

Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: This notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve commercialization of results of federally-funded research and development.

Technology description follows.

Albumin Binding Prostate Cancer Treating Compositions

The invention pertains to a therapeutic agent that includes a chemically conjugated residue derived from (((R)-1-carboxy-2-mercaptoethyl)carbamoyl)-L-glutamic acid that is further bound to an Evans blue analog (EB). The EB analog reversibly binds to circulating serum albumin to provide a radiopharmaceutical that retains affinity and specificity to prostate specific membrane antigen (PSMA; in this case PSMA-617). PSMA is a surface molecule shown to be specifically expressed by prostate tumor cells. PSMA expression levels correlate with disease stage and with hormone refractory cancers. Although most PSMA expression appears to be restricted to the prostate cancer, low levels of expression can also be detected in the brain, kidneys, salivary glands, and small intestine. The antigen is also shown to be expressed by neovascular tumor vessels of multiple other cancers. Inclusion of the Evans blue analog promotes high internalization and retention rates of the conjugated target ligand, and therefore, higher accumulation in PSMA positive tumors. Labeling EB-PSMA-617 derivatives with the therapeutic beta emitters, *e.g.*, 90Y, 86Y, and 177Lu gives rise to improved tumor response and survival rates.

Potential Commercial Applications:

- Cancer therapeutics
- Higher stability/Lower toxicity

Development Stage:

- Early stage

Inventors: Xiaoyuan Chen and Orit Jacobson Weiss (both of NIBIB).

Intellectual Property: HHS Reference No. E-054-2018/0; U.S. Provisional Patent Applications 62/633,648 filed February 22, 2018.

Licensing Contact: Michael Shmilovich, Esq. CLP; 301-435-5019; shmilovm@mail.nih.gov.

Dated: July 20, 2018.

Michael Shmilovich,

*Senior Licensing and Patenting Manager,
National Heart, Lung, and Blood Institute,
Office of Technology Transfer and
Development.*

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BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Barry Buchbinder, Ph.D., 240-627-3678; barry.buchbinder@nih.gov. Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Self-Assembling Insect Ferritin Nanoparticles for Display of Co-assembled Trimeric Antigens Description of Technology

Antigens on the surface of virus particles are displayed in a regular, repetitive pattern which facilitates B cell activation. Presenting trimeric antigens on engineered particles that mimic the geometric patterns observed for native viral proteins can lead to an improved host antibody response.

Self-assembling globular ferritin nanoparticles have previously been used to display multiple copies of a co-assembled trimeric antigen to the immune system. However, prior ferritin nanoparticle technologies only permit a

random co-assembly of diverse trimeric antigens, and therefore cannot guarantee the pattern and ratio of diverse trimeric antigens on a single ferritin nanoparticle.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases are developing novel recombinant ferritin nanoparticles that are based on insect ferritin proteins, and that have been engineered to display two different trimeric antigens in a defined ratio and geometric pattern. This system has been tested with antigens derived from HIV-1 envelope (Env) and influenza hemagglutinin (HA). Interestingly, when guinea pigs are immunized with ferritin nanoparticles displaying two different trimeric antigens, induced B cells could simultaneously recognize both trimeric antigens, thus leading to an immune response with improved neutralization breadth.

This technology can be used as a platform for multimerized display of trimeric antigens such as viral type I fusion glycoproteins, and may be applied to many high-priority vaccine targets, such as HIV-1, influenza, respiratory syncytial virus, parainfluenza viruses, and coronaviruses.

Potential Commercial Applications:

- Platform for multimerized immunogen presentation and vaccine design.
- Vaccines for pathogens that use genetic diversity to escape the immune response.

Competitive Advantages:

- Particles have equal fractions of two different antigens in a specific configuration on the nanoparticle surface (unlike regular ferritin used previously)
- Designed particles have a geometry that allows for attachment of trimeric antigens (unlike the native insect ferritin).

Development Stage:

- *In vivo* testing (rodents).

Inventors: Peter Kwong (NIAID), Ivelin Georgiev (NIAID), Michael Gordon Joyce (NIAID), Masaru Kanekiyo (NIAID), Aliaksandr Druz (NIAID), Ulrich Baxa (NIAID), Joseph Van Galen (NIAID), Rita Chen (NIAID), Cheng Cheng (NIAID), John Mascola (NIAID), Yaroslav Tsybovsky (Leidos Biomedical Research, Inc), Yongping Yang (NIAID), Paul Thomas (NIAID), Barney Graham (NIAID).

Publications: Georgiev, Ivelin S., et al., ACS Infectious Diseases (2018) 4 (5), 788-796.

Intellectual Property: HHS Reference Number E-270-2015; U.S. Patent Application No. 62/355,212 filed 06/27/

2016; PCT Application No. PCT/US2017/039595 filed 06/27/2017 (pending).

Related Intellectual Property: HHS Reference Number E-531-2013, E-293-2011, E-060-2015.

Licensing Contact: Barry Buchbinder, Ph.D., 240-627-3678; barry.buchbinder@nih.gov.

Dated: July 20, 2018.

Suzanne M. Frisbie,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Scientific Advisory Committee on Alternative Toxicological Methods; Announcement of Meeting; Request for Comments

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM). SACATM, a federally chartered, external advisory group composed of scientists from the public and private sectors, including representatives of regulated industry and national animal protection organization, will review and provide advice on programmatic activities. SACATM advises the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the National Institute of Environmental Sciences (NIEHS) and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. The meeting is open to the public and registration is requested for both attendance and oral comment and required to access the webcast. Information about the meeting and registration are available at <https://ntp.niehs.nih.gov/go/32822>.

DATES:

Meeting: September 5-6, 2018; Begins at 9:00 a.m. (EDT) each day and continues until adjournment.

Written Public Comment Submissions: Deadline is August 29, 2018.

Oral Comments: Deadline is August 29, 2018.

Registration for Meeting: Deadline September 6, 2018.

Registration to view the meeting via the webcast is required.

ADDRESSES:

Meeting Location: Rodbell Auditorium, Rall Building, National Institute of Environmental Health Sciences (NIEHS), 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Meeting web page: The preliminary agenda, registration, and other meeting materials are at <https://ntp.niehs.nih.gov/go/32822>.

Webcast: The meeting will be webcast; the URL will be provided to those who register for viewing.

FOR FURTHER INFORMATION CONTACT: Dr. Mary Wolfe, Designated Federal Official for the SACATM, Office of Liaison, Policy and Review, Division of NTP, NIEHS, P.O. Box 12233, K2-03, Research Triangle Park, NC 27709. Phone: 984-287-3209, Fax: 301-451-5759, Email: wolfe@niehs.nih.gov. Hand Deliver/Courier address: 530 Davis Drive, Room K2130, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Meeting and Registration: The meeting is open to the public with time scheduled for oral public comments; attendance at the meeting is limited only by the space available.

SACATM will provide input to ICCVAM, NICEATM, and NIEHS on programmatic activities and issues. Preliminary agenda includes the US Strategic Roadmap including challenges to and opportunities for implementing non-animal approaches to evaluate chemicals and medical products and the importance of international harmonization through the Organisation for Economic Co-operation and Development activities. Please see the preliminary agenda for information about the specific presentations. The preliminary agenda, roster of SACATM members, background materials, public comments, and any additional information, when available, will be posted on the SACATM meeting website (<https://ntp.niehs.nih.gov/go/32822>) or may be requested in hardcopy from the Designated Federal Official for SACATM. Following the meeting, summary minutes will be prepared and made available on the BSC meeting website.

The public may attend the meeting in person or view the webcast. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration.

Individuals who plan to provide oral comments (see below) are encouraged to register online at the SACATM meeting website (<https://ntp.niehs.nih.gov/go/32822>) by August 29, 2018, to facilitate planning for the meeting. Individuals are encouraged to access the website to stay abreast of the most current information regarding the meeting. Visitor and security information for those attending in-person is available at ntp.niehs.nih.gov/about/visiting/index.cfm. Individuals with disabilities who need accommodation to participate in this event should contact Ms. Robbin Guy at phone: (984) 287-3136 or email: guyr2@niehs.nih.gov. TTY users should contact the Federal TTY Relay Service at 800-877-8339. Requests should be made at least five business days in advance of the event.

Written Public Comments: Written and oral public comment are invited for the agenda topics. Guidelines for public comments are available at https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.

The deadline for submission of written comments is August 29, 2018. Written public comments should be submitted through the meeting website. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP website, and the submitter will be identified by name, affiliation, and sponsoring organization (if any).

Oral Public Comment Registration: The preliminary agenda allows for several public comment periods with each allowing for up to 4 commenters for up to 5 minutes per speaker. Oral comments may be presented in person at NIEHS or by teleconference line. Registration for oral comments is on or before August 29, 2018, at <https://ntp.niehs.nih.gov/go/32822>. Registration is on a first-come, first-served basis, and registrants will be assigned a number in their confirmation email. Each organization is allowed one time slot per comment period. After the maximum number of speakers per comment period is exceeded, individuals registered to provide oral comment will be placed on a wait list and notified should an opening become available. Commenters will be notified after August 29, 2018, about the actual time allotted per speaker, and the teleconference number will be sent to those registered to give oral comments by teleconference line.

If possible, oral public commenters should send a copy of their slides and/or statement or talking points to Robbin