

claiming rights worldwide, as provided below (websites for patent application publications are included).

Patents and patent applications for the aminoflavone compounds, entitled "5-Aminoflavone Derivative," consist of:

1. U.S. Patent No. 5,539,112 (issued 07/23/1996), (<http://patft.uspto.gov/netaagi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1=5539112.WKU.&OS=PN/5539112&RS=PN/5539112>);

2. European Patent No. 0638566 (issued 01/07/1999 and validated in GB, DE, FR, ES and IT), (<http://v3.espacenet.com/textdoc?DB=EPODOC&IDX=EP0638566&F=0>);

3. Canadian Patent Application No. 2129813 (filed 08/09/1994), ([http://patents1.ic.gc.ca/details?patent\\_number=2129813&language=EN](http://patents1.ic.gc.ca/details?patent_number=2129813&language=EN)).

Patents and patent applications for the aminoflavone prodrug, entitled "Aminoflavone Compounds, Compositions, and Methods of Use Thereof," consist of:

1. U.S. Patent No. 6,812,246 (issued 11/02/2004), (<http://patft.uspto.gov/netaagi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1=6812246.WKU.&OS=PN/6812246&RS=PN/6812246>);

2. European Patent Application No. 01923228.9 (filed April 6, 2001, now allowed and validated in GB, DE, FR, IT, ES, LU, BE, CH, and IE), (<http://v3.espacenet.com/textdoc?DB=EPODOC&IDX=US2004019227&F=0>);

3. Canada Patent Application No. 2405747 (filed April 6, 2001), ([http://patents1.ic.gc.ca/details?patent\\_number=2405747&language=EN](http://patents1.ic.gc.ca/details?patent_number=2405747&language=EN));

4. Australia Patent Application No. 2001249940 (filed April 6, 2001), (<http://apa.hpa.com.au:8080/ipapa/view?hit=1&page=1>).

*Licensing and Cooperative Research and Development Agreement Opportunity:* The National Cancer Institute (NCI) seeks a collaborator to co-develop the aminoflavone pro-drug (AFP-464) for clinical use. A Cooperative Research and Development Agreement (CRADA) is the anticipated collaborative agreement to be entered into with NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of April 10, 1987, as amended. A CRADA is an agreement designed to enable certain collaborations between Government laboratories and non-Government

laboratories. A CRADA is not a grant, and it is not a contract for the procurement of goods/services. The NCI is prohibited from transferring funds to a CRADA collaborator. Under a CRADA, NCI can contribute facilities, staff, materials, and expertise. The CRADA collaborator can contribute facilities, staff, materials, expertise, and funds. The CRADA collaborator will also have an option to negotiate the terms of an exclusive or non-exclusive commercialization license to subject inventions arising under the CRADA. The goals of the CRADA include the rapid publication of research results and timely commercialization of products, diagnostics, and treatments that result from the research. Licensing the above patent rights will be necessary to commercialize AFP-464 if clinical trials results are favorable. It is expected that a licensee to the above patent rights will become the NCI CRADA collaborator in the clinical development of AFP-464.

Those interested in this CRADA opportunity should prepare a confidential proposal and submit it to the NCI Technology Transfer Branch. Preference will be given to proposals received by the NCI within thirty days of publication of this announcement. Selection criteria for choosing the CRADA Collaborator shall include, but not be limited to: 1. Demonstrated expertise and success in clinical development of anti-cancer agents; 2. possession of the resources needed to support and perform the research and development activities to develop AFP-464 (e.g. facilities, personnel and expertise); 3. the ability to provide financial support for the CRADA-related Government activities; 4. the demonstration of the necessary resources to produce and supply formulated AFP-464 for all clinical trials in a timely manner; 5. the willingness to cooperate with the NCI in the timely publication of research results; 6. the willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any; and 7. the agreement to be bound by the appropriate HHS regulations relating to human subjects.

Dated: July 15, 2005.

**Steven M. Ferguson,**

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

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**BILLING CODE 4140-01-U**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

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

**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. 207 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.

**ADDRESSES:** 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.

#### Standardizing Criteria on Cancer Biomarkers as Foundation of a Database: Creating a Common Language (Data Elements) for Cancer Biomarkers Tracking and Utilization for Professionals in Oncology Research

Mahin Khatami (NCI)

HHS Reference No. E-147-2005/0—  
Research Tool

*Licensing Contact:* Michelle A. Booden;  
(301) 451-7337;  
[boodenm@mail.nih.gov](mailto:boodenm@mail.nih.gov).

Cancer biomarkers (CBs) are important biological tools in modern oncology research for diagnosis, prognosis, prevention, therapy and outcome. Biological characters of biomarkers are as diversified as their utilization potentials. Biomarkers may be proteins/peptides, glycoproteins, lipids, glycolipids, antigens/antibodies, cytokines/chemokines, receptors, enzymes, inhibitors, nutrients/metabolites, DNA/RNA mutations, etc. CBs are found in blood/serum, urine, other biological fluids, and/or tissue specimen.

The NCI has identified a common set of data elements or criteria to describe a large number of cancer biomarkers. These data elements may be used as a foundation for a cancer biomarker

database to track a wide range of data on biomarkers. Generic data elements selected by the NCI will be incorporated into a database and a set of elements will be chosen to tailor for specific markers for suitability and utilization.

The database may be further developed and improved by creation of a web accessible interface providing guidance on how to access a marker of choice according to relevant set of data elements from the foundation; e.g., data elements that best define the marker for specific clinical utilization. Addition and identification of suitable markers within the database and tailoring of data elements could be accomplished by recommendation of a review panel of experts for suitability and/or utilization of selected markers. Marker data will be updated by individual investigators or by a database administrator as additional pertinent information becomes available in the literature on specific marker.

A fully enabled database would allow professionals within industry, research and clinical centers to easily access, retrieve and study the state of technology of a specific biomarker at a point of need. Standardization and proper evaluation and packaging of relevant integrated data on cancer biomarkers into a central database should eventually account for characteristics of an individual's state of health that will not only lead to improved detection of cancer, but also to better prevention and treatment of cancer. Access to archived data will direct industry to better assess the need for development of technologies dependent upon knowledge of the markers and may enhance communication among professionals by enabling them to correspond using a common vocabulary of standardized data elements for biomarkers by referring to the data elements that is the foundation of the database.

In order to facilitate the rapid adaptation of the biomarker database, the NCI inventors would be interested in collaborating with qualified commercial entities to develop the technology (software) under terms of a Cooperative Research and Development Agreement (CRADA).

#### Use of 8-C1-cAMP as Anticancer Drug

Yoon S. Cho-Chung (NCI)

U.S. Patent No. 5,792,752 issued 11 Aug 1998 (HHS Reference No. E-132-1988/0-US-05)

U.S. Patent No. 5,902,794 issued 11 May 1999 (HHS Reference No. E-132-1988/0-US-06)

*Licensing Contact:* Michelle A. Booden; (301) 451-7337; [boodenm@mail.nih.gov](mailto:boodenm@mail.nih.gov).

Site-selective cAMP analogues that preferentially bind and activate PKA-I or PKA-II exhibit specificity not mimicked by parental cAMP. These analogues demonstrate a synergism of binding in appropriate combinations. 8-Cl-cAMP, which belongs to the ISD (isozyme site discriminator) class of site-selective cAMP analogues, activates and down-regulates PKA-I, but not PKA-II, by binding to both site A and B of RI and to site B of RII. 8-Cl-cAMP inhibits growth, in vitro and in vivo, in a broad spectrum of human carcinoma, fibrosarcoma, and leukemia cell lines without causing cytotoxicity. The growth-inhibitory effect of 8-Cl-cAMP correlates with the down-regulation of RI, the up-regulation of RII, and the suppression of c-myc and c-ras oncogene expression.

8-Cl-cAMP is a promising cancer chemotherapeutic agent that in preclinical studies can reverse the transformed phenotype of, and induce apoptotic cell death in, human cancer cells. Results of a Phase I clinical trial suggest that effective plasma levels (determined in preclinical studies) of 8-Cl-cAMP can be maintained below the maximum tolerated dose. More recently, the NCI has initiated and supported ongoing Phase I clinical trials of 8-Cl-cAMP for the treatment of colon cancer and multiple myeloma. The present invention provides compositions and methods for use of cAMP analogs, including 8-Cl-cAMP, as a therapeutic intervention for multiple human diseases.

This technology is available for licensing on an exclusive or a non-exclusive basis.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Dated: July 15, 2005.

**Steven M. Ferguson,**

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

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#### Adult Human Dental Pulp Stem Cells in vitro and in vivo

Dr. Songtao Shi *et al.* (NIDCR)

U.S. Patent Application No. 10/333,522 filed 17 Jan 2003 (HHS Reference No. E-233-2000/0-US-03), claiming priority to 21 Jul 2000.

*Licensing Contact:* Marlene Shinn-Astor; (301) 435-4426; [shinnm@mail.nih.gov](mailto:shinnm@mail.nih.gov).

Many individuals with ongoing and severe dental problems are faced with the prospect of permanent tooth loss. Examples include dentinal degradation due to caries or periodontal disease; (accidental) injury to the mouth; and surgical removal of teeth due to tumors associated with the jaw. Clearly, a technology that offers a possible alternative to artificial dentures by designing and transplanting a set of living teeth fashioned from the patient's own pulp cells would greatly improve the individual's quality of life.

The NIH announces a new technology wherein dental pulp stem cells from an individual's own postnatal dental pulp tissue (one or two wisdom teeth) can potentially be used to engineer healthy living teeth. This technology is based upon the discovery of a subpopulation of cells within normal human dental