DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Invention; Availability for Licensing

AGENCY: National Institutes of Health

ACTION: Notice

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing in the U.S. to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC 2479, Bethesda, MD 20892-2479; telephone: 301-402-5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

**ApoA-1 Mimetic Peptides Promoting Lipid Efflux from Cells for Treatment of Vascular Disorders**

**Description of Technology:** This invention involves ApoA-1 mimetic peptides with multiple amphipathic alpha-helical domains that promote lipid efflux from cells and are useful in the treatment and prevention of dyslipidemic, inflammatory and vascular disorders. IND-enabling studies for one of the peptides, named Fx-5A, are completed in preparation for an IND filing at the FDA, to be followed by a Phase I clinical trial planned for 2017. Disorders amenable to treatment with the peptides include hyperlipidemia, hyperlipoproteinemia, hypercholesterolemia, HDL deficiency, hypertriglyceridemia, apoA-I deficiency, acute coronary syndrome, angina pectoris, aortic valve stenosis, atherosclerosis, carotid atherosclerosis, congestive heart failure, cerebral stroke, coronary artery disease, inflammation of the cardiovascular system, intermittent claudication, myocardial infarction, peripheral vascular disease, post-ischemic reperfusion, renal artery stenosis, reperfusion myocardial injury, restenosis, and thrombotic stroke.

**Potential Commercial Applications:**
- Treatment and prevention of many hereditary, chronic and acute dyslipidemic and vascular disorders, where other treatments are not effective or too invasive, such as statins, partial ileal bypass surgery, portacaval shunt, liver transplantation, and removal of atherogenic lipoproteins by one of several apheresis procedures.
• Also applicable to the treatment of inflammation, asthma, colitis, inflammatory bowel disease (IBD), chronic kidney disease (CKD).

**Development Stage:** Early-stage; In vitro data available; In vivo data available (animal)

**Inventors:** Alan T. Remaley, Stephen J. Demosky, John A. Stonik, Marcelo J.A. Amar, Edward B. Neufeld, Fairwell Thomas, H. Bryan Brewer (all of NHLBI)

**Publications:**


**Intellectual Property:** NIH Reference No. E-114-2004/0 - Issued Patents:

- US 7,572,771 issued 2009-11-08;
- US 8,071,746 issued 2011-12-06;
- US 8,148,323 issued 2012-04-03;
- US 8,835,378 issued 2014-09-16;
- AU 2005295640 issued 2011-11-10;
- CA 2584048 issued 2016-08-09;
- EP 1812474 issued 2010-05-26, validated in CH, DE, ES, FR, GB and IT; and

**Licensing Contact:** Cristina Thalhammer-Reyero, Ph.D., M.B.A.; 301-435-4507; thalhamc@mail.nih.gov

**Collaborative Research Opportunity:** The National Heart, Lung, and Blood Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize ApoA-1 mimetic peptides. For collaboration opportunities, please contact Denise Crooks, Ph.D. at 301-435-0103 or crooksd@nhlbi.nih.gov.

Dated: November 30, 2016
Cristina Thalhammer-Reyero,

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Office of Technology Transfer and Development

National Heart, Lung, and Blood Institute

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