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Genocea Announces Positive 6-Month Results from GEN-003 Phase 2b Clinical Trial

- Trial meets statistical significance vs. placebo for multiple clinical endpoints through six months -

- End of Phase 2 meeting with FDA expected in Q1 2017 -

- Phase 3 launch expected in Q4 2017 -

- GEN-003 has potential to be first new treatment for genital herpes infections in more than 20 years -

- Company to host conference call at 9 a.m. ET today -

CAMBRIDGE, Mass., Jan. 05, 2017 (GLOBE NEWSWIRE) -- Genocea Biosciences, Inc. (NASDAQ:GNCA), a biopharmaceutical company developing T cell-directed vaccines and immunotherapies, today announced positive clinical results from a planned interim analysis of its ongoing placebo-controlled Phase 2b trial evaluating GEN-003 for the treatment of genital herpes infections. Even in a trial this small, at six months after dosing, GEN-003 demonstrated statistically significant improvements versus placebo across multiple clinical endpoints.

The 60 µg per antigen / 50 µg of adjuvant dose of GEN-003 significantly reduced the rate of genital lesions during the six months following dosing compared to placebo (4.5 percent of days vs. 7.9 percent, respectively; 41% reduction vs. placebo, $p < 0.05$). The genital lesion rate is an important overall measure of disease that captures both the frequency and duration of recurrences, both of which are important to both patients and their caregivers. In the trial, GEN-003 also consistently demonstrated significant benefits versus placebo across several other clinical endpoints across the dose groups (see data summary below).

In aggregate, the data from the GEN-003 Phase 2 clinical trials continue to support the selection of the 60 µg per antigen / 50 µg of adjuvant dose for the planned Phase 3 program. GEN-003 also continues to demonstrate a safety profile appropriate for its therapeutic setting in the judgment of the trial's independent Drug Monitoring Committee.

"We are very pleased to have demonstrated such a powerful impact on genital herpes clinical disease in this trial, supporting the groundbreaking potential of GEN-003 to be the first-ever therapeutic vaccine for a chronic infection and the first advance in the treatment of genital herpes in more than 20 years," said Chip Clark, president and chief executive officer of Genocea. "We look forward to meeting with the FDA in the first quarter of 2017 and to commencing our GEN-003 Phase 3 program in the fourth quarter of 2017. It's an exciting time for Genocea as we also continue to extend the potential of our ATLAS platform to harness the power of T cells in immuno-oncology."

"In my experience, genital herpes is unique among sexually transmitted diseases, in terms of its physical and emotional impact on patients, who experience significant fear upon receiving the diagnosis, as well as isolation during their lifelong struggle with the disease," said Nicholas Van Wagoner, M.D., Ph.D., Assistant Professor of Medicine, Division of Infectious Diseases, at the University of Alabama at Birmingham. "Today's results, showing that GEN-003 significantly reduces the number of days with genital lesions, indicates that GEN-003 has the potential to be a much needed additional treatment option that could address compliance challenges and help me take better care of my patients."

Summary of Reported Clinical Endpoint Data

Secondary clinical endpoint	Placebo (n=44)	60/50 (n=43)	60/75 (n=44)
Mean genital lesion rate (percent of days with lesions over 6 months)	**7.9%**	**4.5%**	**4.6%**
p-value versus placebo[1]	NA	0.03	0.03
Mean duration of recurrences (days)	**4.8**	**3.3**	**4.3**
p-value versus placebo[1]	NA	0.01	0.64
Mean number of recurrences over 6 months	**2.7**	**2.1**	**1.9**
p-value versus placebo[1]	NA	0.08	0.02

Kaplan-Meier estimate of percent recurrence free after first dose	**10%**	**29%**	**31%**
p-value versus placebo[(2)]	NA	0.03	0.03
Kaplan-Meier estimate of percent recurrence free after last dose	**13%**	**22%**	**36%**
p-value versus placebo[(2)]	NA	0.17	0.02

Statistical tests pre-specified in Phase 2b trial protocol as follows:
(1) Wilcoxon Rank Sum test
(2) Log rank test

About the GEN-003 Phase 2b Clinical Trial
This Phase 2b trial is the first study testing potential Phase 3 endpoints with the improved formulation of GEN-003 - manufactured with commercially-scalable processes - that will be used in future Phase 3 trials. The trial enrolled 131 subjects from 9 institutions in the United States. Subjects have been randomized to one of three dose groups - placebo, 60 µg per antigen / 50 µg of adjuvant and 60 µg per antigen / 75 µg of adjuvant - and have received three injections at 21-day intervals. All subjects will be followed for 12 months after the last dose.

In September 2016, Genocea reported that the trial achieved its primary endpoint, with GEN-003 demonstrating a statistically significant reduction of 40 percent in the rate of viral shedding in the 60 µg per antigen / 50 µg of adjuvant dose group compared to both baseline and placebo. Safety in the trial is continuously reviewed by an independent Drug Monitoring Committee. There has been no grade 4 reactogenicity or related serious adverse events in this trial and discontinuations due to adverse events have been low and similarly distributed across active dose groups and placebo. 12-month clinical data from the trial is expected in the middle of 2017.

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

Conference Call
Genocea management will host a conference call and webcast today at 9 a.m. ET to review these data. The conference call may be accessed by dialing (844) 826-0619 for domestic participants and (315) 625-6883 for international callers (reference conference ID 44780200). A live webcast of the conference call will be available online from the investor relations section of the Company's website at http://ir.genocea.com. A webcast replay of the conference call will be available on the Genocea website beginning approximately two hours after the event, and will be archived for 30 days.

About GEN-003
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 and identifies antigen targets that drive effective T cell responses. GEN-003 includes the antigens ICP4 and gD2 along with Matrix-M™ adjuvant (licensed from Novavax, Inc. (NASDAQ:NVAX)). For more information about GEN-003, please visit the GEN-003 section of our website.

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 immunity. 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 includes GEN-003, a novel T cell-enabled immunotherapy for genital herpes currently in Phase 2 clinical development, and earlier-stage investments in immuno-oncology. For more information, please visit the company's website at www.genocea.com.

About Matrix-M
Matrix-M™ is a next-generation, patented saponin-based adjuvant comprised of purified saponin fractions mixed with synthetic cholesterol and a phospholipid to form stable particles than can be readily formulated with a variety of vaccine antigens. Saponin-based adjuvants act in part by stimulating the entry of antigen-presenting cells into the injection site and enhancing antigen presentation in the local lymph nodes. Thus, Matrix-M™ induces both a cell-mediated and antibody

mediated immune response. Matrix-M is manufactured by Novavax, Inc (NASDAQ:NVAX), in Uppsala Sweden.

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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