ADDRESSES: You may submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to*http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments.

FOR FURTHER INFORMATION CONTACT: Aleta Sindelar, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9004, FAX: 240–276–9020, e-mail: *aleta.sindela@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: If you would like to submit written comments to the docket regarding the Animal Drug User Fee Act, please send your comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any written comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be reviewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–1571 Filed 2–15–06; 2:42 pm]

BILLING CODE 4160–01–S

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.

Methodology for Large Scale Manufacture of Stable Disulfide-Conjugated Antibody-Ribonuclease

David F. Nellis, Dianne L. Newton, Susanna M. Rybak (NCI)

U.S. Provisional Application filed 30 Sep 2005 (HHS Reference No. E–218–2005/0–US–01)

Licensing Contact: David A. Lambertson; 301/435–4632; *lambertsond@mail.nih.gov*

Large scale clinical production of disulfide-conjugated antibody-RNase therapeutics using previously reported technologies usually results in an unstable product that forms undesired multimeric antibody/RNase species. This invention describes improved methods for the large scale manufacture of stable disulfide-conjugated antibody therapeutics. Antibody-RNase conjugates produced by this method were specific and highly active in vitro in killing selected carcinoma, and also showed in vivo activity in the treatment of disseminated B-cell lymphoma. These methods are broadly applicable to disulfide-linked conjugation of cytotoxic proteins. The claims for this invention encompass methods for preparing a protein for disulfide conjugation with another molecule, such as an RNase to an antibody.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Identification of Biomarkers by Serum Protein Profiling

Thomas Ried and Jens Habermann (NCI)

U.S. Provisional Application No. 60/664,681 filed 22 Mar 2005 (HHS Reference No. E–106–2005/0-US–01)

Licensing Contact: Thomas P. Clouse; 301/435–4076; *clouset@mail.nih.gov*

This invention describes serum features that distinguish colorectal carcinoma malignant patient samples versus healthy samples using surface-enhanced laser desorption ionization time-of-flight (SELDI-TOF) mass spectrometry. By comparing healthy versus malignant samples, the investigators were able to identify thirteen (13) serum features that have been validated using an independently collected, blinded validation set of 55 sera samples. The features are characterized by the mass to charge ratio (m/z ratio). The investigators have shown that SELDI-TOF based serum marker protein profiling enables minimally invasive detection of colon cancer with 96.7 percent sensitivity and 100 percent specificity.

Colorectal cancer is the third most common cancer and the third leading cause of cancer-related mortality in the United States. Current diagnostic methods for colorectal cancer have a large non-compliance rate because of discomfort, e.g., sigmoidoscopy or colonoscopy, or have a high rate of false positive results, e.g., fecal occult blood tests. The claimed invention has the potential to be a widely used, easy-to-use, and inexpensive diagnostic.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Novel Form of Interleukin–15, Fc–IL–15, and Methods of Use

Morihiro Watanabe *et al.* (NCI)

U.S. Provisional Application No. 60/670,862 filed 12 Apr 2005 (HHS Reference No. E–296–2004/0–US–01)

Licensing Contact: Thomas P. Clouse, J.D.; 301/435–4076; *clouset@mail.nih.gov*

Interleukin–15 (IL–15) is a potent cytokine that enhances host immune system function by proliferating and activating leukocytes. IL–15 increases innate immunity and CD8 memory. The investigators fused IL–15 with protein Fc, a fragment of immunoglobulin. The new fused moiety, Fc–IL–15, has a longer half life in vivo than naturally occurring IL–15 in a gene therapy setting and has more potent anti-tumor effects than IL–15 in some mouse tumor models. The new moiety can serve as an alternative to IL–15, particularly if long term delivery is essential for a therapy. The moiety can serve as a therapeutic for both tumors and viral infections. The moiety can include peptide linkers such as, for example, a T cell inert sequence or a non-immunogenic sequence.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

ELISA Assay of Serum Soluble CD22 To Assess Tumor Burden/Relapse in Subjects with Leukemia and Lymphoma

Robert J. Kreitman *et al.* (NCI)

U.S. Patent Application No. 10/514,910 filed 16 Nov 2004 (HHS Reference No. E–065–2002/0–US–03), with priority to 20 May 2002

Licensing Contact: Jesse Kindra; 301/435–5559; *kindraj@mail.nih.gov*

Disclosed are methods of using previously unknown soluble forms of CD22 (sCD22) present in the serum of subjects with B-cell leukemias and lymphomas to assess tumor burden in the subjects. Also disclosed are methods of diagnosing or prognosing development or progression of a B-cell lymphoma or leukemia in a subject, including detecting sCD22 in a body fluid sample taken or derived from the subject, for instance serum. In some embodiments, soluble CD22 levels are quantified. By way of example, the B-cell lymphoma or leukemia can be hairy cell leukemia, chronic lymphocytic leukemia, or non-Hodgkin's lymphoma. Soluble CD22 in some embodiments is detected by a specific binding agent, and optionally, the specific binding agent can be detectably labeled.

Also disclosed are methods of selecting a B-cell lymphoma or leukemia therapy that include detecting an increase or decrease in sCD22 levels in a subject compared to a control, and, if such increase or decrease is identified, selecting a treatment to prevent or reduce B-cell lymphoma or leukemia or to delay the onset of B-cell lymphoma or leukemia.

Other embodiments are kits for measuring a soluble CD22 level, which kits include a specific binding molecule that selectively binds to the CD22, e.g. an antibody or antibody fragment that selectively binds CD22.

Further disclosed methods are methods for screening for a compound useful in treating, reducing, or preventing B-cell lymphomas or leukemias, or development or progression of B-cell lymphomas or leukemias, which methods include determining if application of a test compound lowers soluble CD22 levels in a subject, and selecting a compound that so lowers sCD22 levels.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Dated: February 10, 2006.

Steven M. Ferguson,

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

[FR Doc. E6–2362 Filed 2–17–06; 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.

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Human Sweet and Umami Taste Receptor Variants

Dennis Drayna and Un-Kyung Kim (NIDCD)

U.S. Provisional Application No. 60/671,173 filed 13 Apr 2005 (HHS Reference No. E–099–2005/0–US–01)

Licensing Contact: Susan Carson; 301/435–5020; *carsonsu@mail.nih.gov*

The complexity of taste discrimination (salty, sour, sweet, umami and bitter) varies between human individuals and populations. Sweet and umami (the taste of glutamate) tastes play a major role in the perception of calorically-rich and essential nutrients and there are well-documented differences in individual perception of sweet and umami flavorings, many of which appear to be genetic in origin. Studies of individuals within and between populations that vary in any of the taste receptors should be of direct interest to the multi-billion dollar food and flavoring industry as the characterization of such variants could be used to aid in the development of a variety of taste improvements in foods and orally administered medications. NIH researchers previously characterized bitter taste receptor variants in world wide populations [Human Mutation 26, 199–204; HHS Ref. No. E–222–2003/0] and have now extended their studies to the sweet and umami receptors in global populations.

The group of Dr. Dennis Drayna at NIDCD have now discovered novel coding sequence polymorphisms in the human TAS1R genes. These genes encode dimeric receptors that sense sweet taste (as TAS1R2+TAS1R3) and the taste of umami (as TAS1R1+TAS1R3). To achieve maximum genetic diversity, TAS1R receptors from a panel of 30 Europeans, 20 East Asian, 10 Native Americans, 8 South Asians and 20 sub-Saharan Africans were sequenced. Approximately 60% of the identified SNPs caused an amino acid substitution in the encoded receptor protein. This variation may account for individual preferences in sweet and umami tastes in foods and could be of use in the understanding and control of dietary preferences that lead to obesity and diabetes.

These novel variants and methods of use are available for licensing and should be of particular use to those using sensorial analysis in the food and flavoring industry where the use of taster panels in the development of flavors and flavor enhancers for different foods is key to the development of new food products and taste masking compounds. The ability, for example, to genetically match taster individuals employed by industry with the target consumer populations can both guide improved formulations and marketing decisions as well as reducing the total sample size in the testing of new products in this highly competitive industry.

The Human Taste Receptor Haplotype patent portfolio is also available for licensing and includes: HHS Ref No. E–169–2001/0–PCT–02, Phenylthiocarbamide Taste Receptor, International Publication No. WO 2003/008627, PCT filed 19 July 2002 and global IP and HHS Ref. No 222–2003/1: Variants of Human Taste Receptor Genes, International Publication No. WO 2005/007891, PCT filed 18 June 2004 and global IP.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Genes for Niemann-Pick Type C Disease

Eugene D. Carstea (NINDS) *et al.*

U.S. Patent No. 6,426,198 issued 30 Jul 2002 (HHS Reference No. E–122–1997/0–US–03)