

THE UNIVERSITY OF MICHIGAN
REGENTS COMMUNICATION

ACTION REQUEST

Subject: Project Agreements with the University of Michigan

Action Requested: Authorization to enter into or amend Agreements

Preamble:

Statutory conflicts of interest situations were identified by the Office of Research and Sponsored Projects while reviewing Proposal Approval Forms that then triggered a review by the Medical School Conflict of Interest Board and/or the UMOR Conflict of Interest Review Committee. Plans for management of the possible risks associated with the conflicts of interest will be developed and approved by the Board and/or Committee and may require agreement by the parties involved at time of award.

These proposed project (e.g., research, sponsored activity, and/or subcontract) agreements (“Agreement”) and/or amendments to Agreements (“Amendments”) fall under the State of Michigan Conflict of Interest Statute because University of Michigan (“University”) employees have activities, relationships, or interests in the companies as described in Attachment A. The law permits such Agreements provided they are disclosed to the Board of Regents (“Regents”) of the University and approved in advance by a 2/3 vote.

Agreement Terms:

The terms of the Agreements and/or Amendments conform to University policy. The funding support will not exceed the amount reported in Attachment A for each Agreement and/or Amendment. Since projects are often amended, these Agreements and/or Amendments include provisions 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 Agreements and/or Amendments will provide support of investigator’s effort to use their expertise and University laboratories, as well as other University resources, to execute the projects as reported in Attachment A.

Recommendations:

These matters have been reviewed and approved by the Medical School Conflict of Interest Board and/or the UMOR Conflict of Interest Review Committee. In light of this disclosure and our finding that the Agreements and Amendments were negotiated in conformance with standard University practices, I recommend that the Board of Regents approve the University’s entering into or amending the Agreements referenced in Attachment A.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Rebecca Cunningham', written in a cursive style.

Rebecca Cunningham
Vice President for Research and Innovation

March 2024

Attachment A

Project #1

SBIR Phase I Subcontract Agreement between the University and AmpedRNA Biosciences, LLC Reviewed by the UMOR Conflict of Interest Review Committee	
<u>Project Information</u>	
Title: Highly Stable Mini-CircRNA Vaccine with Maximally Activated and Long-Lasting T Cells for HPV-Related Cancer Combination Immunotherapy	U-M Project ID: 24-PAF01405
Direct Sponsor: AmpedRNA Biosciences, LLC	Prime: National Institutes of Health
Principal Investigator/Department: Guizhi Zhu, Pharmaceutical Sciences	
Project Duration: One (1) Year	Funding Support: \$99,887
Purpose: The purpose of this project is to develop a highly immunogenic mini-circular RNA cancer vaccine for HPV related cancers that is superior to a state-of-the-art mRNA cancer vaccine.	
<u>University Employee; University Title; Relationship with AmpedRNA Biosciences, LLC</u>	
<ul style="list-style-type: none">• Guizhi Zhu; Associate Professor, Pharmaceutical Sciences; Partial Owner	

Project #2

Second Amendment to Research Agreement between the University and Ascentage Pharma Group Inc. (formerly known as Ascentage Pharma Group Corporation, Ltd.) Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: Design and development of new anticancer drugs	U-M Project ID: 24-PAF04335
Direct Sponsor: Ascentage Pharma Group Inc.	
Principal Investigator/Department: Haibin Zhou, Hematology/Oncology	
Agreement Originally Approved by the Regents: December 7, 2017 First Amendment Approved by the Regents: December 3, 2020	
Current Project Duration: Six (6) Years Additional Project Duration: Three (3) Years, Six (6) Months	Current Funding Support: \$6,936,766 Additional Funding Support: \$3,624,056
Purpose: The purpose of this amendment is to add additional time and funds so that Dr. Zhou may continue supporting further optimization and testing of potent small molecule inhibitors for several targets to select one or more compounds suitable for clinical development and identification and validation of potential biomarkers for clinical trials.	
<u>University Employee; University Title; Relationship with Ascentage Pharma Group Inc.</u>	
<ul style="list-style-type: none">• Shaomeng Wang; Professor, Hematology/Oncology; Partial Owner	

Project #3

Subcontract Agreement between the University and Dermira, Inc. (acquired by Eli Lilly and Company) Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: 5634-Gudjonsson DERM 792 Eli Lilly Eli Lilly and Almirall Lebrikizumab Mechanistic Study	U-M Project ID: 24-PAF04207
Direct Sponsor: Dermira, Inc.	Prime Sponsor: Almirall Prodesfarma, S.A.
Principal Investigator/Department: Johann Gudjonsson, Dermatology	
Project Duration: Two (2) Years	Funding Support: \$6,540,193
Purpose: The purpose of this project is to map out the molecular response to lebrikizumab and determine if effective long-term neutralization of IL-13 in treated atopic dermatitis (AD) skin leads to long-term normalization of immune homeostasis in resolved AD skin lesions, normalization of non-lesional AD skin towards that of healthy (non-AD) subjects, and resolution of epigenetic changes in stromal cells (keratinocytes/fibroblasts/endothelial cells/mast cells).	
<u>University Employee; University Title; Relationship with Eli Lilly and Company</u>	
<ul style="list-style-type: none">• Marschall Runge; Executive Vice President for Medical Affairs, Dean of the Medical School; Board of Directors Member	

Project #4

Subcontract Agreement between the University and Greenmark Biomedical, Inc. Reviewed by the UMOR Conflict of Interest Review Committee	
<u>Project Information</u>	
Title: Intraoral Camera Development for Fluorescent Nanoparticle-Labeled Caries Detection and Monitoring	U-M Project ID: 24-PAF01158
Direct Sponsor: Greenmark Biomedical, Inc.	Prime Sponsor: National Institutes of Health
Principal Investigator/Department: Livia Tenuta, Cariology, Restorative Sciences and Endodontics	
Project Duration: Six (6) Months	Funding Support: \$8,577
Purpose: The purpose of this project is to optimize intraoral camera parameters for liquid chromatography (LC) fluorescence detectability and imaging, and to develop and evaluate in vitro efficacy of Artificial Intelligence model.	
<u>University Employee; University Title; Relationship with Greenmark Biomedical, Inc.</u>	
<ul style="list-style-type: none">• Joerg Lahann; Professor, Chemical Engineering; Board of Directors Member	

Project #5

Second Amendment to Research Agreement between the University and ONL Therapeutics, Inc. Reviewed by the Medical School Conflict of Interest Board	
<u>Project Information</u>	
Title: Feasibility of Fas inhibition in preventing photoreceptor cell death in inherited retinal degeneration	U-M Project ID: 24-PAF05099
Direct Sponsor: ONL Therapeutics, Inc.	
Principal Investigator/Department: David Zacks, Ophthalmology and Visual Sciences	
Agreement Originally Approved by the Regents: May 20, 2021 First Amendment Approved by the Regents: July 20, 2023	
Current Project Duration: Three (3) Years Additional Time: One (1) Year	Current Funding Support: \$803,903 Additional Funding Support: \$363,050
Purpose: The purpose of this amendment is to add additional funds and time so Dr. Zacks may continue to test the potential for ONL Therapeutics, Inc.'s Fas inhibitors to protect photoreceptor cells in mouse models of inherited retinal degeneration.	
<u>University Employee; University Title; Relationship with ONL Therapeutics, Inc.</u>	
<ul style="list-style-type: none">• David Zacks; Professor, Ophthalmology and Visual Sciences; Board of Directors Member	

Project #6

Subcontract Agreement between the University and Propel Aero, Inc. Reviewed by the UMOR Conflict of Interest	
<u>Project Information</u>	
Title: High Energy Reloadable Sodium-Air Redox Engine & Fuel Cell System	U-M Project ID: 24-PAF02445
Direct Sponsor: Propel Aero, Inc.	Prime Sponsor: Department of Energy
Principal Investigator/Department: Venkat Viswanathan, Aerospace Engineering	
Project Duration: Three (3) Years	Funding Support: \$2,000,000
Purpose: The purpose of this project is to deliver a safe, refuelable battery pack that can provide specific energy ≥ 1000 Wh/kg at a continuous power density of ≥ 500 W/kg and at a levelized electricity cost of $\leq \$0.30$ /kWh.	
<u>University Employee; University Title; Relationship with Propel Aero, Inc.</u>	
<ul style="list-style-type: none">• Venkat Viswanathan; Associate Professor, Aerospace Engineering; Partial Owner	