DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies 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 infromaiton 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.

Aspirin Metabolites As Protectors Against Oxidative Stress And Chemotherapy Drug Toxicity

JB Mitchell, A Russo, CM Krishna, W DeGraff, AM DeLuca, L Myers, SM Hahn (NCI)

Serial No. 60/039,375 filed 20 Mar 97

Licensing Contact: Leopold J. Luberecki, Jr., 301/496–7735 ext. 223

Although oxygen is required to sustain most life forms, a variety of toxic oxygen-related species, such as hydroxyl radicals, hydrogen peroxide, and superoxide, are produced, which could damage cells if left unchecked. Cells usually possess systems which rid themselves of these by-products, yet there is a small amount of these substances which escapes the biochemical defense network. It is not known whether chronic exposure to low levels of oxygen-derived free radical species is deleterious. It is postulated that the aging process may be a manifestation of the organism's inability to cope with sustained oxidative stress. In addition, some cancer treatment modalities exert their cytotoxicity via production of free radicals. This invention describes methods of using a composition made of a hydroxybenzoate metabolite, a hydroxybenzoate analogue, or a mixture thereof, in the preventative and therapeutic treatment for oxidative stress. The use of the compounds to treat oxidative stress is superior to aspirin itself for reasons including avoidance of gastric and duodenal ulcers and platelet function disorders, and the ability to realize high concentrations of specific metabolities or analogues, which cannot be achieved using aspirin. In addition, compositions may be used to protect biological material from the cytotoxic effects of cancer chemotherapeutic agents, including adriamycin, one of the most widely used chemotherapeutic agents. As an example, the effectiveness of adriamycin is limited by the resulting bone marrow suppression, gastorintestional damage, and cumulative cardiotoxicity caused by the treatment. The compositions of this invention could act as anti-cytotoxic agents. The compositions also could be used to treat extravasation tissue injury. Extravasation occurs when a hypodermic injection, such as an injection of a chemotherapeutic agent, misses the vein, as frequently occurs in older persons, thereby causing release of a high localized concentration of the agent into the surrounding tissue, which results in cellular damage and a disfiguring ulceration. A composition as described in this invention could be rapidly injected at the site of the missed injection to alleviate or prevent this damage.

Trophic and Cell Differentiating Effects of Glucagon-Like Peptite (GLP–1) and Exedin-4

J Egan, R Perfetti, A Passaniti, N Greg, H Holloway (NIA)

DHHS Reference No. E–251–97/0

Licensing Contact: Charles M. Maynard, 301/496–7735 ext. 243

GLP–1 is a hormone produced and predominantly found in the mammalian gut. GLP–1 has been found to stimulate insulin production and suppress glucagon production in response to increases in serum glucose levels caused by a variety of events, such as ingestion of a mixed meal. Consequently, it has generated a considerable amount of investigation as a potentially useful therapeutic agent in the treatment of diabetes. Clinical trials of administration of synthetic GLP–1 have shown a reduction of the need for insulin injection in patients with diabetes, both type I and type II. GLP–1 also has the distinct advantage over traditional treatment of these conditions, in that the insulinotropic effect of GLP–1 is dependent on serum glucose concentration, resulting in the fact that in vivo administration of significant amounts of GLP–1 appears not to trigger hyperinsulinemia. Unfortunately, GLP–1 has an effective pharmaceutical half-life in the realm of five minutes, requiring repeated dosing.

Exedin–4 is an abstract from the venom of the Gila monster, about 50% structurally related to GLP–1, which was found to be a potent agonist of GLP–1, and which also was found to increase insulin production when administered by itself. Exedin–4 also has the advantage of a significantly longer effective duration, on the order of ten hours. Research, therefore, has focused on finding combinations of GLP–1 and exedin–4 that are likely to provide the longest effect, as well as on the mechanisms through which they mediate insulin production.

Oncoimmunins

B Packard, A Komoriya (FDA)

U.S. Patent 5,364,619 issued 15 Nov 94 and U.S. Patent 5,635,356 issued 3 Jun 97

Licensing Contact: Jaconda Wagner, 301/496–7735 ext. 284

Two tumor-derived soluble proteins named oncoimmunin-L and oncoimmunin-M have been isolated and partially characterized. Oncoimmunin-L is a T-cell mitogen and oncoimmunin-M is a myeloid differentiation inducing agent. The partial characterization of these two factors has shown that they are similar to human leukocyte elastase inhibitor and human lactate dehyrodrogenase M, respectively. As cells of both lymphoid and myeloid origin are known to play roles in immune defense, factors which can modulate their number and/or function may be useful in the diagnosis and treatment of cancer. Since these factors are derived from tumors, their appearance in blood may signal the presence of tumor or of metastatic disease. The in vivo bioactivities of these factors suggests their utility as therapeutic agents for cancer and infectious diseases.

This research has been published in Biochim Biophys Acta 1995 Oct 19; 1269(1): 41–50.

Dated: February 11, 1998.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 98–4236 Filed 2–19–98; 8:45 am]

BILLING CODE 4140–01–M