

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

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FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

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Date of Report (Date of earliest event reported): November 8, 2000

IMMUNOGEN, INC.  
(Exact name of registrant as specified in its Charter)

Massachusetts (State or other jurisdiction of incorporation)	0-17999 (Commission File Number)	04-2726691 (IRS Employer Identification No.)
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128 Sidney Street, Cambridge, Massachusetts 02139  
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (617) 995-2500

## ITEM 5. OTHER EVENTS

On November 8, 2000, ImmunoGen, Inc. ("ImmunoGen") announced that huN901-DM1/BB-10901, a Tumor-Activated Prodrug (TAP) for the treatment of small-cell lung cancer (SCLC), was well-tolerated in monkeys when administered on a weekly dosing schedule. In addition, the TAP showed exceptional anti-tumor activity in mouse studies, even at very low doses. The preclinical results were presented November 8, 2000, at the 11th NCI-EORTC-AACR (National Cancer Institute-European Organization for Research and Treatment of Cancer-American Associate for Cancer Research) Symposium on New Drugs in Cancer in Amsterdam.

ImmunoGen is developing huN901-DM1/BB-10901 in collaboration with British Biotech plc. British Biotech is responsible for conducting the clinical trials necessary to achieve regulatory approval in the US, EU and Japan. British Biotech has been granted the exclusive right to develop and commercialize huN901-DM1/BB-10901 in the European Union and Japan. ImmunoGen retains the rights to commercialize huN901-DM1/BB-10901 in the United States and the rest of the world, as well as the right to manufacture the product worldwide.

The press release announcing the huN901-DM1/BB-10901 preclinical results is incorporated herein by reference and filed as Exhibit 99.1 hereto.

On November 10, 2000, ImmunoGen announced favorable safety data from the initial twenty patients enrolled in the first human clinical trial of huC242-DM1/SB-408075, its lead Tumor-Activated Prodrug (TAP) for the treatment of colorectal, pancreatic, and certain non-small-cell lung cancers. In a dose-escalating Phase I/II study, the TAP has been well tolerated at very high doses, has demonstrated the expected pharmacokinetic profile, and has shown no evidence of immunogenicity. In addition, encouraging decreases in a colorectal tumor marker have been observed. The preliminary findings were presented November 10, 2000, at the 11th NCI-EORTC-AACR Symposium on New Drugs in Cancer in Amsterdam.

HuC242-DM1/SB-408075 is a TAP created by conjugating the cytotoxic maytansinoid drug DM1 with the humanized monoclonal antibody C242. In preclinical studies, ImmunoGen has shown the eradication of colorectal, pancreatic and certain non-small-cell tumors in animal models. ImmunoGen has an agreement with SmithKline Beecham plc to develop and commercialize huC242-DM1/SB-408075.

The press release announcing the favorable safety data from the initial patients enrolled in the first huC242-DM1/SB-408075 human clinical trial is incorporated herein by reference and filed as Exhibit 99.2 hereto.

## ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS

(c) Exhibits.

99.1 The Registrant's Press Release dated November 8, 2000.

99.2 The Registrant's Press Release dated November 10, 2000.

SIGNATURE

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 hereto duly authorized.

ImmunoGen, Inc.  
(Registrant)

Date: November 16, 2000

/s/ MITCHEL S. SAYARE

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Mitchel S. Sayare  
Chairman and CEO

FOR IMMEDIATE RELEASE

IMMUNOGEN REPORTS FAVORABLE PRECLINICAL RESULTS FOR huN901-DM1/BB-10901

- Results Presented at NCI-EORTC-AACR International Conference in Amsterdam -

CAMBRIDGE, MASS., NOVEMBER 8, 2000 - ImmunoGen, Inc. (Nasdaq: IMGN) today announced that huN901-DM1/BB-10901, a Tumor-Activated Prodrug (TAP) for the treatment of small-cell lung cancer (SCLC), was well-tolerated in monkeys when administered on a weekly dosing schedule. In addition, the TAP showed exceptional anti-tumor activity in mouse studies, even at very low doses. These preclinical results were presented today at the 11th NCI-EORTC-AACR (National Cancer Institute-European Organization for Research and Treatment of Cancer-American Associate for Cancer Research) Symposium on New Drugs in Cancer in Amsterdam.

"Demonstrating the safety of this TAP on a weekly dosing schedule in monkeys is important because we intend to use this schedule in the upcoming human clinical trials," said Mitchel Sayare, Ph.D., Chairman and CEO of ImmunoGen, Inc. "With the conclusion of these final preclinical studies, we and our development partner, British Biotech, are on track to submit an Investigational New Drug (IND) application to the FDA later this year. We are eager to begin human evaluation of this TAP because we believe huN901-DM1/BB-10901 holds great promise to treat patients suffering from SCLC, an aggressive and usually fatal disease."

HuN901-DM1/BB-10901 is a TAP created by conjugating the cytotoxic maytansinoid drug DM1 with the humanized monoclonal antibody N901. In tumor xenograft models, huN901-DM1/BB-10901 eradicated human SCLC tumors. In a direct comparison study, even a low dose of huN901-DM1/BB-10901 was significantly more efficacious than an optimal dose of topotecan, a chemotherapeutic agent approved for treatment of SCLC. HuN901-DM1/BB-10901 demonstrated cures lasting at least 200 days in animal models where the combination of cisplatin and VP-16, currently the most effective SCLC agents, caused only a modest effect. In monkey studies, there was minimal toxicity at total doses significantly higher than those which effected cures in mice.

HuN901-DM1/BB-10901 is being developed in collaboration with British Biotech plc. British Biotech is responsible for conducting the clinical trials necessary to achieve regulatory approval in the US, EU and Japan. British Biotech has been granted the exclusive right to develop and commercialize huN901-DM1/BB-10901 in the European Union and Japan. ImmunoGen retains the rights to commercialize huN901-DM1/BB-10901 in the United States and the rest of the world, as well as the right to manufacture the product worldwide.

ImmunoGen, Inc. develops innovative biopharmaceuticals, primarily for cancer treatment. The Company has created potent tumor-activated prodrugs, consisting of drugs coupled to monoclonal antibodies for delivery to and destruction of cancer cells. The Company's lead TAP, huC242-DM1/SB-408075 for treatment of colorectal, pancreatic, and certain non-small-cell lung cancers, is currently under evaluation in two Phase I/II human clinical trials. Besides British Biotech, the Company has collaborative arrangements with SmithKline Beecham, Genentech, Abgenix, and MorphoSys.

THIS PRESS RELEASE INCLUDES FORWARD-LOOKING STATEMENTS BASED ON MANAGEMENT'S CURRENT EXPECTATIONS. FACTORS THAT COULD CAUSE FUTURE RESULTS TO DIFFER MATERIALLY FROM SUCH EXPECTATIONS INCLUDE, BUT ARE NOT LIMITED TO: THE ABILITY TO SECURE FUTURE FUNDING; THE SUCCESS OF THE COMPANY'S RESEARCH STRATEGY; THE APPLICABILITY OF THE DISCOVERIES MADE THEREIN; THE DIFFICULTIES INHERENT IN THE DEVELOPMENT OF PHARMACEUTICALS, INCLUDING UNCERTAINTIES AS TO THE TIMING AND RESULTS OF PRECLINICAL STUDIES; DELAYED ACHIEVEMENTS OF MILESTONES; RELIANCE ON COLLABORATORS; UNCERTAINTY AS TO WHETHER THE COMPANY'S POTENTIAL PRODUCTS WILL SUCCEED IN ENTERING HUMAN CLINICAL TRIALS AND UNCERTAINTY AS TO THE RESULTS OF SUCH TRIALS; UNCERTAINTY AS TO WHETHER ADEQUATE REIMBURSEMENT FOR THESE PRODUCTS WILL EXIST FROM THE GOVERNMENT, PRIVATE HEALTHCARE INSURERS AND THIRD-PARTY PAYORS; AND THE UNCERTAINTIES AS TO THE EXTENT OF FUTURE GOVERNMENT REGULATION OF THE PHARMACEUTICAL BUSINESS.

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## IMMUNOGEN REPORTS PRELIMINARY PHASE I/II CLINICAL DATA ON huC242-DM1/SB-408075

- Data Reported at NCI-EORTC-AACR International Conference in Amsterdam -

CAMBRIDGE, MASS., NOV. 10 /PRNewswire/ -- ImmunoGen, Inc. (Nasdaq: IMGN) today announced favorable safety data from the initial twenty patients enrolled in the first human clinical trial of huC242-DM1/SB-408075, its lead Tumor-Activated Prodrug (TAP) for the treatment of colorectal, pancreatic, and certain non-small-cell lung cancers. In a dose-escalating Phase I/II study, the TAP has been well tolerated at very high doses, has demonstrated the expected pharmacokinetic profile, and has shown no evidence of immunogenicity.

In addition, encouraging decreases in a colorectal tumor marker have been observed. These preliminary findings were presented today at the 11th NCI-EORTC-AACR (National Cancer Institute-European Organization for Research and Treatment of Cancer-American Associate for Cancer Research) Symposium on NewDrugs in Cancer in Amsterdam.

Anthony W. Tolcher, M.D., Principal Investigator of the study, presented the preliminary data. This escalating-dose study is designed to establish the safety and pharmacokinetic profile of huC242-DM1/SB-408075 when administered every three weeks and is being conducted at the Institute for Drug Development of the Cancer Therapy and Research Center (CTRC), San Antonio, Texas. Included in the study are patients suffering from refractory colorectal cancer, pancreatic cancer, and certain non-small-cell lung cancers. HuC242-DM1/SB-408075 is administered alone, not in conjunction with chemotherapeutic agents or other treatments. A second Phase I/II clinical trial with a weekly dosing regimen is ongoing at the University of Chicago Cancer Research Center under the direction of Richard L. Schilsky, M.D.

"We are extremely pleased with the progress of this clinical trial," said John M. Lambert, Ph.D., Senior Vice President, Pharmaceutical Development of ImmunoGen, Inc. "With the very promising data from our preclinical animal studies, we have high hopes for the use of huC242-DM1/SB-408075 in humans. We are enthusiastic that this product may be a more potent, less toxic treatment for patients suffering from these cancer types."

Patient enrollment in the study is continuing. The TAP's dosage level will continue to be increased to define the maximum tolerated dose (MTD) and better characterize the safety profile. Patients are now being dosed at the seventh dosage level, at a dose of 295 mg/m<sup>2</sup> administered via intravenous infusion every three weeks. Encouraging decreases in the CEA tumor marker have been observed at the higher doses. Serial measurement of CEA levels is an important monitor of clinical response, but is not considered a direct measure of tumor response.

CEA, or carcinoembryonic antigen, is a protein normally found only in very small amounts in the blood of healthy people, but it can become elevated in some people who have cancer or certain benign conditions. Physicians may use changes in tumor marker levels, such as CEA, to follow the course of the disease, to measure the effect of treatment, and to check for recurrence. In some cases, the tumor marker level reflects the extent of the disease or indicates how quickly the disease is likely to progress.

HuC242-DM1/SB-408075 is a TAP created by conjugating the cytotoxic maytansinoid drug DM1 with the humanized monoclonal antibody C242. In preclinical studies, ImmunoGen has shown the eradication of colorectal, pancreatic and certain non-small-cell tumors in animal models. ImmunoGen has an agreement with SmithKline Beecham plc to develop and commercialize huC242-DM1/SB-408075.

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THIS PRESS RELEASE INCLUDES FORWARD-LOOKING STATEMENTS BASED ON MANAGEMENT'S CURRENT EXPECTATIONS. FACTORS THAT COULD CAUSE FUTURE RESULTS TO DIFFER MATERIALLY FROM SUCH EXPECTATIONS INCLUDE, BUT ARE NOT LIMITED TO: THE ABILITY TO SECURE FUTURE FUNDING; THE SUCCESS OF THE COMPANY'S RESEARCH STRATEGY; THE APPLICABILITY OF THE DISCOVERIES MADE THEREIN; THE DIFFICULTIES INHERENT IN THE DEVELOPMENT OF PHARMACEUTICALS, INCLUDING UNCERTAINTIES AS TO THE TIMING AND RESULTS OF PRECLINICAL STUDIES; DELAYED ACHIEVEMENTS OF MILESTONES; RELIANCE ON COLLABORATORS; UNCERTAINTY AS TO WHETHER THE COMPANY'S POTENTIAL PRODUCTS WILL SUCCEED IN ENTERING HUMAN CLINICAL TRIALS AND UNCERTAINTY AS TO THE RESULTS OF SUCH TRIALS; UNCERTAINTY AS TO WHETHER ADEQUATE REIMBURSEMENT FOR THESE PRODUCTS WILL EXIST FROM THE GOVERNMENT, PRIVATE HEALTHCARE INSURERS AND THIRD-PARTY PAYORS; AND THE UNCERTAINTIES AS TO THE EXTENT OF FUTURE GOVERNMENT REGULATION OF THE PHARMACEUTICAL BUSINESS.