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Brii Biosciences advances mRNA cancer vaccine into clinical evaluation for liver cancer

August 21, 2026 | News

The company has dosed the first participant with BRII-5395 in a study evaluating the mRNA therapeutic vaccine with anti-PD-1 and anti-VEGF therapies in advanced hepatocellular carcinoma.

Brii Biosciences has advanced its internally developed mRNA therapeutic cancer vaccine BRII-5395 into clinical evaluation in patients with advanced hepatocellular carcinoma.

The first participant was dosed on 12 August 2026 in a study being conducted at the Cancer Hospital of the Chinese Academy of Medical Sciences.

BRII-5395 is being evaluated as part of a combination immunotherapy approach together with an anti-PD-1 antibody and an anti-VEGF antibody.

The study is designed to assess safety, tolerability, immunogenicity and preliminary antitumour activity.

BRII-5395 is the first internally developed mRNA-based cancer therapeutic vaccine from Brii Biosciences to enter clinical evaluation.

The programme expands the company’s RNA technology platform beyond infectious diseases and into oncology.

Brii said the candidate is being developed for hepatitis B virus-related hepatocellular carcinoma, where existing immune checkpoint inhibitor-based treatment approaches still leave significant unmet need.

The company is also continuing development of its hepatitis B functional cure portfolio.

During the first half of 2026, Brii generated additional clinical data from its HBV programmes and plans to present detailed findings from the ENRICH and ENHANCE studies during the second half of the year.

Brii disclosed that a commercial assay kit used for HBsAg testing in part of the ENHANCE study was subject to a recall by one of its laboratory providers.

The company said its preliminary assessment suggests the potential impact is limited to end-of-treatment HBsAg data from Part A-2 of the study and that affected samples are being identified for retesting.

Brii said it has not identified evidence that the issue materially changes its overall interpretation of the programme to date.

The advancement of BRII-5395 into the clinic represents a broader expansion of the company's RNA platform into cancer immunotherapy while its HBV programmes continue towards additional clinical readouts.