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Genocea Files Investigational New Drug Application for Neoantigen Cancer Vaccine Candidate GEN-009

- Company plans to initiate Phase 1/2a clinical program later this year -
- Top-line immune response data expected in the first half of 2019 -

CAMBRIDGE, Mass., April 30, 2018 (GLOBE NEWSWIRE) -- [Genocea Biosciences, Inc.](http://www.genocea.com) (NASDAQ:GNCA), a biopharmaceutical company developing neoantigen cancer vaccines, today announced the filing of an Investigational New Drug (IND) Application with the U.S. Food and Drug Administration (FDA) to begin a Phase 1/2a clinical program testing the safety, immunogenicity, and clinical efficacy of GEN-009, the company's lead personalized neoantigen cancer vaccine candidate.

"We are excited to have advanced GEN-009 one step closer to the clinic," said Chip Clark, president and chief executive officer of Genocea. "Our GEN-009 program is designed to use our proprietary ATLAS platform to include only empirically confirmed neoantigens and to exclude what we've identified as inhibitory neoantigens in each patient's vaccine. Our scientific data continue to demonstrate that widely used *in silico*-based neoantigen prediction methods fail to identify most empirically confirmed neoantigens and, critically, misclassify as good the inhibitory neoantigens that vastly outnumber stimulatory neoantigens. We therefore believe that ATLAS distinguishes GEN-009 from other neoantigen vaccine approaches and should enable better immune responses and, ultimately, therapeutic benefit for patients."

Genocea plans to commence the GEN-009 Phase 1/2a clinical program later this year, first studying the safety and immunogenicity of GEN-009 as monotherapy in cancer patients with no evidence of disease, but at high risk of relapse. This part of the program is expected to enroll at least six patients previously treated for melanoma, non-small cell lung cancer, head or neck cancer, or urothelial carcinoma. Genocea expects to announce the first top-line data from this study in the first half of 2019. Following proof of immunogenicity, Genocea expects to study GEN-009 in combination with checkpoint inhibitors in patients with advanced or metastatic solid tumors and as monotherapy in patients who have failed checkpoint inhibitory therapy.

About Genocea Biosciences, Inc.

Genocea's mission is to help conquer cancer by designing and delivering targeted vaccines and immunotherapies. While traditional immunotherapy discovery methods have largely used predictive methods to propose T cell targets, or antigens, Genocea has developed ATLAS™, its proprietary technology platform, to identify clinically relevant antigens of T cells based on actual human immune responses. Genocea is using ATLAS in immuno-oncology applications to develop neoantigen cancer vaccines, while also exploring partnership opportunities for general cancer vaccines and a vaccine targeting cancers caused by Epstein-Barr Virus. Genocea expects to begin clinical development of its first neoantigen cancer vaccine, GEN-009, in 2018. For more information, please visit www.genocea.com.

Forward-Looking Statements

This press release includes forward-looking statements, including statements relating to the expected clinical development of GEN-009 and timing of the announcement of top-line data from the GEN-009 Phase 1/2a clinical program, within the meaning of the Private Securities Litigation Reform Act. Such forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Genocea cautions that these forward-looking statements are subject to numerous assumptions, risks and uncertainties, which change over time. Applicable risks and uncertainties include those identified under the heading "Risk Factors" included in Genocea's Annual Report on Form 10-K for the year ended December 31, 2017 and any subsequent SEC filings. These forward-looking statements speak only as of the date of this press release and Genocea assumes no duty to update forward-looking statements, except as may be required by law.

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