Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Shruti Modi, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 2020 (85 FR 5445), FDA published a notice with a 90-day comment period to request comments on the document entitled ''Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations; Draft Guidance for Industry.'' FDA is extending the comment period, in response to a request from a stakeholder, until July 22, 2020. The Agency believes that a 90-day extension allows adequate time for interested persons to submit comments without significantly delaying publication of the final version of the guidance.

II. Reference

The following reference is on display in the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.*

1. Email from Mr. Aleksandr Merenkov, Regulatory Intelligence Specialist, Regeneron Pharmaceuticals, Inc., to Jenifer Roe, Regulatory Counsel, Center for Biologics Evaluation and Research, FDA (March 26, 2020).

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: April 16, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–08609 Filed 4–22–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.18 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest, which is determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that the Department of Health and Human Services becomes entitled to recovery. The rate cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the ''Schedule of Certified Interest Rates with Range of Maturities'' unless the Secretary waives interest in whole or part, or a different rate is prescribed by statute, contract, or repayment agreement. The Secretary of the Treasury may revise this rate quarterly. The Department of Health and Human Services publishes this rate in the **Federal Register**.

The current rate of 9⅝%, as fixed by the Secretary of the Treasury, is certified for the quarter ended March 31, 2020. This rate is based on the Interest Rates for Specific Legislation, ''National Health Services Corps Scholarship Program (42 U.S.C. 254o(b)(1)(A))'' and ''National Research Service Award Program (42 U.S.C. 288(c)(4)(B)).'' This interest rate will be applied to overdue debt until the Department of Health and Human Services publishes a revision.

David C. Horn,

Director, Office of Financial Policy and Reporting.

[FR Doc. 2020–08564 Filed 4–22–20; 8:45 am]

BILLING CODE 4150–04–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: Chris Kornak at 240–627–3705 or *Chris.Kornak@nih.gov.* Licensing information may be obtained by communicating with 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 information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Use of the Intracellular Signaling Domain of Receptor CD28H as a Component of Chimeric Antigen Receptors To Overcome Inhibition of Cytotoxic Lymphocytes by Checkpoint Receptors

Description of Technology: Engineered chimeric antigen receptors (CARs) that are expressed in cytotoxic T cells and natural killer (NK) cells have been used to specifically target tumor cells. However, CAR–T and CAR–NK cells are still subject to downregulation by their inhibitory receptors after injection into patients.

Scientists at NIAID have developed CAR constructs that overcome inhibition of NK cells by receptors for human major histocompatibility complex molecules HLA–E and HLA–C, based on *in vitro* studies. The CAR contains an antigen binding domain of receptor CD28 homolog (CD28H), a CD28H transmembrane domain (TM), a CD28H signaling domain, and other intracellular signaling domains, such as 2B4 (CD244) and CD3 zeta chain (CD3zeta). A variant of this CAR, in which the antigen binding domain of CD28H is replaced by a single-chain antibody variable region (scFv) that binds to CD19, rendered NK cells resistant to inhibition by HLA–E and HLA–C on $CD19^+$ tumor cells.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Method of adoptive therapy where CAR–NK cell or CAR–T cell is the effector cell.

Competitive Advantages:

- Resistant to inhibition of NK cells or T cells by HLA–E and HLA–C.
- Manufacturing efficiency.
- CAR–NK can be developed without the need to genetic silencing of TCR.

Development Stage:

• Pre-clinical.

Inventors: Eric O. Long (NIAID), Xiaoxuan Zhuang (NIAID).

Publications: Zhuang X and Long E.O., ''CD28 homolog is a strong activator of natural killer cells for lysis of B7H7-positive tumor cells.'' Cancer Immunol Res 7(6):939–951. *https://cancerimmunolres.aacrjournals.org/content/7/6/939.long.* April 24, 2019.

Trends Immunol: ''Inhibition-resistant CARs for NK cell cancer immunotherapy'' Trends Immunol 40:1078–1081, December 2019.

Intellectual Property: HHS Reference No. E–097–2020–0–PCT–01, PCT Patent Application No. PCT/US2020/024985.

Licensing Contact: To license this technology, please contact Chris Kornak at 240–627–3705 or *Chris.Kornak@nih.gov,* and reference E–097–2020–0.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Chris Kornak at 240–627–3705 or *Chris.Kornak@nih.gov.*

Dated: April 12, 2020.

Wade W. Green,

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

[FR Doc. 2020–08562 Filed 4–22–20; 8:45 am]

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: Amy F. Petrik, Ph.D., 240–627–3721; *amy.petrik@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:

Recombinant Prefusion Measles and Mumps F and F–HN (H) Glycoproteins for Vaccine Development.

Description of Technology: The Measles virus (MeV) and Mumps virus (MuV) are highly contagious paramyxoviruses that can be transmitted by respiratory droplets from or on direct contact with an infected person. The resulting diseases can lead to serious complications or death among children. The existing vaccines for MeV and MuV are live attenuated virus vaccines which are administered in two subcutaneous doses at 1 year of age and as early as one month later. Two doses of a combination measles, mumps and rubella vaccine are 97% effective against measles and 88% against mumps. A single dose of a combination measles, mumps, and rubella vaccine is 93% effective against measles and 78% effective against mumps.

Despite the effectiveness of the current licensed vaccines against MeV and MuV, incidences of both have increased in recent years. Contributing factors include reduced vaccination rates (especially in the U.S) due to vaccine hesitancy and circulation of divergent strains against which the licensed MMR vaccine offers limited protection.

In the case of MuV, recent studies have shown that immunity wanes significantly after the second MMR vaccination which normally occurs in childhood. In response to recent recurring MuV disease outbreaks in the U.S and Europe, the Advisory Committee on Immunization Practices is advising a third MMR vaccination to boost protection. However, existing immunity neutralizes a third MMR vaccination limiting its effectiveness. Genotype G MuV is the main cause of recent outbreaks in the US and Europe, and a genotype-matched vaccine has been suggested as a solution for the recurring outbreaks.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) used structure-guided design to create immunogen constructs aimed at stabilizing the measles and mumps F glycoproteins in their prefusion conformations. This was achieved by following the discovery that the pre-fusion stabilized F glycoproteins from other members of the paramyxoviridae family induced high titer neutralizing responses.

The researchers developed recombinant immunogens based on: (a) The measles F glycoprotein trimer stabilized in its prefusion conformation (preF–MeV); (b) genotype G mumps F glycoprotein trimers stabilized in its prefusion conformation (preF–MuV); (c) a chimera in which a genotype G mumps F glycoprotein trimer stabilized in its prefusion conformation is fused with mumps HN protein (preF–HN); and (d) a chimera in which a genotype G mumps F glycoprotein trimer stabilized in its prefusion conformation is fused with measles H protein (preF–MuV/MeV H).

The prefusion stabilization of both the mumps and measles F glycoproteins relies on amino acid substitutions to allow the formation of intra-protomer disulfide bonds. Researchers found that the preF and preF–HN immunogens are stable for over a month at 37 °C and hypothesize that lyophilized product would be stable at room temperature for months.

When mice are immunized in a prime-boost-boost regimen with the MuV immunogen constructs, the group receiving the preF–HN immunogens elicited similar antibody titers against genotype G MuV and Jeryl Lynn strain of MuV (genotype A) indicating that the preF–HN immunogens offer broad protection against divergent strains of MuV. Interestingly, mice immunized in a prime-boost regimen with the pre–F MuV/MeV H chimeric immunogen elicited antibody titers to both MuV and MeV that are above the determined protective thresholds.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications:

• The products can be used as measles or mumps vaccines.

Competitive Advantages:

• Currently, there is no licensed recombinant measles or mumps vaccine for use as boosters as a third vaccination.

• The preF–HN immunogens offer broad protection against divergent strains of mumps.

• The stabilized prefusion F molecules may be deliverable as mRNA vaccines, increasing yields of expressed antigen and presentation of the optimal conformation of target proteins.