Neon Therapeutics Logo

Neon Therapeutics and Apexigen Announce First Patient Dosed in Neon's NT-003 Phase 1b Combination Trial of NEO-PV-01 in Metastatic Melanoma

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CAMBRIDGE, Mass. and SAN CARLOS, Calif., Dec. 06, 2018 (GLOBE NEWSWIRE) -- Neon Therapeutics, Inc. (Nasdaq: NTGN), a clinical-stage immuno-oncology company developing neoantigen-based therapeutics, and Apexigen, Inc., a clinical-stage biopharmaceutical company, today announced that patient dosing has begun in NT-003, Neon's Phase 1b combination trial of NEO-PV-01 in metastatic melanoma. NEO-PV-01 is a personal neoantigen vaccine custom-designed and manufactured based on the unique mutational fingerprint of each individual patient.

The Phase 1b trial is evaluating NEO-PV-01 and nivolumab in combination with other agents in first-line patients with advanced or metastatic melanoma. One arm of the multi-arm study will evaluate the vaccine and nivolumab in combination with Apexigen's APX005M, an investigational CD40 agonist. Another will evaluate NEO-PV-01 and nivolumab in combination with ipilimumab.

"We believe that there is very strong scientific rationale for treating patients with these additional agents as they may enhance neoantigen immune responses induced by NEO-PV-01 with the potential to drive additional clinical benefit," said Richard Gaynor, M.D., President of Research and Development at Neon Therapeutics.

"CD40 agonists such as APX005M have been shown to enhance antigen presentation, resulting in improved magnitude and quality of T cell responses and we share the enthusiasm of the team at Neon to conduct this clinical trial," said Ovid Trifan, M.D., Ph.D., Chief Medical Officer of Apexigen.

James P. Allison, Ph.D., a Nobel Prize winner, developer of the first FDA-approved checkpoint inhibitor (ipilimumab) and one of Neon's founders, commented, "Both preclinical and clinical work have demonstrated that CTLA-4 antagonism enhances the priming of *de novo* immune responses and increases T cell infiltration into the tumor. These findings provide clear rationale for combining a checkpoint inhibitor such as ipilimumab with NEO-PV-01 to augment the immune response and potentially transform how we treat cancer."

About NT-003

NT-003 is a Phase 1b, open-label, multicenter clinical study of NEO-PV-01 with nivolumab, in combination either with APX005M or low dose ipilimumab, for the treatment of advanced or metastatic melanoma. APX005M or ipilimumab will only be dosed during the vaccination period.

More information regarding NT-003 can be found here.

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.

About Apexigen

Apexigen is a clinical-stage biopharmaceutical company discovering and developing a new generation of antibody therapeutics for oncology, with an emphasis on new immuno-oncology agents that could harness the patient's immune system to combat and eradicate cancer. The Company's lead immuno-oncology therapeutic APX005M, a CD40 agonist, is currently being evaluated in seven Phase 2 and two Phase 1 clinical trials for the treatment of patients with solid tumors. APX005M and the additional preclinical programs were discovered using APXiMAB™, Apexigen's proprietary product discovery platform. For more information, please visit www.apexigen.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; 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 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 Quarterly Report on Form 10-Q, 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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