



This document is scheduled to be published in the Federal Register on 08/28/2013 and available online at <http://federalregister.gov/a/2013-20945>, and on [FDsys.gov](http://FDsys.gov)

**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive Patent License:** Use of Exenatide for the Treatment of Neurodegenerative Diseases

**AGENCY:** National Institutes of Health, HHS

**ACTION:** Notice

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to Peptron, Inc., a company having a place of business in Daejeon, South Korea, to practice the inventions embodied in U.S. Provisional Patent Application No. 60/309,076, filed July 31, 2001, entitled “Long-Acting Insulinotropic Peptides and Uses Thereof” (HHS Ref. No. E-049-2001/0-US-01); U.S. Patent No. 7,576,050, issued August 18, 2009, entitled “GLP-1 Exendin-4 Peptide Analogs and Uses Thereof” (HHS Ref. No. E-049-2001/0-US-03); U.S. Patent No. 8,278,272, issued October 2, 2012, entitled “GLP-1, Exendin-4, Peptide Analogs and Uses Thereof” (HHS Ref. No. E-049-2001/0-US-14); U.S. Patent Application No. 13/594,313, filed August 24, 2012, entitled “GLP-1, Exendin-4, Peptide Analogs and Uses Thereof” (HHS Ref. No. E-049-2001/0-US-21); PCT Patent Application No. PCT/US2002/024141, filed July 30, 2002, entitled “GLP-1, Exendin-4, Peptide Analogs and Uses Thereof” (HHS Ref. No. E-049-2001/0-PCT-02); Australian Patent No. 2002317599, issued July 17, 2008, entitled “GLP-1, Exendin-4, Peptide Analogs and Uses Thereof” (HHS Ref. No. E-049-

2001/0-AU-04); Australian Patent No. 2008202893, issued April 26, 2012, entitled “GLP-1, Exendin-4, Peptide Analogs and Uses Thereof” (HHS Ref. No. E-049-2001/0-AU-10); Australian Patent Application No. 2012202081, filed April 11, 2012, entitled “GLP-1, Exendin-4, Peptide Analogs and Uses Thereof” (HHS Ref. No. E-049-2001/0-AU-20); Canadian Patent Application No. 2455963, filed January 29, 2004, entitled “GLP-1, Exendin-4, Peptide Analogs and Uses Thereof” (HHS Ref. No. E-049-2001/0-CA-05); European Patent No. 1411968, issued September 17, 2008, entitled “GLP-1, Exendin-4, Peptide Analogs and Uses Thereof” (HHS Ref. No. E-049-2001/0-EP-06) and validated in Germany (HHS Ref. No. E-049-2001/0-DE-11), France (HHS Ref. No. E-049-2001/0-FR-12), and Great Britain (HHS Ref. No. E-049-2001/0-GB-13); European Patent No. 2022505, issued December 14, 2011, entitled “GLP-1, Exendin-4, Peptide Analogs and Uses Thereof” (HHS Ref. No. E-049-2001/0-EP-09) and validated in Germany (HHS Ref. No. E-049-2001/0-DE-17), France (HHS Ref. No. E-049-2001/0-FR-18), and Great Britain (HHS Ref. No. E-049-2001/0-GB-19); European Patent Application No. 10177860.3, filed September 21, 2010, entitled “GLP-1, Exendin-4, Peptide Analogs and Uses Thereof” (HHS Ref. No. E-049-2001/0-EP-16); Indian Patent Application No. 0488/DELNP/2004, filed February 27, 2004, entitled “GLP-1, Exendin-4, Peptide Analogs and Uses Thereof” (HHS Ref. No. E-049-2001/0-IN-07); Japanese Patent Application No. 2003-517083, filed February 2, 2004, entitled “GLP-1, Exendin-4, Peptide Analogs and Uses Thereof” (HHS Ref. No. E-049-2001/0-JP-08); Japanese Patent Application No. 2009-262568, filed November 18, 2009, entitled “GLP-1, Exendin-4, Peptide Analogs and Uses Thereof” (HHS Ref. No. E-049-2001/0-JP-15); and Japanese Patent Application No. 2013-007743, filed January 18, 2013, entitled “GLP-1, Exendin-4, Peptide Analogs and Uses Thereof” (HHS Ref. No. E-049-2001/0-JP-22). The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective Exclusive Patent License may be worldwide, and the field of use may

be limited to “Methods of using exenatide for the treatment of neurodegenerative disease in humans.”

**DATE:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 30 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

**ADDRESS:** Requests for copies of the patent application(s), inquiries, comments, and other materials relating to the contemplated Exclusive Patent License should be directed to: Tara L. Kirby, Ph.D., Senior Licensing and Patenting Manager, 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: [tarak@mail.nih.gov](mailto:tarak@mail.nih.gov). A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

**SUPPLEMENTARY INFORMATION:** This technology relates to the use of glucagon-like peptide-1 (GLP-1), exendin-4, and analogs for the treatment of neurodegenerative diseases. These peptides are GLP-1 receptor agonists and incretin mimetics, and enhance glucose-dependent insulin secretion and regulate glucagon secretion. As such, they have been used in the treatment of type 2 diabetes. The inventors have shown that these peptides also exert neurotrophic and neuroprotective effects in a variety of predictive models of neurodegeneration, and thus may represent potential therapeutics for neurodegenerative diseases, including Alzheimer's disease, Parkinson's disease, Huntington's disease, amyotrophic lateral sclerosis (ALS), peripheral neuropathy (associated or unassociated with diabetes) and stroke.

The prospective Exclusive Patent License may be granted unless the NIH receives written evidence and argument, within thirty (30) days from the date of this published notice, that establishes that the grant of the contemplated license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the Exclusive Patent License. Comments and objections submitted 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.

August 22, 2013  
Date

---

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

[FR Doc. 2013-20945 Filed 08/27/2013 at 8:45 am; Publication Date: 08/28/2013]