

Long-term Dosing with ALG-000184 in HBeAg Positive Subjects Results in Unprecedented Multi-log Reductions in HBV Markers Including HBsAg

> Lawrence M. Blatt, PhD Founder, CEO and Chairman HEP DART December 5th, 2023

I am an employee and stockholder of Aligos Therapeutics, Inc.

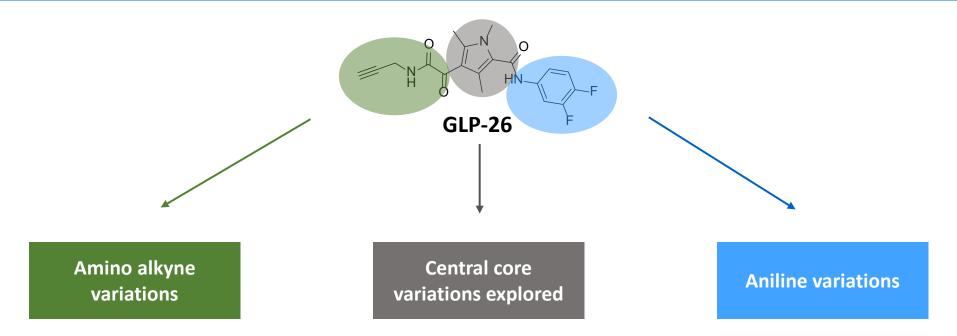
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This presentation concerns drug candidates, some of which are undergoing nonclinical studies and others of which are under clinical investigation, and all of which have not yet been approved for marketing by the U.S. Food and Drug Administration. These drug candidates are currently limited by federal law to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

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Capsid Assembly Modulator Estate Advanced in Collaboration with Professor Raymond Schinazi (Emory University)

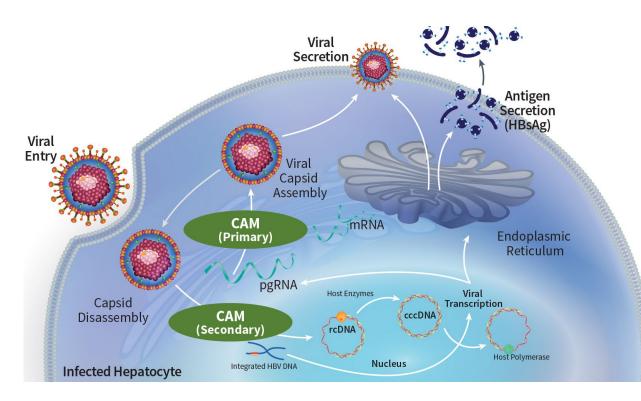


- ALG-001075 was discovered and advanced preclinically as a highly potent CAM-E (picomolar EC₅₀)
- ALG-000184, a highly soluble prodrug of ALG-001075, demonstrated improved DMPK properties
- ALG-000184 has been well tolerated in Phase 1 in CHB subjects (dosing ≤48 weeks)
- Phase 2 enabling activities for ALG-000184 are currently underway

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Hepatitis B Virus Treatment The Dual Role of Capsid Assembly Modulators (CAMs)

- Two mechanisms of action (MoA) can be demonstrated preclinically
 - Primary mechanism
 - Promotes the premature assembly of core protein, leading to the formation of empty capsids
 - Responsible for the deep reductions of HBV DNA and RNA observed clinically with CAMs
 - Secondary mechanism
 - Requires ~10-fold higher drug concentrations
 - Prevents the establishment / replenishment of cccDNA, which produces HBcrAg, HBeAg, and (some of) HBsAg
- 1st generation CAMs in development
 - Demonstrated DNA, RNA reductions (1st MoA)
 - No clear evidence of effects on cccDNA (2nd MoA)



Observing both mechanisms clinically requires potent compounds with excellent PK properties



ALG-000184 In Vitro Superior Potency vs. Competitor CAM-Es

Compound	Current Status	HBV DNA reduction (EC ₅₀ nM)	Cell Type	
Aligos ALG-000184	Dhace 4	0.63	HepG2.117	
	Phase 1	0.53	HepG2.2.15	-2 nd
Assembly ABI-4334	Phase 1	1.2	AD38	Gen
Assembly ABI-H3733	Partnered, BeiGene	5	AD38	
Enanta EDP-514	Phase 1	17	HepG2.115	
Vebicorvir	Discontinued	172	AD38	_1 st
Janssen JNJ-6379	Discontinued	54	HepG2.117	Gen
Arbutus AB-836	Discontinued	10	HepDE19	

ALG-000184 is generally >25-fold more potent vs. first generation CAM-Es Exposures of ALG-001075 are also enhanced via PK optimization strategies



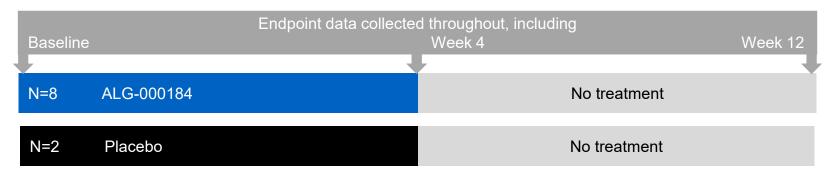
4

ALG-000184-201 Phase 1 Study in HV (Parts 1& 2) and CHB Subjects (Parts 3-5)

Parts 1-3: Complete

- Part 1 (SAD): single oral doses (40, 100, 250 and 500 mg) in HV
- Part 2 (MAD): 7 QD oral doses (150 and 250 mg) in HV
- Part 3: QD oral doses (10-300 mg) x 28 days in treatment naïve (TN)/currently not treated (CNT) CHB

Multiple Doses in Currently Not Treated/Treatment Naïve CHB Subjects HBV DNA > 2000 IU/mL, HBeAg Negative or Positive Up to 6 cohorts (n=10 per Cohort, n=8 ALG-000184, n=2 Placebo) 28 daily oral doses Endpoints: PK, safety, antiviral activity (e.g., DNA, RNA)



Part 1 & 2: Single oral dose ≤500 mg and multiple oral daily doses ≤250 mg x 7 days well tolerated with linear PK in HV Part 3: multiple daily doses ≤300 mg well tolerated with linear PK and excellent antiviral activity (next slides)

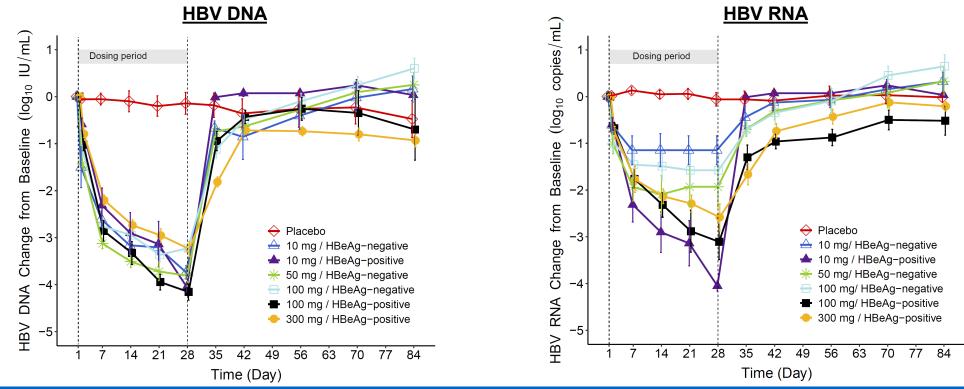


ALG-000184-201 - Part 3 Antiviral Activity Data in CHB Subjects

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Mean (SEM) Serum HBV DNA* and HBV RNA** Levels Change from Baseline Through the End of Study



HBeAg- CHB subjects: Similar HBV DNA reduction for 10, 50 and 100 mg (~3-4 log₁₀ IU/mL) HBV DNA, HBV RNA <LLOQ in ≥75% and 100% of subjects, respectively

HBeAg+ CHB subjects: Potent HBV DNA, HBV RNA reductions observed (10 mg ≈ 100 mg ≈ 300 mg)

*Roche Cobas® HBV DNA (LLOQ = 10 IU/mL). **Roche Cobas® assay (LLOQ =10 copies/mL). **China HBV RNA local assay (LLOQ=200 copies/mL).

ALG-000184 In Vivo Superior Activity vs. Competitor CAMs (HBeAg Negative*)**

Drug Name	Most Advanced Status	Dose	HBV DNA	
			Mean Decline from BL to EOT (Log ₁₀ IU/mL)	% < LLOQ at Day 28
ALG-000184	Phase 1	10 mg	3.7	100
ABI-H0731 ^{1,2}	Phase 2a	300 mg	2.5	25
JNJ-6379 ^{3,4}	Phase 2	250 mg	2.7	56
EDP-514⁵	Phase 1b	200 mg	2.9	N/A
		800 mg	3.4	N/A
AB-836 ⁶	Phase 1	100 mg	3.1	N/A

10 mg ALG-000184 has more potent antiviral activity than competitor CAMs dosed at 100-800 mg

*89% of subjects were HBeAg negative in 250 mg JNJ-6379 arm. An unknown percentage of subjects dosed with 800 mg EDP-514 were HBeAg negative.

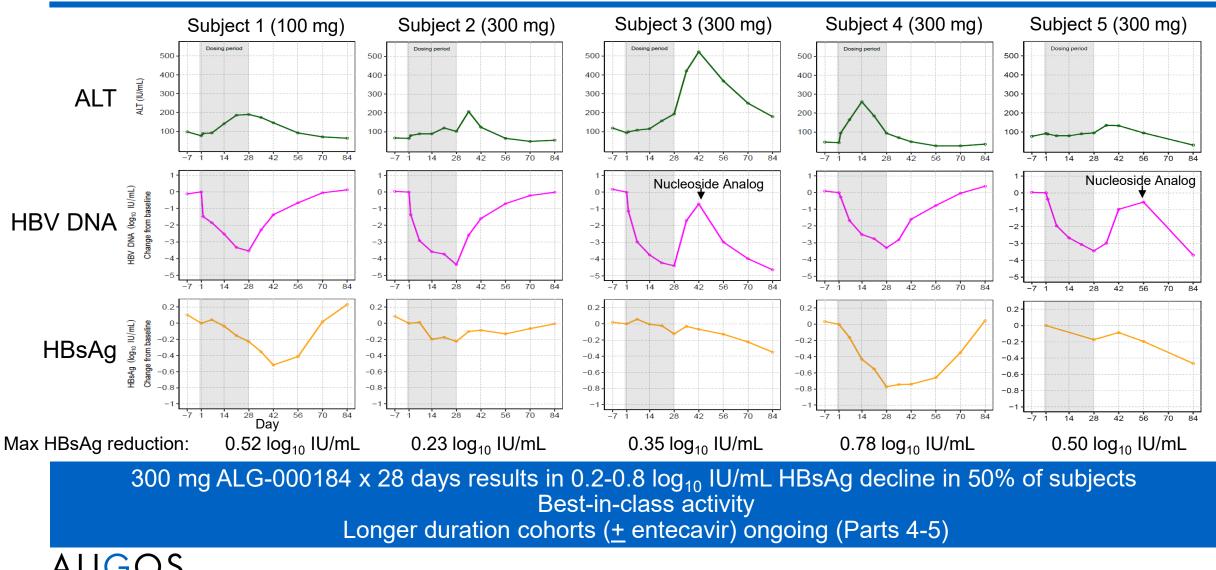
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**The comparisons shown in the table above are not based on data resulting from headto-head trials and are not direct comparisons. Different protocol designs, trial designs, patient selection and populations, number of patients, trial endpoints, trial objectives and other parameters that are not the same between the relevant trials may lead to bias in the results causing comparisons of results from different trials to be unreliable.

N/A – not available. LLOQ (DNA) was ≤20 IU/mL for ABI and JNJ and 10 IU/mL for Aligos. 1. MF Yuen et al. Lancet Gastroenterol Hepatol 2019. 2. MF Yuen AASLD 2018. 3. Zoulim F., et al AASLD 2018. 4. Zoulim F., et al. Gastroenterology 2020. 5. MF Yuen, et al AASLD 2021 (Poster 823). 6. HepDart 2021 (preliminary data).

7

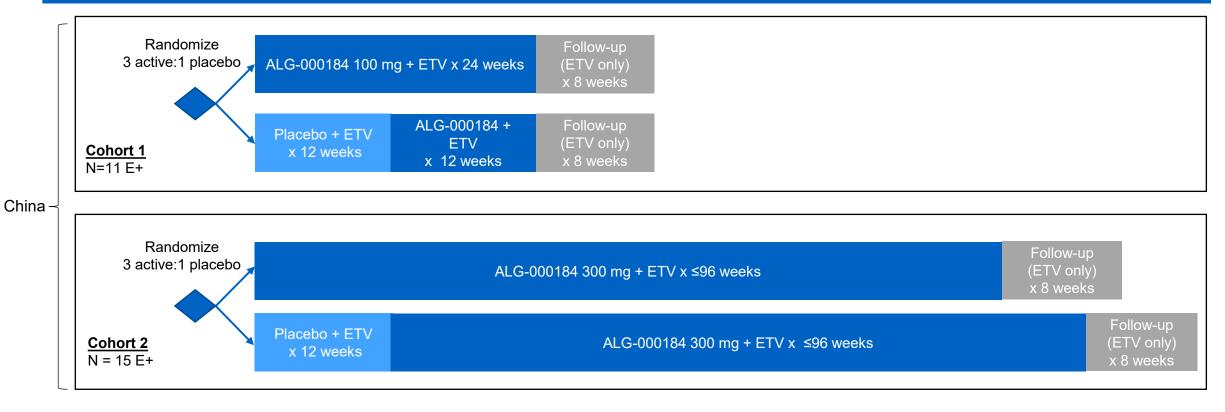
ALG-000184 - Part 3 HBsAg Reductions Observed in 28-Day Monotherapy (HBeAg+)



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Hou et al., Poster #1329, AASLD 2022. NCT04536337. 8

ALG-000184-201 - Part 4 Cohort Designs





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9

ALG-000184-201 - Part 4 Cohort 2 & B Baseline Characteristics

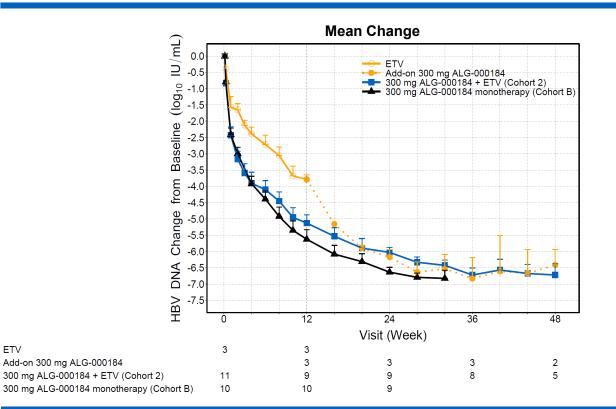
Characteristic	P4C2 (n=15*)	P4CB (n=10)	
Age, years, mean (SEM)	31.4 (3.3)	36.8 (2.9)	
Male, n(%)	8 (53)	7 (70)	
Asian, n(%)	3 (100)	9 (90)	
BMI, kg/m ² , mean (SEM)	22.2 (0.8)	22.4 (0.8)	
HBV Genotype, n(%)	B: 5 (33); C: 10 (67)	B: 5 (50); C: 4 (40); D: 1 (10)	
HBV DNA, log ₁₀ IU/mL, mean (SEM)	8.1 (0.2)	8.0 (0.2)	
HBV RNA, log ₁₀ copies/mL, mean (SEM)	6.7 (0.3)	5.3 (0.4)	
HBsAg, log ₁₀ IU/mL, mean (SEM)	4.4 (0.2)	4.3 (0.1)	
HBeAg, log ₁₀ PEI U/mL, mean (SEM)	2.4 (0.1)	2.6 (0.3)	
HBcrAg, log ₁₀ U/mL, mean (SEM)	8.3 (0.3)	8.3 (0.2)	
ALT, U/L, mean (SEM)	38.7 (5.2)	60.7 (11.7)	

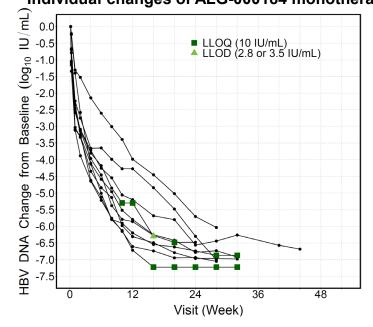
SEM: standard error of mean. *Three subjects prematurely discontinued due to non-safety related personal reasons (n=2) and non-compliance of dosing (n=1)

Baseline characteristics were comparable and typical for a HBeAg+ population 53% of subjects with normal baseline ALT levels in P4C2 compared to only 10% in P4CB



ALG-000184-201 - Antiviral Effect: Part 4 Cohort 2 & B HBV DNA Change from Baseline





Individual changes of ALG-000184 monotherapy

300 mg ALG-000184±ETV

- Showed greater HBV DNA reduction than ETV monotherapy

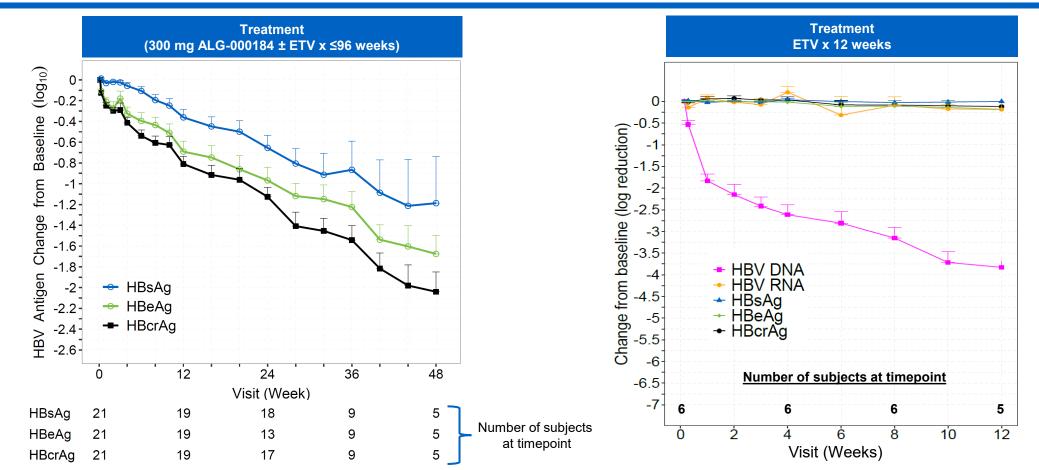
- Achieved similar DNA reductions

No viral breakthrough was observed in ALG-000184 monotherapy $x \leq 44$ weeks



ETV

ALG-000184-201 - Antiviral Effect: Part 4 Cohort 2 & B HBV Antigen Change from Baseline

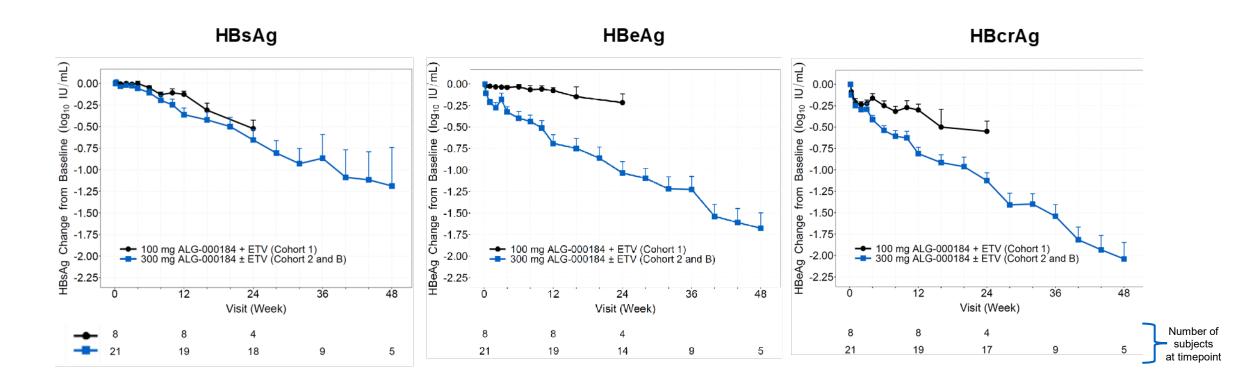


Substantial HBsAg, HBeAg, and HBcrAg reductions seen with combo Max declines: 2.0, 2.1 and 2.5 log₁₀, respectively ETV alone only impacted HBV DNA; no impact on HBV RNA or antigens

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Graph plots subjects initially randomized to ALG-000184 <u>+</u> ETV and were compliant (confirmed by PK)

ALG-000184-201 - Antiviral Effect: Part 4 Cohorts 1 vs. 2 HBV Antigen Change from Baseline



ALG-000184 treatment results in dose-dependent HBV antigen declines



Safety Overview Treatment Emergent Adverse Events

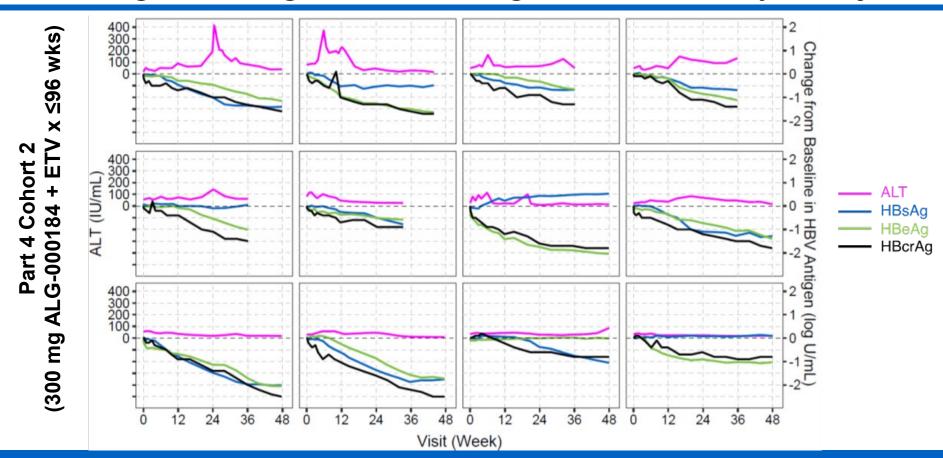
300 mg ALG-000184 +/- ETV	Part 4 Cohort 2 (n=15)	Part 4 Cohort B (n=10)	
Serious Adverse Events (SAEs)	None		
Treatment emergent AEs (TEAEs) leading to study drug discontinuation	None		
Subjects with Grade ≥3 TEAEs	2 ALT/AST↑ (n=2) neutropenia↑ (n=1)*	3 ALT/AST↑	
Concerning TEAE, laboratory, ECG, vital sign, or physical examination findings or trends	None		

- Neutropenia considered probably related to an acute upper respiratory infection and resolved following resolution of this infection in the setting of continued dosing with study drug
- Five Grade ≥3 TEAEs of liver transaminase elevations were transient, resolved on study drug, and were associated with decline in antigens. None were considered clinically concerning by the AFC.

A favorable safety profile was observed in untreated HBeAg+ CHB subjects with long term (\leq 48 weeks) treatment with 300 mg ALG-000184 ± ETV

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Antiviral Effect ALT, HBsAg, HBeAg and HBcrAg Over Time by Subject – P4C2



All subjects (n=12) observed HBcrAg declines after receiving 300 mg ALG-000184 + ETV x \ge 12 weeks 11/12 had HBeAg declines and 9/12 had HBsAg reductions

ALT flares seen in context of antiviral activity (antigen declines); resolve while continuing ALG-000184

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ALG-000184

Unprecedented Antiviral Activity with a Favorable Safety Profile

- Oral dosing with 300 mg ALG-000184±ETV x ≤48 weeks in untreated HBeAg+ CHB subjects results in:
 - A favorable safety profile
 - ALG-000184 \pm ETV shows greater suppression of HBV DNA/RNA vs. ETV alone (1st MoA)
 - No viral breakthrough when ALG-000184 is given as monotherapy x ≤44 weeks
 - Multi-log reductions in HBsAg, HBeAg and HBcrAg, which may be mediated by ALG-000184 (2nd MoA)
- ALG-000184 may play an important role in enhancing rates of chronic suppression (superior/non-inferior to NAs) and functional cure
- Dosing is ongoing ≤96 week cohorts
- Phase 2 enabling activities are underway



Acknowledgements



Thanks to the entire Aligos and Emory teams!

