Vaccibody AS and Nektar Therapeutics Announce First Patient Dosed in a Phase 1/2a Study Arm Evaluating VB10.NEO, a Personalized Neoantigen Cancer Vaccine, with Bempegaldesleukin (NKTR-214) in Patients with Squamous Cell Carcinoma of the Head and Neck

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OSLO, Norway and SAN FRANCISCO, Aug. 12, 2020 /PRNewswire/ -- Vaccibody AS and Nektar Therapeutics (NASDAQ: NKTR) today announced that the first patient has been dosed in the combination therapy of the Phase 1/2a study evaluating bempegaldesleukin (bempeg), Nektar's CD122-preferential IL-2 pathway agonist, with VB10.NEO, Vaccibody's personalized neoantigen cancer vaccine, in patients with advanced squamous cell carcinoma of the head and neck (SCCHN).

"We're pleased to advance our collaboration with Vaccibody to evaluate the potential of bempeg given with a personalized vaccine, VB10.NEO, in patients with advanced head and neck cancer," said Jonathan Zalevsky, Ph.D., Chief Research & Development Officer at Nektar. "The rationale for this clinical study is supported by our promising preclinical data which demonstrated how a personalized cancer vaccine and a T cell proliferator can work synergistically to induce maximal expansion of vaccine-induced T cell clones, provide deep and durable responses and, at the same time, offer specific anti-tumor immunity."

VB10.NEO is designed to specifically activate a patient's immune system to tumor-specific antigens, called neoantigens, while bempeg is designed to expand and proliferate tumor antigen-specific T cells in the periphery and in the tumor microenvironment. Addition of bempeg to VB10.NEO is intended to drive maximal expansion of vaccine-induced neoantigen-specific T cells for the treatment of cancer.

At the 2019 Society for Immunotherapy of Cancer (SITC) Annual Meeting, Vaccibody presented interim data for VB10.NEO in a group of patients with various solid tumor types who had all received multiple lines of prior anti-cancer therapy and had been treated with at least one checkpoint inhibitor (CPI) (nivolumab or pembrolizumab) for a range of 5 to 32 months. The data presented showed that 50 percent (7/14) of patients treated with VB10.NEO achieved clinical responses, including four patients with SCCHN. Clinical response was defined as either >10% reduction in the target lesions (as identified at screening) or converting progressive lesions into stable lesions (<20% increase, up to 37 weeks follow-up).

"We are pleased that our initial data with VB10.NEO demonstrated that the vaccine induced strong neoantigen-specific T cell responses and clinical benefit, particularly in patients who did not respond to checkpoint inhibitor monotherapy," said Agnete Fredriksen, President and Chief Scientific Officer of Vaccibody and continued: "We believe combining bempeg, a T cell stimulator, with VB10.NEO can further drive the expansion of VB10.NEO elicited neoantigen-specific T cells and potentially deepen and broaden anti-tumor activity. Siri Torhaug, Chief Medical Officer of Vaccibody added, "We are happy to announce the first patient dosed with the combined therapy of VB10.NEO and bempegaldesleukin and look forward to seeing the first read outs from this unique approach in patients with head and neck cancer."

Preclinical studies evaluating the combination of VB10.NEO and bempeg demonstrated the synergy of the two mechanisms to elicit greater breadth and depth of neoantigen-specific T cell responses as compared to each agent individually. In preclinical models of solid tumors, the combination induced strong immunogenic CD8+ T cell responses, and when combined with anti-PD-1, induced rapid, complete and durable tumor regression of small tumors, and long-lasting disease control of large tumors.[1]

About VB10.NEO
VB10.NEO, is Vaccibody's proprietary therapeutic DNA vaccine which uses the patient's own neoantigens for the personalized treatment of cancer patients. A phase 1/2a neoantigen clinical trial is currently enrolling patients with locally advanced or metastatic melanoma, non-small cell lung carcinoma, clear renal cell carcinoma as well as urothelial cancer or squamous cell carcinoma of the head and neck. In clinical trials, VB10.NEO has demonstrated induction of strong neoantigen-specific immune responses which led to clinical responses in patients with locally advanced or metastatic disease.

About Bempegaldesleukin (NKTR-214)
Bempegaldesleukin is designed to stimulate cancer-killing immune cells in the body by targeting CD122 receptors found on the surface of these immune cells. CD122, which is also known as the Interleukin-2 receptor beta subunit, is a key signaling receptor that is known to increase proliferation of these effector T cells.[2] In clinical and preclinical studies, treatment with bempegaldesleukin resulted in expansion of these cells and mobilization into the tumor micro-environment.[3,4]

About Vaccibody
Vaccibody is a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies. The Company is a leader in the rapidly developing field of individualized cancer neoantigen vaccines and is using the Vaccibody technology to generate best-in-class therapeutics to treat cancers with a high unmet medical need. Further, the Company has initiated research on infectious diseases.

Vaccibody is developing cutting-edge, targeted DNA vaccines for clinical use, based on a deep understanding of immunological principles. Vaccibody's vaccines specifically target Antigen Presenting Cells (APC), which are essential for inducing rapid, strong and specific immune responses and elicit efficacious clinical responses. By intelligent design, Vaccibody's vaccines can be tailored to induce the desired immune response profile correlating with protection for each specific disease with any given antigen. Hence, the Vaccibody vaccine platform has the potential to address many disease areas with a high unmet medical need such as cancer and infectious diseases. In addition, Vaccibody has collaborations with Roche and Nektar Therapeutics.

Vaccibody's lead product candidates are VB10.NEO, a personalized therapeutic cancer neoantigen vaccine currently being evaluated in a Phase I/IIa clinical trial, and VB10.16, a therapeutic cancer vaccine against HPV16-related cancers that is currently being tested in a Phase IIa clinical trial.

Vaccibody's shares are traded on NOTC, a marketplace for unlisted shares managed by NOTC AS, which is owned 100% by Oslo Børs ASA, the Oslo Stock Exchange.

Further information about the Company may be found at http://www.vaccibody.com

About Nektar Therapeutics

Nektar Therapeutics is a biopharmaceutical company with a robust, wholly owned R&D pipeline of investigational medicines in oncology and immunology as well as a portfolio of approved partnered medicines. Nektar is headquartered in San Francisco, California, with additional operations in Huntsville, Alabama and Hyderabad, India. Further information about the company and its drug development programs and capabilities may be found online at http://www.nektar.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements which can be identified by words such as: "may," "can," "developing," "design," "intend," and similar references to future periods. Examples of forward-looking statements include, among others, statements we make concerning the therapeutic potential of bempegaldesleukin in combination with VB10.NEO, the future development plans for bempegaldesleukin in combination with VB10.NEO, and the availability of results and outcomes from clinical studies of bempegaldesleukin in combination with VB10.NEO. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results to differ materially from those indicated in the forward-looking statements include, among others: (i) the extent and duration of the impact of the COVID-19 pandemic on our business, regulatory efforts, research and development, clinical trials (including those being led by us and our partner), and corporate development activities will depend on future developments that are highly uncertain and cannot be accurately predicted, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S. and in other countries, as well as the effectiveness of actions taken globally to contain and treat the disease; (ii) both bempegaldesleukin and VB10.NEO are investigational agents and continued research and development for these drug candidates (both alone and in combination) is subject to substantial risks, including negative safety and efficacy findings in ongoing clinical studies (notwithstanding positive findings in earlier preclinical and clinical studies); (iii) the timing of the commencement or end of clinical trials and the availability of clinical data may be delayed or unsuccessful due to regulatory delays, decisions and policies of our partner, slower than anticipated patient enrollment, manufacturing challenges, changing standards of care, evolving regulatory requirements, clinical trial design, clinical outcomes, competitive factors, or delay or failure in ultimately obtaining regulatory approval in one or more important markets; (iv) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future regulatory approval of potential new drug candidates (such as bempegaldesleukin and VB10.NEO) is therefore very uncertain and unpredictable; (v) patents may not issue from our patent applications for our drug candidates, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and (vi) certain other important risks and uncertainties set forth in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 7, 2020. Any forward-looking statement made by us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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