IMMUNOMEDICS INC
Form DEFA14A
February 17, 2017

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

SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of
the Securities Exchange Act of 1934 (Amendment No.)

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Check the appropriate box:

¨ Preliminary Proxy Statement

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Immunomedics, Inc.
(Name of Registrant as Specified In Its Charter)

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Therapy for Chemo - Pretreated Metastatic Urothelial Cancer (mUC) with the Antibody - Drug Conjugate (ADC), Sacituzumab Govitecan (IMMU - 132) Scott T. Tagawa 1 , Allyson J. Ocean 1 , Elaine Lam 2 , Philip Saylor 3 , Aditya Bardia 3 , Julio J. Hajdenberg 4 , Alicia K. Morgans 5 , Kevin Kalinsky 6 , Matthew D. Galsky 7 , Bishoy Faltas 1 , Ana Molina 1 , Emerson Lim 6 , Pius Maliakal 8 , Robert M. Sharkey 8 , Boyd Mudenda 8 , William A. Wegener 8 , David M. Goldenberg 8 1 Weill Cornell Medicine, New York, NY; 2 University of Colorado Cancer Center, Aurora, CO; 3 Massachusetts General Hospital Cancer Center, Harvard Medical School, Boston, MA; 4 UF Health Cancer Center - Orlando Health, Orlando, FL ; 5 Vanderbilt Ingram Cancer Center, Nashville, TN; 6 Columbia University - Herbert Irving Comprehensive Cancer Center, New York, NY; 7 Icahn School of Medicine Mount Sinai, Tisch Cancer Institute, New York, NY; 8 Immunomedics, Inc., Morris Plains, NJ Sacituzumab govitecan (IMMU - 132) is an investigational agent. Drs. Wegener, Sharkey, Maliakal, Mudenda and Goldenberg are employees of Immunomedics which provided funding for the other investigators for the conduct of this trial . Abstract #: 327 • 44 patients received 556 doses (278 cycles) of IMMU - 132 • Median number of doses: 6 (range, 1 - 50) • 36 Response - Assessable patients (75% ≥ 2 lines of prior therapy) • Best response: 1 CR, 10 PRs, 19 SDs, 6 PDs • Objective Response Rate: 31% (11/36) (95% CI: 17%, 48%) – 1 prior chemotherapy: 44% (4/9) – 2 to 6 prior chemotherapies: 26% (7/27) – Prior I - O: 17% (2/12) • Median duration of response: 7.5 months (95% CI: 4.4, 12.9) • Clinical benefit rates: PR + SD ≥ 4 mos , 63% ; PR + SD ≥6 mos , 52% • Median PFS: 7.2 months (95% CI, 6.7, 11.7) • Median OS: 15.5 months (95% CI, 8.9, 17.2) • Major grade ≥ 3 toxicity: neutropenia (29.6%), febrile neutropenia (11.1%) • No treatment - related SAEs or death; no immune reaction to ADC or antibody response SUMMARY CONCLUSION With an ORR of 31% and a median duration of response of 7.5 months in a heavily pre - treated population, sacituzumab govitecan (IMMU - 132) is an active and promising agent as a 2nd or later - line monotherapy for platinum - or I - O - pretreated, metastatic (stage IV) mUC patients