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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
BUSINESS UPDATE

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 new data demonstrating that the Company’s long-acting COVID-19 neutralizing antibody therapy, the amubarvimab/romlusevimab combination, retains neutralizing activity against the Omicron BA.2 SARS-CoV-2 subvariant.

These data, which were assessed in both in vitro pseudovirus neutralization testing and through live virus neutralization assays conducted at independent laboratories, suggest that exposures of intravenous amubarvimab 1,000mg and romlusevimab 1,000mg are expected to remain above the level required for neutralizing activity against Omicron BA.2 SARS-CoV-2 subvariant, for the treatment of COVID-19 based on the human pharmacokinetic data gathered on the amubarvimab/romlusevimab combination.

Data from the live virus neutralization assay performed at a laboratory certified by the U.S. National Institutes of Health (“**NIH**”) and the National Institute of Allergy and Infectious Diseases (“**NIAID**”) at the University of Maryland suggest that the total serum concentrations of the amubarvimab/romlusevimab combination will remain 60 times of the level required for greater than 90% neutralization (Neut99: 2.50 µg/mL) against the live virus isolate Omicron BA.2 SARS-CoV-2 subvariant after 14 days post-dose period. As a result, even though the mutations found in the Omicron BA.2 SARS-CoV-2 subvariant spike protein increase the half maximal inhibitory concentration (“**IC50**”) relative to wild-type SARS-CoV-2, adequate therapeutic exposures are expected to persist for a minimum of two weeks and longer.

“Omicron BA.2 SARS-CoV-2 subvariant cases now represent the majority of COVID-19 infections globally, so these data offer timely insights into the longevity and durability of the amubarvimab/romlusevimab combination as a potential new tool to help patients in need of more treatment options,” said Dr. David Margolis, M.D., MPH, the Vice President and Head of Infectious Diseases Therapy Area at the Company. “There continues to be a critical need for highly effective therapies against COVID-19 infection, which can greatly reduce the risk of hospitalization and death in individuals at high risk. Our combination therapy is one of the very few treatments that is proven to retain neutralizing activity against Omicron BA.2 SARS-CoV-2 subvariant and all previous variants of concern as a result of its unique combination strategy.”

Current in vitro pseudovirus testing data suggest that the amubarvimab/romlusevimab combination retains neutralizing activity against major SARS-CoV-2 variants of concern, including the following commonly identified variants, namely, Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Epsilon (B.1.429), Delta (B.1.617.2), Delta Plus (AY.4.2), Lambda (C.37), Mu (B.1.621), Omicron (B.1.1.529-BA.1) and Omicron subvariants (BA.1.1 and BA.2).

“The Company stepped up to this public health challenge. We made a point to work with some of the most respected public sector partners, including the Third People’s Hospital of Shenzhen, Tsinghua University, the NIH, the NIAID and the AIDS Clinical Trial Group. We worked expeditiously with our partners to deliver best-in-class research and data that demonstrate improved clinical outcomes with the amubarvimab/romlusevimab combination for a broad range of COVID-19 patients at high risk of severe disease progression,” said Mr. Yongqing Luo, the President and General Manager of Greater China of the Company. “As a relatively young biotech company, we have worked tirelessly to advance the amubarvimab/romlusevimab combination as a treatment option to help addressing this global crisis. We have received purchase orders and stockpiling requests from nearly 20 provincial Health Commissions as well as more than 100 healthcare institutions and commercial organizations. We will continue to work closely with global regulatory bodies and our contract development and manufacturing organization (“CDMO”) to deliver this clinically proven therapy to patients in need.”

The Company’s emergency use authorization (“EUA”) application for the amubarvimab/romlusevimab combination is under review by the U.S. Food and Drug Administration (“US FDA”) and is pending on satisfactory completion of the US FDA’s inspection of the manufacturing sites at our CDMO. Following China’s initial biologics license application (“BLA”) approval of the amubarvimab/romlusevimab combination in December 2021, the Beijing Municipal Medical Products Administration is currently reviewing the Company’s Market Authorization Holder (“MAH”) inspection and application, a necessary administrative step required for commercial sales of the amubarvimab/romlusevimab combination in China. The Company is actively working with the regulatory bodies in China to ensure the amubarvimab/romlusevimab combination to obtain the Good Manufacturing Practice (“GMP”) certification. The Company will continue to work closely with its CDMO to assist in the inspections by both the US FDA and China’s provincial and municipal regulatory bodies.

Cautionary Statement: 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, May 9, 2022

As at the date of this announcement, the Board comprises Dr. Zhi Hong and Mr. Yongqing Luo as executive directors; Mr. Robert Taylor Nelsen and Dr. Axel Bouchon as non-executive directors; and Dr. Martin J Murphy Jr, Ms. Grace Hui Tang, Mr. Yiu Wa Alec Tsui and Mr. Gregg Huber Alton as independent non-executive directors.