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Brii Biosciences Limited
騰盛博藥生物科技有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2137)

VOLUNTARY ANNOUNCEMENT

Presents Late-Breaking Data from Ongoing Phase 2 ENSURE Study at AASLD 2025

This announcement is made by the board of directors (the “**Board**”) of Brii Biosciences Limited (the “**Company**”) on a voluntary basis.

The Board is pleased to announce the 24-week post end of treatment (“**EOT**”) follow-up results from Cohort 4 of its ongoing Phase 2 ENSURE study. These late-breaking data were presented at the American Association for the Study of Liver Diseases (“**AASLD**”) The Liver Meeting®, held in Washington D.C. from November 7-11, 2025, and were simultaneously published in Nature Medicine.

ENSURE (NCT05970289) is a multicenter, open-label Phase 2 study in the Asia-Pacific region. Cohort 4 evaluates a novel sequential combination treatment strategy for hepatitis B virus (“**HBV**”), utilizing the Company’s therapeutic vaccine, BRII-179, to prime and enrich patients, with a goal to improve responsiveness to therapies potentially offering a functional cure. Participants previously treated with nine doses of elebsiran and BRII-179 treatment in a prior Phase 2 study BRII-179-835-001 (NCT04749368) were enrolled to this cohort to receive 48 weeks of combination treatment with elebsiran and PEG-IFN α . These participants were categorized as BRII-179 anti-HBs responders or non-responders based on their peak hepatitis B surface antibody (“**anti-HBs**”) levels during the prior study (≥ 10 IU/L or < 10 IU/L, respectively).

EOT data from Cohort 4 were previously presented at the European Association for the Study of the Liver (EASL) Congress 2025. The newly reported data confirm that the hepatitis B surface antigen (“**HBsAg**”) loss benefit in the BRII-179 responder group was sustained over time. At EOT, 58% (11/19) HBsAg loss was observed in BRII-179 anti-HBs responders. In anti-HBs non-responders, only 17% (2/12) achieved HBsAg loss. At 24 weeks post EOT, 42% (8/19) of anti-HBs responders maintained HBsAg loss compared to 8% (1/12) of anti-HBs non-responders. 50% (4/8) of anti-HBs responders with sustained HBsAg loss at 24 weeks post EOT had baseline HBsAg levels between 1,514-3,086 IU/mL when enrolled in the previous BRII-179-835-001 study suggesting BRII-179 may elicit anti-HBs responses even in patients with higher baseline surface antigen levels. This supports BRII-179’s potential to improve functional cure outcomes and broaden its applicability across diverse patient populations.

To further define BRII-179's role in treatment of HBV infection and optimize combination regimens for pivotal studies, The Company is conducting two additional Phase 2b trials. The ENRICH study evaluates the role of BRII-179 in priming HBV-specific immunity and/or identifying immuno-responsive patients with a higher likelihood of achieving functional cure. The ENHANCE study includes two parts: one to evaluate the triple combination of BRII-179, elebsiran and PEG-IFN α given concurrently for 48 weeks, and another exploring a sequential approach of BRII-179 and elebsiran for 24 weeks followed by triple combination for 24 weeks, and a 48-week PEG-IFN α control arm. Both studies are fully enrolled, and EOT data are expected to be presented in 2026.

“We are encouraged to see that the difference in HBsAg seroclearance rates observed at EOT was maintained through 24 weeks of follow-up.” said David Margolis, MD, Chief Medical Officer of the Company. “These results support BRII-179's potential to deliver more rapid and durable HBsAg loss and potentially enable a shorter treatment duration of PEG-IFN α . We look forward to validating these findings in our ongoing confirmatory studies.”

Publication Number: 5036

Title: Chronic hepatitis B virus infected participants responding to prior BRII-179 treatment achieved higher rate of sustained hepatitis B virus surface antigen loss on elebsiran plus pegylated interferon alfa: follow-up data from ENSURE study

Presenter: Grace Lai-Hung Wong, MBChB (CUHK), MD (CUHK), FRCP (Lond, Edin), FHKCP, FHKAM (Medicine), Professor of Gastroenterology and Hepatology at CUHK Medical Data Analytics Centre (MDAC) and Department of Medicine and Therapeutics in Hong Kong SAR, China

- A total of 31 participants were analyzed, with 19 BRII-179-induced anti-HBs responders and 12 non-responders.
- Median range HBsAg at baseline of this ENSURE study was numerically higher in anti-HBs responders (520 [34-2,165] IU/mL) than in non-responders (185 [51-672] IU/mL).
- At 24 weeks post EOT, a notably higher rate of HBsAg loss was achieved in BRII-179-induced anti-HBs responders (8/19, 42.1%) compared to non-responders (1/12, 8.3%).
- Although all participants with sustained HBsAg loss had HBsAg < 1,500 IU/mL at baseline of this ENSURE study, 4/8 (50.0%) from anti-HBs responders had baseline HBsAg ranging from 1,514-3,086 IU/mL when enrolled in the previous study, suggesting that BRII-179 may induce anti-HBs responses regardless of baseline HBsAg level.
- The elebsiran and PEG-IFN α combination was generally safe and well-tolerated.

Cautionary Statement: There is no assurance that BRII-179 and elebsiran will ultimately be successfully developed or marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company. When in doubt, shareholders of the Company and potential investors are advised to seek advice from professional or financial advisers.

By order of the Board
Brii Biosciences Limited
Dr. Zhi Hong
Chairman

Hong Kong, November 10, 2025

As at the date of this announcement, the Board comprises Dr. Zhi Hong and Dr. Ankang Li as executive directors; and Dr. Martin J Murphy Jr, Ms. Grace Hui Tang, Mr. Yiu Wa Alec Tsui, Mr. Gregg Huber Alton and Dr. Taiyin Yang as independent non-executive directors.