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Genocea Presents New 12 month Data on Genital Herpes Immunotherapy GEN-003 at IDWeek 2016

- Increase in CD4$^+$ polyfunctional T cells indicates GEN-003 is stimulating a multi-faceted T cell immune response to genital herpes -

- GEN-003 elicited strong antibody responses at 12 months post-dosing -

CAMBRIDGE, Mass., Oct. 28, 2016 (GLOBE NEWSWIRE) -- Genocea Biosciences, Inc. (NASDAQ:GNCA), a company developing T cell-directed vaccines and immunotherapies, today presented new 12 month immunogenicity data from the Phase 2a trial of its genital herpes immunotherapy GEN-003. This analysis shows that GEN-003 immunization results in the development of CD4$^+$ polyfunctional T cells, which indicates that GEN-003 is stimulating a multi-faceted T cell immune response to genital herpes. The presentation also details the strong, antigen-specific antibody responses elicited by GEN-003 for up to 12 months post-dosing, consistent with its sustained effect on viral shedding and clinical disease at the same time point. Data were presented at the Infectious Disease Society of America (IDSA) annual meeting in New Orleans, Louisiana.

"These data provide strong evidence of clear and robust T and B cell immune responses that support the positive 12 month clinical results from the Phase 2a trial, which show that GEN-003 has a significant and durable effect on genital herpes viral shedding and clinical disease for at least 12 months after dosing," said Jessica Baker Flechtner, Ph.D., chief scientific officer at Genocea. "We are particularly excited about the data showing the development of polyfunctional T cells, which are considered to deliver a more effective immune response than those T cells which secrete only one mediator. This immunological data once again demonstrates that GEN-003 can have a true biological effect against genital herpes and supports our confidence in its potential to become a cornerstone treatment for this serious disease."

Twelve-month clinical data previously reported from this Phase 2a trial found that, for the 60 µg per protein / 50 µg of adjuvant dose, which has been selected as the best dose for Phase 3 trials, viral shedding was reduced by 66 percent vs. baseline ($p < 0.0001$). Significant clinical efficacy was also demonstrated at this dose with a 65 percent reduction in the genital lesion rate vs. baseline ($p=0.003$) and 30 percent of patients remaining lesion free for 12 months post dosing. These data show that a single course of injections with GEN-003 can result in similar outcomes to taking a year of daily oral antiviral therapy.

This new analysis found that GEN-003 induced polyfunctional T cells post-immunization that peaked at day 8 and persisted through at least day 50. This data could have important implications for the understanding of how the immune system controls genital herpes infections given that polyfunctional T cells have been linked to the control of HIV and other persistent viral infections. Furthermore, mean IgG titers increased up to 21-fold to ICP4.2 and 8-fold to gD2DTMR and persisted 7- and 3-fold above baseline, respectively, at one year. Mean neutralizing antibody titers increased more than 5-fold and remained more than 2-fold over baseline at one year. These increases in antigen-specific immune response was accompanied by reductions in both viral shedding and genital lesion rates. *(Poster #1343, Functional Antibody Responses to GEN-003, a Herpes Simplex Virus Immunotherapy that Durably Reduces Viral Shedding up to 12 Months Post Dosing,* Friday, October 28, 2016 between 12:30pm and 2:00pm ET*).*

About the GEN-003 Phase 2a Clinical Trial
This Phase 2a study enrolled 310 subjects from 17 institutions in the United States. Subjects were randomized to one of six dosing groups of either 30 µg or 60 µg per protein paired with one of three adjuvant doses (25 µg, 50 µg, or 75 µg). A seventh group received placebo. Subjects received three doses of GEN-003 or placebo at 21-day intervals. Baseline viral shedding and genital lesion rates were established for each subject in a 28-day observation period prior to the commencement of dosing by collecting 56 genital swab samples (two per day), which were analyzed for the presence of HSV-2 DNA, and by recording the days on which genital lesions were present. This 28-day observation period was repeated immediately after the completion of dosing and at six and, twelve months following dosing. No booster doses were given. After the 28-day observation period immediately after dosing, patients in the placebo arm were rolled over across the 6 active combinations of GEN-003 and Matrix-M2 under a separate protocol.

For more information about this clinical study of GEN-003 please visit www.clinicaltrials.gov.

About GEN-003
We believe that inducing a T cell response against genital herpes is critical to treating the clinical symptoms of disease and controlling transmission of the infection. GEN-003 is a first-in-class T cell directed immunotherapy designed to elicit both a T cell and B cell (antibody) immune response. The immunotherapy was designed using Genocea's ATLAS™ platform, which profiles the comprehensive spectrum of actual T cell responses mounted by humans in response to disease, to identify antigen targets that drive T cell response. GEN-003 includes the antigens ICP4 and gD2 along with Matrix-M2^{TM} adjuvant, which Genocea licensed from Novavax, Inc. For more information about GEN-003, please visit http://www.genocea.com/platform-pipeline/pipeline/gen003-for-genital-herpes/.

About Genital Herpes
Genital Herpes affects more than 400 million people worldwide and causes recurrent, painful genital lesions. It can be transmitted to sexual partners, even when the disease is asymptomatic. Current genital herpes therapies only partially control clinical symptoms and viral shedding, a process which drives disease transmission. Incomplete control of genital lesions and transmission risk, expense and the perceived inconvenience of taking a daily medication are hurdles for long-term disease management. Immunity through T cells is believed to be particularly critical to the control and possible prevention of genital herpes infections.

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 genital herpes, GEN-004 for the prevention of infection by all serotypes of pneumococcus (development suspended; actively seeking partnership opportunities to conduct a Phase 2 infant and toddler study), and earlier-stage programs in chlamydia, genital herpes 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 ability of ATLAS to identify promising oncology vaccine and immunotherapy product candidates; the scope, rate and progress of its preclinical studies and clinical trials and other research and development activities; anticipated clinical trial results; current results may not be predictive of future results; even if the data from preclinical studies or clinical trials is positive, regulatory authorities may require additional studies for approval and 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; risks associated with the manufacture and supply of clinical and commercial product; 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 rate of cash utilized by Genocea in its business and the period for which existing cash will be able to fund such operation; Genocea's 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, 2015 and other filings with the Securities and 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.

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