Dated: October 10, 2007.

Steven M. Ferguson,

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

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.

Alpha 1-3 N-Acetylgalactosaminyltransferases With Altered Donor and Acceptor Specificities, Compositions, and Methods of Use

Description of Invention: The present invention relates to the field of glycobiology, specifically to glycosyltransferases. The present invention provides structure-based design of novel glycosyltransferases and their biological applications.

The structural information of glycosyltransferases has revealed that the specificity of the sugar donor in these enzymes is determined by a few residues in the sugar-nucleotide binding pocket of the enzyme, which is conserved among the family members from different species. This conservation has made it possible to reengineer the existing glycosyltransferases with broader sugar donor specificities. Mutation of these residues generates novel glycosyltransferases that can transfer a sugar residue with a chemically reactive functional group to N-acetylglucosarnine (GlcNAc), galactose (Gal) and xylose residues of glycoproteins, glycolipids and proteoglycans (glycoconjugates). Thus, there is potential to develop mutant glycosyltransferases to produce glycoconjugates carrying sugar moieties with reactive groups that can be used in the assembly of bio-nanoparticles to develop targeted-drug delivery systems or contrast agents for medical uses.

Accordingly, methods to synthesize N-acetylglucosamine linkages have many applications in research and medicine, including in the development of pharmaceutical agents and improved vaccines that can be used to treat disease.

This application claims compositions and methods based on the structure-based design of alpha 1-3 N-Acetylgalactosaminyltransferase (alpha 3 GalNAc-T) mutants from alpha 1-3galactosyltransferase (a3Gal-T) that can transfer 2′-modified galactose from the corresponding UDP-derivatives due to mutations that broaden the alpha 3Gal-T donor specificity and make the enzyme alpha3 GalNAc-T.

Application: Development of pharmaceutical agents and improved vaccines.

Developmental Status: Enzymes have been synthesized and preclinical studies have been performed.

Inventors: Pradman Qasba, Boopathy Ramakrishnan, Elizabeth Boeggman, Marta Pasek (NCI).

Patent Status: PCT Patent Application filed 22 Aug 2007 (HHS Reference No. E–279–2007/0–PCT–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute's Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize structure-based design of novel glycosyltransferases. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Beta 1,4-Galactosyltransferases With Altered Donor and Acceptor Specificities, Compositions and Methods of Use

Description of Invention: The present invention relates to the field of glycobiology, specifically to glycosyltransferases. The present invention provides structure-based design of novel glycosyltransferases and their biological applications.

The structural information of glycosyltransferases has revealed that the specificity of the sugar donor in these enzymes is determined by a few residues in the sugar-nucleotide binding pocket of the enzyme, which is conserved among the family members from different species. This conservation has made it possible to reengineer the existing glycosyltransferases with broader sugar donor specificities. Mutation of these residues generates novel glycosyltransferases that can transfer a sugar residue with a chemically reactive functional group to N-acetylglucosarnine (GlcNAc), galactose (Gal) and xylose residues of glycoproteins, glycolipids and proteoglycans (glycoconjugates). Thus, there is potential to develop mutant glycosyltransferases to produce glycoconjugates carrying sugar moieties with reactive groups that can be used in the assembly of bio-nanoparticles to develop targeted-drug delivery systems or contrast agents for medical uses.

Accordingly, methods to synthesize N-acetylglucosamine linkages have many applications in research and medicine, including in the development of pharmaceutical agents and improved vaccines that can be used to treat disease.

The invention claims beta (1,4)-galactosyltransferase I mutants having altered donor and acceptor and metal ion specificities, and methods of use thereof. In addition, the invention claims methods for synthesizing oligosaccharides using the beta (1,4)-galactosyltransferase I mutants and to using the beta (1,4)-galactosyltransferase I mutants to conjugate agents, such as therapeutic agents or diagnostic agents, to acceptor molecules. More specifically, the invention claims a double mutant beta 1,4 galactosyltransferase, human beta-1,4-Tyr289Leu-Met344His-Gal-T1, constructed from the individual mutants, Tyr289Leu-Gal-T1 and Met344His-Gal-T1, that transfers modified galactose in the presence of magnesium ion, in contrast to the wild-type enzyme which requires manganese ion.

Application: Development of pharmaceutical agents and improved vaccines.

Developmental Status: Enzymes have been synthesized and preclinical studies have been performed.

Inventors: Pradman Qasba, Boopathy Ramakrishnan, Elizabeth Boeggman (NCI).

Patent Status: PCT Patent Application filed 22 Aug 2007 (HHS Reference No. E–280–2007/0–PCT–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*

Collaborative Research Opportunity: The CCR Nanobiology Program of the National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize glycosyltransferases. Please contact John D. Hewes, Ph.D., Technology Transfer Specialist, NCI, at (301) 435–3121 or *hewesj@nail.nih.gov.*

Targeting Poly-Gamma-Glutamic Acid to Treat Staphylococcus Epidermidis and Related Infections

Description of Invention: Over the past decade, *Staphylococcus epidermidis* has become the most prevalent pathogen involved in nosocomial infections. Usually an innocuous commensal microorganism on human skin, this member of the coagulase-negative group of staphylococci can cause severe infection after penetration of the epidermal protective barriers of the human body. In the U.S. alone, *S. epidermidis* infections on in-dwelling medical devices, which represent the main type of infection with *S. epidermidis*, cost the public health system approximately $1 billion per year. Importantly, *S. epidermidis* is frequently resistant to common antibiotics.

Immunogenic compositions and methods for eliciting an immune response against *S. epidermidis* and other related staphylococci are claimed. The immunogenic compositions can include immunogenic conjugates of poly-γ-glutamic acid (such as γDLPGA) polypeptides of *S. epidermidis*, or related staphylococci that express a γPGA polypeptide. The γPGA conjugates elicit an effective immune response against *S. epidermidis*, or other staphylococci, in subjects to which the conjugates are administered. A method of treating an infection caused by a *Staphylococcus* organism that expresses *cap* genes is also disclosed. The method can include selecting a subject who is at risk of or has been diagnosed with the infection by the *Staphylococcus* organism which expresses γPGA from the *cap* genes. Further, the expression of a γPGA polypeptide by the organism can then be altered.

Application: Prophylactics against *S. epidermidis*.

Developmental Status: Preclinical studies have been performed.

Inventors: Michael Otto, Stanislava Kocianova, Cuong Vuong, Jovanka Voyich, Yufeng Yao, Frank DeLeo (NIAID)

Publication: S Kocianova *et al.* Key role of poly-gamma-DL-glutamic acid in immune evasion and virulence of *Staphylococcus epidermidis.* J Clin Invest. 2005 Mar;115(3):688–694.

Patent Status: PCT Patent Application No. PCT/US2006/026900 filed 10 Jul 2006 (HHS Reference No. E–263–2005/0–PCT–02).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; soukasp@mail.nih.gov

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases, Laboratory of Human Bacterial Pathogenesis, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of poly-γ-glutamic acid of staphylococci. Please contact Dr. Michael Otto at *motto@niaid.nih.gov* for more information.

Dated: October 10, 2007.

Steven M. Ferguson,

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

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Multiple Donor Tissue-Derived Large IgM VH-Based F_{ab} Human Antibody Library

Description of Technology: Available for licensing as a biological material for either internal use or commercial distribution is a human F_{ab} immunoglobulin/antibody fragment phage display library. The library contains 10^{10} F_{abs} derived from the peripheral blood of ten (10) healthy human donors. The high quality of the library was demonstrated in the successful selection of high affinity antibodies specific for Hendra and Nipah viruses; however, the library is useful for selecting a variety of antigen specific immunoglobulin/antibody F_{ab} fragments especially for cancer or viruses.

Applications: Antibody discovery—Diagnostics, Therapeutics, Research Reagents.

Advantages and Benefits: High affinity multi-purpose antibodies.

Inventors: Dimiter S. Dimitrov (NCI) et al.

Publications:

1. Zhang et al. Selection of a novel gp41-specific HIV–1 neutralizing human antibody by competitive antigen panning. J Immunol Methods. 2006 Dec 20; 317(1–2):21–30. Epub 2006 Oct 16.

2. Zhu et al. Potent neutralization of Hendra and Nipah viruses by human monoclonal antibodies. J Virol. 2006 Jan;80(2):891–899.

3. Zhang et al. Human monoclonal antibodies to the S glycoprotein and related proteins as potential therapeutics for SARS. Curr Opin Mol Ther. 2005 Apr;7(2):151–156. Review.

Patent Status: HHS Reference No. E–188–2007/0—Research Tool. Patent protection is not being sought for this technology.

Licensing Status: Available for non-exclusive licensing as biological material.

Licensing Contact: Michael Shmilovich, Esq.; 301/435–5019; *shmilovm@mail.nih.gov*.

Collaborative Research Opportunity: The NCI-Frederick is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize therapeutic, diagnostic