



May 7, 2015

Genocea Reports First Quarter 2015 Financial Results

Phase 2 top-line data for GEN-003 for the treatment of genital herpes expected this quarter

\$52 million financing completed in March 2015

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 first quarter ended March 31, 2015.

"2015 is an important year for Genocea with significant clinical data readouts upcoming for both our lead programs. Top-line Phase 2 data for GEN-003, for the treatment of genital herpes, is expected this quarter. Building on the first-in-class efficacy data we reported in 2014 from our Phase 1/2a trial, the selection of the best dose in this trial represents an important validating step towards advancing this program into Phase 3," said Chip Clark, president and chief executive officer of Genocea. "The recent completion of enrollment in the Phase 2 trial for our second lead program, GEN-004 for the prevention of infections caused by all serotypes of pneumococcus, supports our goal of announcing top-line data for this trial in the fourth quarter of 2015. With our recent \$52 million public offering in March, we are now well funded through the third quarter of 2016."

Business Highlights and Anticipated Milestones

GEN-003 - Immunotherapy for genital herpes in Phase 2 dose optimization trial. > \$1 billion revenue opportunity in the US.

- ***Completed enrollment ahead of schedule in January 2015***
- ***Top-line results expected late in the second quarter of 2015***
- ***GEN-003 boosted neutralizing antibody titers against HSV-2 and HSV-1 in Phase 1/2a trial***

In January 2015, Genocea announced that it completed enrollment early in its Phase 2 dose optimization clinical trial for GEN-003, its first-in-class treatment for genital herpes. The goals of this trial are to explore and justify the protein and adjuvant dose for Phase 3 and confirm the efficacy of the 30 microgram per protein / 50 microgram of adjuvant dose which was the best dose in the Phase 1/2a trial. The study enrolled over 300 subjects from 17 institutions in the United States. Subjects were randomized into one of six dosing groups of either 30 micrograms or 60 micrograms per antigen paired with one of three doses of Matrix-M™ adjuvant (25 micrograms, 50 micrograms, or 75 micrograms), licensed from Novavax, Inc. A seventh group received placebo. Subjects received three doses of GEN-003 or placebo at 21-day intervals. The primary end point for the study is the change from baseline in viral shedding rate, a measure of anti-viral activity. The study will also evaluate the impact on genital lesion rates as well as immunogenicity and safety.

Genocea expects to report the viral shedding rate and genital lesion rate changes from baseline for each dose group for the 28-day monitoring period after vaccination late in the second quarter of 2015.

In April 2015, Genocea presented data from a Phase 1/2a study of GEN-003, demonstrating that the immunotherapy boosted neutralizing antibody titers against both HSV-2 and HSV-1. Future clinical studies are designed to demonstrate whether these cross-reactive antibodies can translate to protection against genital HSV-1, in addition to HSV-2. The data were presented at the 25th European Congress of Clinical Microbiology and Infectious Diseases in Copenhagen, Denmark.

GEN-004 - Vaccine for the prevention of infections by all serotypes of pneumococcus in ongoing Phase 2a human challenge study. Potentially disruptive to greater than \$5 billion global market.

- ***Completed enrollment in April 2015***
- ***Top-line results expected in the fourth quarter of 2015***

Genocea announced in April 2015 that it had completed enrollment in its Phase 2a human challenge study for GEN-004. The objective of this trial is to demonstrate proof-of-concept that GEN-004 can reduce the frequency, magnitude or duration of

colonization of pneumococcus in the nasopharynx of healthy adults. The Phase 2a trial enrolled 98 healthy adult subjects at one site in the United Kingdom. Subjects are randomized to receive three doses of either placebo or GEN-004 at 100 micrograms per protein and 350 micrograms of alum adjuvant. All subjects are challenged with pneumococcus after the third dose of the assigned treatment and subsequently tested for the establishment of colonization.

Top-line results from this trial evaluating the effect of GEN-004 on the frequency, magnitude and duration of colonization by pneumococcus in the nasopharynx of healthy adults are expected in the fourth quarter of 2015.

Existing vaccines for pneumococcus command a greater than \$5 billion global market and are effective against only a small number of historically the most prevalent serotypes of pneumococcus. GEN-004 has been designed to be a universal vaccine against all serotypes of pneumococcus

Completed \$51.7 million public offering in March 2015.

- ***GEN-003 program accelerated***
- ***Two new research programs planned for 2015***
- ***Strong balance sheet provides foundation for ongoing business development activities***

In March 2015, Genocera closed a public offering of 6,272,726 shares of common stock, including the exercise in full by the underwriters of their overallotment option. Gross and net proceeds to Genocera from this offering were approximately \$51.7 million and \$48.4 million respectively.

The financing has enabled Genocera to accelerate manufacturing investment in GEN-003 and, in doing so, bring forward the expected date of the end-of-Phase 2 meeting with the U.S. Food and Drug Administration to the middle of 2016. Genocera also now plans to initiate two additional discovery research programs in 2015. The strengthened balance sheet provides greater flexibility in capital strategy in advance of important clinical milestones and a strong foundation for ongoing business development activities.

Appointed Michael Higgins to its Board of Directors.

Genocera announced in February 2015 the appointment of Michael Higgins to its board of directors. Mr. Higgins is currently an entrepreneur-in-residence at Polaris Venture Partners, and he previously served as chief operating officer and chief financial officer at Ironwood Pharmaceuticals. Mr. Higgins also previously worked at Genzyme Corporation from 1997 through 2003 in a variety of leadership roles including vice president of corporate finance and vice president of business development.

First Quarter 2015 Financial Results & Financial Guidance

- **Cash Position:** Cash, cash equivalents and marketable securities as of March 31, 2015 were \$84.5 million, compared to \$47.1 million as of December 31, 2014. The increase was as a result of Genocera's public offering in March 2015 which raised net proceeds of \$48.4 million. Genocera expects that these funds will be sufficient to fund its operating expenses and capital expenditure requirements through the third quarter of 2016.
- **Research and Development (R&D) Expenses:** R&D expenses for the quarter ended March 31, 2015 were \$8.5 million, compared to \$4.4 million for the same period in 2014, reflecting higher personnel costs, the manufacturing and clinical trial costs associated with the continued advancement of GEN-003, increased clinical trial costs associated with the ongoing Phase 2a clinical trial for GEN-004 and investments in Genocera's pre-clinical pipeline.
- **General and Administrative (G&A) Expenses:** G&A expenses for the quarter ended March 31, 2015 were \$3.4 million, compared to \$2.0 million for the same period in 2014 reflecting higher personnel costs and increased costs to support Genocera's operations as a public company.
- **Net Loss:** Net loss was \$12.1 million for the first quarter of 2015, compared to a net loss of \$7.3 million for the same period in 2014.

Conference Call

Genocera will host a conference call and webcast today, at 9:00 a.m. EDT. The conference call may be accessed by dialing (844) 826-0619 for domestic participants and (315) 625-6883 for international callers (reference conference ID 29667440). 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

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 immune response. Using ATLAS™, its proprietary technology platform, Genoccea identifies these targets to potentially enable the rapid development of medicines to address critical patient needs. Genoccea's pipeline of novel clinical stage T cell-directed product candidates includes GEN-003 to treat genital herpes, GEN-004 to prevent infections caused by pneumococcus, and earlier-stage programs in chlamydia, genital herpes prophylaxis, malaria and cancer immunotherapies. For more information, please visit the company's website at www.genoccea.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. Genoccea 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 Genoccea'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; Genoccea'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; Genoccea'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 Genoccea in its business and the period for which existing cash will be able to fund such operation; Genoccea'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 Genoccea'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 Genoccea's business, financial conditions and results of operations is contained in Genoccea'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 Genoccea assumes no duty to update forward-looking statements.

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

	March 31, 2015	December 31, 2014
Cash, cash equivalents and marketable securities	\$ 84,493	\$ 47,079
Other assets	3,923	3,352
Total assets	<u>\$ 88,416</u>	<u>\$ 50,431</u>
Note payable	\$ 11,582	\$ 11,488
Accounts payable	2,758	2,692
Accrued expenses	3,262	2,486
Other liabilities	1,068	1,258
Total liabilities	18,670	17,924
Stockholders' equity	69,746	32,507
Total liabilities, and stockholders' equity	<u>\$ 88,416</u>	<u>\$ 50,431</u>

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

	Three months ended March 31,	
	2015	2014
Grant revenue	\$ 121	\$ -
Operating expenses:		

Research and development	8,509	4,407
General and administrative	3,389	1,966
Total operating expenses	<u>11,898</u>	<u>6,373</u>
Loss from operations	(11,777)	(6,373)
Other expense, net	(307)	(956)
Net loss	<u>\$(12,084)</u>	<u>\$(7,329)</u>
Accretion of redeemable convertible preferred stock to redemption value	-	(180)
Net loss attributable to common stockholders	<u>\$(12,084)</u>	<u>\$(7,509)</u>
Net loss per share attributable to common stockholders - basic and diluted	<u>\$ (0.64)</u>	<u>\$ (0.76)</u>
Weighted-average number of common shares used in net loss per share attributable to common stockholders - basic and diluted	<u>18,834</u>	<u>9,859</u>

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