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GENOCEA BIOSCIENCES INITIATES PHASE 1 STUDY OF VACCINE CANDIDATE GEN-004 TO PREVENT INFECTIONS CAUSED BY PNEUMOCOCCUS

- Novel approach using T cell immunology protects against all strains of pneumococcus; Second clinical program to emerge from Genocea's proprietary antigen discovery platform, ATLAS™ -

Cambridge, MA, December 5, 2013—Genocea Biosciences, Inc., a clinical-stage company pioneering novel T cell vaccines, announced today that it has initiated a Phase 1 study of GEN-004, an investigational vaccine candidate for pneumococcus (*Streptococcus pneumoniae*), a major cause of infectious disease-related death globally. GEN-004 is the first vaccine candidate designed to prevent infections caused by all strains of pneumococcus through a novel T cell-mediated mechanism of action.

According to The World Health Organization, roughly half a million children less than five years of age die of pneumococcal disease annually. Pneumococcus naturally colonizes the nasopharynx, or nose and throat. The bacterium can become dangerous, especially to the very young and the elderly, if it is not cleared from the nasopharynx and enters the lungs and bloodstream, where it can be responsible for life-threatening illnesses such as bacteremic pneumonia, meningitis and sepsis.

Several publications have indicated that T_H17 responses are a natural mechanism to clear pneumococcus from the nasopharynx. GEN-004 contains three unique protein antigens, SP0148, SP1912, and SP2108, shown by Genocea's proprietary antigen discovery platform, ATLAS™, to be associated with protective T_H17 T cell responses against pneumococcus in humans. In preclinical studies presented at the International Symposium on Pneumococci and Pneumococcal Diseases (ISPPD) in 2012, GEN-004 significantly reduced nasopharyngeal colonization by stimulating T_H17 immune responses.

Each protein in GEN-004 is also conserved across all sequenced strains of pneumococcus, meaning that GEN-004 could represent a universal vaccine against pneumococcus working through a novel mechanism of action. There are more than 90 known strains of pneumococcus. Approved vaccines prevent disease caused by the most prevalent strains of pneumococcus, but do not prevent disease caused by strains not in the vaccines. Emerging evidence suggests that strains not in the existing vaccines play an increased role in causing pneumococcal disease.

“Despite the availability of safe and effective vaccines to prevent pneumococcal infection, pneumococcus continues to evolve away from our defenses. The potential to use a T cell-directed vaccine covering all pneumococcal strains to combat the bacterium in the nasopharynx, where its evolution takes place, may enable the next-generation of pneumococcal vaccines,” noted George Siber, M.D., executive director of the Genocea board and chairman of its scientific advisory board. Dr. Siber is the former CSO of Wyeth Vaccines, where he led the development of Prevnar-7®, the first commercial vaccine in the market-leading Prevnar franchise of pneumococcal vaccines from Pfizer, Inc.

The Phase 1 study is a randomized, double-blind, dose-escalation, placebo-controlled clinical trial enrolling approximately 90 healthy adult volunteers. The study will seek to evaluate the safety and immunogenicity of GEN-004 across a range of doses. Genocea expects initial results in the second quarter of 2014.

GEN-004 is the second clinical candidate designed with insights from Genocea’s ATLAS™ antigen discovery platform, which identifies vaccine targets by profiling the T cell responses to a pathogen in large populations of humans exposed to that pathogen. The program to develop this product received support from PATH, an international non-profit organization. Genocea’s lead program is GEN-003, a therapeutic vaccine candidate designed to treat people infected with Herpes Simplex Virus type 2 (HSV-2). Genocea recently reported positive interim Phase 1/2a data for GEN-003, including a statistically significant 51 percent reduction in viral shedding frequency. These data were presented in a late-breaker oral presentation at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in September 2013.

To learn more please visit www.genocea.com.

About Genocea Biosciences, Inc.
Genocea is harnessing the power of T cell immunity to develop the next generation of vaccines. T cells are increasingly recognized as a critical element of protective immune responses to a wide range of infectious disease pathogens, but are difficult to target using traditional vaccine discovery methods. Genocea is able to identify protective T cell antigens in humans exposed to a pathogen using ATLAS™, its proprietary technology platform, potentially enabling vaccines against pathogens for which vaccine solutions do not exist or are sub-optimal. Genocea’s pipeline of novel T cell vaccines includes GEN-003 for HSV-2 therapy, GEN-004, and earlier-stage programs in chlamydia, HSV-2 prophylaxis and malaria.

About PATH
PATH is an international nonprofit organization that transforms global health through innovation. PATH takes an entrepreneurial approach to developing and delivering high-impact, low-cost solutions, from lifesaving vaccines, drugs, diagnostics, and devices to collaborative programs with communities. Through its work in more than 70 countries, PATH and its partners empower people to achieve their full potential. For more information, please visit www.path.org.

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