Studies of Adverse Effects of Marketed Drugs, Biologics, and Devices; Availability of Grants (Cooperative Agreements); Request for Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of February 5, 1997 (62 FR 5429). The document announced the availability of $1.4 million in Fiscal Year 1997 funds for cooperative agreements to study adverse effects of marketed drugs, biologics, and devices. The document was published with an incorrect application acceptance date. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Robert L. Robins, Grants Management Officer, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, Park Bldg., rm. 3–40, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6170.

In FR Doc. 97–2870, appearing on page 5429, in the Federal Register of Wednesday, February 5, 1997, the following correction is made:

1. On page 5432, in the first column, in the first full paragraph, in line four, ''March 14, 1997'' is corrected to read ''March 21, 1997''.

Dated: February 7, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–3660 Filed 2–12–97; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Institute of Child Health and Human Development: Licensing Opportunity and/or Opportunity for a Cooperative Research and Development Agreement (CRADA) for Novel Progesterone Antagonists and Pharmaceutical Compositions Thereof

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

ACTION: Notice.

SUMMARY: The National Institutes of Health is seeking licensees and/or CRADA partners for the further development, evaluation, and commercialization of novel progesterone antagonists and pharmaceutical compositions thereof. The invention claimed in U.S. Patent Application 60/016,628 entitled ''21-Substituted Progesterone Derivatives As New Antiprogestational Agents'' (HK Kim, RP Blye, PN Rao, JW Cessac, and CK Acosta), filed May 1, 1996, is available for either exclusive or non-exclusive licensing (in accordance with 35 U.S.C. 207 and 37 CFR part 404) and/or further development under a CRADA for clinical and research applications described below in **SUPPLEMENTARY INFORMATION.**

To expedite the research, development, and commercialization of this new class of drugs, the National Institutes of Health is seeking one or more license agreements and/or CRADAs with pharmaceutical or biotechnology companies in accordance with the regulations governing the transfer of Government-developed agents. Any proposal to use or develop these drugs will be considered.

DATES: There is no deadline by which license applications must be received. CRADA proposals must be received on or before May 14, 1997.

ADDRESSES: CRADA proposals and questions about this opportunity should be addressed to Dr. Diana Blithe, Contraceptive Development Branch, Center for Population Research, National Institute of Child Health and Human Development, 6100 Executive Boulevard, Room 8B13, Bethesda, Maryland 20892; Telephone: 301/496–1661.

Licensing proposals and questions about this opportunity should be addressed to Ms. Carol Lavrich, 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. 287.

Information about the patent application and pertinent information not yet publicly described can be obtained under a Confidential Disclosure Agreement. Respondees interested in licensing the invention(s) will be required to submit an Application for License to Public Health Service Inventions. Respondees interested in submitting a CRADA proposal should be award that it may be necessary to secure a license to the above patent rights in order to commercialize products arising from a CRADA.

SUPPLEMENTARY INFORMATION: The discover of antiprogestational steroids can be traced back to the work of chemists at Roussel in the early 1970s who were trying to develop synthetic routes for some new glucocorticoids which require substitution at position 11 of the steroid nucleus. They found that the size of the substituent largely determined whether the compound exhibited agonist or antagonist activity. By extending this work to the sex steroids, Georges Teutsch and his colleagues prepared RU 38486 or mifepristone in 1980 which was subsequently shown to exhibit both antiprogrestational and antiglucocorticoid activity. Clinical studies showed that mifepristone could terminate pregnancy when it was administered prior to day 49 of gestation when the source of progesterone shifts from the corpus luteum to the placenta and could also prevent pregnancy when administered within 72 hours of unprotected intercourse.

As part of its steroid synthetic program, a novel antiprogestin, code named CDB–2914, was prepared by the Research Triangle Institute under contract to the Contraceptive Development Branch and subsequently evaluated by the Branch's Biological Testing Facility. Chemically, CDB–2914 is 17α-acetoxy-11β-(4-N,N-dimethylaminophenyl)-19-norpregna-4,9-diene-3,20-dione. It differs from mifepristone in that it is a derivative of progesterone rather than 19-nortestosterone. However, it shares many pharmacological properties with mifepristone, and is being developed as a postcoital contraceptive.

The compounds available for licensing under this notice are 21-substituted analogs of CDB–2914. Although they have not been studied as extensively as CDB–2914, they exhibit greater antiprogestational and reduced antiglucocorticoid activity and thus have substantial clinical potential as contraceptive agents and for a broad spectrum of therapeutic uses in gynecic medicine. While a licensee/CRADA partner may wish to pursue development of these antiprogestins for the most extensive clinical applications, contributions by the Government will be limited to contraceptive development. Development as abortifacients will be prohibited.

In an effort to expedite research, development, and commercialization of the novel antiprogestational steroids, the National Institute of Child Health and Human Development seeks a CRADA partner(s) for joint exploration and possible commercialization. Any CRADA proposed for these purposes will be considered.

The CRADA aims will include the rapid publication of research results consistent with protection of proprietary information and patentable inventions as well as the timely exploitation of commercial opportunities. The CRADA partner will enjoy the benefits of first negotiation for licensing Government

rights to any inventions arising under the agreement and will advance funds payable upon signing the CRADA to help defray Government expenses for patenting such inventions and other CRADA-related costs.

The role of the National Institute of Child Health and Human Development will be as follows:

1. Provide the collaborator with all biological data on compositions of matter covered by the agreement.
2. Provide samples of compositions of matter covered by the agreement.
3. Provide chemical data on compositions of matter covered by the agreement including synthetic routes, analytical methods employed, and purity.
4. Provide conformational analysis of compositions of matter covered by the agreement where possible.
5. Continue studies on the pharmacokinetics and biological activity of compositions of matter covered by the agreement.
6. Conduct studies to optimize formulations for administration of the compositions of matter covered by the agreement by various routes in rodents and primates.
7. Conduct Ames Test and other genetic toxicology on compositions of matter covered by the agreement scheduled for clinical evaluation.
8. Participate in meetings with the Food and Drug Administration for establishment of the drug safety studies required for Phase I, II, and III clinical investigations of any of the compositions of matter covered by the agreement and provide liaison with that Agency.

The role of the collaborator will be as follows:

1. Undertake studies to identify any unique properties of the compositions of matter covered by the agreement including pharmacological differences from mifepristone.
2. Undertake relative binding affinity studies using human receptor proteins.
3. Undertake acute, subacute, chronic, carcinogenicity, and reproductive toxicology studies necessary to proceed with the orderly evaluation of selected compositions of matter covered by the agreement in human subjects.
4. Undertake an orderly sequence of clinical investigations of selected compositions of matter covered by the agreement for their safety and efficacy as postcoital contraceptives and for therapeutic use in gynecic medicine.

Selection criteria for choosing the CRADA partner(s) will include but are not limited to the following:

1. The collaborator must present in their proposal a clear statement of their capabilities and experience with respect to the tasks to be undertaken. This would include experience in drug development, regulatory affairs, and marketing.
2. The proposal must contain a clear and concise outline of the work to be undertaken, a schedule of significant events, an outline of objectives to be accomplished in a timely manner and such experimental details as will provide a basis for evaluation of competing submissions.
3. The proposal must contain the level of financial support the collaborator will supply for CRADA-related Government activities.
4. A willingness to cooperate with the NICHD in publications of research results consistent with the protection of proprietary information and patentable inventions which may arise during the period of the agreement.
5. Agreement to be bound by DHHS rules and regulations regarding the use of human subjects in clinical investigations, patent rights, ethical treatment of animals, and randomized clinical trials.
6. Agreement with provisions for equitable distribution of patent rights to any inventions developed under the CRADA(s). Generally, the rights of ownership are retained by the organization which is the employer of the inventor, with an irrevocable, non-exclusive, royalty-free license to the Government (when a company employee(s) is the sole inventor) or an option to negotiate an exclusive or non-exclusive license to the company on terms that are appropriate (when the Government employee(s) is the sole inventor).

Dated: February 4, 1997.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 97–3527 Filed 2–12–97; 8:45 am]

BILLING CODE 4140–01–M

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

The invention referenced below is owned by an agency of the U.S. Government and is 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 U.S. companies and may also be available for licensing.

ADDRESSES: Licensing information and a copy of the U.S. patent application referenced below may be obtained by contacting Stephen Finley, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; Telephone: 301/496–7735 ext 215; Fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive a copy of the patent application.

Allelic Variation of the Serotonin $5HT_7$ Receptor

U Pesonen, M Koulu, M Linnoila, D Goldman, and M Virkkunen (NIAAA)

Serial No. 08/745,269 filed 08 Nov 96 (claiming priority date of November 09, 1995

The $5HT_7$ serotonin receptor is structurally distinct from known serotonin receptors and exhibits a high affinity for serotonin and several antipsychotic and antidepressant drugs. The neurotransmitter serotonin has a variety of functions in the CNS, and disruption of serotonergic systems may be a factor in a number of clinical disorders or conditions including schizophrenia, depression, obsessive compulsive disorder, anxiety, sleep disorders, migraine headaches, and pain. This invention identifies a rare nonconservative mutation of the human $5HT_7$ serotonin receptor. The mutation from Pro_{279}, a common amino acid found in the helical turns of proteins, to Leu_{279} in the third cytoplasmic loop may alter the secondary and tertiary structure of the receptor and create changes in binding affinities. The $5HT_{7\ Leu279}$ receptor may prove valuable for studying the function of this neurotransmitter in the CNS and make it possible to find biochemical and genetic variables that predict vulnerability to psychiatric disorders, including antisocial personality, and therefore predict these behaviors and also facilitate implementation of preventative and therapeutic measures. The receptor may also be used in medication development and screening for ligands that may bind to the receptor,as well as in receptor inhibition studies.

(Portfolios: Central Nervous System—Research Materials receptors and cell lines; Central Nervous System—Research Materials, cDNA clones and probes)