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Antibodies That Specifically Recognize SUMO-Conjugated Proteins

Dr. Mary Dasso (NICHD).

U.S. Provisional Application Serial No. 60/438,685 filed 08 Jan 2003 (DHHS Reference No. E-066-2002/0-US-01).

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SUMO-1 is an ubiquitin-like heat shock protein that can be covalently conjugated to other proteins through an isopeptide linkage. This technology describes polyclonal antibodies that recognize SUMO-1 conjugated proteins, including conjugated RanGAP1. These antibodies could be used as a diagnostic tool to test for diseases that contain SUMO-1 mis-regulation with further development. It is also foreseen that they could be used in large-scale screening of small molecule libraries to find compounds capable of either inhibiting or enhancing the SUMO-1 conjugation pathway.

Modulators of Nuclear Hormone Receptor Activity: Novel Compounds, Diverse Applications for Infectious Diseases, Including Anthrax (*B. anthracis*)

E. M. Sternberg (NIMH), J. I. Webster (NIMH), L. H. Tonelli (NIMH), S. H. Leppla (NIAID), and M. Maoyeri (NIAID).

DHHS Reference No. E-247-2002/0-US-01 filed 18 October 2002.

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Technology summary and benefits: Nuclear hormones such as glucocorticoids dampen inflammatory responses, and thus provide protection to mammals against inflammatory disease and septic shock. The Anthrax lethal factor represses nuclear hormone receptor activity, and thus may contribute to the infectious agent causing even more damage to the host. This observation can be exploited to find new means of studying and interfering with the normal function of nuclear hormone receptors. Scientists at NIH have shown that under the appropriate conditions, these molecules can be used to modulate the activity of various nuclear hormone receptors.

Identifying useful agents that modify these important receptors can provide relief in several human disorders such as inflammation, autoimmune disorders, arthritis, malignancies, shock and hypertension.

Long-term potential applications: This invention provides novel agents that can interfere with the action of nuclear hormone receptors. It is well known that malfunction or overdrive of these receptors can lead to a number of diseases such as enhanced inflammation; worse sequelae of infection including shock; diabetes; hypertension and steroid resistance. Hence a means of controlling or fine-tuning the activity of these receptors can be of great benefit. Current means of affecting steroid receptor activity are accompanied by undesirable side-effects. Since the conditions for which these treatments are sought tend to be chronic, there is a critical need for safer drugs that will have manageable side-effects.

Uniqueness or innovativeness of technology: The observation that the lethal factor from Anthrax has a striking effect on the activity of nuclear hormone receptors opens up new routes to controlling their activity. The means of action of this repressor is sufficiently different from known modulators of hormone receptors (*i.e.*, the classical antagonists). For instance, the repression of receptor activity is non-competitive, and does not affect hormone binding or DNA binding. Also, the efficacy of nuclear hormone receptor repression by Anthrax lethal factor is sufficiently high that the pharmacological effect of this molecule is seen at vanishingly small concentrations. Taken together, these attributes may satisfy some of the golden rules of drug development such as the uniqueness or novelty of the agent's structure, a low threshold for activity, high level of sophistication and knowledge in the field of enquiry, and the leeway to further refine the molecule by rational means.

Stage of Development: In vitro studies have been completed, and a limited number of animal studies have been carried out.

Method for the Treatment of Multiple Sclerosis

Roland Martin *et al.* (NINDS).

U.S. Provisional Application Serial No. 60/393,021 filed 28 Jun 2002 (DHHS Reference No. E-143-2002/0-US-01), PCT/US02/38290 filed 27 Nov 2002 (DHHS Reference No. E-143-2002/0-PCT-02), U.S. Patent Application filed 27 Jun 2003 (DHHS Reference No. E-143-2002/0-US-03), and PCT/

US03/20428 filed 27 Jun 2003 (DHHS Reference No. E-143-2002/0-PCT-04).

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The invention relates to the discovery that humanized antibodies to the interleukin-2 receptor (IL-2R) such as (daclizumab) are effective in treating multiple sclerosis (MS). In particular, it has been discovered that patients who have failed to respond to therapy with interferon-beta show dramatic improvement when treated with daclizumab, with patients showing both a reduction in the total number of lesions and cessation of appearance of new lesions during the treatment period. Daclizumab is effective both in combination with interferon-beta and alone.

The above-mentioned invention is available for licensing on an exclusive or non-exclusive basis.

Dated: August 4, 2003.

Steven M. Ferguson,

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

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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 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.

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