

development of a tailored therapeutic plan.

- Provide genetic epidemiologic data to elucidate the role of genetic factors in the progression of the disease.

*Advantage:* Easy, rapid high-throughput method to diagnose ARMD.

*Development Status:* This technology requires analytic validation before commercialization.

*Market:* There are an estimated 15 million cases of age-related macular degeneration in the United States, and 50 million cases worldwide.

*Inventors:* Cigdem F. Dogulu, Owen M. Rennert, Wai-Yee Chan (NICHD)

*Patent Status:*

- U.S. Patent Application No. 12/089,694 filed 09 Apr 2008 (HHS Reference No. E-023-2006/0-US-07).
- Australian Patent Application No. 2006311966 filed 02 Nov 2006 (HHS Reference No. E-023-2006/0-AU-03).
- Canadian Patent Application No. 2,627,686 filed 02 Nov 2006 (HHS Reference No. E-023-2006/0-CA-04).
- European Patent Application No. 06836855.4 filed 02 Nov 2006 (HHS Reference No. E-023-2006/0-CA-04).
- Japanese Patent Application No. 2008-539046 filed 01 May 2008 (HHS Reference No. E-023-2006/0-JP-06).

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

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

*Collaborative Research Opportunity:*

The NICHD Section on Clinical Genomics is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Method Evolved for Recognition and Testing of Age-Related Macular Degeneration (MERT-ARMD). Please contact John D. Hewes, PhD at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

Dated: November 3, 2008.

**Richard U. Rodriguez,**

*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

#### 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.

#### Radiation Induced and Targeted Chemotherapy

*Description of Technology:* The invention relates to a novel method of targeted chemotherapy for the treatment of cancer using hydrophobic photoactivatable compounds like 1,5-iodoanthylazide (INA) and its analogues. The invention evolved from the discovery that electron dense atom-containing photoactivatable compounds can be activated by radiation (i.e., by x-rays and/or ultrasound) to form reactive intermediates that are highly toxic to living cells. Such compounds are termed "radiation-activatable" compounds. These radiation-activatable compounds do not become toxic until activated by radiation which allows for the targeting of the toxic compound by irradiation. Preliminary in vitro data show that INA and its derivatives can quickly and efficiently kill tumor cell lines upon irradiation.

*Applications:* Cancer Treatment.

*Advantages:* Novel method of cancer treatment.

*Development Status:* In vitro data can be provided upon request.

*Market:* Cancer Therapy.

*Inventors:* Yossef Raviv *et al.* (NCI).

*Patent Status:* U.S. Provisional Application No. 61/026,654 filed 06 Feb 2008 (HHS Ref. No. E-256-2007/0-US-01).

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

*Licensing Contact:* Kevin W. Chang, PhD, 301-435-5018, [changke@mail.nih.gov](mailto:changke@mail.nih.gov).

#### Small-Molecule Modulators of the Thyroid-Stimulating Hormone (TSH) Receptor

*Description of Technology:* The thyroid gland plays a major role in the body, secreting hormones that regulate the metabolic rate, production of other hormones, and the growth and maturation of body tissues. Thyroid disorders affect energy metabolism, neurological state, fertility, cardiovascular condition, and other body functions. In patients with hyperthyroidism, or an overactive thyroid gland, the disease is often caused by autoimmune over-stimulation of the thyroid gland (Graves' disease), or by thyroid tumors. Drugs currently used for short-term treatment of hyperthyroidism inhibit synthesis of thyroid hormones, although long-term treatment usually requires removal of the thyroid gland by surgery or administration of radioiodine. Hypothyroidism, or an underactive thyroid gland, can be caused by autoimmune disease, atrophy of the thyroid gland, or through a deficiency of thyroid-stimulating hormone (TSH). TSH, produced by the pituitary gland, binds to the TSH receptor in the thyroid to stimulate thyroid hormone production. Hypothyroidism is typically treated by direct replacement of the thyroid hormones.

The inventors have discovered a series of low-molecular weight compounds that act as TSH receptor antagonists (inhibitors) or agonists (activators). Antagonists of the TSH receptor could be used to treat hyperthyroidism, with the advantage of directly downregulating the TSH receptor, rather than inhibiting thyroid hormone synthesis. Agonists of the TSH receptor could be used to monitor thyroid activity and potential cancer recurrence in patients who have been treated for thyroid cancer, and may also be useful for treatment of certain forms of hypothyroidism. Additionally, some compounds in this family may be useful for treatment of fertility and reproductive disorders involving the luteinizing hormone/choriogonadotropin (LH/CG) receptor and the follicle-stimulating hormone (FSH) receptor, which are structurally related to the TSH receptor.

*Applications:*

- Development of therapeutics for hyperthyroidism or hypothyroidism.
- Development of diagnostic tools for evaluation of thyroid cancer patients.
- Development of therapeutics for infertility.

*Market:* Approximately 1 in 13 Americans suffers from a thyroid

disorder, and 10 million have a thyroid-related condition that requires ongoing immunodiagnostic monitoring.

*Development Status:* Early stage.

*Inventors:* Marvin C. Gershengorn *et al.* (NIDDK).

*Publications:*

1. S Moore, H Jaeschke, G Kleinau, S Neumann, S Costanzi, JK Jiang, J Childress, BM Raaka, A Colson, R Paschke, G Krause, CJ Thomas, MC Gershengorn. Evaluation of small-molecule modulators of the luteinizing hormone/choriogonadotropin and thyroid stimulating hormone receptors: structure-activity relationships and selective binding patterns. *J Med Chem.* 2006 Jun 29;49(13):3888–3896.

2. S Titus, S Neumann, W Zheng, N Southall, S Michael, C Klumpp, A Yasgar, P Shinn, CJ Thomas, J Inglese, MC Gershengorn, CP Austin. Quantitative high throughput screening using a live cell cAMP assay identifies small molecule agonists of the TSH receptor. *J Biomol Screen.* 2008 Feb;13(2):120–127.

3. S Neumann, G Kleinau, S Costanzi, S Moore, BM Raaka, CJ Thomas, G Krause, MC Gershengorn: A low molecular weight antagonist for the human thyrotropin receptor with therapeutic potential for hyperthyroidism. *Endocrinology.* 2008 31 Jul; published online ahead of print, doi:10.1210/en.2008–0836.

*Patent Status:* International Patent Application No. PCT/US2007/011951 filed 17 May 2007 (HHS Reference No. E–223–2006/0–PCT–02).

*Licensing Status:* This technology is available for exclusive, co-exclusive, or nonexclusive licensing.

*Licensing Contact:* Tara L. Kirby, PhD; 301–435–4426; [tarak@mail.nih.gov](mailto:tarak@mail.nih.gov).

### Methods for Accurately Measuring and Regulating Bound Adrenomedullin

*Description of Technology:* This technology involves an array of applications relating to a key discovery regarding adrenomedullin-binding proteins.

Adrenomedullin (AM) is a ubiquitously expressed peptide first found in human pheochromocytoma, a cancer of the adrenal medulla. AM appears to function as a universal autocrine growth factor, driving cell proliferation, as a vasodilator, as a mechanism for protecting cells against oxidative stress in hypoxic injury, and as a dose-dependent inhibitor of insulin secretion. Accordingly, methods for measuring *in vivo* levels of AM accurately, and methods for regulating the activity of available AM, may be critically important in diagnosis and treatment of many conditions, such as

heart disease, pulmonary disease, liver cirrhosis, cancer, diabetes, sepsis, and inflammation.

The present technology centers on the observation that AM binds to Complement Factor H (CFH) *in vivo*. Without a means to determine the amount of AM that is bound to CFH, measurements of AM are inaccurate, and therapies focused on the AM-CFH complex may have advantages compared to therapies focused on AM alone.

The technology includes methods for measuring and utilizing purified AM-binding proteins, or functional portions thereof, to diagnose, treat, and monitor AM-related diseases. A second aspect includes the identification and isolation of the AM-CFH complex. Antibodies and small-molecule antagonists (which can down-regulate the function of AM, CFH, and the AM-CFH complex) have also been isolated. Collectively, the technology provides methods for diagnosis and treatment of conditions such as cancer, diabetes, or other conditions that are influenced by AM levels.

*Applications and Advantages:*

- More accurate measurements of serum adrenomedullin than current tests
- Antibodies targeting AM-CFH decrease bioavailable AM, which may be useful in suppressing angiogenesis in cancers
- Antibodies targeting the CFH binding site increase bioavailable AM, which may be useful in therapies involving vasodilation, angiogenesis, and tolerance for hypoxic or ischemic injury during stroke or myocardial infarction

*Development Status:* *In vivo* and *in vitro* proof of concept data are available.

*Inventors:* Frank Cuttitta *et al.* (NCI).

*Related Publications:*

1. AJ Dwivedi *et al.* Adrenomedullin and adrenomedullin binding protein-1 prevent acute lung injury after gut ischemia-reperfusion. *J Am Coll Surg.* 2007 Aug;205(2):284–293.

2. D Ajona *et al.* Down-regulation of human complement factor H sensitizes non-small cell lung cancer cells to complement attack and reduces *in vivo* tumor growth. *J Immunol.* 2007 May 1;178(9):5991–5998.

3. A Martínez *et al.* Mapping of the adrenomedullin-binding domains in human complement factor H. *Hypertens Res.* 2003 Feb;26 Suppl:S55–59.

4. R Pio *et al.* Complement factor H is a serum-binding protein for adrenomedullin, and the resulting complex modulates the bioactivities of both partners. *J Biol Chem.* 2001 Apr 13;276(15):12292–12300.

*Patent Status:* HHS Reference No. E–256–1999/0–

- U.S. Patent Application No. 11/530,441 filed 08 Sept 2006, claiming priority to 10 Sept 1999

- Foreign counterparts in Australia, Canada, France, Germany, Great Britain, Italy, Spain, and Portugal

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

*Licensing Contact:* Tara L. Kirby, PhD; 301–435–4426; [tarak@mail.nih.gov](mailto:tarak@mail.nih.gov).

*Collaborative Research Opportunity:*

The National Cancer Institute (NCI)/Angiogenesis Core Facility is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize AM-CFH complex involvement with tumor angiogenesis and identifying potential Rx's to disrupt this effect. Please contact John D. Hewes, PhD at 301–435–3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

Dated: November 3, 2008.

**Richard U. Rodriguez,**

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

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