Neon Therapeutics Logo

Neon Therapeutics Announces Updated Data Presented at Society for Immunotherapy of Cancer (SITC) Annual Meeting

November 8, 2019

Updated Results from NT-001 Trial of NEO-PV-01 Demonstrate Prolonged Progression-Free and Overall Survival vs. Historical Benchmark Data

Advanced Process Development Supports Clinical Trial Application to be Filed in Europe by End of Year for T cell Therapy Candidate NEO-PTC-01

CAMBRIDGE, Mass., Nov. 08, 2019 (GLOBE NEWSWIRE) -- Neon Therapeutics, Inc. (Nasdaq: NTGN), a clinical-stage immuno-oncology company developing neoantigen-based therapeutics, today presented updated data at the Society for Immunotherapy of Cancer's (SITC) 34th Annual Meeting in National Harbor, MD.

"We are pleased to present these updates for both NEO-PV-01 and NEO-PTC-01, both of which demonstrate Neon's continued leadership in advancing neoantigen-based science and drug development. We continue to believe that these personalized approaches to treating cancer represent significant potential to reshape the treatment landscape for solid tumors," said Richard Gaynor, M.D., Neon's President of Research and Development.

NEO-PV-01: Updated Results from the NT-001 Clinical Trial

Neon today announced updated results (August 2019 data cut) from the ongoing, multicenter Phase 1b clinical trial evaluating NEO-PV-01, Neon's personal neoantigen vaccine candidate, in combination with OPDIVO® (nivolumab) in patients with advanced or metastatic melanoma, smoking-associated non-small cell lung cancer (NSCLC) and bladder cancer. Across all three distinct tumor types, results demonstrated prolonged and consistent improvements in progression-free survival (PFS) and overall survival (OS) that compare favorably to that observed with checkpoint inhibitor monotherapy, based on historical benchmark data. Further, neoantigen-specific immune responses and epitope spread to RECON®-predicted targets were associated with longer PFS and major pathological responses post-administration of NEO-PV-01 in melanoma patients were also associated with longer PFS. The safety data for NT-001 were consistent with the safety profile for OPDIVO monotherapy. These updated results come from 82 patients who received at least one dose of OPDIVO in the Phase 1b NT-001 trial. The NT-001 trial was initiated in November 2016 and completed enrollment in July 2018.

NT-001 Clinical Trial Results
August 2019 data cut; overall survival analysis includes previously censored patients from April 2019 data cut
Initiated OPDIVO: Patients that received at least one dose of OPDIVO (ITT set)
Initiated NEO-PV-01: Patients who received at least one dose of NEO-PV-01 (ITT subset)

	Metastatic Melanoma		**Metastatic NSCLC**		**Metastatic Bladder Cancer**	
	Initiated OPDIVO (ITT)	Initiated NEO-PV-01 (ITT Subset)	Initiated OPDIVO (ITT)	Initiated NEO-PV-01 (ITT Subset)	Initiated OPDIVO (ITT)	Initiated NEO-PV-01 (ITT Subset)
NT-001 Enrollment (N)	34	27	27	18	21	15
NT-001 Median Follow-Up (months)	20.3	20.3	15.2	15.2	17.5	17.5
NT-001 Median PFS (months)	15.1	23.5	4.3	8.5	5.6	5.8
Historical Benchmark Median PFS (months)	3.1-6.9[1]	-	2.3-4.2[2]	-	2.1-2.8[3]	-
NT-001 Median OS (months)	Not Reached	Not Reached	16.2	Not Reached	20.7	20.7
Historical Benchmark Median OS (months)	15.7-37.6[1]	-	12.2-14.4[2]	-	9.7-15.9[3]	-
NT-001 1 Year Survival (%)	85	96	59	83	60	67
Historical Benchmark 1 Year Survival (%)	59-74[1]	-	51-56[2]	-	44-57[3]	-
Objective Response Rate (ORR) (%)	47	59	26	39	22	27
Historical Benchmark ORR (%)	27-44[1]	-	19-26[2]	-	21-24[3]	-

[1] Historical checkpoint inhibitor data for advanced or metastatic melanoma: Larkin, et al, *JCO* 2017; Schachter, et al, *Lancet* 2017; Wolchok, et al, *NEJM* 2017.
[2] Historical checkpoint inhibitor data for advanced or metastatic non-small cell lung cancer: Borghaei, et al, *Lancet* 2015; Carbone, et al, *NEJM* 2017; Herbst, et al, *Lancet* 2016.
[3] Historical checkpoint inhibitor data for advanced or metastatic bladder cancer: Balar, et al, *Lancet* 2017; Bellmunt, et al, *NEJM* 2017; Sharma, et al, *Lancet* 2016.

NEO-PTC-01: Advanced Process Development Supports Clinical Trial Application Filing in Europe by End of 2019

Neon continues to advance its preclinical and process development work for NEO-PTC-01, its personal neoantigen-targeted T cell therapy candidate consisting of multiple T cell populations targeting the most therapeutically relevant neoantigens from each patient's tumor. NEO-PTC-01 leverages Neon's RECON bioinformatics platform to individually select a set of neoantigen targets for each patient, and NEO-STIM™, its proprietary process to directly prime, activate and expand neoantigen-targeting T cells *ex vivo.* Neon believes that this approach will allow NEO-PTC-01, a non-engineered T cell product that leverages peripheral blood mononuclear cells (PBMCs) as its starting material, to specifically target each patient's individual tumor

with T cells that can drive a robust and persistent anti-tumor response.

In the update presented today at SITC, Neon demonstrated that it can reproducibly generate a potent T cell product from PBMCs of melanoma patients, as well as at therapeutic scale using a healthy donor sample. This process development work showed that NEO-PTC-01 induced multiple $CD8^+$ and $CD4^+$ T cell responses from both the memory and naïve T cell compartments. The induced T cell responses were mutant-specific, showed a polyfunctional profile and had a central and effector memory phenotype. The induced T cell responses had cytotoxic capability, shown by the recognition of antigen-expressing tumor cell lines. Importantly, NEO-PTC-01 induced T cell cultures that directly recognized autologous tumor digest.

Neon is focusing the initial clinical development of NEO-PTC-01 in patients with solid tumors that are refractory to checkpoint inhibitors. Neon expects to file a clinical trial application, or CTA, in Europe by the end of 2019 to evaluate NEO-PTC-01 in the solid tumor setting.

Details for the NEO-PV-01 poster presentation are as follows:

Presentation Title: Disease-related Biomarkers are Associated with Extended Progression-Free Survival after Treatment with NEO-PV-01 in Combination with Anti-PD1 in Patients with Metastatic Cancers
Poster Hall Hours: Friday, November 8 from 7:00 a.m. - 8:00 P.M. ET
Poster Number: P437
Location: Gaylord National Convention Center

Details for the NEO-PTC-01 poster presentation are as follows:

Presentation Title: The Development of an Autologous Neoantigen-Specific T cell Product from Peripheral Blood, NEO-PTC-01, through the *ex-vivo* Induction Protocol, NEO-STIM™
Poster Hall Hours: Friday, November 8 from 7:00 a.m. - 8:00 P.M. ET
Poster Number: P197
Location: Gaylord National Convention Center

The posters will also be made available at https://neontherapeutics.com/publications/.

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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 hormone receptor-positive (HR+) breast cancer.

For more information, please visit 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 clinical trials; the potential timing and manner of data readouts from our ongoing and planned clinical trials; the design and potential efficacy of our therapeutic approaches; financial plans and projections; and our ability to replicate results achieved in our preclinical studies or clinical trials in any future studies or trials. 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 may not 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; risks related to our capital requirements and use of capital; 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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