

## II. Meeting Format

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. The Committee may limit the number and duration of oral presentations to the time available. Your comments should focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following Web site prior to the meeting: [http://www.cms.hhs.gov/mcd/index\\_list.asp?list\\_type=mcac](http://www.cms.hhs.gov/mcd/index_list.asp?list_type=mcac). We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. At the conclusion of the day, the members will vote and the Committee will make its recommendation(s) to CMS.

## III. Registration Instructions

CMS's Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone, fax number(s), and e-mail address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified the seating capacity has been reached.

## IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the

Federal Protective Service or Guard Service personnel.

- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.

- Inspection, via metal detector or other applicable means of all persons entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

**Note:** Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting. All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

**Authority:** 5 U.S.C. App. 2, section 10(a). (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 4, 2010.

**Barry M. Straube,**

*Chief Medical Officer and Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive License: Treatment of Glaucoma by Administration of Adenosine A3 Antagonists

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** This is 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. Provisional Patent Application 60/010,737, entitled "Dihydropyridine, pyridine-,

benzopyran one-, and triazoloquinazoline derivatives, their preparation and use as adenosine receptor antagonists," filed January 29, 1996 [HHS Ref. No. E-225-1995/0-US-1], U.S. Provisional Patent Application 60/021,191, entitled "Dihydropyridine, pyridine-, benzopyran one-, and triazoloquinazoline derivatives, their preparation and use as adenosine receptor antagonists," filed July 3, 1996 [HHS Ref. No. E-225-1995/1-US-1], PCT Application PCT/US97/01252, entitled "Dihydropyridine, pyridine-, benzopyran one-, and triazoloquinazoline derivatives, their preparation and use as adenosine receptor antagonists," filed January 29, 1997 [HHS Ref. No. E-225-1995/2-PCT-1], U.S. Patent 6,066,642, entitled "Dihydropyridine, pyridine-, benzopyran one-, and triazoloquinazoline derivatives, their preparation and use as adenosine receptor antagonists," issued May 23, 2000 [HHS Ref. No. E-225-1995/2-US-08], Australian Patent 709190, issued December 9, 1999 [HHS Ref. No. E-225-1995/2-AU-04], European Patent Application No. 97905627.2, filed January 29, 1997 [HHS Ref. No. E-225-1995/2-EP-05], Hong Kong Application No. 99102653.6, filed January 29, 1997 [HHS Ref. No. E-225-1995/2-HK-06], Japanese Patent Application No. 527065/1997, filed January 29, 1997 [HHS Ref. No. E-225-1995/2-JP-07], Australian Patent 755525, issued March 27, 2003 [HHS Ref. No. E-225-1995/2-AU-02], and Canadian Patent 2244774, issued October 17, 2006 [HHS Ref. No. E-225-1995/2-CA-03], U.S. Provisional Patent Application 60/092,292, entitled "A3 Adenosine Receptor Antagonists," filed July 10, 1998 [HHS Ref. No. E-096-1998/0-US-1], PCT Application PCT/US99/15562, entitled "A3 Adenosine Receptor Antagonists," filed July 2, 1999 [HHS Ref. No. E-096-1998/0-PCT-2], U.S. Patent 6,376,521, entitled "A3 Adenosine Receptor Antagonists," issued April 23, 2003, [HHS Ref. No. E-096-1998/0-US-04], and Canadian Patent Application No. 2336967, filed July 2, 1999 [HHS Ref. No. E-096-1998/0-CA-03], U.S. Provisional Patent Application 61/085,588, entitled "Truncated Methanacarba Adenosine Derivatives as A3 Antagonists," filed August 1, 2008 [HHS Ref. No. E-285-2008/0-US-1], PCT Application PCT/US2009/52439, entitled "Truncated Methanacarba Adenosine Derivatives as A3 Antagonists," filed July 31, 2009 [HHS Ref. No. E-285-2008/0-PCT-2], and Korean International Application No. PCT/KR2007/001131, entitled

“Adenosine derivatives, method of synthesis thereof, and the pharmaceutical compositions for the prevention and treatment of the inflammatory diseases containing the same as an active ingredient,” filed March 7, 2007, [HHS Ref. No. E-109-2006/0-PCT-01] to Acorn Biomedical, Inc., having an office in at 612 SE. 5th Avenue, Suite #3, Fort Lauderdale, FL 33301 U.S.A. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the use of adenosine A3 antagonists for treatment of glaucoma and intraocular pressure.

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before March 29, 2010 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: Steven Standley, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4074; Facsimile: (301) 402-0220; E-mail: [ssstand@od.nih.gov](mailto:ssstand@od.nih.gov).

**SUPPLEMENTARY INFORMATION:** Adenosine a3 antagonists applied topically to the cornea have been shown to cause a reduction in intraocular pressure, which is a means of treating glaucoma.

The invention relates to several structurally different pharmacophores that have been shown to antagonize adenosine a3 receptors. Molecules are to be tested to optimize for the treatment of glaucoma and intraocular pressure in humans.

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 thirty (30) 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: February 16, 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

### Centers for Medicare & Medicaid Services

[CMS-3224-N]

#### Medicare Program; Request for Nominations for Members for the Medicare Evidence Development & Coverage Advisory Committee

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the request for nominations for consideration for membership on the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). Among other things, the MEDCAC advises the Secretary of the Department of Health and Human Services (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services, as requested by the Secretary, whether medical items and services are “reasonable and necessary” and therefore eligible for coverage under Title XVIII of the Social Security Act.

We are requesting nominations for both voting and nonvoting members to serve on the MEDCAC. Nominees are selected based upon their individual qualifications and not as representatives of professional associations or societies. We have a special interest in ensuring that the interests of both women and men, members of all racial and ethnic groups, and physically challenged individuals are adequately represented on the MEDCAC. Therefore, we encourage nominations of qualified candidates who can represent these interests.

The MEDCAC reviews and evaluates medical literature, reviews technology assessments, and examines data and information on the effectiveness and appropriateness of medical items and services that are covered or eligible for coverage under Medicare.

**DATES:** Nominations will be considered if postmarked by Monday, March 29, 2010 and mailed to the address

specified in the **ADDRESSES** section of this notice.

**ADDRESSES:** You may mail nominations for membership to the following: Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Attention: Maria Ellis, 7500 Security Boulevard, Mail Stop: C1-09-06, Baltimore, MD 21244-1850.

**FOR FURTHER INFORMATION CONTACT:** Maria Ellis, Executive Secretary for MEDCAC, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Coverage and Analysis Group, C1-09-06, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410-786-0309) or via e-mail at [Maria.Ellis@cms.hhs.gov](mailto:Maria.Ellis@cms.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) announcing establishment of the Medicare Coverage Advisory Committee (MCAC). The Secretary signed the initial charter for the Medicare Coverage Advisory Committee on November 24, 1998. On January 26, 2007 the Secretary published a notice in the **Federal Register** (72 FR 3853), changing the Committee’s name to the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC). The charter for the committee was renewed by the Secretary and will terminate on November 24, 2010, unless renewed again by the Secretary.

The MEDCAC is governed by provisions of the Federal Advisory Committee Act, Public Law 92-463, as amended (5 U.S.C. App. 2), which sets forth standards for the formulation and use of advisory committees, and is authorized by section 222 of the Public Health Service Act as amended (42 U.S.C. 217A).

The MEDCAC consists of a pool of 100 appointed members including: 6 patient advocates, who are standard voting members; and 6 representatives of industry interests, who are nonvoting members. Members are selected from among authorities in clinical medicine of all specialties, administrative medicine, public health, biologic and physical sciences, health care data and information management and analysis, patient advocacy, the economics of health care, medical ethics, and other related professions such as epidemiology and biostatistics, and methodology of trial design.

The MEDCAC functions on a committee basis. The committee reviews and evaluates medical literature, reviews technology assessments, and