• Presenters must clearly explain the actions that they are requesting CMS to take in the appropriate section of the form. A presenter’s relationship with the organization that they represent must also be clearly listed.
• The form is now available through the CMS Forms Web site. The Uniform Resource Locator (URL) for linking to this form is as follows: http://www.cms.hhs.gov/cmsforms/downloads/cms20017.pdf

IV. Oral Comments
In addition to formal oral presentations, which are limited to 5 minutes total per presentation, there will be an opportunity during the meeting for public oral comments, which will be limited to 1 minute for each individual and a total of 3 minutes per organization.

V. Meeting Attendance
The meeting is open to the public; however, attendance is limited to space available. Priority will be given to those who pre-register, and attendance may be limited based on the number of registrants and the space available.

Persons wishing to attend this meeting, which is located on Federal property, must register by following the instructions in the “Meeting Registration Timeframe” section of this notice. A confirmation email will be sent to the registrants shortly after completing the registration process.

VI. Security, Building, and Parking Guidelines
The following are the security, building, and parking guidelines:
• Persons attending the meeting, including presenters, must be pre-registered and on the attendance list by the prescribed date.
• Individuals who are not pre-registered in advance may not be permitted to enter the building and may be unable to attend the meeting.
• Attendees must present valid photo identification to the Federal Protective Service or Guard Service personnel before entering the building. Without a current, valid photo ID, persons may not be permitted entry to the building.
• Security measures include inspection of vehicles, inside and out, at the entrance to the grounds.
• All persons entering the building must pass through a metal detector.
• All items brought into CMS including personal items, for example, laptops and cell phones are subject to physical inspection.
• The public may enter the building 30 to 45 minutes before the meeting convenes each day.

• All visitors must be escorted in areas other than the lower and first-floor levels in the Central Building.
• The main-entrance guards will issue parking permits and instructions upon arrival at the building.

VII. Special Accommodations
Individuals requiring sign-language interpretation or other special accommodations must include the request for these services during registration.

VIII. Panel Recommendations and Discussions
The Panel’s recommendations at any Panel meeting generally are not final until they have been reviewed and approved by the Panel on the last day of the meeting, before the final adjournment. These recommendations will be posted to our Web site after the meeting.

IX. Collection of Information Requirements
This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

(Catalog of Federal Domestic Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 29, 2013,
Marilyn Tavenner,
Administrator, Centers for Medicare & Medicaid Services.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HH5.

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. 209 and 37 CFR Part 404 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.

FOR FURTHER INFORMATION CONTACT: 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.

Use of Antisense Oligodeoxynucleotides (ODNs) for Inhibiting JC Virus (JCV)

Description of Technology: Progressive multifocal leukoencephalopathy (PML) is a rare, fatal demyelinating disease of the brain caused by the polyomavirus JC (JCV) under immunosuppressive conditions. It is pathologically characterized by progressive damage of white matter of the brain by destroying oligodendrocytes at multiple locations. Clinically, PML symptoms include weakness or paralysis, vision loss, impaired speech, and cognitive deterioration. The prognosis of PML is generally poor. No effective therapy for PML has been established. The current strategies to develop a PML therapy focus on blocking viral infection or inhibiting JCV replication. Antisense oligodeoxynucleotides (ODNs) that can block JCV replication and multiplication have been identified and optimized. Use of the ODNs provide a method of inhibiting JCV replication and thereby provide a treatment for PML.

Potential Commercial Applications:
• JCV/PML Therapeutics.
• JCV Diagnostics.
• JCV Kits.

Competitive Advantages:
• Low cost PML therapeutics.
• Lower cost JCV diagnostics.
• Ease of synthesis.

Development Status:
• Pre-clinical.
• In vitro data available.
• In vivo data available (animal).

Inventors: Laura B. Jaeger, Avindra Nath, Eugene O. Major (all of NINDS).


Licensing Contact: Peter Soukas, J.D.; 301–435–4646; ps193c@nih.gov.

Collaborative Research Opportunity: The National Institute of Neurological Disorders and Stroke is seeking statements of capability or interest from parties interested in collaborative
research to further develop, evaluate or commercialize anti-JCV antisense cocktails. For collaboration opportunities, please contact Melissa Maderia, Ph.D. at maderiam@mail.nih.gov or 240–276–5533.

A Novel HIV–1 Anti-HIV and Anti-Retroviral Compound

Description of Technology: The subject invention describes the thioester prodrug that targets the highly conserved nucleocapsid protein 7 (NCp7) of HIV. In contrast to clinically approved anti-retroviral drugs used to treat HIV, the virus is not able to develop resistance to the drug in this invention. In addition, the prodrug is stable at room temperature, crystalline, easily synthesized in two steps on the kilogram scale from inexpensive starting materials, orally bioavailable, and is non-toxic in all animal models investigated to date. There is potential to use the molecule described in the invention as an orally administered systemic drug for the treatment of HIV infection either alone or in combination with other approved anti-retroviral therapies. Animal safety testing is in process as are efficacy studies.

Potential Commercial Applications:
• HIV therapeutics.
• Prophylactics.
• Topical application.

Competitive Advantages:
• More stable than thioesters.

Development Stage:
• Early-stage.
• Pre-clinical.
• In vitro data available.
• In vivo data available (animal).

Inventors: Charles P. Venditti and Eirini Manoli (NNCRIR)


Licensing Contact: Vince Contreras, Ph.D.; 301–435–4711; venditti@mail.nih.gov

Collaborative Research Opportunity: The National Human Genome Research Institute, Organic Acid Research Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize renotherapeutic or renoprotective small molecules, gene and/or cell therapies to treat MMA. For collaboration opportunities, please contact Charles P. Venditti, M.D., Ph.D. at venditti@mail.nih.gov or 301–496–6213.

Reporter Plasmid To Identify Cancer Stem Cells

Description of Technology: Scientists at the NIH have developed a research tool, an efficient lentiviral plasmid to visualize and purify cancer stem cells, which is useful for screening compounds that specifically kill or inhibit cancer stem cells. Cancer stem cells are a minority population of cells that initiate and sustain tumors. These cells are resistant to therapy and may cause tumors to recur after curative treatment. Current therapies generally do not target cancer stem cells. The key feature of the plasmid is a reporter system that only detects cells expressing the core stem cell transcription factors Sox2 and Oct4. The plasmid can identify the putative cancer stem cell population through the expression of fluorescent or luminescent proteins and has the potential to advance new therapies.

Potential Commercial Applications:
• Laboratory tool to visualize, quantify and purify cancer stem cells.
• Research tool to monitor cancer stem cells in transplanted tumors in vivo.
• Research tool to identify cancer stem cells in high through-put screening
of libraries for compounds that specifically inhibit or kill cancer stem cells.

- Research tool to optimize therapeutic regimens in preclinical models.
- Potential to support precision medicine approach by screening therapeutics for efficacy against cancer stem cells in patient-derived xenografts.
- Competitive Advantages:
  - Efficient visualization of cancer stem cells by functional property rather than by use of highly variable cell surface markers.
  - Flexible modular Gateway cloning technology allows constructs with alternative reporters to be readily generated.
  - Approach is independent of cell-of-origin of tumor.
  - Cancer stem cell behavior can be monitored in real-time.

Development Stage:
- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

Inventors: Lalage Wakefield and Binwu Tang (NCI).

Publication: Manuscript under review. Text available on request.


Licensor: The National Cancer Institute, Laboratory of Cancer Biology and Genetics, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize a cancer stem cell reporter construct for use in drug screens and therapy selection. For collaboration opportunities, please contact John D. Hewes, Ph.D. at hewes@nih.gov.

AAV-Aquaporin-1 Gene Therapy for Sjögren's Syndrome

Description of Technology: Sjögren’s syndrome is a chronic inflammatory disease affecting over 2 million Americans, whereby moisture-producing glands are attacked by the body’s immune system. The disease is marked by disabling dryness of the mouth and eyes as well as fatigue and pain. Researchers at the National Institute of Dental and Craniofacial Research have developed a therapy that alleviates xerostomia in an animal model of Sjögren’s syndrome. This technology consists of local delivery of adeno-associated virus (AAV) mediated aquaporin-1 (AQPI) fusion protein to salivary glands. Using a murine model that mimics Sjögren’s dry mouth symptoms, it was discovered that treatment restored salivary fluid movement upon expression of AQPI. Targeted delivery of the AAV–AQPI system makes this invention a novel and potential long-term therapeutic for restoration of exocrine gland function and prevention of xerostomia-associated pain associated with Sjögren’s syndrome.

Potential Commercial Applications:
- Prevention of dry mouth (xerostomia) associated with salivary gland dysfunction in patients with Sjögren’s syndrome.

Competitive Advantages:
- AAV gene transfer to salivary glands is highly efficient.
- AAV–AQPI promotes de novo salivary flow.

Development Stage:
- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

Inventor: John (Jay) Chiorini (NIDCR).


Related Technologies:

Licencing Contact: Vince Contreras, Ph.D.; 301–435–4711; vince.contreras@nih.gov.

Collaborative Research Opportunity: The National Institute of Dental and Craniofacial Research, AAV Biology Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize AAV-Aquaporin-1 Gene Therapy for Sjögren’s. For collaboration opportunities, please contact David Bradley at bradleyda@nidcr.nih.gov.