### INTRODUCTION

- Worldwide, more than 296 million people are affected by Chronic Hepatitis B (CHB) and approximately 820,000 people per year die from cirrhosis and hepatocellular carcinoma (HCC) due to CHB.
- Long-term treatment with standard care for CHB, nucleos(t)ide analogues, suppresses HBV replication and reduces liver injury in most patients, but only results in functional cure, the goal of CHB treatment. Therefore, there is a significant medical need for novel approaches to enhance cure rates.

### METHODS

**ALG-000184** is a pan-genotypic Class II CAPCAM (empty capsid) with piconomial potency. ALG-000184 is being developed as a chronic regimen to achieve higher rates of functional cure and as a potential component of a finite duration combination suppressive therapy in CHB subjects with high HBV DNA titers and because the subject did not attend Day 28 visit due to COVID lockdown (N=1).

### SAFETY

#### BASELINE CHARACTERISTICS

<table>
<thead>
<tr>
<th>Dose level</th>
<th>N (%): 100 mg ALG-000184/PBO</th>
<th>50 mg ALG-000184/PBO</th>
<th>10 mg ALG-000184/PBO</th>
<th>N (%): 10 mg ALG-000184/PBO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug:</td>
<td>6 (100)</td>
<td>6 (100)</td>
<td>5/6a (83)</td>
<td>0/0 (0)</td>
</tr>
<tr>
<td>ALT Flare:</td>
<td>4/6a (67)</td>
<td>5/6a (83)</td>
<td>0/0 (0)</td>
<td>N/A</td>
</tr>
<tr>
<td>DNA:</td>
<td>0.14 (0.4)</td>
<td>0.4 (0.4)</td>
<td>0.3 (0.1)</td>
<td>0.4 (0.4)</td>
</tr>
<tr>
<td>RNA:</td>
<td>0.2 (0.2)</td>
<td>0.2 (0.2)</td>
<td>0.2 (0.2)</td>
<td>0.4 (0.4)</td>
</tr>
</tbody>
</table>

#### ANTIVIRAL ACTIVITY

Among HBeAg negative subjects, the 10 mg, 50 mg, and 100 mg dose levels were associated with comparable declines in DNA (3.2-3.8 log10 IU/mL) and RNA (1.1-1.9 log10 copies/mL).

### PHARMACOKINETICS

- Plasma ALG-000184 exposure increased proportionally with low PK variability.
- Minimal accumulation (~30%) was seen with dosing x 28 days of therapy.

### CONCLUSIONS

- Oral daily dosing for 28 days with 10 mg, 50 mg, and 100 mg of ALG-000184/placebo was generally well tolerated.
- Similar rapid declines in HBV DNA and HBV RNA were observed at all dose levels, regardless of HBeAg status.

### ACKNOWLEDGEMENTS

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### REFERENCES


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