

December 14, 2016

# Genocea R&D Day Highlighted Lead Program, GEN-003, for the Treatment of Genital Herpes and Introduced Immuno-Oncology Programs & Strategy

- GEN-003 Phase 2b placebo-controlled clinical efficacy data six months after dosing expected in January 2017 -

- Announced new research collaborations with Checkmate Pharmaceuticals in advanced melanoma and US Oncology Research across multiple cancers -

- Neoantigen cancer vaccine IND expected in 2017 -

CAMBRIDGE, Mass., Dec. 14, 2016 (GLOBE NEWSWIRE) -- Genocea Biosciences, Inc. (NASDAQ:GNCA), a company developing T cell-directed vaccines and immunotherapies today held its first R&D day for investors and analysts. The company highlighted its lead program, GEN-003, a T cell-directed immunotherapy for the treatment of genital herpes infections for which six-month Phase 2b placebo-controlled clinical efficacy is expected in January 2017. The Company also introduced its immuno-oncology strategy, including its plans to file an IND for a neoantigen cancer vaccine in 2017 and announced new research collaborations with Checkmate Pharmaceuticals, Inc. (Checkmate) and US Oncology Research.

"Genocea is a leader in the development of innovative therapies at the forefront of the T cell revolution with GEN-003 for genital herpes and our emerging work in immuno-oncology," said Chip Clark, president and chief executive officer of

Genocea. "We believe that ATLAS<sup>TM</sup>, our T cell antigen discovery platform, that is the basis of our clinical success to date in infectious diseases, is ideally suited to advance the understanding of the role T cells play in killing cancer. Our confidence in our immuno-oncology programs is strengthened by the collaborations we announced today, which reflect broad interest in our unique ability to comprehensively profile a person's actual T cell responses to cancer."

## **GEN-003 Program Highlights**

Today, Genocea highlighted the significant body of clinical data it has generated over the course of three clinical trials for what may be the first new therapy for genital herpes in more than 20 years. GEN-003 is a first-in-class T cell-directed immunotherapy designed to elicit both a T cell and B cell immune response to antigens prioritized using the ATLAS platform. Genocea's ATLAS platform profiled the comprehensive spectrum of actual T cell responses mounted by humans in response to their genital herpes disease to identify the antigen targets that drove protective T cell responses.

Based on clinical data to date, as well as market research showing the significant dissatisfaction among patients with current treatment options for genital herpes, GEN-003 may offer patients an important new treatment option with the promise of improved 'real-world' clinical outcomes and sustained reductions in viral shedding with the convenience of annual maintenance dosing. The Company expects to report six-month clinical efficacy data from its ongoing Phase 2b placebo-controlled trial in January 2017.

Guest speaker Nicholas Van Wagoner, M.D., Ph.D., Assistant Professor, Division of Infectious Diseases at the University of Alabama, Birmingham, School of Medicine provided an overview of the disease and reviewed the current treatment approach for genital herpes and affirmed his belief that a product with the profile of GEN-003 could create a much-needed additional treatment option for patients and physicians.

Genocea also today for the first time presented the results of extensive new market research based on GEN-003's demonstrated clinical profile, suggesting that patients, physicians and payers all view GEN-003 favorably. Mr. Clark presented data demonstrating the Company's belief that GEN-003 could have upwards of \$2 billion global revenue potential if successfully developed worldwide.

## Immuno-Oncology Program Highlights

Guest speaker Charles G. Drake, M.D., Ph.D., Director of GU Medical Oncology, Co-Director: Immunotherapy Program, Associate Director for Clinical Research, and Professor of Oncology and Immunology at the Herbert Irving Cancer Center at Columbia University, provided an overview of immunotherapy in cancer. His presentation reviewed the progress made in

treating cancer with checkpoint inhibitors and the opportunity to further improve clinical outcomes, including through a better understanding of which patients will benefit from existing therapies and combining checkpoint inhibitors with cancer vaccines.

A Genocea presentation followed, introducing its immuno-oncology strategy and highlighting the unique ability of its ATLAS platform to comprehensively elucidate the T cell responses that patients make to cancers.

This capability is currently being applied to profiling T cell responses of patients who are treated with checkpoint inhibitors and other immune modulators, with the goal of finding signatures of T cell response that associate with positive and negative outcomes. Genocea plans to use these insights to help prospectively define, in a commercial or clinical setting, patients who could benefit from these therapies.

Genocea is also advancing a personalized neoantigen cancer vaccine program toward the filing of an Investigational New Drug (IND) application in 2017. This program leverages Genocea's deep vaccinology experience along with ATLAS's differentiated ability to select vaccine antigens based on an individual's comprehensive T cell responses to the mutations in their own cancer. The company believes that ATLAS overcomes the weaknesses of conventional algorithm approaches to cancer antigen selection, which have significant false positive prediction rates.

The company also updated progress on the development of a vaccine for cancers associated with Epstein Barr Virus (EBV). ATLAS screening has already identified novel T cell antigens, including those which appear to be associated with natural immunity against EBV infection and antigen selection and prioritization is ongoing.

## Collaboration with Checkmate Pharmaceuticals, Inc.

This morning, the Company announced a research collaboration with Checkmate to characterize patterns of T cell responses to tumor-associated antigens in advanced melanoma. The goal of the collaboration is to identify the specificity and characteristics of T cells associated with protective T cell responses to potentially optimize clinical development and ultimately, clinical practice with CMP-001. ATLAS will be used to profile the T cell responses of approximately 20 patients enrolled in Checkmate's ongoing Phase 1b clinical trial of CMP-001 in combination with the checkpoint inhibitor pembrolizumab to a library of tumor-associated antigens common to patients with advanced melanoma. The T cell response signatures of those patients who respond to CMP-001 / pembrolizumab combination therapy will be compared to the signatures of those who do not respond, thereby potentially identifying antigens associated with positive or negative patient outcomes.

#### Collaboration with US Oncology Research

Genocea also announced this morning a new collaboration with US Oncology Research, one of the USA's largest research programs specializing in oncology clinical trials, to screen the T cell responses of cancer patients with solid tumors who will be treated with checkpoint inhibitors against the complete repertoire of patient-specific putative cancer neoantigens. The objective of the collaboration is to use ATLAS to further Genocea's expertise in identifying signatures of T cell responses in cancer patients and to discover new T cell cancer vaccine antigens.

## R&D Day Replay

A replay of the R&D day can be accessed at: http://ir.genocea.com/events.cfm.

#### About ATLAS

ATLAS is a first of its kind proprietary rapid antigen identification screening system designed to find targets of protective T cell responses. The technology solves challenges to date associated with finding targets of T cell responses. ATLAS can examine T cell responses from large, diverse human populations, and comprehensively screen every potential antigen from a pathogen or cancer in a rapid, high-throughput manner, taking weeks versus years to find relevant antigens. Because targets identified by ATLAS are based on actual human immune responses to all potential antigens, with no guesswork or predictions, by the time these candidates reach clinical trials there may be a greater likelihood of success in clinical development. This approach provides the ability to identify smarter targets for use in developing vaccines and immunotherapies to treat infectious disease, cancer and autoimmunity.

#### **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<sup>TM</sup>, 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 in Phase 2 clinical development, and earlier-stage investments in immuno-oncology. For more information, please visit the

#### **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 product candidates in oncology; 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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