



Enrollment Criteria (Adult)

Patient ID ___ - ___ ID ___ - ___

Date of Determination: **ERLDATE**

Check if rescreen: **RSC**

SECTION I: INCLUSION CRITERIA

1. Patient is enrolled in and completed the baseline evaluation for the HBRN Cohort Study INCOHORT	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. Patient is ≥ 18 years of age at the time of randomization INAGEIT Patients > 50 years of age at randomization will need to have a liver biopsy as standard of care with HAI ≤ 3 and Ishak fibrosis score ≤ 1 within 24 weeks prior to randomization. AGE50 <input type="checkbox"/> Patient >50 year of age: Biopsy: HAI HAIAGE Ishak score ISHAKAGE BIOPAM/D/Y (mm/dd/yy)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3. Documented chronic HBV infection as evidenced by detection of HBsAg in serum for at least 24 weeks prior to randomization OR at least one positive HBsAg and negative anti-HBc IgM within 24 weeks prior to randomization INCHB	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4. Presence of HBeAg in serum at the last screening visit within 6 weeks of randomization AND for at least 24 weeks prior to randomization INHBE	<input type="checkbox"/> Yes	<input type="checkbox"/> No
5. Serum HBV DNA >10 ⁷ IU/mL on at least 2 occasions drawn at least 12 weeks apart during the 52 weeks before randomization. The HBV DNA from the last of the screening visits (within 6 weeks of randomization) can be used to meet this criterion. INDNA HBV DNA results: Level (IU/mL) Date (mm/dd/yy) Lower limit of detection BDNA1 BDNA1M/D/Y BDNALL1 BDNA2 BDNA2M/D/Y BDNALL2	<input type="checkbox"/> Yes	<input type="checkbox"/> No
6. ALT levels persistently ≤ 60 IU/L for males and ≤ 40 IU/L for females (approximately 2.0 times the upper limit of the normal range) as documented by at least three measurements: one taken 24-52 weeks before randomization; one taken 6-24 weeks before randomization; and the final value taken within 6 weeks of randomization. For patients with one of three ALT values 61-90 in males and 41-60 in females, a biopsy done as standard of care with HAI ≤3 and Ishak fibrosis score ≤1 within 24 weeks prior to randomization is required. INALT ALT result 24-52 weeks prior: ALT48 IU/L ALT48M/D/Y (mm/dd/yy) ALT result 6-24 weeks prior: ALT24 IU/L ALT24M/D/Y (mm/dd/yy) ALT result within 6 weeks: ALT6 IU/L ALT6M/D/Y (mm/dd/yy) Biopsy: HAI ___ HAI ___ Ishak score ___ ISHAK ___ BIOPM/D/Y (mm/dd/yy) <input type="checkbox"/> Not done	<input type="checkbox"/> Yes	<input type="checkbox"/> No
7. No evidence of HCC based upon AFP ≤ 20ng/mL at screening visit (up to 6 weeks prior to randomization): NOHCC a) Participants who meet AASLD criteria for HCC surveillance must have negative liver imaging as shown by US, CT or MRI within 24 weeks of randomization as part of standard of care. Imaging within 24 weeks IMAGM/D/Y (mm/dd/yy) b) Participants with AFP > 20 ng/mL must be evaluated clinically with additional imaging and shown not to have HCC on CT or MRI before they can be randomized.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
8. Patient has provided written informed consent ITCONS	<input type="checkbox"/> Yes	<input type="checkbox"/> No

SECTION II: EXCLUSION CRITERIA

1. Any history of hepatic decompensation, including but not limited to ascites, variceal bleeding, or hepatic encephalopathy ITHDC	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. Evidence of decompensated liver disease prior to or during screening, including direct bilirubin >0.5 mg/dL, INR >1.5, serum albumin <3.5 g/dL DECOMP	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3. Platelet count <120,000/mm ³ , hemoglobin <13 g/dL (males) or <12 g/dL (females), ANC <1500/mm ³ (<1000/mm ³ for African Americans) during the screening period EXLAB	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4. Previous treatment with medications that have established activity against HBV including but not limited to interferon and nucleos(t)ide analogs ≥ 24 weeks. Patients with < 24 weeks of prior HBV treatment and a wash-out period >24 weeks are not excluded. Brief and episodic use of famciclovir or valacyclovir for herpes infection is not exclusionary. TXNAIVE	<input type="checkbox"/> Yes	<input type="checkbox"/> No
5. Known allergy or intolerance to the study medications EXALGY	<input type="checkbox"/> Yes	<input type="checkbox"/> No



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6. Female patient who is pregnant or breastfeeding EXPREG	<input type="checkbox"/> Yes	<input type="checkbox"/> No or N/A
7. Female patient of childbearing potential unable or unwilling to use a reliable method of contraception during treatment EXCONT <input type="checkbox"/> check if female patient not of child bearing potential NOCHILD	<input type="checkbox"/> Yes	<input type="checkbox"/> No or N/A
8. Renal insufficiency with calculated creatinine clearance < 50 mL/min EXRENAL	<input type="checkbox"/> Yes	<input type="checkbox"/> No
9. History of alcohol or drug abuse within 48 weeks of randomization EXALC	<input type="checkbox"/> Yes	<input type="checkbox"/> No
10. Previous liver or other organ transplantation including engrafted bone marrow transplant EXTX	<input type="checkbox"/> Yes	<input type="checkbox"/> No
11. Any other concomitant liver disease, including but not limited to hepatitis C or D. Non-alcoholic fatty liver disease (NAFLD) with steatosis and/or mild to moderate steatohepatitis is acceptable but NALFD with severe steatohepatitis is exclusionary. OTHLVDX	<input type="checkbox"/> Yes	<input type="checkbox"/> No
12. Presence of anti-HDV or anti-HCV (unless HCV RNA negative) in serum on any occasion in the 96 weeks prior to randomization OTHVIRDx	<input type="checkbox"/> Yes	<input type="checkbox"/> No
13. Presence of anti-HIV (test to be completed within the 6 weeks prior to randomization) EXHIV	<input type="checkbox"/> Yes	<input type="checkbox"/> No
14. Pre-existing psychiatric condition(s) including but not limited to: EXPSY a) Current moderate or severe depression as determined by the study physician b) History of depression requiring hospitalization within the past 10 years c) History of suicidal or homicidal attempt within the past 10 years d) History of severe psychiatric disorders including but not limited to schizophrenia, psychosis, or bipolar disorder, as determined by a study physician.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
15. History of immune-mediated or cerebrovascular disease, chronic pulmonary or cardiac disease associated with functional limitation, retinopathy, uncontrolled thyroid disease, poorly controlled diabetes or uncontrolled seizure disorder, as determined by the study physician OTHDX	<input type="checkbox"/> Yes	<input type="checkbox"/> No
16. Any medical condition requiring or likely to require chronic systemic administration of corticosteroids or other immunosuppressive medications during the course of the study IMMTX	<input type="checkbox"/> Yes	<input type="checkbox"/> No
17. Evidence of active or suspected malignancy, or a history of malignancy within the last 144 weeks prior to randomization (except adequately treated carcinoma in situ and basal cell carcinoma of the skin) EXCANC	<input type="checkbox"/> Yes	<input type="checkbox"/> No
18. Expected need for ongoing use of any antivirals with activity against HBV during the course of the study ANTIVTX	<input type="checkbox"/> Yes	<input type="checkbox"/> No
19. Concomitant use of complementary or alternative medications purported to have antiviral activity HERBAL	<input type="checkbox"/> Yes	<input type="checkbox"/> No
20. Participation in any other clinical trial involving investigational drugs within 30 days of randomization or intention to participate in another clinical trial involving investigational drugs during participation in this study INVRX2	<input type="checkbox"/> Yes	<input type="checkbox"/> No
21. Any medical condition that would, in the opinion of the study physician, be predicted to be exacerbated by therapy or that would limit study participation EXDXPI	<input type="checkbox"/> Yes	<input type="checkbox"/> No
22. Any other condition or situation that, in the opinion of the study physician, would make the patient unsuitable for enrollment or could interfere with the patient participating in and completing the study? PIOTH If Yes, specify _____ PIOTHS	<input type="checkbox"/> Yes	<input type="checkbox"/> No

If the responses to all inclusion criteria are YES and all exclusion criteria are NO, the patient is eligible to participate in the Immune Tolerant Trial.

Is the patient eligible to participate in the Immune Tolerant trial? Yes No **ENROLLIT**

Investigator signature: _____

Data collector initials: **DCID**

Date data collection completed (mm/dd/yy): **DCM / DCD / DCY**