Bioorg. Med. Chem. (15 May 2004) 12 (10): 2645–2652.

Dated: February 17, 2005.

Steven M. Ferguson,

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

[FR Doc. 05–3830 Filed 2–25–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are 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 companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Mouse Lactoferrin Antibody

Christina T. Teng (NIEHS), DHHS Reference No. E–158–2004/0—Research Tool. *Licensing Contact:* Marlene Shinn-Astor; 301/435–4426; *shinnm@mail.nih.gov.*

Lactoferrin, an iron-binding glycoprotein, kills bacteria and modulates inflammatory and immune responses. It is expressed in mucosa membrane and is present in saliva, tears, vaginal secretion and neutrophils. It modulates immune and inflammatory response by down-regulating several cytokines. Therefore, lactoferrin is an important protein in first line of defense and protecting health. Changes in lactoferrin expression could also be used as a marker of gene activation, especially estrogen-induced gene activity in the uterus.

The inventors have uniquely purified a novel 70 kDa estrogen-stimulated glycoprotein, lactoferrin, from mouse uterine luminal fluid. CM-Affi-Gel Blue column chromatography provided a simple one step separation of lactoferrin from the other luminal and serum proteins. Furthermore, a polyclonal antibody was created in rabbit, which has been utilized for immunostaining, Western blot, and elisa assays on human, mouse, rat, and hamster tissues. The cDNA to both human and mouse were cloned. Probes designed to detect the methylation status or polymorphisms of the human lactoferrin gene are available and can be used as diagnostic tool in cancer study.

The inventor has available polyclonal antibodies for both human and mouse, as well as purified mouse lactoferrin protein.

References: (1) Teng, CT *et al.* 1986. Purification and properties of an oestrogen-stimulated mouse uterine glycoprotein (approx. 70 kDa). Biochemical Journal. 240:413–422. (2) Teng, *et al.* 2002. Differential expression and estrogen response of lactoferrin gene in the female reproductive tract of mouse, rat, and hamster. Biology of Reproduction. 67:1439–1449.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Antibody to Estrogen Related Receptor Alpha

Christina T. Teng (NIEHS), DHHS Reference No. E–157–2004/0—Research Tool.

Licensing Contact: Marlene Shinn-Astor; 301/435–4426; *shinnm@mail.nih.gov.*

Estrogen related receptor alpha (ERRalpha) is a family member of the steroid/thyroid nuclear receptor superfamily. Estrogen related receptors are thought to regulate similar target genes in the absence of known ligands. For example, the inventors previously cloned the human estrogen receptor-related orphan receptor alpha1 cDNA and demonstrated that it enhances estrogen responsiveness of the lactoferrin gene promoter in transfected human endometrial carcinoma cells.

The inventors have produced a peptide and fusion protein rabbit polyclonal antibody against ERRalpha1-C terminal (anti-ERRalpha-CT), which has been utilized for immunostaining, Chromatin immunoprecipitation (ChIP), immunoprecipitation/immunoblottin (IP/IB) and Western blot. This antibody targets the C-terminus of the protein which is a conserved region in human and mouse. The antibody will be a valuable tool to study the expression and function of the protein in rodent models, whereas the human antibody is already commercially available. The inventors also have available mouse cDNA for ERRalpha1 which can be used to detect mRNA.

Reference: Shigeta, H, *et al.* 1997. The mouse estrogen receptor-related orphan receptor alpha1: molecular cloning and estrogen responsiveness. Journal of Molecular Endocrinology. 19:299–309.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

A Novel, Preservative-Free Steroid Formulation for Use as an Anti-Inflammatory

Michael R. Robinson (NEI), George Grimes (CC), Luisa Gravlin (CC), Gopal Potti (CC), Peng Yuan (CC) and Karl Csaky (NEI), U.S. Provisional Patent Application No. 60/628,741 filed 17 Nov 2004 (DHHS Reference No. E–094–2003/0–US–01).

Licensing Contact: Susan Carson; 301/435–5020; *carsonsu@mail.nih.gov.*

Corticosteroids, such as dexamethasone, methylprednisolone and triamcinolone acetonide (TAC), have been used for many years in the treatment of inflammation and in relieving pain caused by inflammation (for example chronic back and joint pain). Intraocular inflammation is also treated with steroids; however, there are no commercial corticosteroid preparations approved by the FDA for use in the eye and off-label use of current commercial formulations can be accompanied by toxic side effects, which can lead to vision loss. Inflammation is present in eye diseases including uveitis, diabetic retinopathy, venous occlusive disease and age-related macular degeneration, which are estimated to affect more than 200,000 patients in the U.S. alone. This number is likely to increase as the population ages, and there remains a need for a cost-effective, safe, efficient steroid formulation for treating these conditions.

NIH researchers at the National Eye Institute and the Clinical Center have devised a novel preservative-free formulation of the generic steroid TAC with an improved safety profile that permits intravitreal injection. The invention is a pharmaceutical composition free of preservatives and dispersion agents (TAC–PF) that are thought to be responsible for certain toxic side effects. Pre-clinical ocular toxicology and pharmacokinetic studies

have been performed using a commercial formulation (Kenalog™) as a comparator with the invention. No ocular toxicity was seen with TAC–PF. The inventors have an IND in place and have positive results in the treatment of diabetic macular edema with a single dose of TAC–PF. The targeted indications for the present novel TAC formulation include diabetic retinopathy and macular edema, uveitis and age-related macular degeneration. Additionally, this formulation, which benefits from an improved safety profile, could possibly be used in other indications where steroid injections are used to control inflammation.

This formulation is available for licensing and claims are directed to a pharmaceutical composition free of classical preservatives and comprising a glucocorticoid or angiostatic steroid. Claims are also directed to methods of making and treating a variety of ocular conditions and other inflammatory conditions including pain by a variety of routes of administration, including intravitreally, intrathecally, etc.

In addition to licensing, this technology is available for further development through collaborative research with the inventors.

Dated: February 17, 2005.

Steven M. Ferguson,

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

[FR Doc. 05–3832 Filed 2–25–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Mental Health Special Emphasis Panel, January 25, 2005, 1 p.m. to January 25, 2005, 4 p.m. National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD, 20852 which was published in the **Federal Register** on January 12, 2005, 70 FR 2178.

The meeting will be held on March 8, 2005, at the Neuroscience Center, Rockville, MD, from 1 p.m. to 5 p.m. as a telephone conference call. The meeting is closed to the public.

Dated: February 22, 2005.

Laverne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–3881 Filed 2–28–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Second Request for Data on Chemicals Evaluated by In Vitro or In Vivo Ocular Irritancy Test Methods

Summary

The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and NICEATM are collaborating with the European Center for the Validation of Alternative Methods (ECVAM) to evaluate the validation status of in vitro methods for assessing ocular irritation/corrosion. Data was previously requested (**Federal Register**, Vol. 69, No. 57, pp. 13859–13861, March 24, 2004, available at *http://iccvam.niehs.nih.gov/*) and used to prepare draft Background Review Documents (BRD) for four methods [(1) The Bovine Corneal Opacity and Permeability (BCOP) test; (2) the Isolated Rabbit Eye (IRE) test or the Rabbit Enucleated Eye Test (REET); (3) the Isolated Chicken Eye (ICE) test or the Chicken Enucleated Eye Test (CEET); and (4) the Hen's Egg Test—Chorion Allantoic Membrane (HET–CAM)], and to compile a database of *in vivo* data. ICCVAM and NICEATM are now finalizing these BRDs and want to ensure the inclusion of all available data. NICEATM is therefore issuing this second request for data generated using standardized *in vitro* and *in vivo* test methods used to identify severe, moderate, mild, or non-irritating substances. Test methods for identifying severe (irreversible) ocular irritation/corrosion for which data are sought include, but are not limited to: (1) The BCOP test; (2) the IRE test; (3) the ICE test; and (4) the HET–CAM. In addition, high quality data from standardized ocular irritancy test methods using rabbits (*e.g.*, EPA 1998; UN 2003) and *in vivo* data generated from procedures/protocols that might alleviate or reduce pain and suffering (*e.g.*, topical and systemic analgesic) in test animals are requested. These data will be used to evaluate the validation status of existing in vitro test methods for ocular irritancy/corrosion and to develop a list of substances with high quality *in vivo* data that can be considered as reference chemicals for future validation studies. Data from other *in vitro* methods used to assess reversible ocular irritation effects or non-irritation are also requested.

Submission of Chemical and Protocol Information and Test Data

Data and other information submitted in response to this notice should be sent to NICEATM [Dr. William S. Stokes, Director, NICEATM, NIEHS, 79 T. W. Alexander Drive, P.O. Box 12233, MD EC–17, Research Triangle Park, NC 27709, (phone) 919–541–2384, (fax) 919–541–0947, *iccvam@niehs.nih.gov*] and received by March 30, 2005. Data and other information received by this date will be compiled and added to the database maintained by NICEATM and utilized where appropriate for the final BRDs on the four methods listed above. Data received after this date will also be considered and used where applicable for future evaluation activities. All information submitted in response to this notice will be made publicly available upon request to NICEATM.

When submitting data or information on protocols, please reference this **Federal Register** notice and provide appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, as applicable). NICEATM prefers data to be submitted as copies of pages from study notebooks and/or study reports, if available. Each submission for a chemical should preferably include the following information, as appropriate:

- Common and trade name
- Chemical Abstracts Service Registry Number (CASRN)
- Chemical and/or product class
- Commercial source
- *In vitro* test protocol used
- Rabbit eye test protocol used
- Human eye test protocol used
- Individual animal/human or *in vitro* responses at each observation time (*i.e.*, raw data).
- The extent to which the study complies with national/international Good Laboratory Practice (GLP) guidelines
- Date and testing organization

Those persons submitting data on chemicals tested for ocular irritancy in rabbits are referred to the ICCVAM/NICEATM Web site (*http://iccvam.niehs.nih.gov/methods/eyeirrit.htm*) for an example of the type of experimental animal study information and data requested in this notice.