Inventors: Dan A. Buzatu (FDA), Jon G. Wilkes (FDA), Dwight W. Miller (FDA), Jerry A. Darsey (Univ Arkansas), Thomas M. Heinze (FDA), Alexandru S. Biris (Univ Arkansas), Richard Beger (FDA).

Patent Status: U.S. Patent Application No. 11/005,412 filed December 6, 2004 (HHS Reference No. E–090–2004/0-US–01).

Licensing Status: All licensing inquiries should be directed to Michael McAllister, University of Arkansas at Little Rock, Office of Technology Transfer, 2801 South University Avenue, Little Rock, AR 72204–1099; Phone: 501/569–8658; E-mail: *Jmmccalliste@uaur.edu.*

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

Dated: May 24, 2006.

David R. Sadowski,

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

[FR Doc. 06–5105 Filed 6–2–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: GLP-1 Exendin-4 Peptide Analogs and Uses Thereof

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license worldwide to practice the invention embodied in U.S. Patent Application Number 10/485,140 filed January 27, 2004, entitled ''GLP-1 Exendrin-4 Peptide Analogs and Uses Thereof,'' to Amylin Pharmaceuticals, Inc., having a place of business in San Diego, CA 92121. The contemplated exclusive license may be limited to use to human therapeutics for diabetes, obesity and cardiovascular disease, as well as neurological and neurodegenerative diseases, disorders and injuries. The United States of America is the assignee of the patent rights in this invention.

DATES: Only written comments and/or application for a license which is received by the NIH Office of Technology Transfer on or before August 4, 2006 will be considered.

ADDRESSES: Request for a copy of the patent, inquires, comments, and other materials relating to the contemplated license should be directed to: Marlene Astor, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: 301–435–4426; Facsimile: 301–402–0220; e-mail: *ms482m@nih.gov*.

SUPPLEMENTARY INFORMATION: Type-2 diabetes and neurodegeneration (*e.g.*, Alzheimer's disease, Parkinson's disease, peripheral neuropathy, stroke) are leading causes of death in the United States and worldwide. The present invention pertains to the disclosure of novel peptide analogues of Glucagons-like peptide-1 (GLP-1) and Exendin-4 and their uses in the treatment of (i) diabetes and (ii) neurodegenerative disorders.

Type-2 diabetes is caused by dysfunction of the pancreatic beta cells that may result in concomitant decrease in insulin production. Insulin replacement has been an effective therapy for the treatment of Type-2 diabetes. However, insulin therapy, although life saving, does not restore normal levels of glucose and postprandial levels of glucose continues to be excessively high in individuals on insulin therapy. Further, the therapy may result in adverse effects including hyperglycemia, hypoglycemia, metabolic acidosis and ketosis. Therefore, a better therapeutic formula may be needed that may increase the efficacy of the treatment and minimize the side effects. The present invention discloses a method of treating a subject with diabetes with novel GLP-1/Exendin-4 peptides. These are GLP-1 agonists and elicit insulinotropic actions.

The GLP-1 receptor is additionally found in the brain as well as associated to pancreatic islets cells. Its stimulation in brain has been found to be neurotrophic and neuroprotective in both tissue culture and in vivo against a variety of toxic insults. Peptides of the said invention possess activity in a variety of predictive models of neurodegeneration, and may have potential in a variety of diseases both associated (peripheral neuropathy) and unassociated (Alzheimer's disease, Parkinson's disease, stroke and peripheral neuropathy) with diabetes J. Alz. Dis. 4: 487–96, 2002; J. Pharmacol. Exp. Ther. 300:958–66, 2002 & 302:881–888, 2002.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 26, 2006.

David R. Sadowski,

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

[FR Doc. E6–8678 Filed 6–2–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Co-Exclusive License: Human Monoclonal Antibody, Their Fragments and Derivatives as Biotherapeutics for the Treatment of HIV Infections

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a co-exclusive license to practice the inventions embodied in:

1. U.S. Provisional Patent Application Serial No. S/N 60/378,406, PCT/US03/14905, NIH (DHHS) Ref. No. E–144–2002/1–PCT–02 converted into 03733940.5 (E–144–2002/1–EP–04) filed in Europe on November 25, 2004, and 2003239356 (E–144–2002/1–AU–05) filed in Australia October 29, 2004, 10/512,966 (E–144–2002/1–US–03) filed in USA October 28, 2004, as well as 2485120 (E–144–2002/1–CA–06) filed in Canada May 6, 2003, entitled: ''Identification of Novel Broadly Cross-Reactive Neutralizing Human

Monoclonal Antibodies''. Inventor(s): Dimiter S. Dimitrov (NCI) and Mei-Yun Zhang (SAIC).

2. U.S. Patent Application, S/N 60/506,946 (E–316–2003/0–US–01), PCT/US2004/31878 (E–316–2003/0–PCT–02) entered the national stage filing on March 29, 2006 in USA (E–316–2003/0–US–03), in Canada (E–316–2003/0–CA–04), in Europe (E–316–2003/0–EP–05), and in Australia (E–316–2003/0–AU–06), entitled: ''Immunoglobulins With Potent and Broad Antiviral Activity''. Inventor(s): Dimiter S. Dimitrov (NCI) and Mei-Yun Zhang (SAIC) to Virosys Pharmaceuticals Inc. (hereafter Virosys) having a place of business in Los Altos Hills, California, and Profectus Biosciences, Inc. (hereafter Profectus) having a place of business in Baltimore, Maryland. The patent rights in these inventions have been assigned to the United States of America.

DATES: Only written comments and/or application for a license, which are received by the NIH Office of Technology Transfer on or before August 4, 2006 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Sally Hu, Ph.D., M.B.A., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; E-mail: *hus@od.nih.gov*; Telephone: (301) 435–5606; Facsimile: (301) 402–0220.

SUPPLEMENTARY INFORMATION: The first invention (E–144–2002/1–PCT–02) describes two single chain fragment variable (scFv) clones, designated M6 and M9 that were selected from phage-displayed X5 scFv mutants library by panning the library against $gp_{12089.6/IIIB}$–CD4 complex using the alternating antigen panning strategy (AAP). M6 and M9 are stable and have significant improved binding activities to $gp_{120IIIB}$. Both scFvs inhibit more efficiently membrane fusion of HIV mediated by envelop glycoproteins of primary HIV isolates with a broader spectrum compared to other antibodies such as X5, indicating that the scFv form may be a more proper form compared to the Fab form for HIV–1 neutralizing antibodies to inhibit virus infection and transmission. Furthermore, scFv is a single molecule almost half the size of Fab, which makes it more suitable for constructing bivalent and multivalent antibodies and antibody fusion proteins. M6 and M9 are cross-reactive with HIV–1 isolates so that these antibodies could be directly used for therapy of HIV–1 infected individuals. In addition, these antibodies can also be used for screening of peptide phage display libraries, libraries of Envs, and in general as tools for development of HIV vaccines and therapeutics.

The second invention (E–316–2003) describes methods of inhibiting viral infection, such as HIV–1, by administering a fusion protein comprising a small size, single chain Fv (scFv) antibody-binding domain joined to an Fc region by a long flexible linker. In particular, scFv M6 or M9, and their complex with two-domain soluble CD4 are joined to Fc by a long flexible linker to provide a new agent for the inhibition of HIV infection or immunotherapy of HIV-infected individuals. The Fc region provides stability, long half-life, and biological effector functions. The scFv-Fc fragment provides antigen recognition and neutralizing activity. The small size of the scFv-Fc fusion molecule provides easy access to conserved viral epitopes exposed before or during viral entry. In addition, these fusion molecules exhibit neutralization activity that is higher than that of whole IgGs, and comparable to or better than that of scFv. Thus, this invention may offer a novel approach to treat and prevent HIV–1 infection and/or AIDS, is related to invention E–144–2002/1, and may strengthen the company's portfolio of technologies being developed.

The prospective co-exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective co-exclusive license may be granted unless, within 60 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The field of use may be limited to the development of human monoclonal antibodies for use as a therapeutic or preventative in HIV infection either alone or in combination with other compounds.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 26, 2006.

David R. Sadowski,

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

[FR Doc. E6–8680 Filed 6–2–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP); Center for the Evaluation of Risks to Human Reproduction (CERHR); Availability of the Draft NTP Brief on Di-(2-ethylhexyl) phthalate; Request for Public Comments

AGENCY: National Institute for Environmental Health Sciences (NIEHS); National Institutes of Health (NIH).

ACTION: Request for comments.

SUMMARY: CERHR invites the submission of public comments on the draft NTP Brief for di-(2-ethylhexyl)phthalate (DEHP). The draft NTP Brief is available from the CERHR Web site (*http://cerhr.niehs.nih.gov* see ''CERHR Reports & Monographs'') or in hardcopy from CERHR (see **ADDRESSES** below). Public comments will be considered during the peer review and finalization of the NTP Brief.

DATES: Written comments on the draft NTP Brief for DEHP should be received by July 5, 2006.

ADDRESSES: Public comments and any other correspondence should be addressed to Dr. Michael D. Shelby, CERHR Director, NIEHS, P.O. Box 12233, MD EC–32, Research Triangle Park, NC 27709 (mail), (919) 541–3455 (phone), (919) 316–4511 (fax), or *shelby@niehs.nih.gov* (e-mail). Courier address: CERHR, 79 T.W. Alexander Drive, Building 4401, Room 103, Research Triangle Park, NC 27709.

SUPPLEMENTARY INFORMATION:

Background

DEHP (CAS RN: 117–81–7) is a high production volume chemical used as a plasticizer of polyvinyl chloride in the manufacturer of a wide variety of consumer products, such as building products, car products, clothing, food packaging, children's products (but not in toys intended for mouthing) and in polyvinyl chloride medical devices. On October 10–12, 2005, CERHR convened an expert panel to conduct an updated evaluation of the potential reproductive and developmental toxicities of DEHP.