Neon Therapeutics Logo

Neon Therapeutics Provides Business Update and Outlook for 2019

January 3, 2019

CAMBRIDGE, Mass., Jan. 03, 2019 (GLOBE NEWSWIRE) -- Neon Therapeutics, Inc. (Nasdaq: NTGN), a clinical-stage immuno-oncology company developing neoantigen-based therapeutics, today provided a business update and outlook for 2019.

“We have an exciting year ahead of us in 2019, with multiple data readouts from our personal neoantigen vaccine program, NEO-PV-01, in a variety of metastatic cancer settings using a number of rational treatment combinations. We are also continuing to investigate monotherapy opportunities and look forward to sharing our plans later this year,” said Hugh O’Dowd, Neon’s Chief Executive Officer.

“We expect the upcoming data readouts to include correlations between mechanism of action and clinical response and enable development of later-stage trials that will draw on treatment combinations and target patient populations most likely to benefit from our personal cancer vaccine,” said Richard Gaynor, M.D., Neon’s President of Research and Development.

Neon also continues to advance its T cell programs, including the development of a library of high-quality TCRs. “I expect these programs to become increasingly important in 2019, as we continue to build a diversified clinical-stage pipeline,” Mr. O’Dowd said.

With regard to its personal neoantigen T cell program, NEO-PTC-01, Neon continues to build on data presented at the Society for the Immunotherapy of Cancer 2018 Annual Meeting. The Company plans to file a European Clinical Trial Application (CTA) in the first half of 2019 to enable it to initiate a first-in-human clinical study of NEO-PTC-01, which is being developed in collaboration with the Netherlands Cancer Institute (NKI).

“Data from our ongoing research give us added confidence that we can reliably generate multiple enriched neoantigen-specific T cell populations that are capable of killing tumor cells,” said Dr. Gaynor. “We believe NEO-PTC-01 has several significant advantages that could overcome the challenges of other cell therapies in the solid tumor setting and we look forward to evaluating this approach in checkpoint refractory patients.”

John Haanen, M.D., Ph.D., Professor and Head of the Medical Oncology Division at the NKI, remarked: “We are excited to be working with Neon to initiate the first neoantigen adoptive T-cell clinical trial that seeks to elicit both *de novo* and memory T cell responses across a range of solid tumors in patients that are refractory to checkpoint inhibitors.”

With respect to TCRs, Neon has been leveraging its RECON® bioinformatics engine to identify shared neoantigen epitopes and its NEO-STIM™ induction protocol to generate neoantigen-reactive T-cell receptors to these epitopes. Drawing on this work, Neon has assembled libraries of high-quality TCRs against various shared neoantigens across common HLAs.

“Our maturing T cell programs will join our vaccine programs in developing new paradigms for the treatment of solid tumors,” said Dr. Gaynor.

Pipeline Overview and Upcoming Milestones

NEO-PV-01

- **NT-001: *Phase 1b Clinical Trial of NEO-PV-01 in the Metastatic Setting***
  - 52-week data expected in the first half of 2019
- **NT-002: *Phase 1b Clinical Trial of NEO-PV-01 in Metastatic Non-Small Cell Lung Cancer***
  - 52-week data expected in the second half of 2019
- **NT-003: *Phase 1b Clinical Trial of NEO-PV-01 in Metastatic Melanoma Combinations***
  - Immune monitoring data expected in the first half of 2020
- **NT-004: *Phase 1b Clinical Trial of NEO-PV-01 in Earlier Disease Setting***
  - Finalizing plans for first monotherapy study

NEO-PTC-01

- **NC-001: *Phase 1 Clinical Trial in Solid Tumor Setting:*** Neon intends to submit a European CTA for NEO-PTC-01, a personal neoantigen T-cell therapy, for the treatment of checkpoint refractory patients in the first half of 2019.

NEO-SV-01

- **NS-001: *Phase 1 Clinical Trial in Subset of ER^+ Breast Cancer:*** Neon expects to submit an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) in the first half of 2019.

Financial Guidance

Based on its current operating plans, Neon now expects that its existing cash, cash equivalents and marketable securities will enable the Company to fund its anticipated operating expenses and capital expenditure requirements into the second quarter of 2020. As of September 30, 2018, Neon had $121.7 million in cash, cash equivalents and marketable securities.

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; 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 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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