CAMBRIDGE, Mass., Sept. 12, 2013 /PRNewswire/ -- Genocea Biosciences Inc., a clinical-stage biopharmaceutical company developing T cell vaccines to prevent and treat infectious diseases, reported today positive results from a planned analysis of a Phase 1/2a clinical study of its lead candidate, GEN-003, a first-in-class investigational protein subunit vaccine to treat patients with recurrent outbreaks of genital herpes simplex virus type 2 (HSV-2) infection. The data, presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC 2013), show that patients who received three doses of GEN-003 had reductions in the frequency of viral shedding of up to 51 percent ($p<0.001$). By contrast, those who received a placebo had no decline in viral shedding. T cell immune responses, believed to be important for the control of HSV-2 infection, increased more than twentyfold to one vaccine antigen (ICP4) and more than tenfold to the other (gD2). In addition, GEN-003 increased neutralizing antibodies to the HSV-2 virus fivefold, on average, compared to baseline values. GEN-003 was well tolerated overall.

Results from an exploratory analysis also suggest that the interval between the first immunization and the next recurrence of genital herpes may be prolonged in patients who received GEN-003 compared to those who received placebo, though this first-in-human clinical trial was not designed to test whether GEN-003 improves symptoms or reduces the frequency of recurrent disease.

"These are the first data that provide compelling evidence that a vaccine administered to people with genital herpes can affect their infection. We are excited that GEN-003 reduced viral shedding as this finding paves the way for future trials that will measure the impact on clinical outbreaks," said Anna Wald, MD, MPH, Principal Investigator of the study and Professor of Medicine, Epidemiology and Laboratory Medicine, University of Washington , Member, Fred Hutchinson Cancer Research Center. "The ability to reduce viral shedding is critical, as that is the main driver of transmission of HSV-2 to sexual partners and newborns."

"These initial results are unprecedented in the clinical development of vaccines for HSV-2. We are proud to be pioneers in the field of T cell-directed vaccines. We believe these results validate the potential of our unique ATLAS™ platform to discover and develop vaccines for unmet medical needs," noted Chip Clark, President and Chief Executive Officer of Genocea. "We will complete this study and continue clinical development of GEN-003 with urgency, in order to bring this promising treatment to this large patient population that is in dire need of an approved vaccine that can prevent or treat their disease."

About the Clinical Trial The ongoing study is a double-blind, placebo-controlled dose escalation Phase 1/2a clinical trial to evaluate the safety and immunogenicity of GEN-003. The study enrolled 143 volunteers with a history of moderate-to-severe recurrent HSV-2 infection at seven clinics in the U.S. Patients were sequentially enrolled into one of three dose cohorts (10, 30 or 100 ug of each protein) and randomized within cohorts to receive either GEN-003, vaccine antigens without adjuvant or placebo. Patients received three injections of the assigned treatment into an arm muscle at 21 day intervals. Antibody (B cell) and T cell immune responses to the two protein antigens contained in the vaccine were measured. Safety was monitored by an independent Data Safety Monitoring Committee. A secondary objective of the study was to compare the quantitative presence of HSV-2 ("shedding") before and after the treatments. Viral shedding is considered an important marker for risk of recurrence and transmission of infection. For more information about this clinical study of GEN-003 please visit www.clinicaltrials.gov

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About GEN-003 GEN-003 is a first-in-class T cell vaccine intended to reduce the transmission risk and clinical symptoms of herpes simplex virus type 2 (HSV-2). GEN-003 is designed to induce a balanced B cell (antibody) and T cell immune response and includes fragments of ICP4 and gD2 antigens, as well as the proprietary adjuvant, Matrix-M™, licensed from Novavax, Inc. The adjuvant is a novel saponin-derived product that has demonstrated a B and T cell immunostimulatory profile in previous clinical studies. For more information about GEN-003, please visit http://www.genocea.com/pipeline/hsv-2-faq.html .

About HSV-2 Herpes simplex virus type 2 (HSV-2) is a sexually transmitted disease that is estimated to affect more than 500 million people worldwide. In the U.S., an estimated 50-60 million people are affected. HSV-2 infection can cause recurring, painful genital sores and, due to the stigma associated with this disease, can affect patients' ability to form and maintain relationships. No vaccine is currently approved to prevent or treat the disease.

About Genocea Genocea Biosciences Inc. 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 a protective immune response to a wide range of infectious disease pathogens, but are difficult to target using traditional vaccine discovery methods. Genocea is uniquely able to identify protective T cell antigens in humans exposed to a pathogen using ATLAS™, its proprietary technology platform that mimics the human immune response, potentially improving the effectiveness of vaccine candidates and significantly reducing the time needed to create them. Genocea's pipeline of novel T cell vaccines includes GEN-003 for HSV-2 therapy, GEN-004, a protein vaccine directed at Pneumococcus that is expected to enter the clinic in the fourth quarter of 2013, and earlier-stage programs in chlamydia, HSV-2 prophylaxis and malaria.

For more information, please visit the company's website at www.genocea.com .

About Novavax□□ Novavax, Inc. (Nasdaq: NVAX) is a clinical-stage biopharmaceutical company creating novel vaccines and vaccine adjuvants to address a broad range of infectious diseases worldwide. Additional information about Novavax is available on the company's website, www.novavax.com .

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