

IMMUNOGEN INC
Form 8-K
March 01, 2019
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): February 27, 2019

ImmunoGen, Inc.

(Exact name of registrant as specified in its charter)

| | | |
|---|--------------------------|--------------------------------------|
| Massachusetts | 0-17999 | 04-2726691 |
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

830 Winter Street, Waltham, MA 02451

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (781) 895-0600

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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 (see General Instruction A.2. below):

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))

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 1.01. ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT

On February 27, 2019, ImmunoGen, Inc. (also referred to as “we,” and “our”) entered into an Eleventh Amendment to Lease (the “Eleventh Amendment”) with Bobson Norwood Commercial, LLC (“Landlord”) with respect to our facility located at 333 Providence Highway, Norwood, Massachusetts. In connection with our previously announced closure of our Norwood facility, the Eleventh Amendment accelerated the expiration date of the lease from March 31, 2019 to February 28, 2019.

ITEM 8.01. OTHER EVENTS

On March 1, 2019, we disclosed that our Phase 3 FORWARD I trial evaluating the safety and efficacy of mirvetuximab soravtansine compared to chemotherapy in patients with folate receptor alpha (FR α)-positive, platinum-resistant ovarian cancer did not meet its primary endpoint of progression-free survival (PFS) in either the entire study population or in the pre-specified subset of patients with high-FR α expression.

The FORWARD I Phase 3 trial randomized 366 patients 2:1 to receive either mirvetuximab soravtansine or the physician's choice of single-agent chemotherapy (pegylated liposomal doxorubicin, topotecan, or weekly paclitaxel). Eligibility criteria included patients with platinum-resistant ovarian cancer that expressed medium or high levels of FR α who have been treated with up to three prior regimens. The primary endpoint of this study was PFS, which was assessed using the Hochberg procedure in the entire study population and in the subset of patients with high FR α expression. The Hochberg procedure enables the simultaneous testing of two overlapping populations. Under this statistical analysis plan, if the p-value of the primary endpoint in either population is greater than 0.05, the p-value in the other population needs to be less than or equal to 0.025 to achieve statistical significance.

Key initial findings from FORWARD I are as follows:

- In the entire study population, the confirmed overall response rate was higher for mirvetuximab soravtansine than for chemotherapy (22% vs 12%, p-value 0.015), without a significant difference in the primary endpoint of PFS (HR 0.98, p-value 0.897) or overall survival (HR 0.81, p-value 0.248).
- In the pre-specified high FR α subgroup (218/366, 60%)
- PFS was longer in patients who received mirvetuximab soravtansine compared with chemotherapy (HR 0.69, p-value 0.049). Given that the p-value in the entire study population exceeded 0.05, the statistical analysis plan for the study required the p-value in the high subset to be less than or equal to 0.025 to achieve statistical significance.

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- Confirmed overall response rate was higher for mirvetuximab soravtansine than for chemotherapy (24% vs 10%, p-value 0.014).
 - Overall survival was longer in patients who received mirvetuximab soravtansine compared with chemotherapy (HR 0.62, p-value 0.033).
 - Mirvetuximab soravtansine was well-tolerated, with fewer patients experiencing grade 3 or greater adverse events (46% vs 61%), fewer dose reductions (20% vs 31%), and fewer discontinuations due to drug-related adverse events (5% vs 8%) compared with chemotherapy.
 - The safety profile of mirvetuximab soravtansine was confirmed, with the most common adverse events including nausea (54% all grades; 2% grade 3 or greater), diarrhea (44% all grades; 4% grade 3 or greater), and blurred vision (43% all grades; 3% grade 3 or greater).
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We will further assess the data from FORWARD I to determine potential next steps with a monotherapy approach. In parallel, we have generated encouraging data with mirvetuximab combination regimens and will evaluate our ongoing studies as an independent path forward to support a registration in ovarian cancer.

Forward-Looking Statements

This report includes forward-looking statements based on management's current expectations. These statements include, but are not limited to, our plan to further assess the data from FORWARD I, our expectations with respect to the future development of mirvetuximab soravtansine as a monotherapy or in combination regimens, our ability to expand the addressable patient population for mirvetuximab soravtansine and the regulatory and commercial potential of mirvetuximab combinations in earlier lines of therapy. For these statements, we claim the protection of the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. Various factors could cause our actual results to differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this report. It should be noted that there are risks and uncertainties related to the development of novel anticancer products, including risks related to preclinical and clinical studies, their timings and results, and the potential that earlier clinical studies may not be predictive of future results. A review of these risks can be found in our Annual Report on Form 10-K for the year ended December 31, 2017 and other reports filed with the Securities and Exchange Commission.

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.

ImmunoGen, Inc.
(Registrant)

Date: March 1, 2019 /s/ David G. Foster

David G. Foster
Vice President and Chief Accounting Officer
