

and objections submitted in response 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 19, 2005.

Steven M. Ferguson,

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

[FR Doc. 05-15343 Filed 8-2-05; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive License: Therapeutics for the Treatment of Kidney Cancer and Thyroid Neoplasms

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

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), announces that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in

1. E-199-2002/0-US-01, "Treatment Method and Therapeutic Agent of Kidney Cancer", by Susan Bates, and Yoshinori Naoe, Pat. Application No. 60/369,868 (filing date April 5, 2002);

2. E-199-2002/0-PCT-02, "Treatment Method and Therapeutic Agent of Kidney Cancer", by Susan Bates, and Yoshinori Naoe, Pat. Application No. PCT/US03/03823 (filing date March 27, 2003);

3. E-199-2002/0-US-04, "Depsipeptide for Therapy of Kidney Cancer", by Susan Bates, and Yoshinori Naoe, Pat. Application No. 10/508,958 (filing date October 5, 2004);

4. E-199-2002/0-JP-08, "Depsipeptide for Therapy of Kidney Cancer", by Susan Bates, and Yoshinori Naoe, Pat. Application No. 20003581847 (filing date October 5, 2004);

5. E-199-2002/0-EP-05, "Depsipeptide for Therapy of Kidney Cancer", by Susan Bates, and Yoshinori Naoe, Pat. Application No. 037155033-2107 (filing date October 8, 2004);

6. E-286-2000/0-US-01, "Histone Deacetylase Inhibitors in Diagnosis and Treatment of Thyroid Neoplasms", by Tito Fojo and Susan Bates, Pat. Application No. 60/260,733 (filing date January 10, 2001);

7. E-286-2000/0-US-02, "Histone Deacetylase Inhibitors in Diagnosis and Treatment of Thyroid Neoplasms", by Tito Fojo and Susan Bates, Pat. Application No. PCT/US02/0714 (filing date January 9, 2001);

8. E-286-2000/0-EP-03, "Histone Deacetylase Inhibitors in Diagnosis and Treatment of Thyroid Neoplasms", by Tito Fojo and Susan Bates, Pat. Application No. 02718823.4 (filing date January 9, 2001);

9. E-286-2000/0-AU-04, "Histone Deacetylase Inhibitors in Diagnosis and Treatment of Thyroid Neoplasms", by Tito Fojo and Susan Bates, Pat. Application No. 2002249938 (filing date January 9, 2001);

10. E-286-2000/0-CA-04, "Histone Deacetylase Inhibitors in Diagnosis and Treatment of Thyroid Neoplasms", by Tito Fojo and Susan Bates, Pat. Application No. 2434269 (filing date January 9, 2001);

11. E-286-2000/0-US-07, "Histone Deacetylase Inhibitors in Diagnosis and Treatment of Thyroid Neoplasms", by Tito Fojo and Susan Bates, Pat. Application No. 10/250,320 (filing date June 26, 2003);

12. E-286-2000/0-JP-05, "Histone Deacetylase Inhibitors in Diagnosis and Treatment of Thyroid Neoplasms", by Tito Fojo and Susan Bates, Pat. Application No. 2002-556736 (filing date July 10, 2003)

to Gloucester Pharmaceuticals, having a place of business in Cambridge, MA. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to therapeutics for the treatment of Kidney Cancer and Thyroid Neoplasms.

DATES: Only written comments and/or license applications which are received by the National Institutes of Health on or before October 3, 2005 will be considered.

ADDRESSES: Requests for copies of the patent and/or patent applications, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: John Stansberry, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5236; Facsimile: (301) 402-0220; E-mail: stansbej@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The inventions describe methods of treating kidney cancer and thyroid neoplasms

with FK228, which is a histone deacetylase (HDAC) inhibitor. FK228 is currently in Phase II clinical trials, and has been shown to inhibit histone deacetylation, a process instrumental in the regulation of gene expression. FK228 modulates cell cycle arrest and can promote differentiation and apoptosis. To date, FK228 has been administered to more than 300 patients and has shown promising clinical activity in Phase II trials for patients with cutaneous T-cell lymphoma (CTCL). Clinical responses have also been observed in Phase II studies in peripheral T-cell lymphoma, renal cell carcinoma (RCC) and hormone refractory prostate cancer (HRPC).

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, the NIH receives written evidence and argument that establish 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 in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. 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 26, 2005.

Steven M. Ferguson,

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

[FR Doc. 05-15345 Filed 8-2-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive License: Anti-Cancer Vaccines

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

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), announces that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Patent

Application No. 60/498,238, filed August 26, 2003, entitled "Anti-cancer Vaccines" (E-179-2004/0-US-01); U.S. Patent Application No. 10/926,852, filed August 26, 2004, entitled "Anti-cancer Vaccines" (E-179-2004/0-US-03); and PCT Application No. PCT/US04/27790, filed August 26, 2004, entitled "Anti-cancer Vaccines" (E-179-2004/0-PCT-02), to Vaccine Company, having a place of business in Carmel-by-the-Sea, California. The patent rights in these inventions have been assigned to the United States of America and MD Anderson Cancer Center (Part of the University of Texas System).

The prospective exclusive license territory may be worldwide, and the field of use may be limited to development and sale of diagnostic and pharmaceutical products useful in diagnosis and treatment of myeloid neoplasms.

DATES: Only written comments and/or license applications which are received by the National Institutes of Health on or before October 3, 2005 will be considered.

ADDRESSES: Requests for copies of the patent and/or patent applications, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Mojdeh Bahar, J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-2950; Facsimile: (301) 402-0220; E-mail: baharm@od.nih.gov.

SUPPLEMENTARY INFORMATION: This technology is directed to the use of tumor-associated HLA-restricted antigens (peptides from proteinase-3 or myeloperoxidase) as vaccines for treating or preventing cancer, autoimmune diseases and transplant rejection. The technology is more specifically directed to the use of peptides, such as PR1, derived from proteinase-3 (a myeloid tissue-restricted protein) as vaccine to elicit PR1-specific cytotoxic T lymphocytes. The technology encompasses the use of PR1 and other peptides in the treatment of acute and chronic myelogenous leukemia (AML & CML), and myelodysplastic syndrome. Such treatment could result in prolonged remissions or cure in patients who are otherwise refractive to treatment.

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, the NIH receives

written evidence and argument that establish 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 in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. 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 26, 2005.

Steven M. Ferguson,

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

[FR Doc. 05-15344 Filed 8-2-05; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA-1597-DR]

North Dakota; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of North Dakota (FEMA-1597-DR), dated July 22, 2005, and related determinations.

DATES: Effective July 22, 2005.

FOR FURTHER INFORMATION CONTACT:

Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated July 22, 2005, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (the Stafford Act), as follows:

I have determined that the damage in certain areas of the State of North Dakota, resulting from severe storms, flooding, and ground saturation beginning on June 1, 2005, through July 7, 2005, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (the Stafford Act). Therefore, I declare that such a major disaster exists in the State of North Dakota.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas; Hazard Mitigation throughout the State; and any other forms of assistance under the Stafford Act you may deem appropriate. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs. If Other Needs Assistance under Section 408 of the Stafford Act is later requested and warranted, Federal funding under that program will also be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Anthony Russell, of FEMA is appointed to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of North Dakota to have been affected adversely by this declared major disaster:

Benson, Bottineau, Cavalier, Dickey, Grand Forks, Griggs, Kidder, LaMoure, McHenry, Nelson, Pierce, Ramsey, Richland, Sargent, Sioux, Stark, Steele, Traill, Walsh, and Ward Counties, and the Turtle Mountain Indian Reservation, and the portion of the Standing Rock Indian Reservation which lies within the State of North Dakota for Public Assistance.

All counties and Indian Reservations in the State of North Dakota are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program-Other Needs; 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

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