

THE UNIVERSITY OF MICHIGAN  
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Research Agreement between the University of Michigan and Esanik Therapeutics, Inc.

Action Requested: Authorization to enter into Agreement

Preamble:

A statutory conflict of interest situation was identified by the Office of Research and Sponsored Projects while reviewing the Proposal Approval Form which then triggered a review by the Medical School Conflict of Interest Board. A plan for management of the possible risks associated with the conflict of interest was then developed and approved by the Board and agreed to by the parties involved.

This proposed research agreement (“Agreement”) falls under the State of Michigan Conflict of Interest Statute because Professors Gilbert Omenn, Shaomeng Wang, and Arul Chinnaiyan are employees of the University of Michigan (“University”), and partial owners of Esanik Therapeutics, Inc. The law permits such an Agreement provided it is disclosed to the Board of Regents (“Regents”) of the University of Michigan and approved in advance by a 2/3 vote.

Background:

Gilbert Omenn, MD, PhD, a Professor of Internal Medicine, Human Genetics, and Public Health; Shaomeng Wang, PhD, a Professor of Internal Medicine, Pharmacology, and Medicinal Chemistry; and Arul Chinnaiyan, MD, PhD, Professor of Pathology and Urology, are partial owners of a for-profit company called Esanik Therapeutics, Inc. (the “Company”). The Company wishes to fund a project entitled “ERICA: Phase 2 Multi-center Trial of ESK981 in Combination with Nivolumab in Patients with Metastatic Renal Cell Carcinoma” (ORSP #18-PAF06063) in the Department of Internal Medicine – Hematology/Oncology under the direction of Dr. Ajjai Alva. The purpose of this project is to determine the efficacy of ESK981 in combination with Nivolumab.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately five (5) years. The amount of funding support will not exceed \$376,000. Since research projects are often amended, this agreement includes a provision for changes in time and scope. University procedures for approval of these changes will be followed and additional conflict of interest review will be done as appropriate.

Impact of the Agreement:

The Agreement will support an effort by Dr. Alva to use his expertise and University laboratory, as well as other University resources, to determine the efficacy of ESK981 in combination with Nivolumab.

Recommendations:

This matter has been reviewed and approved by the Medical School Conflict of Interest Board. In light of this disclosure and our finding that the Agreement was negotiated in conformance with standard University practices, I recommend that the Board of Regents approve the University's entering into this Agreement with Esanik Therapeutics, Inc.

Respectfully submitted,



S. Jack Hu  
Vice President for Research

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