

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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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

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

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

**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.

#### 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

pulp tissue that has the ability to grow and proliferate in vitro. These (dental pulp) stem cells can be induced under defined culture conditions to form calcified nodules in vitro and have been shown to differentiate into a dentin/pulp like structure in vivo.

#### Postnatal Stem Cells and Uses Thereof

Drs. Songtao Shi and Pamela Robey (NIDCR)

PCT Application No. PCT/US03/12276 filed 19 Apr 2003 (HHS Reference No. E-018-2003/0-PCT-01), which published as WO 2004/094588 A2 on 04 Nov 2004.

*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 of such dental problems include: Dentinal degradation due to chronic dental disease (caries or periodontal); mouth injury; or through surgical removal, such as with tumors associated with the jaw. For many, a technology that offers a possible alternative to artificial dentures by designing and transplanting a set of living teeth fashioned from an individual's own pulp cells would greatly improve their quality of life.

The NIH announces a new technology wherein human postnatal deciduous dental pulp stem cells commonly known as "baby teeth", are used to create dentin and have been shown to differentiate into cells of specialized function such as neural cells, adipocytes, and odontoblasts. It is believed that these cells could be manipulated to repair damaged teeth, induce the regeneration of bone, and treat neural injury or disease.

This research is described, in part, in Miura *et al.*, "SHED: Stem cells from human exfoliated deciduous teeth," Proc. Natl. Acad. Sci. USA, vol. 100 (no. 10; May 13, 2003) pp. 5807-5812.

#### Multipotent Postnatal Stem Cells From Human Periodontal Ligament and Uses Thereof

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

PCT Application No. PCT/US04/39248 filed 22 Nov 2004 (HHS Reference No. E-033-2004/0-PCT-02), claiming priority to 20 Nov 2003.

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

It is estimated that over 40 percent of the adult population in the United States has periodontal disease in one form or another. Periodontal Disease is a chronic infection of the periodontal

ligament (PDL) and the adjacent bone and cementum. The effects of Periodontal Disease range from simple gum inflammation to, in extreme cases, tooth loss.

The NIH announces a new technology wherein stem cells from the PDL have been isolated from adult human PDL. These cells are capable of forming cementum and PDL in immunocompromised mice. In cell culture, PDL stem cells differentiate into collagen fiber forming cells (fibroblasts), cementoblasts, and adipocytes. It is anticipated that these PDL stem cells will be useful for periodontal tissue regeneration to treat periodontal disease.

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**Steven M. Ferguson,**

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

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#### Cloning of a Genomic DNA Fragment Containing the Guinea Pig CXCR1 Gene, a Specific Receptor for Guinea Pig Interleukin-8

Teizo Yoshimura (NCI)

HHS Reference No. E-242-2005/0—Research Tool

*Licensing Contact:* Jesse S. Kindra; (301) 435-5559; [kindraj@mail.nih.gov](mailto:kindraj@mail.nih.gov).

The present invention relates to cloning of a genomic DNA fragment containing the guinea pig CXCR1 gene, a specific receptor for guinea pig interleukin-8 (IL-8).

More specifically, the IL-8-CXCR1 axis is a major chemokine-chemokine receptor system that regulates the recruitment of neutrophils into sites of inflammation. In this invention, the inventors cloned a genomic DNA clone containing the gene for guinea pig IL-8 receptor CXCR1. Mice and rats are the most commonly used small animals to examine the efficacy of drugs developed for human use. However, neither IL-8 nor CXCR1, a specific receptor for IL-8, is present in these animals, making it impossible to use them as a model to test the effects of IL-8 or CXCR1 antagonists. Identification of CXCR1, along with IL-8, in the guinea pig may enable evaluation of the in vivo effects of the antagonists.

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

#### Anti-CD30 Antibodies That Bind To Intact CD30 but not to Soluble CD30

Satoshi Nagata and Ira Pastan (NCI) U.S. Provisional Application No. 60/681,929 filed 16 May 2005 (HHS Reference No. E-208-2005/0-US-01), *Licensing Contact:* Jesse S. Kindra; (301) 435-5559; [kindraj@mail.nih.gov](mailto:kindraj@mail.nih.gov).

Human CD30 is a promising target for cancer immunotherapy since CD30 is highly expressed in Hodgkin's disease and anaplastic large-cell lymphoma. However, soluble CD30, the extracellular domain of CD30 that is shed from the cells, can reduce the effects of CD30-targeting agents by competitive binding.

This invention is the first successful attempt of producing CD30-targeting agents without the disadvantage of the reducing effects caused by soluble CD30. More specifically, two (2) epitopes on membrane-associated CD30 have been identified that are missing on soluble CD30. These epitopes are potentially superior targets for immunotherapy since targeting the epitopes should be free from the competitive effects of soluble CD30. Accordingly, the antibodies described in this invention may be used as targeting reagents for cancer therapy.

In addition to licensing, the technology is available for further