

**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.

**Inhibitors of 6-hydroxymethyl-7,8-dihydropterin Pyrophosphokinase as Novel Antibiotics**

*Description of Invention:* The invention offered for licensing describes and claims novel inhibitors of 6-hydroxymethyl-7,8-dihydropterin pyrophosphokinase (HPPK), a key enzyme in the folate biosynthetic pathway which is essential for microorganisms but absent in mammals. These novel inhibitors are based on linked purine pterin compounds. They can disrupt the folate biosynthesis of bacteria and thus can find utility as potential antimicrobials. Antibiotics based on these lead molecules can be specifically designed and synthesized to serve as broad-spectrum or narrow-spectrum antibiotics. None of the currently established antibiotics target HPPK.

*Applications:*

- Antimicrobial agents.
- Use in anti-bioterrorism.

*Advantages:*

- Potential as broad-spectrum or narrow-spectrum antibiotics.
- The antibiotics of present invention target a new biological pathway that has not been targeted by existing antibiotics, and thus circumvent issues related to drug resistance.

*Inventors:* Genbin Shi, Gary Shaw, Xinhua Ji (NCI).

*Patent Status:* U.S. Provisional Application No. 61/356,213 filed 18 Jun 2010 (HHS Reference No. E-170-2010/0-US-01).

*Relevant Publications:*

1. Blaszczyk J, Shi G, Li Y, Yan H, Ji X. Reaction trajectory of pyrophosphoryl transfer catalyzed by 6-hydroxymethyl-7,8-dihydropterin pyrophosphokinase. *Structure* 2004 Mar;12(3):467-475. [PubMed: 15016362].

2. Blaszczyk J, Shi G, Yan H, Ji X. Catalytic center assembly of HPPK as revealed by the crystal structure of a ternary complex at 1.25Å resolution. *Structure* 2000 Oct 15; 8(10):1049-1058. [PubMed: 11080626].

3. Wood HCS. 1975. Specific inhibition of dihydrofolate biosynthesis—a new approach to chemotherapy. *Chemistry and Biology of Pteridines*, W. Pfeleiderer, ed. (Berlin-New York: Walter de Gruyter).

*Licensing Status:* Available for licensing.

*Licensing Contacts:*

- Uri Reichman, Ph.D., MBA; 301-435-4616; [UR7a@nih.gov](mailto:UR7a@nih.gov).
- John Stansberry, Ph.D.; 301-435-5236; [js852e@nih.gov](mailto:js852e@nih.gov).

*Collaborative Research Opportunity:* The National Cancer Institute, Biomolecular Structure Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the inhibitors of HPPK as novel antibiotics. Please contact John Hewes, PhD at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

**Compositions and Methods for the Treatment of Cancer**

*Description of Invention:* Cancer is the second leading cause of human death next to coronary disease in the United States. Worldwide, millions of people die from cancer every year. In the United States alone, as reported by the American Cancer Society, cancer causes the death of well over a half-million people annually, with over 1.2 million new cases diagnosed per year. While deaths from heart disease have been declining significantly, those resulting from cancer generally are on the rise. Cancer is soon predicted to become the leading cause of death in the United States.

This application claims methods for inducing an immune response to a tumor. These methods include administering a therapeutically effective amount of apoptotic tumor cells conjugated to a K-type CpG

oligodeoxynucleotide (ODN) to a subject. Methods for treating a tumor in a subject are also claimed in this application. These methods include administering a therapeutically effective amount of apoptotic tumor cells conjugated to a K-type CpG oligodeoxynucleotide (ODN) to a subject. More specifically, the tumor cells may be autologous, and the tumor may be a lymphoma, cervical cancer, prostate cancer, breast cancer, colon cancer, or a lung cancer.

*Applications:*

- Vaccines for the prevention of cancer and other indications
- Use of CpG oligonucleotides for prophylaxis and/or therapy

*Advantages:*

- Novel vaccine candidates
- Increased immunogenicity

*Development Status:* Preclinical studies have been conducted by the inventors.

*Inventors:* Dennis M. Klinman and Hidekazu Shirota (NCI).

*Patent Status:* U.S. Provisional Application No. 61/309,802 filed 02 Mar 2010 (HHS Reference No. E-266-2009/0-US-01).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Peter A. Soukas; 301-435-4646; [soukasp@mail.nih.gov](mailto:soukasp@mail.nih.gov).

*Collaborative Research Opportunity:* The Center for Cancer Research, Laboratory of Experimental Immunology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John Hewes, Ph.D. at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

Dated: September 27, 2010.

**Richard U. Rodriguez,**

*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****Food and Drug Administration**

[Docket No. FDA-2007-N-0270]

**Medical Device User Fee and Modernization Act; Notice to Public of Web site Location of Fiscal Year 2011 Proposed Guidance Development**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.