

*Licensing Contact:* Suryanarayana (Sury) Vepa, PhD, J.D.; 301-435-5020; [vepas@mail.nih.gov](mailto:vepas@mail.nih.gov).

*Collaborative Research Opportunity:* The NIEHS is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the ROR gamma mice or related laboratory research interests. Please contact Dr. Elizabeth Denholm at [denholme@niehs.nih.gov](mailto:denholme@niehs.nih.gov) or 919-541-0981 for more information.

### Antibody Composition and Methods for the Prevention and Treatment of Lupus Nephritis

*Description of Technology:* This technology identifies an antibody that induces a protective effect in vivo in a mouse model of lupus nephritis. Lupus is a chronic autoimmune disease that can damage various parts of the body, especially the kidneys. The lupus nephritis-model mice that were treated with this antibody experienced a dramatic increase in survival, demonstrated a reduced immune complex formation deposition in the kidneys, and displayed low levels of proteinuria as compared with untreated mice. The antibody is an autospecific anti-dsDNA IgM.

In addition, this invention may be used as a component of a predictive diagnostic kit. As lupus-related kidney disease may be asymptomatic, significant kidney damage may occur before lupus is diagnosed ([lupus.org](http://lupus.org)). The inventors are currently investigating whether the ratio of protective antibodies to nonprotective or pathogenic antibodies in lupus nephritis models is predictive of disease. Currently available diagnostic methods (proteinuria, creatine clearance, or kidney biopsy) are not predictive and test only for existing kidney impairment or damage.

#### *Applications:*

- A preventative and therapeutic for lupus nephritis.
- A component of a predictive diagnostic kit for lupus nephritis.
- A research tool for investigation of lupus nephritis in a mouse model.

#### *Advantages:*

• Therapeutic antibodies are unlikely to elicit side effects in patient populations, unlike many existing therapies.

• The diagnostic would be predictive, unlike existing diagnostics.

*Development Status:* Early stage, *in vivo* (mouse).

#### *Market:*

• At least 1.5 million Americans have lupus ([lupus.org](http://lupus.org)).

• Up to 67% of children with lupus, and approximately 40% of all individuals with lupus, develop lupus-related kidney complications ([lupus.org](http://lupus.org)).

*Inventors:* Marilyn Diaz, Chuancang Jiang, Ming-Lang Zhao (NIEHS).

*Publication:* In preparation.  
*Patent Status:* U.S. Provisional Application No. 61/176,615 filed 08 May 2009 (HHS Reference No. E-156-2009/0-US-01).

*Licensing Status:* Available for licensing.

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

*Collaborative Research Opportunity:* The NIEHS is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology or related laboratory research interests. Please contact Dr. Elizabeth Denholm at [denholme@niehs.nih.gov](mailto:denholme@niehs.nih.gov) or 919-541-0981 for more information.

### P2Y<sub>1</sub> Receptor Antagonists Useful for the Study of Platelet Aggregation and Clotting Conditions

*Description of Technology:* NIH inventors have developed P2Y<sub>1</sub> receptor antagonists ((N)-Methanocarpa 2'-Deoxyadenosine 3', 5'-Bisphosphate Analogues) for inhibition of platelet aggregation and treatment of clotting conditions. On the platelet surface, simultaneous activation of the P2Y<sub>1</sub> and P2Y<sub>12</sub> receptors by ADP induces aggregation. The P2Y<sub>1</sub>-mediated response is associated with the initial shape change and rapid aggregation, and the P2Y<sub>12</sub> receptor is associated with amplification of the aggregation. P2Y<sub>12</sub> receptor antagonists are both in clinical use and under development as antithrombotic agents. Potent and selective P2Y<sub>1</sub> receptor antagonists, such as the conformationally locked methanocarpa nucleotide MRS2500 1 (K<sub>i</sub> 0.79 nM), have been designed and shown to have promise in preclinical studies as antithrombotic agents. This novel drug concept is also supported by studies of mice in which the P2Y<sub>1</sub> receptor has been genetically deleted, wherein the initiation of clotting events is markedly impaired.

*Applications:* Potential new target for treating intravascular clotting.

*Development Status:* Early-stage of development.

*Market:* There is a very large potential market for P2Y<sub>1</sub> receptor antagonists. For instance, P2Y<sub>1</sub> receptor antagonists may treat deep vein thrombosis, which occurs in 80 of 100,000 individuals in the U.S. annually.

*Inventors:* Kenneth A. Jacobson and Sonia De Castro (NIDDK)

#### *Patent Status:*

• U.S. Provisional Application No. 61/061,309 filed 13 Jun 2008 (HHS Reference No. E-235-2008/0-US-01).

• Patent Cooperation Treaty Application PCT/US2009/47204 filed 12 Jun 2009 (HHS Reference No. E-235-2008/0-PCT-03)

*Licensing Status:* Available for licensing.

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

Dated: November 23, 2009.

**Richard U. Rodriguez,**

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

[FR Doc. E9-28538 Filed 11-27-09; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-6023-CN]

### Medicare Program; Solicitation of Independent Accrediting Organizations To Participate in the Advanced Diagnostic Imaging Supplier Accreditation Program; Correction

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

**ACTION:** Correction notice.

**SUMMARY:** This document corrects a technical error in the notice entitled "Medicare Program; Solicitation of Independent Accrediting Organizations to Participate in the Advanced Diagnostic Imaging Supplier Accreditation Program" which was posted for public inspection by the Office of the Federal Register on October 30, 2009, and published in the **Federal Register** on November 25, 2009.

**FOR FURTHER INFORMATION CONTACT:** Sandra Bastinelli, (410) 786-3630.

#### SUPPLEMENTARY INFORMATION:

#### I. Background

In FR Doc. E9-26209, which was posted for public inspection by the Office of the Federal Register (OFR) on October 30, 2009, and published in the **Federal Register** on November 25, 2009, we made a technical error that is corrected in the Correction of Errors section below. The provisions in this correction notice are effective as if they had been included in the November 25, 2009 notice.

## II. Summary of Errors

In section II.B. of the November 25, 2009 notice, we list the criteria that an accreditation organization must furnish to CMS to be considered for approval as a designated accreditation organization for Medicare under 42 CFR 414.68 (as issued in the "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010" final rule with comment period, FR Doc. E9-26502, posted for public inspection by OFR on October 30, 2009). Due to a technical error, the list of criteria does not accurately reflect the requirements set out at new § 414.68.

## III. Correction of Errors

In FR Doc. E9-26502 published on November 25, 2009 (74 FR 62189), correct section II.B. to read as follows:

*"B. Application Requirements*

To be considered for approval as a designated accreditation organization for Medicare requirements, an accreditation organization must furnish CMS the information and meet the criteria set out at 42 CFR 414.68, as issued in the "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010" final rule with comment period, FR Doc. E9-26502, posted for public inspection by OFR on October 30, 2009."

## III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the notice.

Section 553(d) of the APA ordinarily requires a 30-day delay in effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued.

We note that section 1834(e) of the Act requires us to designate organizations to accredit suppliers furnishing the technical component (TC) of advanced diagnostic imaging services by January 1, 2010. Given the

statutory deadline to designate organizations and the timing of the publication of this final rule with comment period, we believe it is impracticable to provide a notice and comment period or to delay the effective date of these criteria for designating organizations to accredit suppliers furnishing the TC of advanced diagnostic imaging services. In addition, it is unnecessary to provide a period for notice and comment or delay the effective date of this correction, because this correction notice does not change our policies regarding the application process, but merely clarifies that the application process is subject to a regulation that has already been the subject of notice and comment rulemaking. Therefore, we believe that we have good cause for waiving a notice and comment period, and making the imaging accreditation application process correction effective upon publication.

**Authority:** Section 1834(e) of the Act.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: November 23, 2009.

**Dawn L. Smalls,**

*Executive Secretary to the Department.*

[FR Doc. E9-28541 Filed 11-25-09; 11:15 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3218-N]

### Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee

January 27, 2010.

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

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces that a public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) ("Committee") will be held on Wednesday, January 27, 2010. The Committee generally provides advice and recommendations concerning the adequacy of scientific evidence needed to determine whether certain medical items and services can be covered under the Medicare statute. This meeting will focus on the sufficiency of currently available evidence to determine whether the results of pharmacogenomic testing

affect health outcomes of patients with cancer when used as a guide for certain drug treatments. This meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

**DATES:** *Meeting date:* The public meeting will be held on Wednesday, January 27, 2010 from 7:30 a.m. until 4:30 p.m., Eastern Standard Time (E.S.T.).

*Deadline for Submission of Written Comments:* Written comments must be received at the address specified in the **ADDRESSES** section of this notice by 5 p.m., E.S.T. on December 28, 2009. Once submitted all comments are final.

*Deadlines for Speaker Registration and Presentation Materials:* The deadline to register to be a speaker and to submit powerpoint presentation materials and writings that will be used in support of an oral presentation, is 5 p.m., E.S.T. on Monday, December 28, 2009. Speakers may register by phone or via e-mail by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials must be received at the address specified in the **ADDRESSES** section of this notice.

*Deadline for All Other Attendees Registration:* Individuals may register via e-mail at [MEDCAC\\_Registration@cms.hhs.gov](mailto:MEDCAC_Registration@cms.hhs.gov) or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5 p.m., E.S.T. on Wednesday, January 20, 2010.

*Deadline for Submitting a Request for Special Accommodations:* Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to contact the Executive Secretary as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than 5 p.m., E.S.T., Friday, January 8, 2010.

**ADDRESSES:** *Meeting Location:* The meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

*Submission of Presentations and Comments:* Presentation materials and written comments that will be presented at the meeting must be submitted via e-mail to [MedCACpresentations@cms.hhs.gov](mailto:MedCACpresentations@cms.hhs.gov) or by regular mail to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice.

**FOR FURTHER INFORMATION CONTACT:** Maria Ellis, Executive Secretary for