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Genocea Announces Positive Durability Data from 6-Month Analysis of Phase 2 Clinical Trial of Genital Herpes Immunotherapy GEN-003

- Sustained viral shedding rate reduction of 58 percent from baseline at best dose improves upon established attractive product profile -
- Efficacy seen consistently across several potential Phase 3 clinical endpoints -
- End of Phase 2 meeting with FDA expected in late 2016 -
- Company to host conference call at 9 a.m. ET today; data to be presented at IDWeek 2015 -

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Genocea Biosciences, Inc. (NASDAQ:GNCA), a biopharmaceutical company developing T cell-directed vaccines and immunotherapies, today announced positive results from a planned interim analysis of data collected six months after dosing from its ongoing Phase 2 dose optimization trial evaluating GEN-003 for the treatment of genital herpes. At its best performing dose of 60 µg per protein / 75 µg of Matrix-M2™ adjuvant, GEN-003 demonstrated a statistically significant 58 percent reduction from baseline in the viral shedding rate ($p < 0.0001$), the primary endpoint of the study.

In a planned secondary analysis to assess the impact on genital lesion rates, a patient-reported measurement of clinical disease, GEN-003 demonstrated sustained and statistically significant reductions from baseline in five of six dose groups ranging from 43 to 69 percent. In addition, the proportion of patients receiving GEN-003 who were lesion-free at six months after dosing ranged from approximately 30 to 50 percent, similar to results reported in clinical trials with oral antiviral therapies. A further secondary analysis measuring the time to first recurrence after completion of dosing showed a range of 152 days to greater than 180 days among dose groups. The Phase 2 trial continues to show that GEN-003 is safe and well tolerated by patients, with no serious adverse events related to the vaccine.

"These data confirm the durable virological and clinical effect of GEN-003 to at least six months post dosing and further improve upon the results in our prior Phase 1/2a trial," said Chip Clark, president and chief executive officer of Genocea. "These data support the potential of GEN-003 to serve as a cornerstone therapy for genital herpes infections with convenient, long term viral shedding and symptom control. Given the excellent results at six months, which reinforce GEN-003's existing strong profile, upside exists from potential efficacy at twelve months. We look forward to this data in the first quarter of 2016 and to advancing GEN-003 towards an end-of-Phase 2 meeting with the FDA in late 2016."

"The majority of people with genital herpes treat their disease episodically, but episodic treatment is not effective at either reducing the frequency of painful lesion outbreaks or periods of asymptomatic shedding, when the majority of disease transmission occurs," said Nicholas Van Wagoner, M.D. Ph.D., Assistant Professor of Medicine, Division of Infectious Diseases, at the University of Alabama at Birmingham. "These six month data demonstrate the potential for a therapeutic vaccine to advance the treatment of this serious disease, providing durable efficacy, similar to chronic suppressive treatment with oral antivirals, with increased convenience and the potential for better compliance by patients."

Data will be presented in poster number 898 at IDWeek 2015™ on Friday, October 9, 2015 between 12:30 p.m. and 2:00 p.m. PST in the San Diego Convention Center Poster Hall. Nicholas Van Wagoner, M.D. Ph.D., will present the findings.

About the GEN-003 Phase 2 Clinical Trial

In May 2015, Genocea reported initial positive top-line data from this Phase 2 dose optimization trial, which showed that during the 28-day observation period immediately after completion of dosing, the best dose of 60 µg per protein / 75 µg of Matrix-M2™ adjuvant demonstrated a highly statistically significant ($p < 0.0001$) 55 percent reduction from baseline in the viral shedding rate. All dose combinations tested demonstrated a statistically significant viral shedding rate reduction versus baseline and only the lowest dose combination did not demonstrate a statistically significant reduction versus placebo. A planned secondary analysis to assess impact on patient-reported genital lesion rates demonstrated a statistically significant reduction from baseline in all groups, including the placebo group.

This Phase 2 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, in time, twelve months following dosing. No booster doses will be given. After the 28-day observation period immediately after dosing, patients in the placebo arm were rolled over to 1 of the 6 active combinations of GEN-003 and Matrix-M2™.

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. The conference call may be accessed by dialing (844) 826-0619 for domestic participants and (315) 625-6883 for international callers (reference conference ID 55798395). 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 HSV-2 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 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, 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 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, 2014 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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For media:

Spectrum Science Communications

Amanda Johnson, 202-587-2520

ajohnson@spectrumscience.com

or

For investors:

Genocea Biosciences

Jonathan Poole, 617-876-8191

jonathan.poole@genocea.com

Source: Genocea Biosciences, Inc.

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