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*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](mailto:Jmmccalliste@uaur.edu).

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Dated: May 24, 2006.

**David R. Sadowski,**

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

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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](mailto: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.*

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## 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