

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Research Agreement between the University of Michigan and MeiraGTx Limited

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 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 agreement (“Agreement”) falls under the State of Michigan Conflict of Interest Statute because Professor Robin Ali is an employee of the University of Michigan (“University”) and a partial owner of MeiraGTx Limited. 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:

Robin Ali, PhD, FMedScia, a Visiting Professor in the Department of Ophthalmology and Visual Science, is the Chief Scientific Officer and partial owner of MeiraGTx Limited (the “Company”). The Company wishes to amend a research agreement previously approved by the Regents on May 16, 2019 to include the proposal entitled, “Long-term follow-up study of participants following an open label, multi-centre, Phase I/II dose escalation trial of a recombinant adeno-associated virus vector (AAV2/8-hCARp.hCNGB3) for gene therapy of adults and children with achromatopsia owing to defects in CNGB3” (ORSP #20-PAF01705) in the Department of Ophthalmology and Visual Science under the direction of Dr. Cagri Besirli. The purpose of this amendment is to add funding for efforts towards a long-term follow-up study to provide important information about the long-term safety and efficacy of this gene transfer vector for treating patients with achromatopsia caused by mutations in the CNGB3 gene.

Agreement Terms:

The terms of the Amendment conform to University policy. The period of performance for the project is approximately six (6) years. The amount of funding support will be increased by \$1,049,833. 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 provide continued support of an effort by Dr. Besirli to use his expertise and University laboratory, as well as other University resources, to assess the longer-term safety of AAV2/8-hCARp.hCNGB3 for CNGB3 gene replacement in the retina administered to participants in the CNGB3 trial.

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 amending this Agreement with MeiraGTx Limited.

Respectfully submitted,



Rebecca Cunningham
Interim Vice President for Research

December 2019