

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Biomedical Imaging and Bioengineering Special Emphasis Panel.

Date: March 19, 2009.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Democracy Plaza II, 6707 Democracy Blvd., Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ruixia Zhou, PhD, Scientific Review Officer, 6707 Democracy Boulevard, Democracy Two Building, Suite 957, Bethesda, MD 20892, 301-496-4773, zhou@mail.nih.gov.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Tissue Engineering/Regenerative Medicine.

Date: March 20, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: John K. Hayes, PhD, Scientific Review Officer, 6707 Democracy Boulevard, Democracy Two Building, Suite 959, Bethesda, MD 20892, 301-451-3398, hayesj@mail.nih.gov.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

Date: March 20, 2009.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Democracy Plaza II, 6707 Democracy Blvd., Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ruixia Zhou, PhD, Scientific Review Officer, 6707 Democracy Boulevard, Democracy Two Building, Suite 957, Bethesda, MD 20892, 301-496-4773, zhou@mail.nih.gov.

Dated: February 13, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Methods of Using Deacetylase Inhibitors To Treat Dystrophies and Other Tissue Degeneration Disorders

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

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 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 No. 60/335,705, filed October 18, 2001, now abandoned, entitled "Methods of Using Deacetylase Inhibitors as Tools to Promote Cell Differentiation and Regeneration" [HHS Ref. No. E-353-2001/0-US-01]; U.S. Provisional Patent Application No. 60/343,854, filed October 25, 2001, now abandoned, entitled "Methods of Using Deacetylase Inhibitors as Tools to Promote Cell Differentiation and Regeneration" [HHS Ref. No. E-353-2001/1-US-01]; PCT Patent Application No. PCT/US02/33570, filed October 17, 2002, now abandoned, entitled "Methods of Using Deacetylase Inhibitors as Tools to Promote Cell Differentiation and Regeneration" [HHS Ref. No. E-353-2001/2-PCT-01]; U.S. Patent Application No. 10/492,901, filed April 15, 2004, which issued as U.S. Patent No. 7,229,963, on June 12, 2007, entitled "Methods of Using Deacetylase Inhibitors as Tools to Promote Cell Differentiation and Regeneration" [HHS Ref. No. E-353-2001/2-US-02]; and U.S. Patent Application No. 11/800,151, filed May 4, 2007, which published as 2008/0248994, on October 9, 2008, entitled "Methods of Using Deacetylase Inhibitors to Promote Cell Differentiation and Regeneration" [HHS Ref. No. E-353-2001/2-US-03] to ADVANCELL Advanced In Vitro Cell Technologies, S.A. which has an office in Barcelona, Spain. The patent rights in these inventions have been assigned to

the United States of America and The Salk Institute for Biological Studies.

The prospective exclusive license territory may be "worldwide", and the field of use may be limited to "the use of deacetylase inhibitors to treat dystrophies and other disorders involving tissue degeneration."

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before April 21, 2009 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: Suryanarayana (Sury) Vepa, PhD, J.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5020; Facsimile: (301) 402-0220; E-mail: vepas@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This technology relates to methods of enhancing progenitor cell differentiation, including enhancing myogenesis, neurogenesis and hematopoiesis, by contacting a progenitor cell with an effective amount of a deacetylase inhibitor (DI). The progenitor cell can be part of cell culture, such as a cell culture used for *in vitro* or *in vivo* analysis of progenitor cell differentiation, or can be part of an organism, such as a human or other mammal. Contacting the progenitor cell with a DI can lead to enhancement of expression of terminal cell-type specific genes in the progenitor cell, such as enhancing expression of muscle-specific genes in myoblasts, and can lead to skeletal muscle hypertrophy. Administering a DI to a subject also can provide some prophylactic or therapeutic effect for inhibiting, preventing, or treating conditions associated with a degeneration or loss of tissue. The DI can be administered to a subject as part of a pharmaceutical composition.

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 404.7. The prospective exclusive license may be granted unless within sixty (60) 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 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