

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Opportunity for Licensing: Vasostatin, an Inhibitor of Endothelial Cell Growth and Angiogenesis

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

ACTION: Notice.

SUMMARY: The National Institute of Health (NIH), Public Health Service (PHS), Department of Health and Human Services (DHHS), seeks licensee(s) to develop a therapeutic anti-angiogenic agent(s) that would be effective in the treatment of a variety of disease states, in particular, cancer. Scientists at the Food and Drug Administration (FDA) have isolated at NH₂-terminal fragment (1–180 a.a.), vasostatin, from calreticulins which can inhibit endothelial cell proliferation in vitro, suppress neovascularization in vivo and prevent or reduce growth of experimental tumors while having minimal effect on other cell types. Vasostatin is the most conserved domain among calreticulins so far cloned and has no homology to other protein sequences. Data suggests that the antitumor effects of vasostatin are related to inhibition of new blood vessel formation rather than a detrimental effect on established tumor vasculature.

The NIH seeks licensee(s), who in accordance with requirements and regulations governing the licensing of government-owned inventions (37 CFR § 404), has the most meritorious plan for the development of a therapeutic agent(s) to meet the needs of the public and with the best terms for the government. NIH intends to grant the selected firm(s) a world-wide royalty-bearing license(s) to practice the inventions embodied in USSN 60/103,438 from Dr. Giovanna Tosato and Dr. Sandra Pike entitled "Use of Calreticulin and Calreticulin Fragments to Inhibit Endothelial Cell Growth and Angiogenesis, and Suppress Tumor Growth" (DHHS Ref. No. E-082-98/0). The patent rights in these inventions have been assigned to the United States of America.

EFFECTIVE DATE: In view of the priority for developing new antitumor agents, all proposals for either exclusive or non-exclusive licensing must be received on or before September 17, 1999.

ADDRESSES: Licensing information, copy of the U.S. patent application referenced above or a copy of the NIH License Application may be obtained by contacting Richard U. Rodriguez,

M.B.A., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804 (telephone 301/496-7056 ext 287, fax 301/402-0220; and E-mail rr154z@nih.gov). A signed Confidential Disclosure Agreement is required to receive a copy of any patent application.

SUPPLEMENTARY INFORMATION: Vasostatin has key differences from other inhibitors of angiogenesis, for example, angiostatin, thrombospondin and endostatin. It is small, soluble, stable for greater than 9 months in aqueous solution and is easily produced and delivered. By comparison, angiostatin, endostatin and thrombospondin can be difficult to isolate, purify and deliver. Additionally, studies have shown that the effective dose of vasostatin is 4–10 fold lower than the effective doses of endostatin and angiostatin. Therefore, this new and potent and anti-angiogenic molecule should prove highly useful for the prevention and treatment of human disease states that involve mis-regulated endothelial cell proliferation and/or angiogenesis.

In addition to the criteria set forth in 37 CFR § 404.7(a)(1) (ii)–(iv), the NIH is particularly interested in the following capabilities:

1. Prior manufacturing experience for GMP (Good Manufacturing Practice) production of a therapeutic agent(s) and a production plan for said agent(s);
2. Experience in preclinical and clinical drug development;
3. Experience in the evaluation, monitoring and interpretation of data for investigational biologics under an IND;
4. Experience in the evaluation, monitoring and interpretation of data from Phase I and Phase II clinical studies;
5. Ability to produce, package, market and distribute pharmaceutical products in the United States;
6. Willingness to sustain the cost of vasostatin development as outlined above (i.e., bulk drug synthesis, data management, animal studies, clinical studies, etc.);
7. Agreement to be bound by DHHS rules involving human and animal studies; and
8. An aggressive development plan that includes appropriate milestones and deadlines for preclinical and clinical development and for marketing approval.

Dated: July 12, 1999.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

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BILLING CODE 4140-01-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10c of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*):

PRT-013804.

Applicant: Michael Barrett, Finley, California

The applicant requests a permit to import 4.3 Hawaiian goose (*Branta sandvicensis*), 1.1 Blyth's tragopan (*Tragopan blythii*), and 2.0 Cabot's tragopan (*Tragopan caboti*) from Qualicum Beach, British Columbia, Canada, for scientific research and enhancement of the survival of the species through captive propagation.

PRT-013176.

Applicant: University of New Mexico, Albuquerque, NM

The applicant request a permit to import wild and captive bred samples from chimpanzees (*Pan troglodytes*), bonobo chimpanzee (*Pan paniscus*), gorilla (*Gorilla gorilla*), and orangutan (*Pongo pygmaeus*) from various countries for the purpose of scientific research.

PRT-011201.

Applicant: Denver Museum of Natural History

The applicant requests a permit to import and re-export museum artifacts made by the indigenous peoples of Brazil that contain jaguar (*Panthera onca*) and harpy eagle (*Harpia harpyja*), for enhancement of survival of the species.

PRT-012019 and 012020.

Applicant: Hawthorn Corporation, Grayslake, IL

The applicant requests a permit to re-export and re-import wild Asian elephants (*Elephas maximus*) and progeny of the animals currently held by the applicant and any animals acquired in the United States by the applicant to/from worldwide locations to enhance the survival of the species through conservation education. This