

encompassed by this technology are more potent and/or more specific TSH receptor activators than currently-available compounds; also, as small molecules, these compounds are orally available and are expected to be less costly and more straightforward to produce than recombinant protein counterparts currently on the market.

According to the National Cancer Institute, over 37,000 new cases of thyroid cancer were diagnosed in the United States in 2008, and over 1,500 people died of this disease. These numbers reflect a progressive increase in the incidence of thyroid cancer over the last several years. Because most cases of thyroid cancer are diagnosed in patients between the ages of 20 and 54, these patients will undergo decades of follow-up monitoring after cancer treatment. For the last decade, recombinant TSH protein has been used in this follow-up to increase detection sensitivity for recurrent or metastatic thyroid cancer, and to eliminate side effects associated with withdrawal of hormone replacement therapy. A small-molecule TSH receptor agonist encompassed by this technology would have utility similar to recombinant TSH, but would have several distinct advantages. For example, as a small molecule, rather than a recombinant protein, such a compound would be orally available, and would be less difficult and expensive to produce. These compounds are also more potent and/or specific for the TSH receptor than other known small-molecule TSH receptor agonists. In addition to use in thyroid cancer screening, these compounds may also be useful for adjunctive treatment (with radioactive iodide) of thyroid cancer, and certain forms of hypothyroidism.

Hyperthyroidism, or an overactive thyroid gland, affects about 1% of people in the United States and is often caused by autoimmune over-stimulation of the thyroid gland (Graves' disease), or by thyroid tumors. Drugs currently used for treatment of hyperthyroidism inhibit synthesis of thyroid hormones; the TSH receptor antagonist compounds encompassed by this technology have the advantage of directly inhibiting activity of the TSH receptor, rather than inhibiting thyroid hormone synthesis.

#### Applications

- Diagnostic tools for evaluation and treatment of thyroid cancer.
- Therapeutics for thyroid cancer, hyperthyroidism, and hypothyroidism.

**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. Moore S, Jaeschke H, Kleinau G, Neumann S, Costanzi S, Jiang JK, Childress J, Raaka BM, Colson A, Paschke R, Krause G, Thomas CJ, Gershengorn MC. 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. [PubMed: 16789744]

2. Neumann S, Kleinau G, Costanzi S, Moore S, Raaka BM, Thomas CJ, Krause G, Gershengorn MC. A low molecular weight antagonist for the human thyrotropin receptor with therapeutic potential for hyperthyroidism. *Endocrinology* 2008 Dec;149(12):5945–5950. [PubMed: 18669595]

3. Unpublished data are also available for review under a CDA.

#### Patent Status

HHS Reference Nos. E-223-2006/0 and E-223-2006/1—

- International Patent Application No. PCT/US2007/011951 filed 17 May 2007, which published as WO 2007/136776 on 29 Nov 2007
- National Phase entered in Australia, Canada, Europe, Japan, and the United States

HHS Reference No. E-284-2008/0—

- International Patent Application No. PCT/US2008/011958 filed 20 Oct 2008.

**Licensing Status:** Available for licensing.

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

**Collaborative Research Opportunity:** The NIDDK Clinical Endocrinology Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize small molecule TSH receptor modulators. Please contact Marguerite J. Miller at 301-496-9003 or [millermarg@mail.nih.gov](mailto:millermarg@mail.nih.gov) for more information.

Dated: October 12, 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

#### National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Institute of General Medical Sciences Special Emphasis Panel; Review of Minority Biomedical Research Neuro Grant Applications.

**Date:** November 12, 2010.

**Time:** 8:30 a.m. to 5 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Hyatt Regency-Bethesda, 7400 Wisconsin Avenue, One Bethesda Metro Center, Bethesda, MD 20814.

**Contact Person:** John J. Laffan, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18J, Bethesda, MD 20892, 301-594-2773, [laffanjo@mail.nih.gov](mailto:laffanjo@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: October 12, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-26185 Filed 10-15-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of