

account for twenty percent of primary brain tumors and fifty percent of astrocytomas. These indications are designated as rare diseases as there is an annual 2–3 newly diagnosed cases of glioblastoma per 100,000 people in the United States whereas the astrocytoma incidence rate is 1.22 cases per 100,000 for individuals aged 0–19 years in the United States.

*Applications:*

- Blood based diagnostic assays.
- Assay for clinicians to choose effective treatments.
- Therapy to treat human glioblastoma.

*Advantages:*

- Non-invasive diagnostics.
- Easy, ready to use assays.

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

*Market:* Brain cancer market was worth an estimated \$1,094 million in 2009 and expected to reach \$1.3 billion by 2016.

*Inventor:* Zheng-gang Liu (NCI).

*Patent Status:* PCT Patent Application No. PCT/US2010/36394 filed 27 May 2010 (HHS Reference No. E-178-2009/0-PCT-02).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Jennifer Wong; 301-435-4633; [wongje@mail.nih.gov](mailto:wongje@mail.nih.gov).

*Collaborative Research Opportunity:* The National Cancer Institute, Cell and Cancer Biology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John Hewes, Ph.D. at 301-435-3131 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

### **Inflammatory Genes and MicroRNA-21 as Biomarkers for Colon Cancer Prognosis**

*Description of Invention:* Colon adenocarcinoma is the leading cause of cancer mortality world-wide and accounts for approximately 50,000 deaths annually in the United States. Adjuvant therapies improve survival for stage III colon cancer patients; however, it remains controversial if stage II patients should be given these therapies. Some stage II patients will benefit from therapy (such as patients with undetectable micro-metastases where surgery will not be curative); but therapy for others will harm quality of life with little therapeutic benefit (such as patients where surgery removed all cancerous tissue and therefore do not need additional therapy). Thus, there is a need to for biomarkers capable of accurately identifying high risk, stage II

patients that are suitable for therapeutic intervention.

The investigators have identified an inflammatory gene and microRNA biomarker portfolio that can predict aggressive colon cancer, colon cancer patient survival, and patients that are candidates for adjuvant therapy. These biomarkers provide clinicians with a powerful tool to diagnose colon cancer patients and chose effective treatment methods.

*Applications:*

- Method to predict aggressive form of colon cancer, especially in stage II cancer patients.
- Method to determine appropriate colon cancer patients for adjuvant therapy.

- Diagnostic arrays.

*Advantages:*

- Rapid, easy to use arrays to accurately predict colon cancer and patients suitable for adjuvant therapy.

- Method to stratify colon cancer patients for adjuvant therapy to minimize negative side effects.

- Method to identify stage II patients that are likely to have undetectable micro-metastases.

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

*Market:*

- Global cancer market is worth more than eight percent of total global pharmaceutical sales.

- Cancer industry is predicted to expand to \$85.3 billion by 2010.

*Inventors:* Curtis C. Harris and Aaron J. Schetter (NCI).

*Relevant Publication:* AJ Schetter et al. MicroRNA expression profiles associated with prognosis and therapeutic outcome in colon adenocarcinoma. *JAMA*. 2008 Jan 30;299(4):425–436. [*PubMed*: 18230780].

*Patent Status:* PCT Application No. PCT/US09/058425 filed 25 Sep 2009, which published as WO/2010/036924 on 01 Apr 2010 (HHS Reference No. E-314-2008/0-PCT-02).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Jennifer Wong; 301-435-4633; [wongje@mail.nih.gov](mailto:wongje@mail.nih.gov).

*Collaborative Research Opportunity:* The NCI Laboratory of Human. Carcinogenesis is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize cancer biomarkers and therapeutic targets. Please contact [Curtis\\_Harris@nih.gov](mailto:Curtis_Harris@nih.gov) for more information.

Dated: August 11, 2010.

**Richard U. Rodriguez,**

*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, 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.

#### **A Novel Scaffold for Multivalent Display of Ligands**

*Description of Invention:* Multivalent interactions are important in cell attachment, wound healing and immune responses. Such interactions are associated with cancer metastasis, blood clotting and the generation of antibodies from a vaccination. Mimicking multivalent interactions on a synthetic scaffold is challenging especially when large numbers of ligands (such as 5 or more) need to be displayed. There are numerous synthetic scaffolds that have been developed, but there are significant limitations that remain.

Scientists at the NIH have designed a novel multivalent scaffold that can display anywhere from 1 to 200 ligands. This system allows different types of ligands to be displayed in a controlled, spatially-addressable manner. This system uses peptide nucleic acids (PNAs) containing  $\gamma$ -substituted side

chains. PNAs are synthetic molecules that possess the bases derived from DNA. This invention could revolutionize the way in which multivalent display is used in research as well as help make vaccinations or prevent disease.

*Applications:*

- Controlled interactions ensure only a single stoichiometry is attained.
- Simple access to a wide range of multivalent platforms.

*Development Status:* Early stage.

*Inventors:* Daniel Appella *et al.* (NIDDK).

*Patent Status:* U.S. Provisional Application No. 61/333,442 filed 11 May 2010 (HHS Reference No. E-129-2010/0-US-01).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Charlene Sydnor, PhD; 301-435-4689; [sydnorc@mail.nih.gov](mailto:sydnorc@mail.nih.gov).

*Collaborative Research Opportunity:* The NIDDK Laboratory of Bioorganic Chemistry is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this novel scaffold or to collaborate on related laboratory interests. Please contact Marguerite J. Miller at 301-496-9003 and/or [millermarg@nidk.nih.gov](mailto:millermarg@nidk.nih.gov) for more information.

### N-Methanocarba Adenosine Derivatives and Their Dendrimer Conjugates as A<sub>3</sub> Receptor Agonists

*Description of Invention:* This technology relates to specific (N)-methanocarba adenine nucleosides that have been developed and dendrimers that connect these compounds to create molecules with multiple targets. Dendrimers are essentially repeated molecular branches presenting the core receptor-binding molecules. The compounds synthesized function as agonists and antagonists of a receptor of the G-protein coupled receptor (GPCR) superfamily. In particular, the receptors of interest for this invention include A<sub>3</sub> adenosine receptors and agonists and antagonists of P2Y receptors, such as P2Y<sub>1</sub> and P2Y<sub>14</sub>.

Dendrimer conjugates may have one or more advantages, such as increased solubility, reduced toxicity, and improved pharmacokinetic properties. They can also be used to connect other types of molecules without affecting the agonist or antagonists properties. For instance, molecules such as those used for imaging or tracing can be added. Dendrimers can also be used to link

more than one type of agonist or antagonist to confer multiple functionalities. This technology provides a novel mechanism to treat a number of disorders related to dysregulation of A<sub>3</sub> adenosine receptors.

*Applications:*

- Cardiac arrhythmias or ischemia
- Inflammation
- Stroke
- Diabetes
- Asthma
- Cancer
- Imaging

*Development Status:* Research quantities of compounds have been synthesized and tested for receptor selectivity.

*Inventors:* Kenneth A Jacobson and Dilip K. Tosh (NIDDK).

*Patent Status:*

U.S. Provisional Application No. 61/266,084 filed 02 Dec 2009 (HHS Reference No. E-049-2010/0-US-01).

U.S. Provisional Application No. 61/313,961 filed 15 Mar 2010 (HHS Reference No. E-049-2010/1-US-01).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Steven Standley, PhD; 301-435-4074; [sstand@mail.nih.gov](mailto:sstand@mail.nih.gov).

*Collaborative Research Opportunity:* The National Institute of Diabetes and Digestive and Kidney Diseases, Laboratory of Bioorganic Chemistry, Molecular Recognition Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Dr. Kenneth Jacobson at [kjacobs@helix.nih.gov](mailto:kjacobs@helix.nih.gov) for more information.

### Species-Independent A<sub>3</sub> Adenosine Receptor Agonists Which May Be Useful for Treating Ischemia, Controlling Inflammation, and Regulating Cell Proliferation

*Description of Invention:* This invention claims species-independent agonists of A<sub>3</sub>AR, specifically (N)-methanocarba adenine nucleosides and pharmaceutical compositions comprising such nucleosides. The A<sub>3</sub> adenosine receptor (A<sub>3</sub>AR) subtype has been linked with helping protect the heart from ischemia, controlling inflammation, and regulating cell proliferation. Agonists of the human A<sub>3</sub>AR subtype have been developed that are also selective for the mouse A<sub>3</sub>AR while retaining selectivity for the human receptor. This solves a problem for clinical development because animal model testing is important for pre-

clinical validation of drug function. Novel agonists have been made that exhibit as much as 6000x selectivity for A<sub>3</sub> versus A<sub>1</sub> in humans while retaining at least 400x selectivity for A<sub>3</sub> versus A<sub>1</sub> in mice. In addition, the molecules of the invention exhibit very low nanomolar affinity. This innovation will not only facilitate moving A<sub>3</sub> agonists into the clinical phase of drug development by being more amenable to animal studies, but also provide much greater selectivity in humans, and thereby potentially fewer side effects than drugs currently undergoing clinical trials.

*Applications:*

- Cardiac arrhythmias or ischemia
- Inflammation
- Stroke
- Diabetes
- Asthma
- Cancer

*Development Status:* Research quantities of compounds have been synthesized and tested for receptor selectivity.

*Inventors:* Kenneth A. Jacobson and Artem Melman (NIDDK).

*Publication:* A Melman *et al.* Design of (N)-methanocarba adenosine 5'-uronamides as species-independent A<sub>3</sub> receptor-selective agonists. *Bioorg Med Chem Lett.* 2008 May 1;18(9):2813-2819. [PubMed: 18424135].

*Patent Status:* PCT Application No. PCT/US09/38026 filed 24 Mar 2009, which published as WO 2009/123881 on 08 Oct 2009 (HHS Reference No. E-140-2008/0-PCT-02).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Steven Standley, Ph.D.; 301-435-4074; [sstand@mail.nih.gov](mailto:sstand@mail.nih.gov).

*Collaborative Research Opportunity:* The NIDDK Laboratory of Bioorganic Chemistry is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize A<sub>3</sub> Adenosine Receptor Agonists. Please contact Marguerite J. Miller at 301-496-9003 or [millermarg@nidk.nih.gov](mailto:millermarg@nidk.nih.gov) for more information.

Dated: August 11, 2010.

**Richard U. Rodriguez,**

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

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