Brii Biosciences, Vir Biotechnology, and VBI Vaccines Announce Initiation of Phase 2 Clinical Trial of BRII-835 (VIR-2218) in Combination with BRII-179 (VBI-2601) for the Treatment of Hepatitis B

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– New combination trial of an RNA-targeted therapeutic candidate and an HBV immunotherapeutic candidate aimed at delivering a functional cure for chronic hepatitis B infection –

DURHAM, N.C. & BEIJING & SAN FRANCISCO & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 21, 2021-- Brii Biosciences (Brii Bio), Vir Biotechnology, Inc. (Nasdaq: VIR), and VBI Vaccines Inc. (Nasdaq: VBIV) today announced that the first patient has been dosed in a Phase 2 clinical trial evaluating BRII-835 (VIR-2218), an investigational small interfering ribonucleic acid (siRNA) targeting hepatitis B virus (HBV), in combination with BRII-179 (VBI-2601), an investigational HBV immunotherapeutic, for the treatment of chronic HBV infection. This is the first clinical trial in the field to evaluate the combination of these two HBV mechanisms of action.

The multi-center, randomized, open-label study is designed to evaluate the safety and efficacy of BRII-835 (VIR-2218) compared to the combination of BRII-835 (VIR-2218) and BRII-179 (VBI-2601) with and without interferon-alpha as a co-adjuvant. Both agents have demonstrated proof of mechanism in HBV patients (NCT04507269 BRII-835 China study and ACTRN12619001210167 BRII-179 APEC study). Brii Bio has led the design and implementation of this functional cure proof-of-concept study with the support of VIR and VBI, and is the sponsor of the Phase 2 study (NCT04749368). It will be conducted at sites in Australia, China, Taiwan, Hong Kong Special Administrative Region of China, South Korea, New Zealand, Singapore, and Thailand.

Li Yan, M.D., Ph.D., chief medical officer of Brii Bio, said: “Sustained seroclearance of HBV surface antigen, also known as a functional cure, occurs rarely in the natural history of HBV infection or during the current standard of care treatment. We believe that both viral antigen knockdown with BRII-835 (VIR-2218) and sustained induction of HBV-specific host immune responses by BRII-179 (VBI-2601) are required to remove viral immunosuppression and subsequently break immune tolerance. The combination of these two agents is a step toward developing a functional cure for HBV.”

Phil Pang, M.D., Ph.D., chief medical officer of Vir, said: “This new combination trial represents an important addition to our HBV portfolio approach of combining VIR-2218 with various immunomodulators, including pegylated interferon alpha, VIR-3434 and with a TLR8 agonist, via our previously announced collaboration with Gilead. We look forward to determining if such combinations can stimulate an effective immune response that may result in a finite duration of treatment.”

Francisco Diaz-Mitoma, M.D., Ph.D., VBI’s chief medical officer, said: “We believe that a functional cure for HBV is possible, and will require restoration of HBV-specific immunologic control in addition to viral suppression mechanisms. Data from our previous study suggest BRII-179 (VBI-2601) was able to restimulate both antibody and T cell responses specific to HBV. This combination study represents the first combination of a therapeutic HBV vaccine to restore HBV-immunity with antivirals designed to reduce the levels of HBV surface antigens. We look forward to seeing the outcome of the trial, a milestone that will be meaningful in our collective efforts to provide an effective solution for patients with such a complex and highly infectious virus.”

About BRII-835 (VIR-2218)

BRII-835 (VIR-2218) is an investigational subcutaneously administered HBV-targeting siRNA that has the potential to stimulate an effective immune response and have direct antiviral activity against HBV. It is the first siRNA in the clinic to include Enhanced Stabilization Chemistry Plus (ESC+) technology to enhance stability and minimize off-target activity, which potentially can result in an increased therapeutic index. VIR-2218 is the first asset in the Company’s collaboration with Alnylam Pharmaceuticals, Inc. to enter clinical trials. Brii Bio licensed exclusive rights to develop and commercialize VIR-2218 for the greater China territory from Vir in 2020.

In addition to the Phase 2 combination trial with BRII-179 (VBI-2601), VIR-2218 is being evaluated in two ongoing trials: as a monotherapy for HBV, and in combination with pegylated interferon-alpha (PEG-IFN-α). Two additional Phase 2 trials of VIR-2218 are expected to start in 2021.

About BRII-179 (VBI-2601)

VBI-2601 (BRII-179) is a novel recombinant, protein-based HBV immunotherapeutic candidate that builds upon the 3-antigen conformation of VBI’s prophylactic 3-antigen HBV vaccine candidate, and is designed to target enhanced B-cell and T-cell immunity. VBI-2601 (BRII-179) is being developed in collaboration with Brii Biosciences in the licensed territory of China, Hong Kong, Macau, and Taiwan as part of a potential functional cure for chronic hepatitis B infection.

About Brii Biosciences

Brii Biosciences (Brii Bio) is a multi-national company committed to serving patients' needs and improving public health by accelerating the development and delivery of breakthrough medicines through partnerships, best-in-class research and development, and the disruptive application of digital and data insight. With operations in the People's Republic of China and the United States, Brii Bio is poised to serve as a bridge to carry transformative medicines to patients, help create significant growth for our partners and establish an innovation engine to help improve the public health and wellbeing of patients around the world. Brii Bio is developing treatments for illnesses with significant public health burdens, including infectious diseases, liver diseases, and CNS diseases. For more information, visit www.briibio.com.

About Vir Biotechnology

Vir Biotechnology is a clinical-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. Vir has assembled four technology platforms that are designed to stimulate and enhance the immune system by exploiting critical observations of natural immune processes. Its current development pipeline consists of product candidates targeting COVID-19, hepatitis B virus, influenza A and human immunodeficiency virus. For more information, please visit www.vir.bio.

About VBI Vaccines Inc.

VBI Vaccines Inc. ("VBI") is a biopharmaceutical company driven by immunology in the pursuit of powerful prevention and treatment of disease. Through its innovative approach to virus-like particles ("VLPs"), including a proprietary enveloped VLP ("eVLP") platform technology, VBI develops vaccine candidates that mimic the natural presentation of viruses, designed to elicit the innate power of the human immune system. VBI is committed to targeting and overcoming significant infectious diseases, including hepatitis B, coronaviruses, and cytomegalovirus (CMV), as well as aggressive cancers including glioblastoma (GBM). VBI is headquartered in Cambridge, Massachusetts, with research operations in Ottawa, Canada, and a research and manufacturing site in Rehovot, Israel. For more information, please visit www.vbivaccines.com.

Vir Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "potential," "aim," "could" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Vir's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include statements regarding the potential benefits of VIR-2218, BRII-179, pegylated interferon-alpha, and VIR-3434 (individually or in combination), the expected timing of commencement of clinical trials and availability of clinical data, our goals with respect to the prophylaxis and/or treatment of HBV, the potential ability of our product candidates (individually or in combination with other agents) to functionally cure HBV and change the standard of care, the potential of ESC+ technology to enhance the therapeutic index of VIR-2218, and the potential benefits of Vir's collaboration with Brii Biosciences and other partners. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data or results observed during clinical trials, difficulties in obtaining regulatory approval, difficulties in collaborating with other companies, challenges in accessing manufacturing capacity, clinical site activation rates or clinical trial enrollment rates that are lower than expected, successful development and/or commercialization of alternative product candidates by our competitors, changes in expected or existing competition, delays in or disruptions to Vir's business or clinical trials due to the COVID-19 pandemic, geopolitical changes or other external factors, and unexpected litigation or other disputes. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Vir's filings with the U.S. Securities and Exchange Commission, including the section titled "Risk Factors" contained therein. Except as required by law, Vir assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

VBI Cautionary Statement on Forward-Looking Information

Certain statements in this press release that are forward-looking and not statements of historical fact are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and are forward-looking information within the meaning of Canadian securities laws (collectively, "forward-looking statements"). The Company cautions that such statements involve risks and uncertainties that may materially affect the Company's results of operations. Such forward-looking statements are based on the beliefs of management as well as assumptions made by and information currently available to management. Actual results could differ materially from those contemplated by the forward-looking statements as a result of certain factors, including but not limited to, the impact of general economic, industry or political conditions in the United States or internationally; the impact of the ongoing COVID-19 pandemic on our clinical studies, manufacturing, business plan, and the global economy; the ability to establish that potential products are efficacious or safe in preclinical or clinical trials; the ability to establish or maintain collaborations on the development of therapeutic candidates; the ability to obtain appropriate or necessary governmental approvals to market potential products; the ability to obtain future funding for developmental products and working capital and to obtain such funding on commercially reasonable terms; the Company's ability to manufacture product candidates on a commercial scale or in collaborations with third parties; changes in the size and nature of competitors; the ability to retain key executives and scientists; and the ability to secure and enforce legal rights related to the Company's products. A discussion of these and other factors, including risks and uncertainties with respect to the Company, is set forth in the Company's filings with the SEC and the Canadian securities authorities, including its Annual Report on Form 10-K filed with the SEC on March 2, 2021, and filed with the Canadian security authorities at sedar.com on March 2, 2021, as may be supplemented or amended by the Company's Quarterly Reports on Form 10-Q. Given these risks, uncertainties and factors, you are cautioned not to place undue reliance on such forward-looking statements, which are qualified in their entirety by this cautionary statement. All such forward-looking statements made herein are based on our current expectations and we undertake no duty or obligation to update or revise any forward-looking statements for any reason, except as required by law.

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