September 29, 2016

Genocea's Genital Herpes Immunotherapy GEN-003 Demonstrates Significant Reduction of Viral Shedding in Phase 2b Clinical Trial

- Trial achieves primary endpoint -

- Dose confirmed for subsequent trials -

- Phase 3 expected to start in 2H 2017 -

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

CAMBRIDGE, Mass., Sept. 29, 2016 (GLOBE NEWSWIRE) -- Genocea Biosciences, Inc. (NASDAQ:GNCA), a biopharmaceutical company developing T cell-directed vaccines and immunotherapies, today announced positive results from its ongoing Phase 2b trial evaluating a new Phase 3-ready formulation of GEN-003 for the treatment of genital herpes. The study 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 protein / 50 µg of Matrix-M2 dose group compared to both baseline and placebo. The viral shedding rate reduction for this dose was consistent with its performance at the same time point in a prior Phase 2 trial.

"We are very encouraged by this positive data and have now selected a dose of 60 µg per protein / 50 µg of Matrix-M2 of GEN-003 for our planned Phase 3 trials. This is the third consecutive trial in which GEN-003 has demonstrated a statistically significant reduction in viral activity immediately post-dosing. In the previous Phase 2 trial, success in this measure translated into a significant impact on genital herpes clinical disease, durable to at least 12 months," said Chip Clark, president and chief executive officer of Genocea. "This body of data supports our strong belief that GEN-003 could be a cornerstone treatment for genital herpes. We look forward to reporting six-month placebo-controlled clinical data from this trial in January 2017 and expect to commence our Phase 3 program in the second half of 2017."

During the 28-day observation period immediately after completion of dosing, the 60 µg per protein / 50 µg of Matrix-M2 dose of GEN-003 demonstrated a statistically significant 40 percent reduction from baseline in the viral shedding rate versus a marginal increase of 6 percent for placebo. The 60 µg per protein / 75 µg of Matrix-M2 dose demonstrated a 27 percent reduction in the viral shedding rate. The top-line viral shedding rate reductions for all of the dose groups in the trial are summarized in the following table:

	60 µg per protein / 50 µg of Matrix-M2	**60 µg per protein / 75 µg of Matrix-M2**	**Placebo**
Viral shedding rate reduction	**-40%**	**-27%**	**+6%**
p-value vs. baseline*	0.03	0.16	0.76
p-value vs. placebo*	0.05	0.20	NA

* Statistical analysis performed using a modified Poisson model (refined since Phase 2a trial with reference to advances in the field: Magaret, Amalia, "Models for HSV shedding must account for two levels of overdispersion" (January 2016). UW Biostatistics Working Paper Series. Working Paper 410. http://biostats.bepress.com/uwbiostat/paper410)

Safety in the trial was continuously reviewed by an independent Data Safety Monitoring Board. There was no grade 4 reactogenicity or related serious adverse events in this trial and discontinuations due to adverse events were low and similarly distributed across active dose groups and placebo.

"The established clinical profile of GEN-003 is one that could be highly beneficial to patients looking for an effective treatment which potentially offers greatly improved convenience over daily oral antivirals, the only current treatment option for the millions of people suffering from genital herpes," said Lori A. Panther, M.D., MPH, Infectious Diseases specialist at Beth Israel Deaconess Medical Center and Assistant Professor of Medicine at Harvard Medical School. "I'm extremely encouraged by these results, once again demonstrating that GEN-003 reduces viral shedding. Control of viral shedding is fundamental to the control of genital herpes outbreaks and the epidemic spread of the disease."

About the GEN-003 Phase 2b Clinical Trial
This Phase 2b trial is the first study testing potential Phase 3 endpoints with an improved formulation of GEN-003 - manufactured with commercially-scalable processes - which 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 protein / 50 µg of Matrix-M2 and 60 µg per protein / 75 µg of Matrix M2 - and have received three injections at 21-day intervals. Viral shedding rate reductions were measured to demonstrate the efficacy of the new formulation. The study will also compare GEN-003 efficacy to placebo for the clinical endpoints of: the proportion of patients who are lesion free at six and 12 months after dosing; the time to first lesion recurrence after dosing; and, the impact on percentage of days with genital herpes lesions at six and 12 months after dosing. All subjects will be followed for 12 months after the last dose.
For more information about this clinical study of GEN-003 please visit www.clinicaltrials.gov.

Conference Call
Genocea management will host a conference call and webcast today at 9 a.m. ET to review this 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 87103963). 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, to identify antigen targets that drive T cell response. GEN-003 includes the antigens ICP4 and gD2 along with Matrix-M2™ adjuvant, which Genocea licenses 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 pending further data analysis and consultation with our advisers), and earlier-stage programs in cancer immunotherapy, chlamydia, genital herpes prophylaxis and malaria . 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.

For media:

Liz Bryan

Spectrum Science Communications

O: 202-587-2526

lbryan@spectrumscience.com

For investors:

Jonathan Poole

Genocea Biosciences

O: 617-876-8191

jonathan.poole@genocea.com

Primary Logo

Source: Genocea Biosciences

News Provided by Acquire Media