Vaccibody AS and Nektar Therapeutics Present New Preclinical Data from their Immuno-Oncology Collaboration at the American Association for Cancer Research (AACR) Annual Meeting 2019

April 1, 2019

OSLO, Norway and SAN FRANCISCO, April 1, 2019 /PRNewswire/ -- Vaccibody AS and Nektar Therapeutics (Nasdaq: NKTR) today announced the presentation of new preclinical data for VB10.NEO, a personalized neoantigen cancer vaccine, combined with bempegaldesleukin (NKTR-214 or bempeg), a CD122-preferential IL-2 pathway agonist. These data were presented today in a poster session at the American Association for Cancer Research (AACR) Annual Meeting 2019.

"We are excited to present these novel preclinical data that show combining bempeg with VB10.NEO synergize to increase both the breadth and the depth of the neoantigen-specific immune response. These unique and non-overlapping mechanisms produced an expansion of the VB10.NEO elicited neoantigen-specific T cells and demonstrated enhanced anti-tumor efficacy in mice. We look forward to evaluating this novel immuno-oncology combination in a clinical study in patients with advanced or metastatic squamous cell carcinoma of head and neck later this year," said Agnete B. Fredriksen, Ph.D., Vaccibody's President and Chief Scientific Officer.

VB10.NEO is designed to specifically activate a patient's immune system to tumor-specific antigens, called neoantigens. Bempeg is designed to expand and proliferate tumor antigen-specific T cells 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.

"Personalized T cell vaccines could play a critical and central role in cancer immunotherapy," said Jonathan Zalevsky, Ph.D., Chief Scientific Officer at Nektar. "These preclinical data highlight the potential of combining a personalized cancer vaccine with a T cell proliferator to induce maximal expansion of vaccine-induced T cell clones and durable responses and specific anti-tumor immunity. We are highly encouraged by these results and look forward to testing this unique approach to personalized cancer treatment in patients with squamous cell carcinoma of the head and neck."

Details of the poster presentation at AACR are as follows and will be available for download at the time of presentation at http://www.vaccibody.com/scientific-presentations/ and https://www.nektar.com/download_file/662/0.

Abstract #2256
Title: "*Combination of neoantigen DNA plasmid vaccine VB10.NEO and NKTR-214, a CD122-biased immunostimulatory cytokine, induces strong neoantigen-specific T cell responses and sustained tumor regression in pre-clinical models*"
Session: Clinical Research – Combination Therapies 1
Session Data and Time: Monday, April 1, 2019, 1:00 p.m. - 5:00 p.m. Eastern Time

- Combination of VB10.NEO and NKTR-214 synergizes to elicit greater breadth and depth of neoantigen-specific T cell responses than each individual treatment.
- The synergistic effect was observed in both CD4 and CD8 T cells, and most pronounced on CD8 T cell responses, further supporting the combination's potential to induce strong immunogenic CD8+ T cell responses.
- VB10.NEO in combination with NKTR-214 and anti-PD-1 induce rapid, complete and durable tumor regression of small tumors and long-lasting stabilization of large tumors supporting the rationale for examining the combination clinically.

In September 2018, Nektar and Vaccibody entered into a clinical collaboration to evaluate bempegaldesleukin in combination with VB10.NEO. A pilot study evaluating the combination in patients with squamous cell carcinoma of the head and neck is planned to begin mid-2019.

About VB10.NEO
VB10.NEO, is a proprietary therapeutic DNA vaccine which uses the patient's own neoantigens for the personalized treatment of cancer patients. A phase I/IIa 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.

About bempegaldesleukin (NKTR-214)
Bempegaldesleukin is an investigational, first-in-class, CD122-preferential IL-2 pathway agonist designed to provide rapid activation and proliferation of cancer-killing immune cells, known as CD8+ effector T cells and natural killer (NK) cells, without over activating the immune system. Bempegaldesleukin stimulates these 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.[1] In clinical and preclinical studies, treatment with bempegaldesleukin resulted in expansion of these cells and mobilization into the tumor micro-environment.[2,3] Bempegaldesleukin has an antibody-like dosing regimen similar to the existing checkpoint inhibitor class of approved medicines.

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. A phase I/IIa 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 or squamous cell carcinoma of the head and neck. Vaccibody's most advanced program (VB10.16) is a therapeutic DNA vaccine against HPV16 induced pre-malignancies and malignancies. The first-in-human study (phase I/IIa), which has reported positive 12M data demonstrating a well-tolerated safety profile, strong immunogenicity and clinical efficacy of VB10.16 in women with high grade cervical intraepithelial neoplasia (HSIL; CIN 2/3). Further information about the company and its drug development programs and capabilities may be found online at http://www.vaccibody.com.

About Nektar Therapeutics
Nektar Therapeutics is a research-based, development stage biopharmaceutical company whose mission is to discover and develop innovative medicines to address the unmet medical needs of patients. Our R&D pipeline of new investigational medicines includes treatments for cancer, autoimmune disease and chronic pain. We leverage our proprietary and proven chemistry platform in the discovery and design of our new therapeutic candidates. Nektar is headquartered in San Francisco, California, with additional operations in Huntsville, Alabama and Hyderabad, India. Further information about Nektar and its drug development programs and capabilities may be found online at http://www.nektar.com.

Nektar Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements which can be identified by words such as: "will," "intend," "may," "planned," "believe," "designed," and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the therapeutic potential of bempegaldesleukin in combination with VB10.NEO, the future development plans bempegaldesleukin in combination with VB10.NEO, and the availability of results and outcomes from our clinical and preclinical studies. 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, 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) our statements regarding the therapeutic potential of bempegaldesleukin in combination with VB10.NEO are based on preclinical findings studies and future data generated from new studies may be materially different; (ii) bempegaldesleukin and VB10.NEO are in early stage clinical development and the risk of failure remains high and failure can unexpectedly occur at any stage for one or more of the cancer indications being studied prior to regulatory approval due to lack of sufficient efficacy, safety considerations or other factors that negatively impact drug development; (iii) the timing of the commencement and end of clinical studies and the availability of clinical data may be delayed due to regulatory delays, slower than anticipated patient enrollment, manufacturing challenges, changing standards of care, evolving regulatory requirements, clinical trial design, or clinical outcomes; (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 Nektar's Annual Report on Form 10-K for the year ended December 31, 2018 filed with the Securities and Exchange Commission on March 1, 2019. 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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1 Boyman, J., et al., Nature Reviews Immunology, 2012, 12, 180-190.

2 Charych, D., et al., Clin Can Res; 22(3) February 1, 2016
3 Diab, A., et al., Journal for ImmunoTherapy of Cancer 2016, 4(Suppl 1): P369

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