July 24, 2017

Genocea Reports Positive Top-Line 12-Month Phase 2b Data for GEN-003 in Genital Herpes

- Statistically significant result on expected Phase 3 primary endpoint with Phase 3 dose -
- Positive results on multiple secondary clinical endpoints -
- Potentially the first new treatment in more than 20 years for the millions infected with genital herpes -
- Conference call today at 8 a.m. ET -

CAMBRIDGE, Mass., July 24, 2017 (GLOBE NEWSWIRE) -- Genocea Biosciences, Inc. (NASDAQ:GNCA), a biopharmaceutical company developing novel vaccines and immunotherapies targeting T cell antigens, announced today positive 12-month top-line data from the Phase 2b clinical trial for GEN-003, its immunotherapy candidate for patients with genital herpes.

In this 131-subject Phase 2b clinical trial, GEN-003 reduced the median genital lesion rate (or percent days with genital lesions) versus placebo by 49 percent (p=0.01) over the 12 months' post dosing at the 60 µg per antigen / 50 µg of adjuvant dose. Importantly, these results were achieved at the Phase 3 dose and expected Phase 3 primary endpoint. Other clinical endpoints for this dose improved or were consistent with previously reported positive data. No changes were observed to the previously established safety profile of GEN-003.

Chip Clark, President and CEO of Genocea, commented: "We believe these data further solidify the strong clinical profile for GEN-003, which could provide durable, convenient efficacy to a large and, we believe, highly dissatisfied patient population and serve as a cornerstone treatment of this burdensome disease."

"These data and the continued progress of GEN-003 show the potential of this immunotherapy to change the treatment paradigm for patients with genital herpes infections," said Jonathan Temte, M.D., Ph.D., M.S., former chair of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP). "The benefits of using a periodic immunization to achieve fewer and shorter genital herpes outbreaks without the compliance challenges of a daily pill burden would represent an extremely important alternative for patients with genital herpes. I believe the potential individual and societal benefits of a treatment such as GEN-003 to address the uncontrolled growth in genital herpes infections resonates with the goals of bodies such as the ACIP."

Conference Call
Genocea management will host a conference call and webcast today at 8 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 60267894). 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 the GEN-003 Phase 2b Clinical Trial
The Phase 2b trial (GEN-003-003) was a randomized, double-blind, placebo-controlled study evaluating potential Phase 3 endpoints with a formulation of GEN-003 manufactured with commercially-scalable processes and expected to be used in future Phase 3 trials. The trial enrolled 131 subjects from 9 institutions in the United States. Subjects were 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 received three injections at 21-day intervals. Subjects were followed for 12 months after the last dose was administered.

In September 2016, Genocea reported that the trial achieved its primary endpoint, with GEN-003 demonstrating a statistically significant reduction in the rate of viral shedding in the 60 µg per antigen / 50 µg of adjuvant dose group compared to both baseline and placebo. In January 2017, the company reported that the 60 µg per antigen / 50 µg of adjuvant dose of GEN-003 significantly reduced the median genital lesion rate during the six months following dosing compared to placebo. Safety in the trial is continuously reviewed by an independent Drug Monitoring Committee. Throughout the trial, there have been no drug-related serious adverse events or grade 4 reactogenicity and discontinuations due to adverse events have been low and similarly distributed across active dose groups and placebo. A 12-month extension of this study (GEN-003-005) is currently underway to examine the safety, efficacy and durability of a single maintenance dose administered at 12 months after initial dosing.

Summary of Reported 12 Month Data

Endpoint	60/50 (n=43)	60/75 (n=44)	Placebo (n=44)
Number of subjects contributing clinical data	43	44	44
Median genital lesion rate (percent of days with lesions over 12 months)	**2.3%**	**2.8%**	**4.5%**
Percent reduction versus placebo	-49%	-37%	NA
p-value versus placebo[(1)]	0.01	NS	NA
Median number of recurrences over 12 months	**1.5**	**2.0**	**4.0**
Percent reduction versus placebo	-63%	-50%	NA
p-value versus placebo[(1)]	0.01	NS	NA
Median duration of recurrences (days)	**2.7**	**4.0**	**3.6**
Percent reduction versus placebo	-25%	11%	NA
p-value versus placebo[(1)]	0.02	NS	NA
Kaplan-Meier estimate of percent recurrence free after first dose	**20%**	**16%**	**7%**
p-value versus placebo[(2)]	0.04	NS	NA
Kaplan-Meier estimate of percent recurrence free after last dose	**20%**	**17%**	**8%**
p-value versus placebo[(2)]	NS	0.05	NA
Number of subjects contributing shedding data	30	32	31
Viral shedding rate reduction from baseline	**-42%**	**-39%**	**-52%**
p-value versus baseline[(3)]	0.02	NS	0.03
p-value versus placebo [(3)]	NS	NS	NA

Statistical tests pre-specified in Phase 2b trial protocol as follows:
(1) Wilcoxon Rank Sum test
(2) Log rank test
(3) Poisson mixed effect model with empirical variance
NS = p > 0.05

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 investigational 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 the Genocea 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 Biosciences, Inc.
Genocea is harnessing the power of T cell immunity to develop life-changing vaccines and immunotherapies. While traditional immunotherapy discovery methods have largely used predictive methods to propose T cell targets, or antigens, Genocea has successfully developed ATLAS™, its proprietary technology platform, to identify clinically relevant antigens of T cells based on actual human immune responses. Genocea used ATLAS to identify the antigens in its lead clinical candidate, GEN-003, an investigational immunotherapy to treat genital herpes, and is currently using ATLAS in immuno-oncology applications to develop neoantigen cancer vaccines (with an IND filing expected by the end of 2017), general cancer vaccines and a vaccine targeting cancers caused by Epstein-Barr Virus. For more information, please visit 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 that 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; anticipated timing for initiation of new clinical trials; 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 to continue its clinical programs 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, 2016 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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