p<0.01 ***p<0.001.

Only subjects weighing >85 kg were enrolled in the 0.9 mg dose group; no body weight restrictions were implemented in other dose groups.

ALG-055009 Demonstrated Improvements in Lipid/Lipoproteins

Median percent change from baseline at Week 12



LDL-C = low density lipoprotein cholesterol; LpA = lipoprotein (a); ApoB = apolipoprotein B; n: number of subjects with available data at week 12; N: number of subjects in MRI-PDF analysis set; *p<0.05 **p<0.01. Only subjects weighing >85 kg were enrolled in the 0.9 mg dose group; no body weight restrictions were implemented in other dose groups.

HERALD: Favorable Tolerability Profile

Study remains blinded

- Generally well tolerated, with no dose reductions
- No serious adverse events
- One discontinuation due to a treatment emergent adverse event (TEAE) of worsening insomnia in a subject with pre-existing insomnia
- Majority of the TEAEs (98%) were mild or moderate
- Less diarrhea noted for active dose groups compared to placebo, with no dose-response
- No evidence of clinical hypo/hyperthyroidism
- No clinically meaningful findings in laboratory tests, electrocardiograms, vital signs, or physical examinations were observed

HERALD Phase 2a Study

ALG-055009 continues to demonstrate the potential to be the best-in-class THR- β agonist

- **Primary endpoint achieved, with robust reductions in liver fat content at Week 12**
 - Up to 46% placebo-adjusted median reductions from baseline
 - Up to 70% of patients with $\geq 30\%$ decrease in liver fat
- **Significant reductions in atherogenic lipids, including LDL-C, lipoprotein (a) and apolipoprotein B**
- **Dose-dependent increases in SHBG (marker of THR- β activation)**
- **Well-tolerated, with rates of GI-related AEs similar to placebo**
 - No serious AEs and 1 study drug discontinuation (1/102 or 1% of patients)
 - Majority of TEAEs (98%) mild or moderate
 - Less diarrhea noted for active dose groups compared to placebo, with no dose-response
- **ALG-055009 warrants further development**
 - Phase 2b enabling activities underway; expected completion middle of 2025
 - Assessing potential Phase 2b clinical trial study designs with KOLs, and plan to consult with the FDA
 - Early discussions with partners underway; evaluating a variety of options to fund continued development

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