Neon Therapeutics Logo

Neon Therapeutics Announces Completion of Enrollment in Phase 1b NT-002 Clinical Trial of NEO-PV-01 in Metastatic Non-Small Cell Lung Cancer

April 8, 2019

First Clinical Trial to Evaluate the Potential of the Personal Neoantigen Vaccine NEO-PV-01 in Combination with Standard of Care in First-Line Metastatic NSCLC Treatment Setting

CAMBRIDGE, Mass., April 08, 2019 (GLOBE NEWSWIRE) -- Neon Therapeutics, Inc. (Nasdaq: NTGN), a clinical-stage immuno-oncology company developing neoantigen-based therapeutics, today announced the completion of enrollment in NT-002, its Phase 1b clinical trial evaluating NEO-PV-01 with KEYTRUDA® (pembrolizumab) and chemotherapy in patients with untreated advanced or metastatic non-small cell lung cancer (NSCLC). NEO-PV-01 is a personal neoantigen vaccine custom-designed and manufactured based on the neoantigens identified by Neon's proprietary bioinformatics engine, RECON®, as being the most therapeutically relevant for an individual patient.

"Our NT-002 trial has the potential to demonstrate the effect that NEO-PV-01, our personal neoantigen vaccine, may have in combination with pembrolizumab and chemotherapy, the current standard of care in first-line metastatic NSCLC. While the pembrolizumab-chemotherapy regimen has shown improved clinical outcomes in first-line NSCLC, we believe NEO-PV-01 could improve the therapeutic efficacy of this combination by directing T cells to target neoantigens expressed in each patient's tumor," said Richard Gaynor, M.D., President of Research and Development at Neon Therapeutics.

The trial, conducted in collaboration with Merck, is evaluating the safety, tolerability and efficacy of NEO-PV-01 in the metastatic setting. Patients enrolled in the trial undergo an initial tumor biopsy and then begin 12 weeks of treatment with pembrolizumab and chemotherapy. They receive the NEO-PV-01 vaccination at week 12 and treatment with pembrolizumab continues throughout the trial. The primary endpoint of the trial is safety. In addition, Neon is evaluating immune responses and clinical outcomes. Neon expects to report immune and clinical outcome data from NT-002 over the course of 2020.

"This trial seeks to build on the proof-of-mechanism established in our NT-001 trial, which combines NEO-PV-01 with OPDIVO® (nivolumab) in patients with metastatic melanoma, NSCLC and bladder cancer, and will highlight the impact of the addition of chemotherapy to our NEO-PV-01 and anti-PD-1 combination has on the potential to improve the suppressive tumor microenvironment found in many cancers," Dr. Gaynor continued.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA. OPDIVO® is a registered trademark of Bristol-Myers Squibb Company.

About NEO-PV-01

NEO-PV-01 is a fully personal cancer vaccine targeting neoantigens that is custom-designed and manufactured for each individual patient based upon the tumor's unique mutational fingerprint. The neoantigen-targeting peptides in NEO-PV-01 are intended to generate an anti-tumor immune response that directs patients' T cells to target and kill their cancer cells. NEO-PV-01 is being studied in multiple ongoing Phase 1 clinical trials.

About Neon Therapeutics

Neon Therapeutics is a clinical-stage immuno-oncology company and a leader in the field of neoantigen-targeted therapies, dedicated to transforming the treatment of cancer by directing the immune system towards neoantigens. Neon is using its neoantigen platform to develop both vaccine and T cell therapies, including NEO-PV-01, a clinical stage neoantigen vaccine for the treatment of metastatic melanoma, non-small cell lung cancer, and bladder cancer; NEO-PTC-01, a neoantigen T cell therapy for the treatment of solid tumors; and NEO-SV-01, a neoantigen vaccine for the treatment of a subset of estrogen-receptor-positive breast cancer.

For more information, please visit **www.neontherapeutics.com**.

Forward-Looking Statements

This press release contains "forward-looking statements" of Neon Therapeutics, Inc. within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, express or implied statements regarding our ability to obtain and maintain regulatory approval of our product candidates; the potential timing and advancement of our preclinical studies and clinical trials and related regulatory submissions; the potential timing of data readouts from our ongoing and planned clinical trials; the design and potential efficacy of our therapeutic approaches; the ability and willingness of our third-party research institution collaborators to continue research and development activities relating to our product candidates; our ability and the potential to successfully manufacture and supply our product candidates for clinical trials; our ability to replicate results achieved in our preclinical studies or clinical trials in any future studies or trials; regulatory developments in the United States and foreign countries; our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates; and our expectations regarding our uses of capital, expenses, future accumulated deficit and other financial results. Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: uncertainties related to the initiation, timing and conduct of studies and other development requirements for our product candidates; the risk that any one or more of our product candidates will not be successfully developed and commercialized; the risk that the results of preclinical studies and clinical trials will be predictive of future results in connection with future studies or trials; the risk that Neon's collaborations will not continue or will not be successful; risks related to our ability to protect and maintain our intellectual property position; and risks related to the ability of our licensors to protect and maintain their intellectual property position. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Neon's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Neon's most recent Annual Report on Form 10-K, as filed with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in Neon's other filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Neon undertakes no duty to update this

information unless required by law.

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