VBI Vaccines and Agenus Announce Collaboration to Evaluate VBI-1901 in Combination with Anti-PD-1 Balstilimab in a Phase 2 Study in Primary Glioblastoma Patients

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- Randomized, controlled evaluation as part of INSIGhT adaptive platform trial expected to initiate around year-end 2022
- Study expected to assess VBI-1901 with concurrent balstilimab (anti-PD-1) administration in frontline Glioblastoma (GBM) patients following primary tumor resection and radiotherapy
- Recurrent GBM Development:
    - In the ongoing Phase 2a study, one recurrent GBM patient remains on protocol beyond two and a half years with a sustained 93% tumor reduction relative to baseline
    - Randomized, controlled extension study of VBI-1901 in recurrent GBM patients expected to initiate Q4 2022, subject to regulatory approvals

CAMBRIDGE, Mass. and LEXINGTON, Mass., Oct. 12, 2022 (GLOBE NEWSWIRE) -- VBI Vaccines Inc. (Nasdaq: VBIV) (VBI), a biopharmaceutical company driven by immunology in the pursuit of powerful prevention and treatment of disease, and Agenus (NASDAQ: AGEN), an immuno-oncology company with an extensive pipeline of therapeutics designed to activate the immune response to cancers and infections, today announced a collaboration to evaluate the combination of VBI-1901, VBI's cancer vaccine immunotherapeutic, and balstilimab, Agenus' monoclonal antibody (mAb) targeting the programmed death receptor-1 (PD-1) protein, in primary glioblastoma (GBM) patients as part of the adaptive platform trial, INSIGhT. Under the agreement, VBI will be the study sponsor and will be responsible for operational execution of the combination trial, and Agenus will provide drug supply and scientific support.

Despite being the most common primary brain cancer with approximately 14,000 new cases diagnosed in the United States each year, GBM patients have few effective treatment options and face low survival rates. Even with the standard of care – which includes surgical resection, chemotherapy, and radiation therapy in the frontline setting – primary GBM patients have a five-year survival rate of approximately 10%, with median overall survival of only 15-18 months after diagnosis.[1,2]

David E. Anderson, Ph.D., VBI's Chief Scientific Officer, commented, "GBMs are notoriously one of the most immunosuppressive solid tumors, which is why there are few effective treatment options. Based upon the encouraging data we have observed to date, we believe VBI-1901 has the potential to activate and boost specific T cell immunity capable of trafficking to the tumor microenvironment. We are now adding an anti-PD-1 monoclonal antibody to the treatment regimen as it may help to further enhance and sustain a meaningful anti-tumor immune response – an anti-PD-1 is designed to prolong the life of these T cells so that they may have greater opportunity to infiltrate and kill tumor cells. Given this potential synergy, we are excited to be partnering with Agenus in this clinical collaboration."

Steven O'Day, M.D., Agenus' Chief Medical Officer, added, "This clinical collaboration with VBI is aligned with our priority of developing balstilimab as a component of novel combination therapies across a range of tumor types. Balstilimab is a promising anti-PD-1 therapy that has been studied in over 750 patients. Balstilimab has demonstrated clinically meaningful results alone and combined with anti-CTLA-4 therapy in advanced cervical cancer. Combining balstilimab with VBI's vaccine enhances innate and adaptive anti-tumor immunity and may offer promise to patients with GBM, an aggressive and difficult to treat cancer."

In the recurrent setting, VBI-1901 is in an ongoing Phase 2a study and has demonstrated encouraging tumor responses and improvement in overall survival compared to historical controls. In the arm that will be advanced into the primary setting, there have been two (2) partial responses and five (5) stable disease observations among 16 patients with recurrent GBM. One of the patients with a partial response has been on treatment protocol for more than two and a half years with a sustained tumor response reduction of 93% relative to baseline. These tumor responses have translated to clinical benefit with a median overall survival rate of 12.9 months, which compares favorably to the 8-month overall survival historical control in the recurrent setting after treatment with a monotherapy.[3]

About VBI-1901 and GBM

VBI-1901 is a novel cancer vaccine immunotherapeutic candidate developed using VBI's enveloped virus-like particle (eVLP) technology to target two highly immunogenic cytomegalovirus (CMV) antigens, gB and pp65. Scientific literature suggests CMV infection is prevalent in multiple solid tumors, including glioblastoma (GBM). GBM is among the most common and aggressive malignant primary brain tumors in humans. In the U.S. alone, 14,000 new cases are diagnosed each year. The current standard of care for treating GBM is surgical resection, followed by radiation and chemotherapy. Even with aggressive treatment, GBM progresses rapidly and has a high mortality.

To learn more about VBI's ongoing Phase 1/2a study in recurrent GBM and the INSIGhT trial in the frontline setting, visit clinicaltrials.gov (Respective Identifiers: NCT03382977 and NCT02977780).

About Balstilimab

Balstilimab blocks PD-1 in order to restimulate exhausted T cells and enhance their cytotoxicity. Anti-PD-1 therapy has demonstrated benefit in a number of tumor types and can be well-tolerated when used in combination with other therapeutic approaches. Balstilimab has demonstrated superior tumor-killing potential compared to marketed anti-PD-1 therapies in preclinical models, strong anti-tumor potential in cervical cancer clinical studies and a strong track record of safety and tolerability.[4]

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, visit www.vbivaccines.com.

About Agenus

Agenus is a clinical-stage immuno-oncology company focused on the discovery and development of therapies that engage the body's immune system to fight cancer and infections. The Company's vision is to expand the patient populations benefiting from cancer immunotherapy by pursuing combination approaches that leverage a broad repertoire of antibody therapeutics, adoptive cell therapies (through its subsidiary MiNK Therapeutics), and adjuvants (through its subsidiary SaponiQx). The Company is equipped with a suite of antibody discovery platforms and a state-of-the-art GMP manufacturing facility with the capacity to support clinical programs. Agenus is headquartered in Lexington, MA. For more information, please visit www.agenusbio.com and our Twitter handle @agenus_bio. Information that may be important to investors will be routinely posted on our website and Twitter.

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 successfully manufacture and commercialize PreHevbrio; 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 pipeline candidates and the commercialization of PreHevbrio; the ability to obtain appropriate or necessary regulatory 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 7, 2022, and filed with the Canadian security authorities at sedar.com on March 7, 2022, 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.

Agenus Cautionary Statement on Forward-Looking Information

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements relating to Agenus’ technologies, therapeutic candidates, and capabilities, for instance, statements regarding therapeutic benefit and efficacy, mechanism of action, potency, durability, and safety and tolerability profile of our therapeutic candidates, both alone and in combination with each other and/or other agents; statements regarding future plans, including research, clinical, regulatory, and commercialization plans; and any other statements containing the words "may," "believes," "expects," "anticipates," "hopes," "intends," "plans," "will" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include, among others, the factors described under the Risk Factors section of Agenus’ most recent Quarterly Report on Form 10-Q or Annual Report on Form 10-K filed with the Securities and Exchange Commission and available on our website: www.agenusbio.com. Agenus cautions investors not to place considerable reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this press release, and Agenus undertakes no obligation to update or revise the statements, other than to the extent required by law. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.

References

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