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Genocea Reports Fourth Quarter and Year-End 2015 Financial Results

- Multiple 2016 clinical milestones for GEN-003 for genital herpes anticipated -
- Cancer vaccine strategy targeting generation of first clinical candidate in 2017 -

CAMBRIDGE, Mass., Feb. 11, 2016 (GLOBE NEWSWIRE) -- Genocea Biosciences, Inc. (NASDAQ:GNCA), a biopharmaceutical company developing T cell-directed vaccines and immunotherapies, today reported corporate highlights and financial results for the fourth quarter and year ended December 31, 2015.

"2015 was another year of important progress for our lead product candidate, GEN-003 for genital herpes, and our ATLAS™ T cell target discovery platform. In October, we demonstrated significant and durable Phase 2 efficacy for GEN-003, potentially positioning it to become the cornerstone treatment for the millions of people who suffer from genital herpes infections. 2016 will also be a rich year for GEN-003 clinical milestones with 12-month durability data from the ongoing Phase 2 trial expected later this quarter, virologic and clinical efficacy data from a Phase 2b study expected in the middle and second half of 2016, respectively, and an end-of-Phase 2 meeting with the FDA anticipated in the fourth quarter," said Chip Clark, president and chief executive officer of Genocea. "We also announced the application of our ATLAS platform to immuno-oncology and have ongoing cancer vaccine collaborations with leading researchers at Dana-Farber Cancer Institute and Memorial Sloan Kettering Cancer Center. We believe that ATLAS is unique and differentiated in its ability to identify clinically relevant targets for cancer vaccines, potentially enabling better efficacy and better outcomes for patients. We anticipate announcing data from these collaborations in 2016 and hope to be in the clinic with a cancer vaccine in 2017. We are funded into the second half of 2017 and remain in a strong position strategically with full control over the rights to our assets."

2015 Business Highlights and 2016 Anticipated Milestones

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

- | ***Reported positive results six months after dosing from ongoing Phase 2 dose optimization trial in October 2015***

In October 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, 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. In addition, the time to first recurrence after completion of dosing showed a range of 152 days to greater than 180 days among dose groups. GEN-003 also demonstrated sustained and statistically significant reductions from baseline in genital lesion rates in five of six dose groups ranging from 43 to 69 percent. The ongoing 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.

Multiple anticipated 2016 clinical milestones for GEN-003

- | ***Phase 2 12-month durability data expected in the first quarter of 2016***
- | ***Phase 2b virologic efficacy data expected in mid-2016***
- | ***Phase 2b clinical efficacy data expected in second half of 2016***
- | ***End-of-Phase 2 meeting with the U.S. Food and Drug Administration expected in 4Q 2016***

Later in the first quarter of 2016, the Company expects to report 12-month durability data from the ongoing Phase 2 dose optimization trial. Positive results, if achieved, would represent an improvement to the already-attractive 6-month durability of effect which was confirmed in the fourth quarter of 2015. This data is also expected to provide guidance on the frequency of administration of maintenance therapy with GEN-003.

In the middle of 2016, Genocera expects to report virologic efficacy data from a recently-initiated Phase 2b study. Positive results, if achieved, would confirm the activity of GEN-003 manufactured at commercial scale and are an important step towards the FDA end-of Phase 2 meeting, which is expected in the fourth quarter of 2016.

In the second half of 2016, the Company expects to report clinical efficacy data from this Phase 2b study. This placebo-controlled data represents the first opportunity to measure GEN-003 manufactured at commercial scale against potential Phase 3 endpoints at 6-months after dosing.

The Company also expects to commence a planned Phase 2b antiviral combination study in the middle of 2016. Clinical efficacy data from this trial is expected in the first half of 2017. If GEN-003 is additive to the effect of chronic suppressive oral anti-viral therapy, this would further strengthen GEN-003's value proposition to patients and physicians.

Cancer Vaccine Programs - Developed from Genocera's ATLAS technology platform for better T cell target discovery

- ▮ ***New collaboration with Memorial Sloan Kettering Cancer Center announced in November 2015 to identify cancer vaccine candidates***
- ▮ ***Results from Dana-Farber collaboration presented as late-breaker at the Society for Immunotherapy of Cancer (SITC) meeting in November 2015***
- ▮ ***Immunotherapy program initiated in 2015 targeting Epstein-Barr Virus***

The Company's ATLAS T cell antigen discovery platform makes no assumptions about which cancer antigens are meaningful and which are not. It instead takes a panoramic view of the actual T cell responses of human subjects to any possible T cell target in a cancer. When applied across large diverse populations against common tumor-associated antigens, ATLAS could discover better targets for inclusion in general cancer vaccines. When applied to an individual's response to their own cancer neoantigens, ATLAS could enable better personalized cancer vaccines, either as standalone therapies or in combination with other immunotherapies like checkpoint inhibitors.

The core strength of ATLAS is that it does not use predictive algorithms to identify antigens. It discovers clinically relevant T cell antigens associated with protective responses from comprehensive cell-based assays of actual human T cell responses. In contrast to predictive approaches to vaccine antigen selection, Genocera believes that ATLAS has a number of critical benefits, including that it potentially can find antigens to which patients are actually responding, distinguish between clinically relevant and immuno-dominant responses, identify separately targets of CD4+ and CD8+ T cells and is not HLA-limited. Genocera believes better vaccine targets may enable more efficacious and safer cancer vaccines and also the stratification of patients who may be best-suited to respond to immuno-oncology therapy or therapy combinations.

Memorial Sloan Kettering Cancer Center Collaboration

In November 2015, Genocera 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 (CPI) 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.

Dana Farber Cancer Institute Collaboration

In November 2015, findings that support the potential of ATLAS to profile responses to immunotherapies for cancer were presented as a late-breaker at the SITC 30th Anniversary Annual Meeting & Associated Programs. This retrospective analysis of 10 checkpoint inhibitor (CPI) treated patients' T cell responses to 23 known tumor-associated antigens, analyzed 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 potential ability of ATLAS to distinguish clinically relevant targets of T cell responses. Genocera 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 this pilot study. Genocera's collaboration with Dana-Farber Cancer Institute is ongoing as Genocera continues to analyze more tumor and blood samples to characterize T cell response profiles.

Epstein-Barr Virus Program

In November 2015, Genocera commenced a new program focused on Epstein-Barr Virus (EBV). EBV infection causes infectious mononucleosis and has also been linked to cancers with high unmet needs such as post-transplant lymphoproliferative disease, non-Hodgkin's lymphoma, nasopharyngeal carcinoma and gastric carcinoma. Genocera

believes that 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 Genocera has deep experience through its development of GEN-003.

Genocera expects to announce further data from its ongoing immuno-oncology collaborations in 2016 and hopes to commence clinical trials with a cancer vaccine in 2017. For EBV, Genocera expect to have completed its initial ATLAS screening studies and to have identified a number of antigen targets for further research and pre-clinical development this year.

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

- | ***Reported top-line results from Phase 2a clinical trial in October 2015***
- | ***Development suspended pending review of potential paths forward***

In October 2015, Genocera 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. Genocera believes that the consistent apparent effect demonstrates the potential of the vaccine concept and that it is possible that future trials would require a change in some combination of dose, adjuvant or trial population to confirm any effect. Genocera has suspended development in GEN-004 pending further review of the data and expert consultation.

Fourth Quarter 2015 Financial Results

- | **Cash Position:** Cash, cash equivalents and investments as of December 31, 2015 were \$106.4 compared to \$112.5 million as of September 30, 2015. Genocera 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 December 31, 2015 decreased \$2.1 million, to \$6.5 million, from the same period in 2014, reflecting lower clinical and manufacturing costs for GEN-003 and GEN-004 due to the timing of clinical trial-related activities, including the suspension of development of GEN-004. These lower costs were partially offset by higher personnel and lab-related costs related to Genocera's cancer vaccine programs and preclinical pipeline.
- | **General and Administrative (G&A) Expenses:** G&A expenses for the fourth quarter of 2015 were \$3.8 million, compared to \$2.6 million for the same period in 2014. The increase reflects higher personnel costs and depreciation expense, both of which support Genocera's expanding R&D operations.
- | **Net Loss:** Net loss was \$10.3 million for the quarter ended December 31, 2015, compared to a net loss of \$11.7 million for the same period in 2014.

Full Year 2015 Financial Results

- | **Cash Position:** Cash, cash equivalents and investments as of December 31, 2015 were \$106.4 million, compared to \$47.1 million as of December 31, 2014. The increase was due to two follow-on offerings completed during the year with aggregate net proceeds of approximately \$95.2 million, along with additional net borrowings of \$4.7 million from a debt amendment executed in the fourth quarter of 2015 offset by cash used in Genocera's operations and for capital expenditures.
- | **R&D Expenses:** R&D expenses for the year ended December 31, 2015 were \$28.0 million, compared to \$23.7 million for the same period in 2014, reflecting higher personnel costs and lab related costs both of which supported the continued advancement of the Company's clinical programs along with increasing investments in Genocera's cancer vaccine programs and preclinical pipeline.
- | **G&A Expenses:** G&A expenses were \$14.0 million for the year ended December 31, 2015, compared to \$9.7 million for the same period in 2014, reflecting additional personnel costs and depreciation expense supporting overall Company growth.
- | **Net Loss:** Net loss was \$42.5 million for the year ended December 31, 2015, compared to a net loss of \$35.3 million for the same period in 2014.

Conference Call

Genocera 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 35553440. A live webcast of the conference call will be available online from the investor relations section of the Company's website at <http://ir.genocera.com>. A webcast replay of the conference call will be available on the Genocera website beginning approximately two hours after the event, and will be archived for 30 days.

About Genocera Biosciences, Inc.

Genocera 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, its proprietary technology platform, Genoceca identifies these targets to potentially enable the rapid development of medicines to address critical patient needs. Genoceca'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), and earlier-stage programs in chlamydia, genital herpes prophylaxis, malaria and cancer immunotherapy. For more information, please visit the company's website at www.genoceca.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. Genoceca 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 Genoceca'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; Genoceca'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; Genoceca'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 Genoceca in its business and the period for which existing cash will be able to fund such operation; Genoceca'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 Genoceca's Annual Report on Form 10-K for the fiscal year ended December 31, 2014, its Quarterly Report on Form 10-K for the quarter ended September 30, 2015, and other filings with the Securities and Exchange Commission (the "SEC"). Further information on the factors and risks that could affect Genoceca's business, financial conditions and results of operations is contained in Genoceca'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 Genoceca assumes no duty to update forward-looking statements.

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

	December 31, 2015	December 31, 2014*
Cash, cash equivalents and investments	\$ 106,432	\$ 47,079
Other assets	5,710	3,253
Total assets	<u>\$ 112,142</u>	<u>\$ 50,332</u>
Debt, long-term	\$ 16,477	\$ 11,389
Accounts payable	1,757	2,692
Accrued expenses and other liabilities	4,012	2,839
Deferred revenue	235	905
Total liabilities	<u>22,481</u>	<u>17,825</u>
Stockholders' equity	89,661	32,507
Total liabilities and stockholders' equity	<u>\$ 112,142</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.

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

	Three months ended December 31,		Twelve months ended December 31,	
	2015	2014	2015	2014
Grant revenue	\$ 221	\$ 308	\$ 670	\$ 308
Operating expenses:				
Research and development	6,513	8,654	28,049	23,727
General and administrative	3,781	2,580	13,987	9,747
Total operating expenses	10,294	11,234	42,036	33,474
Loss from operations	(10,073)	(10,926)	(41,366)	(33,166)
Other expense, net	(241)	(724)	(1,117)	(2,130)
Net loss	\$ (10,314)	\$ (11,650)	\$ (42,483)	\$ (35,296)
Accretion of redeemable convertible preferred stock to redemption value	-	-	-	(180)
Net loss attributable to common stockholders	(10,314)	(11,650)	\$ (42,483)	\$ (35,476)
Net loss per share attributable to common stockholders - basic and diluted	\$ (0.37)	\$ (0.66)	\$ (1.74)	\$ (2.27)
Weighted-average number of common shares used in net loss per share attributable to common stockholders - basic and diluted	28,118	17,696	24,460	15,618

For media:

Liz Bryan

Spectrum Science Communications, Inc.

O: 202-955-6222

lbryan@spectrumsience.com

For investors:

Jonathan Poole

Genocea Biosciences, Inc.

O: 617-876-8191

jonathan.poole@genocea.com

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