The role of Merck & Co. under the CRADA will include the following:

1. Participate in the selection of the CRADA collaborator and in the development of the CRADA Research Plan.

2. Provide for the licensing of Merck intellectual property rights to the selected Collaborator as necessary for the clinical development and commercialization of CAI as an anticancer agent.

The role of the successful pharmaceutical company under the CRADA will include the following:

1. Provide plans to independently secure future continuing supplies of GMP produced and formulated material to assure continued collaborative clinical development of CAI.

2. Provide funds to supplement the clinical trials support contracts and offer any other necessary support to the NCI for continued collaborative clinical development of this compound. This includes both financial support as well as personnel for data management and clinical care.

3. Provide planning and support for clinical development leading to FDA approval for marketing.

Criteria for choosing the pharmaceutical company include its demonstrated experience and commitment to the following:

1. Experience in preclinical and clinical drug development.

2. Experience and ability to produce, package, market and distribute pharmaceutical products.

3. Experience in the monitoring, evaluation and interpretation of the data from investigational agent clinical studies under an IND.

4. A willingness to cooperate with the NCI in the collection, evaluation, publication and maintaining of data from clinical trials of investigational agents.

5. The provision of adequate quantities of GMP produced and formulated CAI as needed for clinical development of this agent for the specified field of use to be determined upon mutual agreement of the parties.

6. Provide defined financial and personnel support for the clinical trials to be mutually agreed upon.

7. An agreement to be bound by the DHHS rules involving human and animal subjects.

8. The aggressiveness of the development plan, including the appropriateness of milestones and deadlines for preclinical and clinical development.

9. Provisions for equitable distribution of patent rights to any inventions. Generally the rights of

ownership are retained by the organization which is the employer of the inventor, with (1) an irrevocable, nonexclusive, royalty-free license to the Government (when a company employee(s) is (are) the sole inventor(s)) or (2) an option to negotiate an exclusive or nonexclusive license to the company on terms that are appropriate (when the Government employee(s) is (are) the sole inventor(s) or where a joint invention arises).

Dated: April 13, 1995.

Thomas D. Mays,

Director, Office of Technology Development, OD, NCI.

[FR Doc. 95–10109 Filed 4–24–95; 8:45 am] BILLING CODE 4140–01–P

National Cancer Institute: Opportunity for a Cooperative Research and Development Agreement ("CRADA") for the Scientific and Commercial Development of Certain Signal Transduction Inhibitors as Anticancer Agents

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (DHHS) seeks a pharmaceutical company which can effectively pursue the preclinical development and possible eventual clinical development of a family of agents which inhibit the signal transduction pathways required for the growth and metastasis of cancer cells. The National Cancer Institute has preclinical data suggesting that these agents may have potential for the treatment and/or prevention of cancer. The selected sponsor will be awarded a CRADA for the co-development of these agents in a specified field of use to be determined upon mutual agreement of the parties.

ADDRESSES: Questions about this opportunity may be addressed to Mark W. Noel, Office of Technology Development, NCI, Building 31/Room 4A51, 9000 Rockville Pike, Bethesda, Maryland 20892, (301) 496–0477, facsimile (301) 402–2117, from whom further information including a summary copy of the preclinical data may be obtained.

DATES: In view of the important priority of developing new drugs for the treatment or prevention of cancer, interested parties should notify this office in writing no later than June 26, 1995. Respondents will then be provided an additional 60 days for the filing of formal proposals.

SUPPLEMENTARY INFORMATION:

"Cooperative Research and Development Agreement" or "CRADA" means the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of October 10, 1987 to collaborate on the specific research project described below.

The Government is seeking a pharmaceutical company which, in accordance with the requirements of the regulations governing the transfer of Government-developed agents (37 CFR 404.8), can develop the subject agents to a marketable status to meet the needs of the public and with the best terms for the Government. These agents are a novel, chemically-defined family of agents being investigated in the Laboratory of Pathology of the Division of Cancer Biology, Diagnosis and Centers, National Cancer Institute. These agents have been demonstrated to inhibit the signal transduction pathways required for the growth and metastasis of cancer cells and have shown promising antitumor activity in preclinical investigations. The majority of the agents which are the subject of the CRĂDA opportunity are the subject of patent U.S. Patent 5,359,078 which is assigned to the Dept. of Health and Human Services. A method for the detection and quantitation of the levels of these agents in blood is claimed in U.S. Patent 5,405,782 which is also assigned to the Dept. of Health and Human Services. The Cooperative **Research and Development Agreement** ("CRADA") will allow a pharmaceutical company to provide resources, in collaboration with the NCI, for the continuing preclinical development and possibly the clinical development for this group of agents.

The government will provide all relevant available expertise and information to date and will, jointly pursue further preclinical development of these agents with the chosen Collaborator. Relevant background patent rights are available for licensing to the Collaborator.

The successful pharmaceutical company will provide the necessary quantities of the agents plus the necessary technical expertise, financial and organizational support to complete further development of these agents to establish their efficacy and possible commercial status.

The expected duration of the CRADA will be three (3) to five (5) years.

The role of the National Cancer Institute, includes the following:

1. The government will continue preclinical development of the agents as