

*Patent Status:* U.S. Provisional Application No. 61/342,642 filed 16 Apr 2010 (HHS Reference No. E-122-2010/0-US-01).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Betty B. Tong, Ph.D.; 301-594-6565; [tongb@mail.nih.gov](mailto:tongb@mail.nih.gov).

*Collaborative Research Opportunity:* The Center for Cancer Research, Surgery Branch, National Cancer Institute, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize our unique method for isolating cancer stem cells. We are seeking interested parties who would be interested in collaboration with the goal of developing cancer stem cell cell-lines for personalized targeted therapies, drug testing and finding novel targets for cancer treatments. In addition, we would like to collaborate with parties interested in developing normal (not cancer) adult tissue stem-cell cell-lines for adult tissue regeneration such as Parkinson's disease, liver failure, Alzheimer, etc. Please contact John Hewes, Ph.D. at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

#### **Human Single-Domain Antibodies (dAbs) Against Insulin-Like Growth Factor 1 Receptor (IGF-1R) or Its Ligands, IGF-1 and IGF-2**

*Description of Invention:* Insulin-like growth factor (IGF) mediated signaling has been implicated in the development of several epithelial cancers, such as prostate, breast, and colorectal cancers. This technology consists of human single domain antibodies (dAbs) that bind to human insulin-like growth factor 1 receptor (IGF-1R) or its ligands, IGF-1 and IGF-2. These dAbs are comprised of only a single variable domain of an antibody with a human framework and three complementarity determining regions (CDRs). Several of these antibodies inhibit the IGF signaling pathway so they may be therapeutic candidates for the treatment of IGF-related cancers.

#### *Applications*

- A cancer therapeutic agent that inhibits the IGF-mediated signaling pathway.
- A diagnostic employing the detection of insulin-like growth factor 1 receptor (IGF-1R) or its ligands, IGF-1 and IGF-2, in a sample.

#### *Advantages*

- dAbs are about 10-fold smaller than IgG antibodies and exhibit dramatically increased penetration into solid tumors.
- dAbs can be produced in high yields at low cost, have favorable biophysical properties, and are well suited to engineering.
- dAbs are bioactive as monomers or can be linked into larger molecules to create drugs with prolonged serum half-lives or other pharmacological activities.
- dAbs can be fused to other polypeptides or other drugs to provide fusion proteins or conjugates.
- Human framework reduces potential for host immune reactions.

#### *Market*

• Cancer is the second most common cause of death in the US, exceeded only by heart disease. Survival varies greatly by cancer type and stage at diagnosis. The most recent estimate of the economic impact of cancer is that it costs the U.S. some \$228.1 billion annually. Hence, there is a need for the development of medical products that can improve the treatment of cancer patients.

• In the U.S., over 2.4 million new cancer cases are diagnosed yearly. A large proportion of these diagnoses are due to carcinomas of the breast, prostate, colon, lung, pancreas, and bladder. Monoclonal antibodies are increasingly being used to treat these cancers leading to sales of \$13.6 billion in 2008 with a market share of 28.6% of total sales.

*Development Status:* Early-stage development.

*Inventors:* Dimiter S. Dimitrov and Weizao Chen (NCI).

*Publications:* Chen W, Zhu Z, Feng Y, Dimitrov DS. A large human domain antibody library combining heavy and light chain CDR3 diversity. *Mol Immunol.* 2010 Jan;47(4):912-921. [PubMed: 19883941].

*Patent Status:* U.S. Provisional Application No. 61/249,476 filed 07 Oct 2009 (HHS Reference No. E-232-2009/0-US-01).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Whitney Hastings; 301-451-7337; [Whitney.Hastings2@nih.gov](mailto:Whitney.Hastings2@nih.gov).

*Collaborative Research Opportunity:* The Center for Cancer Research Nanobiology Program (CCRNP), National Cancer Institute, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the dAbs that exhibit potent inhibitory activities against the

human IGF signaling pathway. Please contact John Hewes, Ph.D. at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

Dated: July 2, 2010.

**Richard U. Rodriguez,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. 2010-16800 Filed 7-8-10; 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, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 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.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### **Diagnostic H5N1 Avian Influenza Virus Peptides**

*Description of Invention:* The recent spread of highly pathogenic H5N1 avian influenza viruses among poultry and transmission of these viruses to humans raises concerns of a potential influenza pandemic. There is a need to track the spread of these viruses both in the animal and human populations to avert or reduce the impact of any potential influenza pandemic as well as to know the actual number (accurate surveillance) of people infected with H5N1, including individuals with subclinical H5N1 infection.

The subject technology is a specific combination of H5N1 peptides useful for assays to detect antibodies generated

against a wide range of different H5N1 strains. The combination of peptides was able to specifically detect anti-H5N1 antibodies from serum samples of H5N1 survivors at early and later times post infection while excluding antibodies generated in individuals infected with other strains of influenza virus. Also, the peptides did not react with sera from individuals vaccinated with H5N1 vaccine, in contrast to the strain-specific detection of anti-H5N1 antibodies in sera from infected individuals. Immunoassays using the H5N1 peptide combination provide highly specific, sensitive and reproducible methods for diagnosing H5N1 infection in humans and animals.

**Applications:** Diagnostics for influenza virus specific antibodies in humans and animals.

**Advantages:** High specificity, sensitivity, and reproducibility.

**Development Status:** Data obtained from clinical samples can be provided upon request.

**Market:** Influenza virus diagnostics.

**Inventors:** Hana Golding and Surender Khurana (FDA).

#### Patent Status

- U.S. Patent Application No. 12/664,052 filed 10 Dec 2009 (HHS Reference No. E-236-2007/3-US-03).
- U.S. Provisional Patent Application No. 61/325,073 filed 16 Apr 2010 (HHS Reference No. E-093-2010/0-US-01).

**Licensing Status:** Available for licensing.

**Licensing Contact:** Kevin W. Chang, PhD; 301-435-5018; changke@mail.nih.gov.

#### Bacterially Expressed Influenza Virus Recombinant HA Proteins for Vaccine and Diagnostic Applications

**Description of Invention:** Pandemic H1N1 influenza virus is a recently emergent strain of influenza virus that the World Health Organization (WHO) estimates has killed at least 14,711 people worldwide. Avian influenza viruses are emerging health threats with pandemic potential. Due to their global health implications, there has been a massive international effort to produce protective vaccines against these influenza virus strains. Currently, influenza virus vaccines are produced in chicken eggs, a production method that is disadvantaged by lengthy vaccine production times and by inability to meet large-scale, global demands.

The subject technologies are specific recombinant HA proteins from H1N1, H5N1, and other strains of influenza virus produced in bacteria. The HA proteins properly fold, form oligomers, bind fetuin, agglutinate red blood cells

and induce strong neutralizing antibody titers in several in vivo animal models. The key advantages of this technology are that expression of these proteins in bacteria reduces the vaccine production time and offers the ease of scalability for global usage, an issue with current production methods. The recombinant HA proteins can also be used for diagnostic applications.

#### Applications

- Vaccines for the prevention of influenza infection.
- Diagnostics for influenza virus specific antibodies.

#### Advantages

- Novel vaccine candidates.
- Rapid production time.

**Development Status:** In vitro and in vivo data can be provided upon request.

#### Market

- Vaccines.
- Diagnostics.

**Inventors:** Hana Golding and Surender Khurana (FDA).

**Publications:** Manuscripts are available for review under a Confidential Disclosure Agreement.

#### Patent Status

- U.S. Provisional Patent Application No. 61/257,785 filed 03 Nov 2009 (HHS Reference No. E-032-2010/0-US-01).
- U.S. Provisional Patent Application No. 61/325,216 filed 16 Apr 2010 (HHS Reference No. E-032-2010/1-US-01).

**Licensing Status:** Available for licensing.

**Licensing Contact:** Kevin W. Chang, PhD; 301-435-5018; changke@mail.nih.gov.

#### Substituted IL-15

**Description of Invention:** Interleukin-15 (IL-15) is an immune system modulating protein (cytokine) that stimulates the proliferation and differentiation of T-lymphocytes. In the clinical context, IL-15 is being investigated for use in the treatment of diseases such as cancer. In vitro manufacture of IL-15 can be problematic.

The invention relates to substituted IL-15 amino acid sequences of one or more amino acids that are predicted to reduce or eliminate deamidation of a specific asparagine amino acid residue found within the IL-15 protein. Deamidation can lead to protein degradation and interfere with the pharmaceutical purification and processing of IL-15. The invention also provides potential substituted gene sequences that encode the substituted IL-15 amino acid sequences. The

substituted IL-15 amino acid sequences may advantageously facilitate the refolding, purification, storage, characterization, and clinical testing of IL-15.

**Applications:** IL-15 immunotherapies.

**Advantages:** Potential decreased immunogenicity of pharmacologically active IL-15 expressed in *E. coli*.

**Development Status:** Concept Development Phase.

**Market:** Cancer immunotherapy; IL-15 based immunotherapies.

**Inventors:** David F. Nellis *et al.* (NCI/SAIC).

**Patent Status:** PCT Application No. PCT/US09/42355 filed 30 Apr 2009, which published as WO 2009/135031 on 05 Nov 2009 (HHS Reference No. E-123-2008/0-PCT-02).

**Licensing Status:** Available for licensing.

**Licensing Contact:** Kevin W. Chang, PhD; 301-435-5018; changke@mail.nih.gov.

**Collaborative Research Opportunity:** The National Cancer Institute Biological Research Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the topic of this technology. Please contact John D. Hewes, PhD at 301-435-3121 or hewesj@mail.nih.gov for more information.

Dated: July 2, 2010.

**Richard U. Rodriguez,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meetings

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 meetings.

The meetings 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