



Neon Therapeutics Announces FDA Acceptance of Investigational New Drug Application for Cancer Vaccine NEO-PV-01

Cambridge, Mass. – July 29, 2016 – [Neon Therapeutics](#), an immuno-oncology company developing neoantigen-based therapeutic vaccines and T cell therapies to treat cancer, today announced that the U.S. Food and Drug Administration (FDA) has accepted the company’s Investigational New Drug (IND) application for its lead program, NEO-PV-01. NEO-PV-01 is a personalized vaccine designed specifically for each patient based on the neoantigen mutations unique to that patient’s tumor DNA.

The IND enables Neon Therapeutics to initiate its first clinical study, which is a multicenter Phase 1b clinical trial evaluating the safety, tolerability and efficacy of NEO-PV-01 with Opdivo (nivolumab), a PD-1 immune checkpoint inhibitor from Bristol-Myers Squibb, in melanoma, non-small cell lung cancer and bladder cancer. The trial will evaluate immune responses in serial samples of peripheral blood and tumor tissue through a comprehensive immune monitoring program.

“We are in the midst of tremendous momentum for neoantigen biology in the field of cancer immunotherapy,” said Cary Pfeffer, M.D., interim chief executive officer of Neon Therapeutics. “This IND filing acceptance brings us one step closer to deliver on the promise of neoantigen science to bring truly personalized cancer therapies to patients living with this devastating disease.”

This clinical trial is expected to begin in 2016, and is anticipated to enroll a total of 90 patients from multiple clinical sites in the U.S. More information about the trial will be available at www.clinicaltrials.gov.

About Neon Therapeutics

Neon Therapeutics is an immuno-oncology company focused on developing novel therapeutics leveraging neoantigen biology to treat cancer. A neoantigen-based product engine allows Neon to develop multiple treatment modalities, including next-generation vaccines and T cell therapies targeting both personalized and shared neoantigens. Neon’s lead program is a personalized neoantigen vaccine that builds upon years of research and development at the Broad Institute and Dana-Farber Cancer Institute, and is already in multiple clinical trials. For more information, please visit www.neontherapeutics.com.

###

Media Contact:

Katie Engleman
Pure Communications, Inc.
910-509-3977
Katie@purecommunicationsinc.com