

**Licensing Opportunity:** Researchers at the NICHD seek licensing and/or co-development research collaborations for the therapeutic management of Menkes Disease and related copper transport disorders.

#### Contact Information

Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: [john.hewes@nih.gov](mailto:john.hewes@nih.gov).

Dated: February 8, 2016.

#### John D. Hewes,

*Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute.*

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## 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 and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 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 and/or co-development.

**ADDRESSES:** Information on licensing, co-development research collaborations, and/or copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702, Tel. 240-276-5515 or email [ncitechtransfer@mail.nih.gov](mailto:ncitechtransfer@mail.nih.gov). A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

**FOR FURTHER INFORMATION CONTACT:** Requests for copies of the patent application or inquiries about licensing and/or co-development should be sent to John D. Hewes, Ph.D., email: [john.hewes@nih.gov](mailto:john.hewes@nih.gov).

**SUPPLEMENTARY INFORMATION:** Technology description follows.

**Title of invention:** Modified griffithsin tandemers for enhanced activity and reduced viral aggregation.

**Description of Technology:** Griffithsin (GRFT) is a lectin with potent antiviral properties that is capable of preventing and treating infections caused by a number of enveloped viruses (including HIV, SARS, HCV, HSV, and Japanese encephalitis) and is currently in clinical development as an anti-HIV microbicide. In addition to its broad antiviral activity, GRFT is stable at high temperature and at a broad pH range, displays low toxicity and immunogenicity, and is amenable to large-scale manufacturing. Native GRFT is a domain-swapped homodimer that binds to viral envelope glycoproteins and has displayed mid-picomolar activity in cell-based anti-HIV assays. This invention is directed to synthetic proteins that comprise two (or more) obligate monomers ("mGRFT") joined by an amino acid linker to form tandemers ("mGRFT tandemers"). Each obligate monomer is generated by the addition of Gly-Ser residues in the hinge region of wild-type GRFT. Two or more obligate monomers are joined by an amino acid linker to form the mGRFT tandemers. The properties of the mGRFT tandemers can be modulated by the length of the amino acid linker and the number of obligate monomers co-joined. mGRFT tandemers exhibit potent anti-viral properties when compared against native GRFT and are equipotent against viruses that are both sensitive and resistant to native GRFT. As such, potential uses of the invention tandemers include topical and intravenous therapy to treat HIV infection, particularly to treat HIV infections that are resistant to native GRFT.

#### Potential Commercial Applications

- Broad-spectrum antiviral agent similar to wild type GRFT
- Potential activity against SARS CoV, MERS, Ebola, HCV and influenza

#### Value Proposition

- Broad antiviral activity
- Stable at high temperature and at a broad pH range
- Displays low toxicity and immunogenicity.

**Development Stage:** In vivo/Lead Validation.

**Inventor(s):** Barry R. O'Keefe (NCI), A. Wlodawer (NCI), T. Moulaei (NCI).

#### Publication(s)

—Moulaei T. et al., Griffithsin tandemers: flexible and potent lectin inhibitors of the human immunodeficiency virus. *Retrovirology*. 2015 Jan 23;12:6.

—A. Chatterjee et al., Griffithsin and Carrageenan Combination To Target Herpes Simplex Virus 2 and Human Papillomavirus, *Antimicrob Agents Chemother*. 2015 Dec; 59(12): 7290-7298.

#### Intellectual Property

HHS Reference No. E-034-2013/0-US-01.

PCT Application No. PCT/US2014/040992 (HHS Reference No. E-034-2013/0-US-01) filed June 5, 2013 entitled "Modified griffithsin tandemers for enhanced activity and reduced viral aggregation".

**Licensing and Collaborative/Co-Development Research Opportunity:** Researchers at the NCI seek licensees and/or co-development partners for the commercialization of Griffithsin and Griffithsin tandemers, specifically, additional studies on stability, toxicity, immunogenicity, and large-scale production.

Dated: February 1, 2016.

#### John D. Hewes,

*Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute.*

[FR Doc. 2016-02971 Filed 2-12-16; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** Center for Scientific Review Special Emphasis Panel; Special Topic: Social Sciences and Population Studies.

**Date:** February 23, 2016.

**Time:** 12:00 p.m. to 12:30 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

**Contact Person:** Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435-1712, [ryansj@csr.nih.gov](mailto:ryansj@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 9, 2016.

**Sylvia Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016-02973 Filed 2-12-16; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

[CBP Dec. No. 16-04]

#### Expansion of Global Entry Eligibility to All Citizens of the Federal Republic of Germany

**AGENCY:** U.S. Customs and Border Protection; Department of Homeland Security.

**ACTION:** General notice.

**SUMMARY:** U.S. Customs and Border Protection (CBP) has established the Global Entry international trusted traveler program at most major U.S. airports. Global Entry allows pre-approved participants dedicated CBP processing into the United States using Global Entry kiosks located at designated airports. In 2013, CBP announced a limited pilot program through which certain citizens of the Federal Republic of Germany (Germany) were eligible to apply for participation in the Global Entry program. This document announces that CBP is concluding the pilot and expanding eligibility in the Global Entry program to include all German citizens. Additionally, this document announces that certain U.S. citizens may apply for membership in EasyPASS, Germany's registered traveler program.

**DATES:** Global Entry eligibility will be expanded to German citizens on February 16, 2016. Applications will be accepted beginning February 16, 2016.

**FOR FURTHER INFORMATION CONTACT:** Larry Panetta, Office of Field Operations, (202) 344-1253, [Larry.A.Panetta@cbp.dhs.gov](mailto:Larry.A.Panetta@cbp.dhs.gov).

**SUPPLEMENTARY INFORMATION:**

## Background

### Global Entry Program

Global Entry is a voluntary program that allows for dedicated CBP processing of pre-approved travelers arriving in the United States at Global Entry kiosks located at designated airports. On February 6, 2012, CBP issued the final rule that promulgated the regulation (8 CFR 235.12) to establish Global Entry as an ongoing voluntary regulatory program in the **Federal Register** (77 FR 5681). The final rule contains a detailed description of the program, the eligibility criteria, the application and selection process, and the initial airport locations. Travelers who wish to participate in Global Entry must apply via the Global On-Line Enrollment System (GOES) Web site, <https://goes-app.cbp.dhs.gov>, and pay the applicable fee. Applications for Global Entry must be completed and submitted electronically.

Eligibility for participation in Global Entry is limited to U.S. citizens, U.S. nationals, U.S. lawful permanent residents, and certain nonimmigrant aliens from countries that have entered into arrangements with CBP regarding international trusted traveler programs. Specifically, the regulation provides that certain nonimmigrant aliens from countries that have entered into arrangements with CBP concerning international trusted traveler programs may be eligible to apply for participation in Global Entry after CBP announces the arrangement by publication of a notice in the **Federal Register**. The notice will include the country, the scope of eligibility of nonimmigrant aliens from that country (e.g., whether only citizens of the foreign country or citizens and non-citizens are eligible) and other conditions that may apply based on the terms of the arrangement. See 8 CFR 235.12(b)(1)(ii). In the preamble of the Global Entry final rule, CBP recognized the existence of previous arrangements it had with Mexico and the Netherlands regarding the international trusted traveler programs and announced that Mexican nationals and certain citizens of the Netherlands were eligible to apply for the Global Entry program. CBP further specified that Mexican nationals and citizens of the Netherlands who were existing participants in the Global Entry pilot would be automatically enrolled in the ongoing Global Entry program. CBP also stated that pursuant to a previous **Federal Register** notice,<sup>1</sup>

<sup>1</sup> See the Utilization of Global Entry Kiosks by NEXUS and SENTRI Participants **Federal Register**

participants in NEXUS and certain participants in SENTRI would still be allowed to use the Global Entry kiosks.

In a notice published in the **Federal Register** (78 FR 48706) on August 9, 2013, CBP expanded Global Entry eligibility to include citizens of the Republic of Korea who are participants in the Smart Entry System (SES), a trusted traveler program for pre-approved, low-risk travelers at designated airports in the Republic of Korea via the use of e-gates; a limited number of citizens of the State of Qatar; and a limited number of citizens of the United Kingdom who frequently travel to the United States.

In a notice published in the **Federal Register** (80 FR 1509) on January 12, 2015, CBP expanded Global Entry eligibility to include citizens of the Republic of Panama. Additionally, this document announced that U.S. citizens who participate in Global Entry or U.S. citizens who can utilize Global Entry kiosks as NEXUS or SENTRI participants have the option to apply for membership in Panama Global Pass, the Republic of Panama's trusted traveler program.

#### Limited Global Entry Pilot for Certain German Citizens

In the August 9, 2013 notice referenced in the previous section, CBP also announced a limited Global Entry pilot program allowing certain German citizens to apply for Global Entry. This pilot program allowed certain German citizens who participated in ABG Plus, Germany's former trusted traveler program, to apply for participation in Global Entry.<sup>2</sup> During this limited pilot, German citizens who were identified as potentially being eligible for participation in the pilot program received a promotional code and information about the program from the German government. The United States and Germany limited the number of citizens who could apply for Global Entry to allow for the development of the program's infrastructure. The notice stated that CBP expected to be able to expand eligibility to include all German citizens in the near future and that such an expansion would be announced by notice in the **Federal Register** and on <http://www.globalentry.gov>.

#### Expansion of Global Entry Program to Include All Citizens of Germany

This document announces that pursuant to the Joint Declaration signed

notice, December 29, 2010 (75 FR 82202) for further information.

<sup>2</sup> ABG Plus has since been discontinued.