



November 5, 2015

Genocea Reports Third Quarter 2015 Financial Results

- *Company Reports Recent Milestones and Announces Expansion of ATLAS™ Technology into Immuno-Oncology* -
- *Conference Call and Webcast Scheduled for 9:00 a.m. ET Today* -

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Genocea Biosciences, Inc. (NASDAQ:GNCA), a biopharmaceutical company developing T cell-directed vaccines and immunotherapies, today reported recent corporate highlights and financial results for the third quarter ended September 30, 2015.

"In early October, we reported positive six-month durability data for GEN-003 which further support its potential to serve as a cornerstone therapy for genital herpes infections with convenient, long-term disease control. We look forward to reporting 12-month data from this ongoing trial in the first quarter of 2016 and to our end of Phase 2 meeting with the FDA later next year," said Chip Clark, president and chief executive officer of Genocea. "Additionally, we are excited to report several recent milestones as part of the expansion of our ATLAS technology into oncology, following encouraging data from our ongoing collaboration with the Dana-Farber Cancer Institute. Having demonstrated its power in infectious disease, we believe that ATLAS is positioned to enable smarter identification of cancer vaccine antigens and smarter immuno-oncology response profiling to optimize patient care."

Business Highlights and Anticipated Milestones

GEN-003 - Immunotherapy for treatment of genital herpes in Phase 2 development. Greater than \$1 billion potential revenue opportunity in the U.S.

- ***Reported positive results six months after dosing from ongoing Phase 2 dose optimization trial***
- ***12-month data expected in the first quarter of 2016***
- ***End of Phase 2 meeting with U.S. Food and Drug Administration expected in late 2016***

On October 7, 2015, Genocea reported 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 and a measure of anti-viral activity.

In a planned secondary analysis to assess the impact on genital lesion rates, 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 Phase 3 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.

GEN-004 - Vaccine for the prevention of infections by all serotypes of pneumococcus.

- ***Reported top-line results from Phase 2a clinical trial in October***
- ***Development suspended pending review of potential paths forward***

On October 19, 2015, Genocea reported that top-line results from a Phase 2a clinical trial for GEN-004 showed consistent reductions versus placebo in the pre-specified endpoints of the rate and density of colonization, but neither of the endpoints achieved statistical significance. GEN-004 was safe and well tolerated by patients. Genocea has suspended development in GEN-004 pending further review of the data and expert consultation.

ATLAS technology platform - Expansion into immuno-oncology

- **Results from Dana-Farber collaboration to be presented at SITC on November 6; collaboration ongoing**
- **New collaboration with Memorial Sloan Kettering Cancer Center announced today**
- **ATLAS's ability to identify T cell antigens may unlock new cancer vaccines**
- **Immunotherapy program initiated targeting Epstein-Barr Virus**

Genocea was founded to create T cell-directed immunotherapies and vaccines using ATLAS, a unique platform for profiling large and diverse patient populations to find the T cell antigens driving protective responses. The Company believes that data reported to date for GEN-003 represents the first evidence of efficacy by an immunotherapy built around new T cell targets for an infectious disease. Building on the success of ATLAS in genital herpes, Genocea initiated a research collaboration with Dana-Farber in 2014 to apply ATLAS in immuno-oncology. This collaboration centered on the potential of ATLAS to identify patterns of T cell response in cancer patients receiving checkpoint inhibitor therapy.

ATLAS makes no assumptions about which cancer antigens are meaningful and which are not. It instead takes a panoramic view of a large, diverse population of human subjects and reveals clinically relevant T cell antigens of protective responses. In contrast to other high-throughput predictive tools currently being applied in oncology drug discovery, Genocea believes that ATLAS has a number of critical benefits, including that it potentially:

- Can find antigens to which patients are actually responding;
- Can distinguish between clinically relevant and immuno-dominant responses;
- Can identify separately targets of CD4⁺ and CD8⁺ T cells;
- Is not HLA-limited.

These benefits may enable smarter identification of cancer antigens for cancer vaccines and smarter identification of patients best suited to immuno-oncology therapy or therapy combinations.

Dana-Farber Collaboration

In this pilot study, funded by the Ludwig Trust, Genocea partnered with Darren Higgins, Ph.D., professor of microbiology and immunobiology at Harvard Medical School and F. Stephen Hodi, Jr., M.D., director of the Melanoma Center at Dana-Farber Cancer Institute, to conduct a retrospective analysis of 10 checkpoint inhibitor (CPI) treated patients' T cell responses to 23 known tumor-associated antigens. By analyzing the immune responses of both responders and non-responders to CPI therapy, ATLAS successfully identified the cancer antigens to which either (or both) CD4⁺ or CD8⁺ T cells became activated. Although this research was not powered to draw firm conclusions, the analysis of T cell responses in patients receiving CPI therapy revealed a pattern indicating a greater breadth of T cell activation for responders than non-responders. The study also revealed preliminary evidence that different characteristics of T cell responses emerge when comparing patients who respond and those who do not. Some T cell responses did not correspond with improved patient outcomes, and may be classified as "decoys," further validating the ability of ATLAS to distinguish clinically relevant targets of T cell responses. This analysis will be presented as a late-breaker at the Society for Immunotherapy of Cancer's (SITC) 30th Anniversary Annual Meeting & Associated Programs in National Harbor, Maryland. The poster, #342, entitled *Immunoprofiling of T cell responses in melanoma patients undergoing CPI therapy*, will be presented on Saturday, November 7, 2015 between 12:30 - 2:00p.m. ET.

The collaboration with Dana-Farber is ongoing as Genocea continues to analyze more blood samples to characterize T cell response profiles that may be prognostic of CPI efficacy, and to identify T cell antigens that may be included in novel immunotherapies.

Memorial Sloan Kettering Cancer Center Collaboration

The Company today announced a collaboration with Memorial Sloan Kettering Cancer Center to screen the T cell responses of melanoma and non-small cell lung cancer patients treated with checkpoint inhibitors against the complete repertoire of patient-specific putative cancer neoantigens.

The goals of the collaboration are to identify signatures of T cell response in cancer patients associated with response or non-response to CPI therapy and to discover new T cell cancer vaccine antigens. ATLAS will be used in conjunction with Memorial Sloan Kettering's patient-specific cancer neoantigen sequences and blood samples from the same cancer patients. This new collaborative work will be led by investigators Timothy A. Chan, M.D., Ph.D., Vice Chair, Department of Radiation Oncology, and Jedd D. Wolchok, M.D., Ph.D., Chief of Melanoma and Immunotherapeutics Service, Department of Medicine and Ludwig Center.

Epstein-Barr Virus Immunotherapy Program Initiated

Genocea has commenced a new program focused on Epstein-Barr Virus (EBV). EBV infection has been linked to cancers with high unmet needs such as non-Hodgkin's lymphoma, nasopharyngeal carcinoma and gastric carcinoma. We believe the ATLAS platform is highly suited to the creation of a new immunotherapy for EBV given that T cell responses are understood to be crucial for protection against EBV. Furthermore, EBV is part of the herpesvirus family, in which Genocea has deep experience through its development of GEN-003.

Completed \$50 million public offering in August 2015.

- **Funding expected to be sufficient to complete GEN-003 Phase 2 program**
- **Strengthened balance sheet provides foundation for ongoing business development activities**

In August 2015, Genocea closed a public offering of 3,850,000 shares of common stock. Gross and net proceeds to Genocea from this offering were approximately \$50 million and \$47 million, respectively.

Third Quarter 2015 Financial Results & Financial Guidance

- **Cash Position:** Cash, cash equivalents and investments as of September 30, 2015 were \$112.5 million, compared to \$74.6 million as of June 30, 2015. Genocea expects that these funds will be sufficient to fund its operating expenses and capital expenditure requirements into the second half of 2017.
- **Research and Development (R&D) Expenses:** R&D expenses for the quarter ended September 30, 2015 were unchanged at \$6.1 million compared to the same period in 2014, reflecting higher personnel costs and increased lab-related costs offset by reductions in manufacturing and licensing fees related to the commencement of GEN-003 and GEN-004 clinical trials. We continue to make investments in Genocea's preclinical pipeline, which offset lower R&D expense for our GEN-003 and GEN-004 programs on a quarter over quarter basis.
- **General and Administrative (G&A) Expenses:** G&A expenses for the quarter ended September 30, 2015 were \$3.6 million, compared to \$2.8 million for the same period in 2014. The increase reflects higher personnel costs and depreciation expense, both of which support Genocea's expanding R&D operations and the demands of operating as a public company.
- **Net Loss:** Net loss was \$9.8 million for the third quarter of 2015, compared to a net loss of \$9.2 million for the same period in 2014.

Conference Call

Genocea will host a conference call and webcast today at 9:00 a.m. ET. The conference call may be accessed by dialing (844) 826-0619 for domestic participants and (315) 625-6883 for international callers and referencing the conference ID number 60192429. 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 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 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, 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

GENOCEA BIOSCIENCES, INC.
CONDENSED BALANCE SHEETS (UNAUDITED)
(In thousands)

	September 30, 2015	December 31, 2014*
Cash, cash equivalents and investments	\$ 112,545	\$ 47,079
Other assets	5,335	3,253
Total assets	<u>\$ 117,880</u>	<u>\$ 50,332</u>
Debt, current and long-term	\$ 11,658	\$ 11,389
Accounts payable	1,731	2,692
Accrued expenses	4,928	2,486
Other liabilities	678	1,258
Total liabilities	18,995	17,825
Stockholders' equity	98,885	32,507
Total liabilities and stockholders' equity	<u>\$ 117,880</u>	<u>\$ 50,332</u>

* Includes \$99 thousand in deferred financing costs reclassified from Other assets to Debt upon the adoption of a recently issued accounting pronouncement during the second quarter of 2015, which required retrospective application.

GENOCEA BIOSCIENCES, INC.
CONDENSED STATEMENTS OF OPERATIONS (UNAUDITED)
(In thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Grant revenue	\$ 213	\$ -	\$ 449	\$ -
Operating expenses:				
Research and development	6,058	6,115	21,536	15,073
General and administrative	3,645	2,843	10,206	7,167
Total operating expenses	9,703	8,958	31,742	22,240
Loss from operations	(9,490)	(8,958)	(31,293)	(22,240)
Other expense, net	(281)	(213)	(876)	(1,406)
Net loss	<u>\$ (9,771)</u>	<u>\$ (9,171)</u>	<u>\$ (32,169)</u>	<u>\$ (23,646)</u>
Accretion of redeemable convertible preferred stock to redemption value	-	-	-	(180)
Net loss attributable to common stockholders	<u>\$ (9,771)</u>	<u>\$ (9,171)</u>	<u>\$ (32,169)</u>	<u>\$ (23,826)</u>
Net loss per share attributable to common stockholders - basic and diluted	<u>\$ (0.37)</u>	<u>\$ (0.53)</u>	<u>\$ (1.38)</u>	<u>\$ (1.60)</u>
Weighted-average number of common shares used in net loss per share attributable to common stockholders - basic and diluted	<u>26,610</u>	<u>17,465</u>	<u>23,228</u>	<u>14,918</u>

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