

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and the assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. George Nemo, Project Officer, NHLBI, Two Rockledge Center, Room 10142, 6701 Rockledge Drive, MSC 7950, Bethesda, MD 20892-7950, or call 301-435-0075, or e-mail your request to [nemog@nih.gov](mailto:nemog@nih.gov).

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: July 23, 2008.

**George Nemo,**

*Project Officer, NHLBI, 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, 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.

#### Protein-tyrosine Phosphatase Inhibitors as Inhibitors of Human Tyrosyl-DNA Phosphodiesterase (Tdp1) and Methods of Treating Disorders

*Description of Technology:* Tyrosyl-DNA phosphodiesterase (Tdp1) is an enzyme that repairs topoisomerase I (Top1)-mediated DNA damage induced by chemotherapeutic agents (such as camptothecins) and ubiquitous DNA lesions that interfere with transcription and replication. Tdp1 is a relevant target for anticancer therapies due to its role in repairing Top1-mediated DNA damage and DNA damage associated with DNA strand breaks. Tdp1 inhibitors are expected to be effective in cancer treatment when used in combination with Top1 inhibitors.

The current invention is Me-3,4 dephostatin, and more generally protein-tyrosine phosphatase inhibitors, which is a Tdp1 inhibitor. Me-3,4 dephostatin could potentiate the pharmacological action of Top1 inhibitors.

#### Applications and Modality

- It is anticipated that Tdp1 inhibitors in association with Top1 inhibitors can have selective activity toward tumor tissues.

- Tdp1 inhibitors may exhibit antitumor activity by themselves because tumors have excess free radicals.

#### Market

- An estimated 1,444,920 new cancer diagnoses in the U.S. in 2007.

- 600,000 deaths caused by cancer in the U.S. in 2006.

- Cancer is the second leading cause of death in the U.S.

- Cancer drug market will likely double to \$50 billion in 2010 from \$25 billion in 2006.

*Development Status:* The technology is currently in the pre-clinical stage of development.

*Inventors:* Yves Pommier (NCI) *et al.*

*Relevant Publication:* S Antony *et al.* Novel high-throughput electrochemiluminescent assay for

identification of human tyrosyl-DNA phosphodiesterase (Tdp1) inhibitors and characterization for furamidine (NSC 305831) as an inhibitor of Tdp1. *Nucleic Acid Res.* 2007;35(13):4474-4484.

*Patent Status:* U.S. Provisional Application No. 61/042,706 filed 04 Apr 2008 (HHS Ref. No. E-121-2008/0-US-01).

*Licensing Status:* Available for exclusive and non-exclusive licensing.

*Licensing Contact:* Adaku Nwachukwu, J.D.; 301-435-5560; [madua@mail.nih.gov](mailto:madua@mail.nih.gov).

#### Steroid Derivatives as Inhibitors of Human Tyrosyl-DNA Phosphodiesterase (Tdp1)

*Description of Technology:* Tyrosyl-DNA phosphodiesterase (Tdp1) is an enzyme that repairs topoisomerase I (Top1)-mediated DNA damage induced by chemotherapeutic agents and ubiquitous DNA lesions that interfere with transcription. The current technology are steroid derivatives that human inhibit Tdp1.

Currently, there are various types of Top1 inhibitors used in chemotherapy, e.g., camptothecin. However, Tdp1 inhibitors are expected to be effective in combination therapy with Top1 inhibitors for the treatment of cancers. Combining Tdp1 inhibitors with Top1 inhibitors would allow Tdp1 to potentiate the antiproliferative activity of Top1 inhibitors. In addition to Tdp1's effect on Top1, Tdp1 inhibitors can also exhibit antitumor activity independently, as tumors are shown to have excess free radicals, and Tdp1 repairs DNA damage by oxygen radicals.

*Applications and Modality:* It is anticipated that Tdp1 inhibitors in association with Top1 inhibitors can have selective activity toward tumor tissues. Tdp1 inhibitors may exhibit antitumor activity by themselves because tumors have excess free radicals.

*Market:* 600,000 deaths from cancer related diseases were estimated in 2006. In 2006, cancer drug sales were estimated to be \$25 billion.

*Development Status:* The technology is currently in the pre-clinical stage of development.

*Inventors:* Yves Pommier *et al.* (NCI).

*Patent Status:*

- U.S. Provisional Application No. 61/000,430 filed 24 Oct 2007 (HHS Reference No. E-130-2007/1-US-01).

- PCT Application No. PCT/US2008/004541 filed 05 Apr 2008, claiming priority to 05 Apr 2007 (HHS Reference No. E-130-2007/2-PCT-01).

*Licensing Status:* Available for exclusive and non-exclusive licensing.

*Licensing Contact:* Adaku Nwachukwu, J.D.; 301/435-5560; [madua@mail.nih.gov](mailto:madua@mail.nih.gov).

*Collaborative Research Opportunity:* The National Cancer Institute, Center for Cancer Research, Laboratory of Molecular Pharmacology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize inhibitors of Tyrosyl-DNA phosphodiesterase (Tdp1). Please contact John D. Hewes, PhD at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

Dated: July 22, 2008.

**Richard U. Rodriguez,**

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

[FR Doc. E8-17506 Filed 7-30-08; 8:45 am]

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#### Methods for Promoting Stem Cell Proliferation and Survival

*Description of Technology:* Regenerative medicine has the potential to treat numerous human diseases and afflictions including neurodegenerative disorders and spinal cord injury that are typically insidious and worsen over

time. This technology consists of a promising treatment method that coaxes stem cells into a state that promotes survival and proliferation. Two critical elements of this approach involve identifying the target niche and determining the pharmacological agents that can be used to promote stem cell regeneration.

Specifically, this technology consists of a method to activate the endogenous neural stem cells (NSCs) to promote their survival and yield using angiopoietin-2 and a cocktail of ligands and growth factors. This method has demonstrated that it can significantly improve the yield of stem cell cultures in vitro and stimulate behavioral recovery in a model of Parkinson's disease in vivo. This method is applicable to a variety of stem cell types including embryonic stem cells, adult spinal cord cells, and pericytes from blood vessels.

#### *Possible Applications:*

- Method for culturing stem cells for optimal regeneration.
- Treatment of neurological diseases and disorders such as Parkinson's disease, stroke, diabetes-related neuropathies, and spinal cord.
- Diagnostic assays to determine proliferation or inhibition of stem cells.

#### *Development Status:* Pre-clinical.

*Inventors:* Andreas Androutsellis-Theotokis and Ronald D.G. McKay (NINDS).

*Relevant Publication:* A Androutsellis-Theotokis, RR Leker, F Soldner, DJ Hoepfner, R Ravin, SW Poser, MA Rueger, SK Bae, R Kittappa, RD McKay. Notch signaling regulates stem cell numbers in vitro and in vivo. *Nature*. 2006 Aug 17;442(7104):823-826.

*Patent Status:* U.S. Provisional Application No. 60/965,094 filed 16 Aug 2007 (HHS Reference No. E-182-2007/0-US-01)

*Licensing Status:* Available for licensing.

*Licensing Contact:* Fatima Sayyid, M.H.P.M.; 301-435-4521;

[Fatima.Sayyid@nih.hhs.gov](mailto:Fatima.Sayyid@nih.hhs.gov)

*Collaborative Research Opportunity:* The National Institute of Neurological Disorders and Stroke is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize agents with activity on proliferation and/or differentiation of stem cells. Please contact Laurie Arrants at 301-435-3112 or

[ArrantsL@ninds.nih.gov](mailto:ArrantsL@ninds.nih.gov) or Martha Lubet at 301-435-3120 or [lubetm@mail.nih.gov](mailto:lubetm@mail.nih.gov) for more information.

#### Treatment of Alcoholism by Inhibition of the Neuropeptide Y Receptor

*Description of Technology:* Aversive or anticraving medications are currently used to supplement behavioral treatment of alcohol dependence. However, there is a need for developing more effective medications than those available. Neuropeptide Y (NPY) is a neurotransmitter known for increasing appetite and possibly having a role in alcohol preference and dependence. This is likely to be mediated by activation of the post-synaptic NPY-Y1 receptor, but developing molecules suitable for human therapeutics that activate that receptor represents a major challenge. Researchers at the NIH have now shown that administering antagonists of the presynaptic Y2 receptor of NPY decreases alcohol consumption and may be a valuable new treatment for alcoholism.

*Applications:* Treatment of alcohol dependence.

*Market:* In the United States, 17.6 million people—about 1 in every 12 adults—abuse alcohol or are alcohol dependent. It is estimated that on any given day, more than 700,000 people in the United States receive alcoholism treatment. Consequently, billions of dollars are spent in the treatment, prevention, and support of persons suffering from alcoholism. Moreover, the economic loss attributed to alcohol abuse and alcoholism is in the trillions.

*Development Status:* Early stage.

*Inventors:* Markus Heilig (NIAAA) *et al.*

#### *Publications:*

1. R Rimondini *et al.* Suppression of ethanol self-administration by the neuropeptide Y (NPY) Y2 receptor antagonist BIIE0246: Evidence for sensitization in rats with a history of dependence. *Neurosci Lett*. 2005 Feb 28;375(2):129-133.

2. A Thorsell *et al.* Blockade of central neuropeptide Y (NPY) Y2 receptors reduces ethanol self-administration in rats. *Neurosci Lett*. 2002 Oct 25;332(1):1-4.

*Patent Status:* U.S. Patent Application 10/492,785 filed 17 May 2004 (HHS Reference No. E-101-2004/0-US-03); Swedish Patent Application 0103476-8 filed 18 Oct 2001 (HHS Reference No. E-101-2004/0-SE-01)

*Licensing Status:* Available for licensing.

*Licensing Contact:* Norbert Pontzer, JD, PhD; 301-435-5502; [pontzern@mail.nih.gov](mailto:pontzern@mail.nih.gov).

*Collaborative Research Opportunity:* The National Institute on Alcohol Abuse and Alcoholism, Laboratory of Clinical and Translational Studies is seeking