

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

FORM 8-K

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

Date of Report (Date of earliest event reported): September 12, 2022

Vaccinex, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38624
(Commission
File Number)

16-1603202
(IRS Employer
Identification No.)

1895 Mount Hope Avenue, Rochester, New York
(Address of principal executive offices)

14620
(Zip Code)

(585) 271-2700
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

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, par value \$0.0001 per share | VCNX | 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 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.

Item 7.01 Regulation FD Disclosure.

On September 12, 2022, Vaccinex, Inc. (the “Company”) presented at the ESMO Congress 2022. A copy of the presentation presented by the Company is furnished herewith as Exhibit 99.1 and is available on the Company’s website located at www.vaccinex.com under the heading “Presentations.”

The information furnished pursuant to this Item 7.01, including Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities under such section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1944, as amended, or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | Neoadjuvant Pepinemab in Combination with Nivolumab and/or Ipilimumab in Resectable Stage III Melanoma |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

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.

Date: September 13, 2022

VACCINEX, INC.

By: /s/ Scott E. Royer
Scott E. Royer
Chief Financial Officer

Neoadjuvant Pepinemab in Combination with Nivolumab and/or Ipilimumab in Resectable Stage III Melanoma

NCT03769155

Michael Lowe, MD, MA, FACS, FSSO
Associate Professor of Surgery
Emory University School of Medicine

Atlanta, GA, USA
09.12.2022



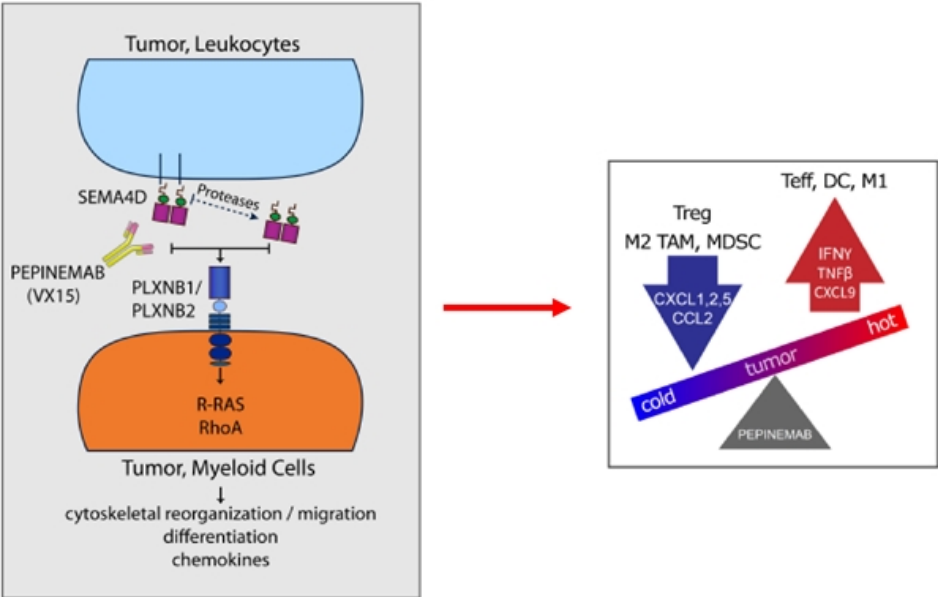
DECLARATION OF INTERESTS

Michael Lowe

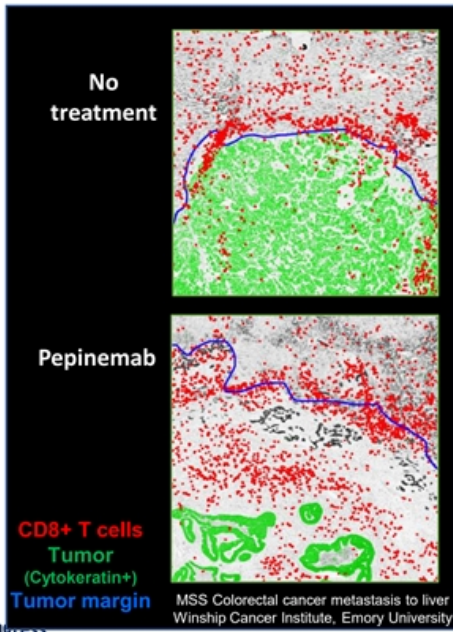
Research Funding: Amgen, **BMS**, Delcath, Merck, Regeneron, Stryker, **Vaccinex**

Advisory Board: BMS

Background



Background



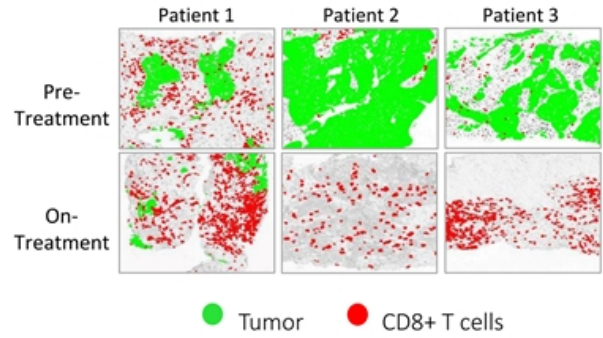
PARIS 2022 ESMO CONGRESS

July 9, 2021 | Volume 27 | Number 13

CLINICAL CANCER RESEARCH
HIGHLIGHTS
Selected Articles from This Issue

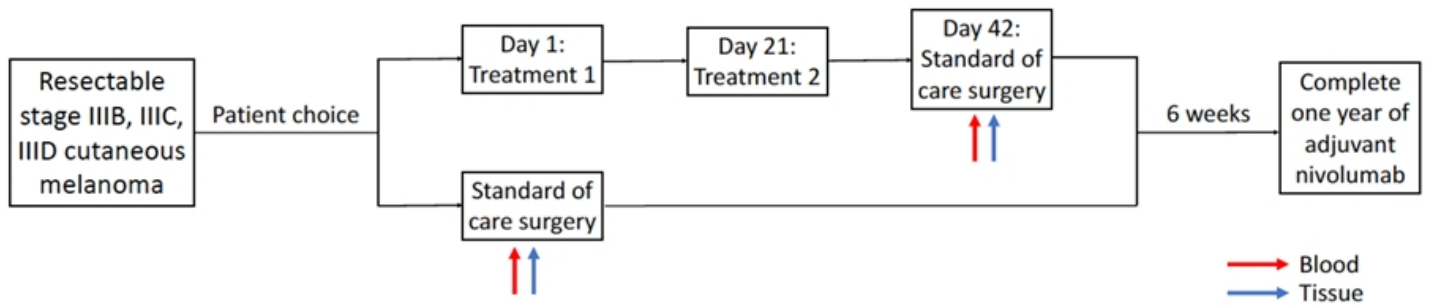
A Phase Ib/2 Study of Pepinemab in Combination with Avelumab in Advanced Non-Small Cell Lung Cancer

Michael Rahman Shafique¹, Terrence Lee Fisher², Elizabeth E. Evans², John E. Leonard², Desia Rae Electa Pastore², Crystal L. Mallow², Ernest Smith³, Vikas Mishra², Andreas Schröder³, Kevin M. Chin⁴, Joseph Thaddeus Beck², Megan Ann Baumgart⁵, Ramaswamy Govindan¹, Nashat Y. Gabrail⁶, Alexander I. Spira⁷, Nagashree Seetharamu¹⁰, Yanyan Lou⁸, Aaron Scott Mansfield⁹, Rachel E. Sanborn¹¹, Jonathan W. Goldman¹⁴, and Maurice Zauderer⁷



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Trial Design



Trial Design

| Cohort | Treatment | Patients |
|--------|---|----------|
| A | VX15/2503 (15mg/kg) Nivolumab 360mg | 8 |
| B | VX15/2503 (15mg/kg) Ipilimumab (3mg/kg) | 8 |
| C | VX15/2503 (15mg/kg) Nivolumab 360mg Ipilimumab (3mg/kg) | 8 |
| D | Nivolumab 360mg | 8 |
| E | No treatment | 6 |

- **Primary Objective:**
 - Effect of pepinemab on T cell infiltrate into the tumor microenvironment in lymph nodes and blood
- **Secondary Objectives:**
 - Assess safety and tolerability of the combination of pepinemab with checkpoint inhibitors in patients with resectable stage III melanoma
 - Document pathologic response rates of the combination of pepinemab with checkpoint inhibitors

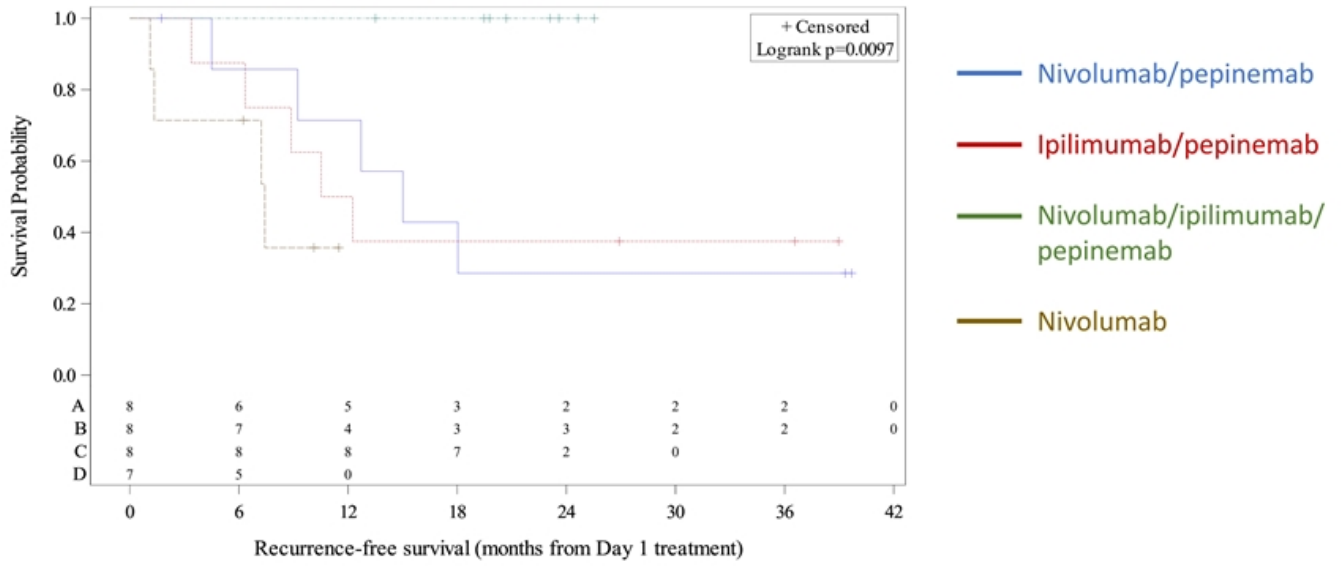
Pathologic Responses

| Cohort | Drug | N | pCR* | pMR^ |
|--------|--------------------------------|---|-------|-------|
| A | Nivolumab/pepinemab | 8 | 25.0% | 37.5% |
| B | Ipilimumab/pepinemab | 8 | 12.5% | 12.5% |
| C | Nivolumab/ipilimumab/pepinemab | 8 | 62.5% | 75.0% |
| D | Nivolumab | 7 | 28.5% | 42.9% |

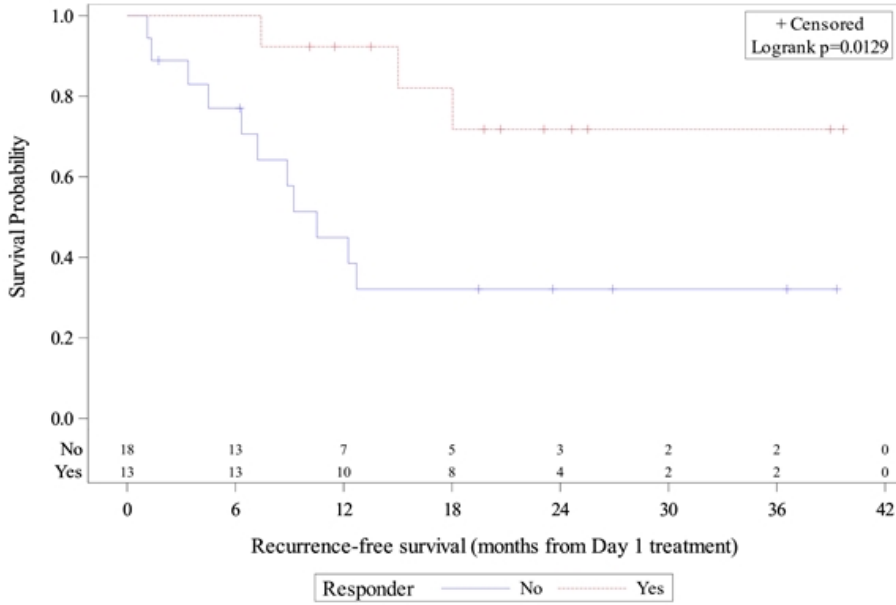
*Pathologic complete response: No viable tumor

^ Major pathologic response: pCR plus near pCR (<10% viable tumor)

Recurrence-free Survival



Recurrence-free Survival by Response



Toxicity

- All patients safely underwent surgery without delay
- Grade 3 adverse events:
 - Nivolumab/pepinemab: 1/8 (arthralgias)
 - Ipilimumab/pepinemab: 3/8 (AI, thrombocytopenia, transaminitis)
 - Nivolumab/ipilimumab/pepinemab: 5/8 (dermatitis, colitis, enteritis, nephritis, AI)
 - Nivolumab: 1/8 (AI)
- Three patients did not receive adjuvant therapy due to AEs

Conclusions

- Pepinemab is well-tolerated and adds no additional toxicity to PD-1 and CTLA-4 inhibitors in the neoadjuvant setting
- The triple combination of nivolumab, ipilimumab and pepinemab shows excellent response rates and with short follow up prolonged RFS compared to doublet therapies
 - Further studies needed to assess durability of response, but this combination could serve as a viable regimen in larger studies
- Correlative biomarker data will be presented at 2022 SITC

Thank you to the Congress organizers and the Discussant

Michael Lowe
mlowe3@emory.edu

European Society for Medical Oncology (ESMO)
Via Ginevra 4, CH-6900 Lugano
T. +41 (0)91 973 19 00
esmo@esmo.org

esmo.org

