Neon Therapeutics Logo

Neon Therapeutics Submits European Clinical Trial Authorization Application for Personal Neoantigen-Targeted T Cell Therapy NEO-PTC-01

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Study of NEO-PTC-01 in metastatic melanoma patients expected to initiate in first half of 2020

CAMBRIDGE, Mass., Dec. 18, 2019 (GLOBE NEWSWIRE) -- Neon Therapeutics, Inc. (Nasdaq: NTGN) today announced that it has filed a Clinical Trial Authorization (CTA) with the Dutch Health Authority for the evaluation of NEO-PTC-01 in patients with metastatic melanoma who are refractory to checkpoint inhibitors. NEO-PTC-01 is a personal neoantigen-targeted T cell therapy candidate derived from patients' peripheral blood mononuclear cells (PBMCs) and consisting of multiple T cell populations targeting the most therapeutically relevant neoantigens from each patient's tumor.

Neon plans to initiate a Phase 1 dose escalation clinical trial in metastatic melanoma in collaboration with the Netherlands Cancer Institute in the first half of 2020. The second planned indication for NEO-PTC-01 is metastatic ovarian cancer, with the potential to both expand to other solid tumor types and pursue clinical development in the United States.

"This filing of a CTA with the Dutch Health Authority for NEO-PTC-01 is the culmination of several years of work to refine our proprietary NEO-STIM™ process to prime, activate and expand neoantigen-targeting T cells *ex vivo.* Importantly, it moves us one step closer to demonstrating NEO-PTC-01's potential to unlock the potency of cell therapy in solid tumors," said Hugh O'Dowd, Neon's Chief Executive Officer.

"We believe NEO-PTC-01 has several key advantages that overcome the challenges of other cell therapy approaches. In preclinical studies, including research using patient tumor samples, we have demonstrated the ability to produce multiple neoantigen-specific $CD8^+$ and $CD4^+$ T cell populations, including both memory and *de novo* T cell responses. We have further shown that these T cell populations kill tumor cells by targeting tumor neoantigens," said Richard Gaynor, M.D., Neon's President of Research and Development. "We believe that our approach to leveraging these neoantigen targets will provide the tumor specificity required to develop safe, effective and durable T cell therapies for the treatment of solid tumors. We look forward to demonstrating these potential benefits in our Phase 1 study in metastatic melanoma."

About NEO-PTC-01

NEO-PTC-01 leverages Neon's neoantigen platforms, including RECON®, its machine-learning bioinformatics platform, and NEO-STIM™, its proprietary process to directly prime, activate and expand neoantigen-targeting T cells *ex vivo.* Neon believes that these platform technologies will allow NEO-PTC-01, a non-engineered product that leverages PBMCs as starting material, to specifically target each patient's individual tumor with T cells that can drive a robust and persistent anti-tumor response.

About Neon Therapeutics

Neon Therapeutics is a biotechnology company developing novel neoantigen-targeted T cell therapies, dedicated to transforming the treatment of cancer by directing the immune system towards neoantigens. Neon is using its neoantigen platform to develop both personal and precision neoantigen-targeted T cell therapy candidates. Neon's most advanced program is 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.

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; our 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, use of capital and unexpected expenditures, including our ability to manage operating expenses or obtain funding to support planned business activities or to explore and establish strategic alternative transactions; risks related to our ability to attract and retain personnel; 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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