

Neurotrophins, such as Nerve Growth Factor (NGF), are crucial to the maintenance and survival of neurons of the peripheral and central nervous system. Although these actions have potential therapeutic use in the treatment of a number of neurodegenerative diseases, problems with peripheral administration of these fairly large molecules limits their clinical usefulness. Survival signaling of neurotrophins is mediated mainly through binding to cell surface Trk tyrosine kinase receptors. The juxtamembrane region of the NGF TrkA receptor binds two key adaptor proteins, Shc and FRS-2/SNT, which become tyrosine phosphorylated and provide a scaffold for other signaling proteins. The binding of FRS-2/SNT to TrkA is also affected by a neighboring three amino acid KFG domain conserved in all Trk receptors. These inventors found that deletion of the three KFG amino acids affects binding and activation of the adaptor proteins FRS-2/SNT and Shc. This effect increases the general ability to activate downstream TrkA activated signaling pathways in response to NGF. This molecular phenotype leads biologically to a trophic effect on the cholinergic neurons of the basal forebrain and of the striatum *in vivo*. This invention provides a target for selecting small drugs that mimic the effect of KFG domain deletion and thus promote trophic effects in degenerative diseases.

Compositions and Methods for Diagnostics and Therapeutics for Hydrocephalus

Perry J. Blackshear, Darryl C. Zeldin, Joan P. Graves, Deborah J. Stumpo (NIEHS); U.S. Provisional Patent Application No. 60/374,184 filed 19 Apr 2002 (DHHS Reference No. E-163-2002/0-US-01); U.S. Provisional Patent Application No. 60/388,266 filed 13 Jun 2002 (DHHS Reference No. E-163-2002/1-US-01); PCT Application No. PCT/US03/12348 filed 18 Apr 2003, which published as WO 03/088919 on 30 Oct 2003 (DHHS Reference No. E-163-2002/2-PCT-01); Licensing Contact: Pradeep Ghosh; 301/435-5282; ghoshpr@mail.nih.gov.

Congenital hydrocephalus is a public health problem and a significant population suffers from this birth defect in the United States. It has been estimated that a significant number of patients with congenital hydrocephalus also suffer from aqueductal stenosis. Congenital hydrocephalus has an adverse effect on developing brain and may persist as neurological defects in children and adults. Some of these defects may manifest in form of mental

retardation, cerebral palsy, epilepsy and visual disabilities. The cost of treatment for such disorders may exceed \$100 million annually. Efficient diagnostics to determine the risks of development of hydrocephalus are lacking in the market.

This invention relates to RFX4_v3 proteins and nucleic acids encoding the RFX4_v3 proteins. RFX4_v3 proteins are associated with congenital hydrocephalus. Congenital hydrocephalus is a common birth defect and many cases of hydrocephalus are caused by chromosome X-linked genetic mutations. The present invention provides assays for the detection of RFX4_v3 polymorphisms associated with congenital hydrocephalus that may lead to the determination of an individual's risk of developing disease states and conditions. Therefore, the present invention would be most useful in developing diagnostic tests for abnormalities that may lead to the development of hydrocephalus and thus, has a market potential of substantial significance.

Dated: July 23, 2004.

Steven M. Ferguson,

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

Government-Owned Inventions; Availability for Licensing

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

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.

Monoclonal Antibody (MP804) That Specifically Binds Stem Cells and Its Use

Neal D. Epstein (NHLBI); U.S. Provisional Application No. 60/565,101 filed 23 Apr 2004 (DHHS Reference No. E-014-2004/0-US-01); Licensing Contact: Fatima Sayyid; (301) 435-4521; sayyidf@mail.nih.gov.

Adult stem cells hold great promise for human disorders that are currently incurable including spinal-cord injury and brain diseases. Although it has been shown that adult stem cells can produce many different tissue types in the body, from blood to muscle to nerve leading hope to their use for repairing or replacing diseased or damaged organs, their use is limited due to lack of reagents for isolation of adult stem cells from tissues. This invention is drawn to antibodies that can detect a subpopulation of primitive stem cells in adult murine skeletal muscle. This subset of cells can be used to repair a variety of neurological disorders, to produce primary and immortalized cell lines for physiologic and pharmaceutical research, and for genomic and proteomic studies focused on the process of neural cell differentiation.

Modulating P38 Kinase Activity

Dr. Jonathan Ashwell (NCI); U.S. Provisional Application No. 60/541,993 filed 05 Feb 2004 (DHHS Reference No. E-010-2004/0-US-01); Licensing Contact: Marlene Shinn-Astor; (301) 435-4426; shinnm@mail.nih.gov.

Protein kinases are involved in various cellular responses to extracellular signals. The protein kinase termed p38 is also known as cytokine suppressive anti-inflammatory drug binding protein (CSBP) and RK. It is believed that p38 has a role in mediating cellular response to inflammatory stimuli, such as leukocyte accumulation, macrophage/monocyte activation, tissue resorption, fever, acute phase responses and neutrophilia. In addition, p38 has been implicated in cancer, thrombin-induced platelet aggregation, immunodeficiency disorders, autoimmune diseases, cell death, allergies, osteoporosis and neurodegenerative disorders.

The NIH announces a new technology that includes compositions and methods for controlling the activity of p38 specifically in T cells through an alternate activation pathway. By controlling p38 activity through

interference with this alternate pathway, the T cells themselves can be controlled which in turn can be a treatment for conditions or diseases characterized by T cell activation such as autoimmune diseases, transplant rejection, graft-versus-host disease, systemic lupus erythematosus, and viral infections such as HIV infections.

Human Neuronal Cells for Therapeutic Uses

Jong-Hoon Kim, Raja Kittappa, and Ronald D. McKay (NINDS); U.S. Provisional Application No. 60/495,346 filed 14 Aug 2003 (DHHS Reference No. E-056-2003/0-US-01); Licensing Contact: Norbert Pontzer; (301) 435-5502; pontzern@mail.nih.gov.

Embryonic stem (ES) cells from various animal models demonstrate pluripotency, the ability to generate the multiple cell types found in the adult body. ES cells can also proliferate indefinitely in an undifferentiated state *in vitro*. These properties may allow cells derived from ES cells to replace diseased or injured cells and tissue. While the local milieu may direct some naïve ES cells into the appropriate fate for that tissue, the formation of teratomas and other unwanted cell types remains an unsolved problem. Thus, the ability to direct the differentiation of embryonic stem (ES) cells into specific fates may be a necessary condition for their use in transplantation therapy for diseases such as Parkinson's.

Using mouse ES cells, this laboratory previously produced a highly enriched population of midbrain neuronal cells that, when transplanted into rat models of Parkinson's disease, improved motor function and demonstrated *in vivo* electrophysiological properties consistent with functioning dopamine neurons. Using a similar culturing strategy, but with conditions specifically modified for human ES cells, these inventors have now produced a highly enriched population of human neuronal cells that exhibit electrical activity and synaptic vesicle release. Another simplified method differentiates ES cells grown as a monolayer into neurons, without going through an embryoid body stage. This intellectual property provides methods for producing human neuronal cells in general and dopaminergic cells specifically, the cells themselves, and methods of treating diseases caused by neuronal degeneration.

Dated: July 21, 2004.

Steven M. Ferguson,

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

[FR Doc. 04-17468 Filed 7-30-04; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Methods and Compositions for the Promotion of Hair Growth Utilizing Actin Binding Peptides

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

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in U.S. Patent Application Serial No. 60/351,386 (re-filed), PCT Patent Application Serial No. PCT/US03/01973, filed January 22, 2003 (DHHS Ref. E-053-2002/0-PCT-02), entitled "Methods and Compositions for the Promotion of Hair Growth Utilizing Actin Binding Peptides" to Panacea Biotech Ltd., which has offices in New Delhi, India. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be limited to India, Sri Lanka, Bangladesh, Pakistan, Nepal, Malaysia, Thailand, Indonesia, Singapore and the Philippines, and the field of use may be limited to the use of actin binding proteins for the development of a topical hydrogel treatment for alopecia to promote hair growth (This notice modifies a previous **Federal Register** notice published in 69 FR 13859, March 24, 2004).

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before October 1, 2004 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Jesse S. Kindra, J.D., M.S., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; telephone: (301) 435-5559;

facsimile: (301) 402-0220; e-mail: kindraj@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The technology describes methods and compositions for treating a subject (human or animal) suffering from hair loss. More specifically, the technology relates to the discovery that actin binding peptides promote hair growth. In one example, the technology describes the exogenous delivery of a seven amino acid peptide of Thymosin- β 4 to promote hair growth.

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 part 404.7. The prospective exclusive license may be granted unless within sixty (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 part 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive 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.

Dated: July 23, 2004.

Steven M. Ferguson,

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

[FR Doc. 04-17465 Filed 7-30-04; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Public Affairs; Submission for Emergency Processing for Ready for Kids Mascot Naming Contest

AGENCY: Public Affairs, DHS.

ACTION: Notice; request for comments; correction.

SUMMARY: On July 26, 2004, the Department of Homeland Security (DHS) published a **Federal Register** notice advising the public that DHS would submit an information collection request to the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995, for the Ready for Kids Mascot Naming Contest.

This notice corrects the July 26, 2004 notice. The Ready for Kids Mascot Naming Contest is not subject to