



## ImmunoGen Announces Completion of Operational Review

June 27, 2019

*Company Will Prioritize Continued Development of Mirvetuximab Soravtansine and a Select Portfolio of Earlier-Stage Candidates*

*Cash Runway Extended Through Readout of Mirvetuximab Soravtansine Pivotal Trial in Ovarian Cancer*

*Conference Call to be Held at 8 a.m. ET Today*

WALTHAM, Mass.--(BUSINESS WIRE)--Jun. 27, 2019-- [ImmunoGen, Inc.](#), (Nasdaq:IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced the completion of an in-depth operational review designed to extend the Company's cash runway and deliver on its commitment to develop next-generation ADCs to bring more good days to patients and generate increased value for shareholders. Based on the outcomes of this review, the Company will prioritize continued development of mirvetuximab and a select portfolio of three earlier-stage product candidates targeting solid tumors and hematological malignancies. The Company will end the current quarter with approximately \$240 million on its balance sheet and expects this cash, together with expense reductions resulting from the operational changes announced today and anticipated cash receipts from partners, will fund operations through the release of top-line results from the upcoming mirvetuximab Phase 3 study in platinum-resistant ovarian cancer, which are expected in the first half of 2022.

The operational review commenced following the announcement that FORWARD I, ImmunoGen's Phase 3 clinical trial evaluating mirvetuximab compared to chemotherapy in women with folate receptor alpha (FR $\alpha$ )-positive, platinum-resistant ovarian cancer, did not meet the primary endpoint. Data from FORWARD I did, however, demonstrate a consistent efficacy signal across a range of parameters in the pre-specified subset of patients with high FR $\alpha$  expression. Following consultation with the U.S. Food and Drug Administration (FDA), the Company will pursue a new Phase 3 study in this patient population.

In light of these developments and with the goal of extending the Company's existing cash runway, ImmunoGen has established three strategic priorities for the business: execute a registration study for mirvetuximab in platinum-resistant ovarian cancer; advance a select portfolio of earlier-stage product candidates; and further strengthen its balance sheet through partnering. Consistent with these priorities, ImmunoGen will focus on the following core activities:

- Initiate the registration study for mirvetuximab as a monotherapy for women with FR $\alpha$ -high, platinum-resistant ovarian cancer by the end of this year;
- Complete enrollment and continue follow up in the ongoing FORWARD II mirvetuximab combination cohorts;
- Continue IMG632 development in patients with relapsed acute myeloid leukemia (AML), blastic plasmacytoid dendritic cell neoplasm (BPDCN), and other CD123-positive hematologic malignancies in collaboration with Jazz Pharmaceuticals;
- Advance two additional assets that demonstrate ImmunoGen's continued innovation in ADCs: IMGC936, which is in co-development with MacroGenics with an IND expected by the end of 2019; and the Company's next generation anti-FR $\alpha$  ADC, which is expected to enter development in mid-2020; and
- Monetize its remaining portfolio and platform technologies through out-licensing transactions or asset sales.

Correspondingly, the Company will reduce ongoing expenses through the following portfolio prioritization and restructuring initiatives:

- Discontinue the development of IMG779 in adults with relapsed/refractory CD33-positive AML;
- Suspend all other research activities;
- Reduce its workforce by approximately 220 employees, with a majority of these employees separating from the business by mid-July 2019; and
- Seek to sub-lease excess office and lab space.

Following a transition period, the savings generated by the restructuring are expected to reduce ImmunoGen's quarterly expenses by more than 50%. As a result of the workforce reduction, the Company expects to record a one-time charge totaling approximately \$16.4 million related to termination benefits and other related expenses. This charge is expected to be recorded in the quarter ending June 30, 2019, and the related cash payments will be substantially paid out by June 30, 2020. In addition, an anticipated charge of \$3.7 million is expected to be incurred for retention benefits in the same time period. Updated 2019 financial guidance will be provided when ImmunoGen announces its second quarter operating results on August 2, 2019.

"I thank the employees separating from the business for their significant contributions to ImmunoGen and to the advancement of the ADC field," said Mark Enyedy, ImmunoGen's President and Chief Executive Officer. "Reorganizing the business is critical to the Company's future, enabling us to extend our cash position and continue the development of mirvetuximab and our portfolio of promising ADCs in earlier stages of development. We look forward to continued progress with the business, including the start of the registration study for mirvetuximab by year-end and additional monotherapy and combination data at ESMO in September, identifying a recommended Phase 2 dose and initiating combination studies with IMG632 in the second half of the year, and filing an IND for IMGC936 by the end of 2019."

"This was an extremely difficult decision for the Board, as we believe deeply in the therapeutic promise of ADCs, the Company's science, and its people," said Steve McCluski, ImmunoGen's Chairman of the Board. "These are, however, the right steps to take to bring mirvetuximab to patients and offer the best opportunity to capture long-term value for our shareholders, whom we thank for their support."

## CONFERENCE CALL INFORMATION

ImmunoGen will hold a conference call today at 8 a.m. ET to discuss these results. To access the live call by phone, dial 1-786-789-4797; the conference ID is 6921368. The call may also be accessed through the Investors section of the Company's website, [www.immunogen.com](http://www.immunogen.com). Following the live webcast, a replay of the call will be available at the same location through July 9, 2019.

## ABOUT MIRVETUXIMAB SORAVTANSINE

Mirvetuximab soravtansine (IMGN853) is the first folate receptor alpha (FR $\alpha$ )-targeting ADC. It uses a humanized FR $\alpha$ -binding antibody to target the ADC specifically to FR $\alpha$ -expressing cancer cells and a potent anti-tumor agent, DM4, to kill the targeted cancer cells.

## ABOUT FORWARD I

FORWARD I is a Phase 3 trial in which 366 patients were randomized 2:1 to receive either mirvetuximab soravtansine or the physician's choice of single-agent chemotherapy (pegylated liposomal doxorubicin, topotecan, or weekly paclitaxel). Eligible patients were diagnosed with platinum-resistant ovarian cancer that expresses medium or high levels of FR $\alpha$  and were treated with up to three prior regimens. The primary endpoint of this study was progression free survival (PFS), which was assessed in the entire study population and in the subset of patients with high FR $\alpha$  expression. ImmunoGen estimates that 12,000-14,000 patients per year in the U.S. meet these criteria, with a comparable number in the major markets in Europe.

ImmunoGen partnered with the GOG Foundation Inc., a leader in clinical research in gynecologic malignancies, on FORWARD I, which was conducted in North America and Europe.

## ABOUT FORWARD II

FORWARD II is a Phase 1b/2 study of mirvetuximab in combination with Avastin<sup>®</sup> (bevacizumab), carboplatin or Keytruda<sup>®</sup> (pembrolizumab) in patients with FR $\alpha$ -positive platinum-resistant or platinum-agnostic ovarian cancer, primary peritoneal, or fallopian tube tumors, as well as a triplet combination of mirvetuximab plus carboplatin and Avastin in patients with platinum-sensitive ovarian cancer.

## ABOUT IMMUNOGEN

ImmunoGen is developing the next generation of antibody-drug conjugates (ADCs) to improve outcomes for cancer patients. By generating targeted therapies with enhanced anti-tumor activity and favorable tolerability profiles, we aim to disrupt the progression of cancer and offer our patients more good days. We call this our commitment to "target a better now." The Company has built a productive platform generating a broad pipeline of ADCs targeting solid tumors and hematologic malignancies.

Learn more about who we are, what we do, and how we do it at [www.immunogen.com](http://www.immunogen.com).

## FORWARD-LOOKING STATEMENTS

*This press release includes forward-looking statements based on management's current expectations. For these statements, ImmunoGen claims the protection of the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. It should be noted that there are risks and uncertainties related to the development of novel anticancer products, including risks and uncertainties related to the execution of the restructuring of the Company's operations, including, without limitation, unanticipated delays and costs in implementing the workforce reduction and subleasing activities, the Company's ability to control future spending to enable it to fund its remaining operations through the release of top-line results from the upcoming mirvetuximab Phase 3 study, as well as the risks and uncertainties inherent in the Company's development programs, including clinical studies and regulatory processes, their timings and results. A review of these risks can be found in ImmunoGen's Annual Report on Form 10-K for the year ended December 31, 2018 and other reports filed with the Securities and Exchange Commission.*

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Source: ImmunoGen

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