targeting even though the adduct is systemically administered and nitric oxide release is spontaneous.

Selective Prevention of Organ Injury in Sepsis and Shock Using Selective Release of Nitric Oxide in Vulnerable Organs

JF Saavedra, TR Billiar, LK Keefer (NCI)
Serial No. 08/509,558 filed 31 Jul 95

The invention provides a method of treating mammalian tissue which is injured or is at risk of injury during sepsis or shock, including septic shock, hemorrhagic stock, and cardiogenic shock. In the suggested method, nitric oxide is delivered to target tissue or cells in a controlled and predictable manner through the administration of a nitric oxide containing compound (diazeniumdiolate) which is protected from the systemic release of nitric oxide under physiological conditions, and/or that is concentrated in at risk organs before releasing its nitric oxide. The diazeniumdiolate is capable of releasing at the targeted tissue a therapeutically effective amount of nitric oxide, sufficient to protect tissue from sepsis or shock-induced injury.

O^2-aryl Substituted Diazeniumdiolates

JE Saavedra, A Srinivasan, LK Keefer (NCI)
Serial No. 60/026,816 filed 27 Sep 96

Diazeniumdiolates, wherein the N^1 position is substituted by an organic moiety and the O^2-oxygen is bound to a substituted or unsubstituted aromatic group, are provided. The O^2-aryl diazeniumdiolates are stable with respect to the hydrolytic generation of nitric oxide in neutral to acidic solutions. These novel compounds generate nitric oxide in basic or nucleophilic environments or microenvironments. Also provided are compositions, including pharmaceutical compositions, comprising such compounds and methods of using such compounds.

Encapsulated and Non-Encapsulated Nitric Oxide Generators Used as Antimicrobial Agents

SJ Green, LK Keefer (NCI)
Serial No. 08/428,632 filed 24 Apr 95

This invention relates to compositions capable of releasing nitric oxide and therapeutic methods of use thereof for the treatment of microorganism-related disease states. The composition comprises one or more nitric oxide generators, preferably encapsulated in vesicles, such as liposomes. The compositions are used therapeutically by administration to humans and animals via different routes for the treatment of infectious diseases caused by pathogenic microbes.

Dated: August 4, 1997.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 97–21149 Filed 8–8–97; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: New Brefeldin a Derivatives

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

ACTION: Notice.

SUMMARY: This is 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 (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive world-wide license to practice the inventions embodied in U.S. Patent Application Serial Number 08/267,525, entitled ''New Brefeldin A Derivatives And Their Utility In The Treatment Of Cancer,'' and corresponding U.S. and foreign patent applications to Allelix Biopharmaceuticals, Inc. of Mississauga, Ontario, Canada. The patent rights of the NIH inventors in these inventions have been assigned to the United States of America.

DATES: Only written comments and/or applications for a license which are received by NIH on or before October 10, 1997, will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments and other materials relating to the contemplated licenses should be directed to: Raphe Kantor, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; Telephone: (301) 496–7056 ext. 247; Facsimile: (301) 402–0220. A signed Confidentiality Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: This invention relates to a new class of compounds which can be characterized as breveldin A derivatives, e.g., 4-O-(N,N-dimethylglycyl) breveldin A; 7-O-(N-N-dimethylglycyl) breveldin A. These breveldin A analogs are more water soluble than the parent compound. These analogs appear to have reduced toxicities which limited the clinical utility of the parent compound. These compounds exhibit activity against a wide variety of cancers, including colon cancer, melanoma, leukemia, ovarian, prostate, breast and renal tumors. However, recently performed toxicity studies on one breveldin A analog (breflate) found that it still retained an unacceptable toxicity profile.

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, 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 filed in response to this notice will be treated as objections to the grant of the contemplated licenses. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 1, 1997.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 97–21093 Filed 8–8–97; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Diagnostic Methods Derived From the Human Metastasis Suppressor Gene KAI1

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

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 world-wide license to practice the inventions embodied in U.S. Patent Applications SN 08/430,225 and corresponding foreign patent applications entitled, ''Diagnostic Methods and Gene Therapy Using Reagents Derived From the Human Metastasis Suppressor Gene KAI1'' to Centocor, Inc. of Malvern, PA. The patent rights in these inventions have been assigned to the United States of

America and Johns Hopkins University. The prospective exclusive license field of use may be limited to: The use of KAI1 monoclonal antibodies in the diagnostic/prognostic fields of use for prostate cancer.

DATES: Only written comments and/or applications for a license which are received by NIH on or before October 10, 1997.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments and other materials relating to the contemplated licenses should be directed to: Joseph K. Hemby, Jr., J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; Telephone: (301) 496-7735 ext. 265; Facsimile: (301) 402-0220. A signed Confidentiality Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: 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, 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.

The invention relates to the KAI1 gene which has been shown to suppress metastasis of prostate cancer and is down regulated in human malignant prostate cancers. The invention further provides methods of detection of alterations in the wild-type KAI1 gene sequence, KAI1 mRNA, and KAI1 protein useful in determining the presence of malignant cancer in a subject or genetic predisposition to malignancy in a subject. Other uses of the KAI1 gene include the possible treatment of patients who are diagnosed with early stage prostate cancer.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated licenses. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 18, 1997.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 97–21094 Filed 8–8–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of Draft Recovery Plan for the Inyo California Towhee of the Southern Argus Range, Inyo County, California, for Review and Comment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability.

SUMMARY: The U.S. Fish and Wildlife Service announces the availability for public review of a draft recovery plan for the threatened Inyo California towhee. The Service solicits review and comment from the public on this draft recovery plan.

DATES: Comments on the draft recovery plan must be received on or before October 10, 1997.

ADDRESSES: A copy of the draft recovery plan can be obtained from the Fish and Wildlife Service's Ventura Fish and Wildlife Office, 2493 Portola Road, Suite B, Ventura, California, 93003, phone 805/644–1766. Written comments and materials regarding the plan should be addressed to the Field Supervisor at the Ventura Fish and Wildlife Office. Comments and materials received are available on request for public inspection by appointment at the Ventura Fish and Wildlife Office.

FOR FURTHER INFORMATION CONTACT: Robert Mesta in the Ventura Fish and Wildlife Office (see **ADDRESSES** section).

SUPPLEMENTARY INFORMATION:

Background

Restoring an endangered or threatened animal or plant to the point where it is again a secure, self-sustaining member of its ecosystem is a primary goal of the U.S. Fish and Wildlife Service's endangered species program. To help guide recovery efforts, the Service prepares recovery plans for most of the listed species native to the United States. Recovery plans describe actions considered necessary for conservation of listed species, establish criteria for the recovery levels for reclassification from endangered to threatened or removal from the list, and estimate the time and cost for implementing the needed recovery measures.

The Endangered Species Act of 1973 (Act), as amended (16 U.S.C. 1531 *et seq.*) requires the development of recovery plans for listed species unless such a plan would not promote the conservation of a particular species. Section 4(f) of the Act, as amended in 1988, requires that public notice and an opportunity for public review and comment be provided during recovery plan development. The Service will consider all information presented during a public comment period prior to approval of each new or revised recovery plan. The Service and other Federal agencies will take these comments into account in the course of implementing approved recovery plans.

Inyo California towhees are restricted in range and number and therefore, are susceptible to habitat destruction and degradation. The recovery strategy for this subspecies will focus on the elimination of threats to all known habitats and the rehabilitation of those that have been degraded or destroyed. The draft recovery plan describes tasks that, when accomplished, should ensure the continued existence of the Inyo California towhee, and thereby justify its removal from the endangered and threatened species list. The draft recovery plan was developed in cooperation with the principle affected agencies: California Department of Fish and Game, Bureau of Land Management, and the Navy.

Public Comments Solicited

The Service solicits written comments on the draft recovery plan described herein. All comments received by the date specified above will be considered prior to approval of the plan.

Authority: The authority for this action is section 4(f) of the Endangered Species Act, 16 U.S.C. 1533(f).

Dated: June 17, 1997.

Thomas J. Dwyer,

Acting Regional Director.

[FR Doc. 97–21095 Filed 8–8–97; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of an Environmental Assessment and Receipt of an Application for an Incidental Take Permit for the Cantara Residential Project in the City of Colton, San Bernardino County, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: The Fish and Wildlife Service has under consideration a proposal to issue an 8-year permit pursuant to the Endangered Species Act of 1973, as amended (Act), that would authorize incidental taking of the endangered Delhi Sands flower-loving fly (*Rhaphiomidas terminatus*