

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Research Agreement between the University of Michigan and Eli Lilly and Company

Action Requested: Authorization to amend an Agreement

Preamble:

A statutory conflict of interest situation was identified by the Office of Research and Sponsored Projects while reviewing the Proposal Approval Form.

This proposed agreement (“Agreement”) falls under the State of Michigan Conflict of Interest Statute because Dr. Marshall Runge is an employee of the University of Michigan (“University”), and a paid member of the Board of Directors of Eli Lilly and Company. 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:

Marshall Runge, MD, PhD, the Executive Vice President for Medical Affairs and Dean of the Medical School, is a paid member of the Board of Directors of the for-profit company called Eli Lilly and Company (the “Company”). The Company wishes to amend a research agreement previously approved by the Regents on December 5, 2019 to include the proposal entitled, “A Multicenter, Randomized, Open-label, Phase 3 Trial Comparing LOXO-292 to Physicians Choice of Cabozantinib or Vandetanib” (ORSP #20-PAF06737) in the Department Internal Medicine – Hematology and Oncology under the direction of Dr. Francis Worden. The purpose of this amendment is to add funds to continue to support efforts to compare LOXO-292 to Cabozantinib or Vandetanib in patients with RET-mutant medullary thyroid cancer. Dr. Runge is not involved in any manner in this research project and was not involved in any manner in the negotiation of the Agreement terms.

Agreement Terms:

The terms of the amended Agreement conform to University policy. The period of performance for the project is extended to November 1, 2026. The amount of funding support will be increased by \$32,538 and will not exceed \$1,553,150 total. 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 amended Agreement will provide continued support of an effort by Dr. Worden to use his expertise and University laboratory, as well as other University resources, to work collaboratively with the Company to focus on comparing LOXO-292 to Cabozantinib or Vandetanib in patients with RET-mutant medullary thyroid cancer.

Recommendations:

Dr. Runge has properly disclosed his service to the Company pursuant to the regular conflict of interest process and policies that apply to Executive Officers of the University. The president has put in place a management plan for this conflict which calls for Dr. Runge to recuse himself from any University decisions involving a business relationship with the Company and to inform the president when he is required to do so. 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 Eli Lilly and Company.

Respectfully submitted,



Rebecca Cunningham
Vice President for Research

May 2020