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Genocea Announces Positive Top-Line Phase 1 Results for Novel Universal Pneumococcus Vaccine Candidate GEN-004

- Phase 2a study to commence in the third quarter of 2014 -

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Genocea Biosciences, Inc. (NASDAQ:GNCA), a clinical-stage biopharmaceutical company developing T cell-enabled vaccines and immunotherapies, today announced positive top-line results from a Phase 1 study of GEN-004, an investigational vaccine candidate designed to prevent infections from all serotypes of pneumococcus (*Streptococcus pneumoniae*), a major cause of infectious disease-related death globally. The Phase 1 study met its safety, tolerability and immunogenicity goals, including measurable increases in the blood of T helper 17 (TH17) cells, a rare cell type that provides immunity at epithelial and mucosal surfaces. Based on these data, the Company plans to advance GEN-004 into a Phase 2a trial in the third quarter of 2014.

"GEN-004 represents a novel approach to prevent colonization by all serotypes of pneumococcus in the nasopharynx and thereby potentially preventing serious pneumococcal infections," said Richard Malley, MD, Division of Infectious Diseases, Boston Children's Hospital. "These findings represent the first step toward potentially demonstrating proof-of-concept which could be shown in the upcoming Phase 2a trial."

GEN-004 is the Company's second clinical-stage program to emerge from its ATLAS™ platform, and is a universal vaccine candidate designed to induce a TH17 T cell response to reduce the colonization of all pneumococcal serotypes in the nasopharynx. In published preclinical studies, performed in collaboration with Boston Children's Hospital, GEN-004 conferred significant protection against pneumococcal colonization. Colonization of the nasopharynx by pneumococcus is the first and necessary step prior to the development of serious and even life-threatening infections. Available vaccines protect by inducing B cell, or antibody, immune responses directed towards a minority of the more than 90 known serotypes of pneumococcus. Serotypes not included in the available vaccines are increasingly responsible for causing pneumococcal disease.

The Phase 1 study was a randomized, double-blind, dose-escalation, placebo-controlled clinical trial that enrolled 90 healthy adult volunteers. Serum IgG titers increased in a dose-dependent manner to each of the antigens included in GEN-004 and measurable increases in peripheral T_H17 responses were seen among subjects receiving the highest dose (100µg) with adjuvant. There were no serious adverse events related to the vaccine. Genocea intends to present the complete results of this trial at a major medical conference in 2014.

About GEN-004
GEN-004, Genocea's second clinical candidate, is a potential universal pneumococcal vaccine designed with insights from the Company's ATLAS™ platform. GEN-004 contains three unique conserved pneumococcal protein antigens, SP0148, SP1912, and SP2108, shown by ATLAS™ to be associated with protective T_H17 T cell responses against pneumococcus in humans.

ATLAS profiles the comprehensive spectrum of actual T cell responses mounted by humans in response to disease, enabling the identification of antigen targets with which to design new vaccines and immunotherapies. For more information about GEN-004, please visit http://www.genocea.com/platform-pipeline/pipeline/gen004-for-pneumococcus/.

About Pneumococcus (*Streptococcus pneumoniae*)
Streptococcus pneumoniae, also known as pneumococcus, is a major cause of infectious disease-related death worldwide. The World Health Organization (WHO) estimates that up to 1.6 million people, including 800,000 children, die each year globally as a result of pneumococcal infection.

Pneumococcus naturally colonizes the nasopharynx, or nose and throat, as a precursor to infection. Pneumococcus causes non-invasive pneumococcal disease (NIPD) when it spreads from the nasopharynx into the upper and lower respiratory system to cause diseases such as otitis media (ear infection) and non-bacteremic pneumonia. When it enters the bloodstream, pneumococcus can cause invasive pneumococcal disease (IPD), including life-threatening illnesses such as sepsis, meningitis and bacteremic pneumonia.

Healthy adults generally naturally clear the pneumococcus from the nasopharynx via a rare type of T cells called T_H17 $CD4^+$ T cells before an infection takes hold. In young children or immunocompromised adults, the lack of an effective T_H17 T cell response in the nasopharynx can lead to infection and invasive pneumococcal disease.

About Genocea
Genocea is harnessing the power of T cell immunity to develop life-changing vaccines and immunotherapies. T cells are increasingly recognized as a critical element of protective immune responses to a wide range of diseases, but traditional discovery methods have proven unable to identify the targets of such protective immune response. Using ATLAS™, its proprietary technology platform, Genocea identifies these targets to potentially enable the rapid development of medicines to address critical patient needs. Genocea's pipeline of novel clinical stage T cell-enabled product candidates includes GEN-003 for HSV-2 therapy, GEN-004 to prevent infections caused by pneumococcus, and earlier-stage programs in chlamydia, HSV-2 prophylaxis, malaria and cancer immunotherapy. For more information, please visit the company's website at www.genocea.com.

Forward Looking Statements
Statements herein relating to future business performance, conditions or strategies and other financial and business matters, including expectations regarding clinical developments, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act. Genocea cautions that these forward-looking statements are subject to numerous assumptions, risks and uncertainties, which change over time. Factors that may cause actual results to differ materially from the results discussed in the forward-looking statements or historical experience include risks and uncertainties, including Genocea's ability to progress any product candidates in preclinical or clinical trials; the scope, rate and progress of its preclinical studies and clinical trials and other research and development activities; clinical trial results; current results may not be predictive of future results; even if the data from preclinical studies or clinical trials is positive, the product may not prove to be safe and efficacious; Genocea's ability to enter into future collaborations with industry partners and the government and the terms, timing and success of any such collaboration; the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; Genocea's ability to obtain rights to technology; competition for clinical resources and patient enrollment from drug candidates in development by other companies with greater resources and visibility; the ability to obtain adequate financing in the future through product licensing, co-promotional arrangements, public or private equity or debt financing or otherwise; general business conditions; competition; business abilities and judgment of personnel; the availability of qualified personnel and other factors set forth under "Risk Factors" in Genocea's Annual Report on Form 10-K for the fiscal year ended December 31, 2013 and other filings with the Securities Exchange Commission (the "SEC"). Further information on the factors and risks that could affect Genocea's business, financial conditions and results of operations is contained in Genocea's filings with the SEC, which are available at www.sec.gov. These forward-looking statements speak only as of the date of this press release and Genocea assumes no duty to update forward-looking statements.

For media:
Linnden Communications
Michelle Linn, 508-362-3087
Mobile: 774-696-3803
Michelle@linndencom.com
or
For investors:
Genocea Biosciences
Bob Farrell, 617-674-8261
bob.farrell@genocea.com

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