



November 3, 2016

## Genocea Reports Third Quarter 2016 Financial Results

*- Positive Phase 2b results recently reported and dose selected for  
GEN-003 Phase 3 program expected to initiate in 2H 2017 -*

*- Conference Call at 9am ET today -*

CAMBRIDGE, Mass., Nov. 03, 2016 (GLOBE NEWSWIRE) -- Genocea Biosciences, Inc. (NASDAQ:GNCA), a company developing T cell-directed vaccines and immunotherapies, today reported corporate highlights and financial results for the third quarter ended September 30, 2016. Genocea's lead clinical candidate, GEN-003, is a T cell-directed immunotherapy for the treatment of genital herpes infections, designed to elicit both a T cell and B cell (antibody) immune response that, if approved, the Company believes would be the first-ever therapeutic vaccine for an infectious disease.

"We achieved an important GEN-003 milestone in the third quarter with the selection of our Phase 3 dose, demonstrating a significant reduction in viral shedding for the third consecutive clinical trial, this time with an improved, Phase 3-ready formulation," said Chip Clark, president and chief executive officer of Genocea. "We also continue to advance our immunoncology program and are now focusing all of our early stage research and pre-clinical resources to these efforts. We believe ATLAS enables better cancer vaccine antigen selection than existing methods and that our demonstrated vaccine development expertise can be a further competitive advantage in this exciting space."

Mr. Clark continued: "We expect to maintain our strong momentum this quarter and throughout 2017. In December, we will be hosting our first R&D day as we set the stage for the expected start of the GEN-003 Phase 3 clinical trials in the second half of 2017, including the important Phase 2b six month placebo-controlled clinical efficacy data expected in January 2017. We will also set out in detail our maturing immuno-oncology strategy and neoantigen cancer vaccine development plans."

### **Recent Business Highlights**

***GEN-003 - Immunotherapy for treatment of genital herpes expected to enter Phase 3 development in 2H 2017.***

- ▮ ***September 2016 - data confirm optimal dose for Phase 3 trials; dose response consistent with T cell therapies and with previous GEN-003 clinical trials***
- ▮ ***October 2016 - IDWeek presentation: GEN-003 induced durable polyfunctional T cells, IgG and neutralizing antibody titers***

In [September 2016](#), Genocea announced positive viral shedding data from its ongoing Phase 2b study. The study achieved its primary endpoint, with GEN-003 demonstrating a statistically significant (versus placebo and baseline) 40 percent reduction in the viral shedding rate immediately after dosing in the 60 µg per protein / 50 µg of adjuvant dose group, using a new Phase 3-ready formulation. This result was consistent with a statistically significant (versus placebo and baseline) viral shedding rate reduction of 41 percent at this same dose and time point in the prior Phase 2 trial. Subsequent data from that prior Phase 2 trial demonstrated virologic and clinical efficacy durable through at least one year after dosing.

The 60 µg per protein / 75 µg of adjuvant dose group in the Phase 2b trial reduced the viral shedding rate by 27 percent, a smaller reduction than that observed in the prior trial, and also showed a less acceptable reactogenicity profile than the prior trial. Research has shown that overstimulation of the T cell immune system, as is suggested by this increase in reactogenicity, leads to a loss in efficacy for T cell therapies. We believe the likely driver of this effect is a more potent adjuvant formulation following customary manufacturing process changes to prepare for Phase 3 trials and commercialization.

In [October 2016](#), the [Company presented](#) immunogenicity data from its previous Phase 2 trial at IDWeek 2016, the premier annual meeting for healthcare professionals focusing on infectious diseases. These data show that GEN-003 induced antigen-specific polyfunctional T cell responses in immunized subjects, a hallmark of potent T cell immunity. These data also demonstrated that GEN-003 elicited increases in IgG and neutralizing antibody levels above baseline that persisted for one year after the last dose, consistent with viral shedding and clinical symptom reduction seen at 12 months.

### **Anticipated Milestones and Events**

## GEN-003

- | Phase 2b 6-month placebo-controlled clinical efficacy data expected in January 2017
- | End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) expected in 1Q 2017
- | Antiviral combination study now planned as part of GEN-003 Phase 3 program

### ***Immuno-oncology collaborations and cancer vaccine strategy***

- | Data showing ATLAS's differentiated neoantigen selection capabilities from the ongoing partnership with Memorial Sloan Kettering Cancer Center to be presented at the Society for Immunotherapy of Cancer's (SITC) 31<sup>st</sup> Annual Meeting & Associated Programs in National Harbor, Maryland. The poster, #374, entitled *Genome-scale neoantigen screening using ATLAS™ prioritizes candidates for immunotherapy in a non-small cell lung cancer patient* will be presented on Saturday November 12, between 11:45 am and 1:00 pm and 6:45 pm and 8 pm ET
- | Immuno-oncology strategy and neoantigen cancer vaccine development plan update expected at R&D Day in December

### ***Upcoming Events & Presentations***

- | Neoantigen Summit 2016, Boston, November 15
- | Stifel 2016 Healthcare Conference, New York City, November 16
- | Piper Jaffray 28th Annual Health Care Conference, New York City, November 30
- | Virtual R&D Day, week of December 12

### **Updated Financial Guidance:**

Genocea now expects that its existing cash, cash equivalents and marketable securities are sufficient to support its operating expenses and capital expenditure requirements into the first quarter of 2018, without assuming any receipt of proceeds from potential business development partnerships, equity financings or debt drawdowns. This guidance is made on the basis of Genocea's current operating plans, which include focusing its research activities on immuno-oncology, conducting the antiviral combination study as part of the GEN-003 Phase 3 program and initiating Phase 3 trials for GEN-003 in the second half of 2017.

### **Third Quarter 2016 Financial Results**

**Cash Position:** Cash, cash equivalents and investments as of September 30, 2016 were \$75.5 million compared to \$86.0 million as of June 30, 2016.

**Research and Development (R&D) Expenses:** R&D expenses for the quarter ended September 30, 2016 increased \$2.8 million, to \$8.8 million, from the same period in 2015. The increase was driven by increases in headcount and related expenses to support the GEN-003 program and higher clinical costs for the ongoing and anticipated GEN-003 trials. Higher personnel and lab-related costs to advance Genocea's pre-clinical product candidates and develop the ATLAS platform for immuno-oncology also contributed to the increase. These higher R&D costs were partially offset by lower GEN-004 costs due to the Phase 2a trial which was ongoing in the third quarter of 2015 and has since been completed.

**General and Administrative (G&A) Expenses:** G&A expenses for the quarter ended September 30, 2016 were unchanged at approximately \$3.6 million from the same three-month period in 2015.

**Net Loss:** Net loss was \$12.8 million for the third quarter ended September 30, 2016, compared to a net loss of \$9.8 million for the same period in 2015.

### **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 96207224. 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 Biosciences, Inc.**

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™, 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 company's website at [www.genocea.com](http://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](http://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 CONSOLIDATED BALANCE SHEETS (UNAUDITED)**  
(In thousands)

	September 30 2016	December 31, 2015
Cash, cash equivalents and investments \$	75,461	\$ 106,432
Other assets	7,408	5,710
Total assets	<u>\$ 82,869</u>	<u>\$ 112,142</u>
Debt, current and long-term	\$ 16,833	\$ 16,477
Accounts payable	1,888	1,757
Accrued expenses and other liabilities	3,799	4,012
Deferred revenue	—	235
Total liabilities	<u>22,520</u>	<u>22,481</u>
Stockholders' equity	<u>60,349</u>	<u>89,661</u>
Total liabilities and stockholders' equity	<u>\$ 82,869</u>	<u>\$ 112,142</u>

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Grant revenue	\$ —	\$ 213	\$ 235	\$ 449
Operating expenses:				

Research and development	8,811	6,058	22,821	21,536
General and administrative	3,619	3,645	11,569	10,206
Refund of research and development expense	—	—	(1,592)	—
Total operating expenses	<u>12,430</u>	<u>9,703</u>	<u>32,798</u>	<u>31,742</u>
Loss from operations	(12,430)	(9,490)	(32,563)	(31,293)
Other income and expense:				
Interest income	103	39	323	70
Interest expense	(438)	(320)	(1,299)	(946)
Total other income and expense	<u>(335)</u>	<u>(281)</u>	<u>(976)</u>	<u>(876)</u>
<b>Net loss</b>	<u><b>\$ (12,765)</b></u>	<u><b>\$ (9,771)</b></u>	<u><b>\$ (33,539)</b></u>	<u><b>\$ (32,169)</b></u>
Net loss per share - basic and diluted	<u>\$ (0.45)</u>	<u>\$ (0.37)</u>	<u>\$ (1.18)</u>	<u>\$ (1.38)</u>
Weighted-average number of common shares used in computing net loss per share	<u>28,370</u>	<u>26,610</u>	<u>28,267</u>	<u>23,228</u>

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