

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): June 3, 2019**

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**GENOCEA BIOSCIENCES, INC.**  
(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation)

**001-36289**  
(Commission File Number)

**51-0596811**  
(IRS Employer  
Identification No.)

**Cambridge Discovery Park  
100 Acorn Park Drive, 5th Floor  
Cambridge, MA 02140**  
(Address of principal executive offices, including zip code)

**(Registrant's telephone number, including area code): (617) 876-8191**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)  
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)  
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))  
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, \$0.001 per value per share	GNCA	NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging Growth Company

If an emerging growth company, indicate by a check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release of Genocera Biosciences, Inc. dated June 3, 2019</a>

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**GENOCEA BIOSCIENCES, INC.**

By: /s/ DEREK MEISNER

Derek Meisner

*Senior Vice President,*

*General Counsel and Corporate Secretary*

Date: June 3, 2019



**Contact:**

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**Genocea's GEN-009 Vaccine Demonstrates Best-in-Class Immune Responses to ATLAS™-selected Neoantigens in Cancer Patients**

*Post-vaccination T cell responses detected to 91% of vaccine neoantigens, including CD8<sup>+</sup> T cell responses to 53% of vaccine neoantigens*

*Conference call and webcast to discuss results TODAY at 8:30 am ET*

**CAMBRIDGE, Mass., June 3, 2019** – [Genocea Biosciences, Inc.](#) (NASDAQ: GNCA), a biopharmaceutical company developing personalized cancer immunotherapies, today announced best-in-class clinical results from its ongoing Phase 1/2a trial for GEN-009, the company's lead neoantigen vaccine candidate. The results were presented in a poster over the weekend at this year's Annual Meeting of the American Society of Clinical Oncology (ASCO 2019). The full poster is available on the Genocea website [here](#).

In the poster entitled "**A phase 1/2a study of GEN-009, a neoantigen vaccine based on autologous peptide immune responses,**" Roger B. Cohen, M.D. who is Associate Director Clinical Research at the Abramson Cancer Center, Professor of Medicine at the Perelman School of Medicine at the University of Pennsylvania, and the principal investigator in Genocea's ongoing GEN-009 clinical trial (GEN-009-101), highlighted the following results:

- In the five patients for whom immune response results are available to date, GEN-009 monotherapy elicited T cell responses to 91% of the vaccine neoantigens administered.
- GEN-009 has proven to be unique among neoantigen vaccines in its ability to elicit *ex vivo* CD8<sup>+</sup> T cell responses, which were observed for 47% of vaccine neoantigens. Inclusive of the results seen after *in vitro* stimulation, the CD8<sup>+</sup> T cell response frequency was 53%.
- GEN-009 has been well tolerated to date, with no dose-limiting toxicities.

Dr. Cohen commented, "I believe that these data could represent a breakthrough in the development of neoantigen vaccines. The Genocea data indicate that using the patients' own T cells and antigen-presenting cells to select vaccine neoantigens results in higher immunogenicity than previously reported results using *in silico* methods. I look forward to investigating GEN-009 in combination with checkpoint inhibitors to explore whether this higher immunogenicity translates into greater clinical efficacy than seen with other neoantigen vaccines."

Chip Clark, Genocea's President & CEO also commented: "These data clearly differentiate ATLAS, our neoantigen discovery platform, from first-generation, machine-based approaches. As we continue to say, "targets matter," and these data highlight the necessity of selecting the right neoantigens to drive immune responses in cancer patients. We believe that ATLAS holds the potential to benefit the clinical efficacy of both GEN-009 and GEN-011, our neoantigen-specific T cell therapy program, and to enable additional immunotherapy modalities."

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About Part A of the GEN-009-101 Clinical Trial (NCT03633110):

- GEN-009-101 is a multicenter Phase 1/2a study being conducted in patients with melanoma, non-small cell lung cancer (NSCLC), squamous cell carcinoma of the head and neck (SCCHN), and urothelial carcinoma; in Part A of the clinical trial, enrolled patients had no evidence of disease at the time of vaccination.
- Each patient's GEN-009 vaccine consists of 4 to 20 synthetic long peptides administered with the adjuvant poly-ICLC (Hiltonol®).
- Unlike *in silico* methods, Genocea uses its ATLAS platform to query the patient's own immune cells to characterize (as stimulatory, irrelevant, or inhibitory) antigens from each patient's tumor and then selects only stimulatory neoantigens for vaccine inclusion.
- Part A of the trial is expected to result in as many as 9 evaluable patients.

**Conference Call and Webcast – TODAY at 8:30 am ET**

Genocea will host a conference call and webcast to discuss the clinical results presented at ASCO at 8:30 am ET TODAY. Interested participants may access the conference call by dialing (844) 826-0619 (domestic) or (315) 625-6883 (international) and referring to conference ID number 9068006. To join the live webcast, please visit the presentation page of the investor relations section of the Genocea website at <https://ir.genocea.com/events-and-presentations>. 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 90 days.

**About Genocea Biosciences, Inc.**

Genocea is a biopharmaceutical company developing personalized cancer immunotherapies. Our unique ATLAS™ technology platform allows us to identify immunotherapy targets based on each person's tumor antigen-specific T cell responses. Using ATLAS, we can both optimize neoantigens for inclusion in our immunotherapies and exclude so-called "inhibitory" antigens that appear to exert an immunosuppressive effect on the patient. We are advancing complementary programs built from ATLAS insights: GEN-009, our neoantigen vaccine candidate for which we are conducting a Phase 1/2a clinical trial across a variety of solid tumor types, and GEN-011, our neoantigen-specific adoptive T cell therapy, for which we intend to file an Investigational New Drug Application in the first half of 2020. To learn more, please visit [www.genocea.com](http://www.genocea.com)

**Forward-Looking Statements**

*This press release includes forward-looking statements, including statements relating to the expectations for GEN-009 and intentions for filing an Investigational New Drug Application for GEN-011, within the meaning of the Private Securities Litigation Reform Act. Such forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Genocea cautions that these forward-looking statements are subject to numerous assumptions, risks and uncertainties that change over time. Applicable risks and uncertainties include those identified under the heading "Risk Factors" included in Genocea's Annual Report on Form 10-K for the year ended December 31, 2018 and any subsequent SEC filings. These forward-looking statements speak only as of the date of this press release and Genocea assumes no duty to update forward-looking statements, except as may be required by law.*

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