

Dated: December 21, 2005.

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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

Prospective Grant of Exclusive License: Fusion Proteins Comprising Circularly Permuted Ligands

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

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in United States Patent No. 4,892,827, issued on January 9, 1990, entitled "Recombinant Pseudomonas Exotoxin: Construction Of An Active Immunotoxin With Low Side Effects" [E-385-1986/0-US-01]; U.S. Patent No. 5,635,599, issued on June 3, 1997, entitled "Fusion Proteins Comprising Circularly Permuted Ligands" [E-047-1994/0-US-01]; PCT Patent Application No. PCT/US95/04468, filed April 6, 1995, entitled "Fusion Proteins Comprising Circularly Permuted Ligands" [E-047-1994/0-PCT-02]; Switzerland Patent No. 0754192, issued on January 29, 2003, entitled "Fusion Proteins Comprising Circularly Permuted Ligands" [E-047-1994/0-CH-03]; Spain Patent No. 0754192, issued on January 29, 2003, entitled "Fusion Proteins Comprising Circularly Permuted Ligands" [E-047-1994/0-ES-04]; United Kingdom Patent No. 0754192, issued on January 29, 2003, entitled "Fusion Proteins Comprising Circularly Permuted Ligands" [E-047-1994/0-GB-05]; Italy Patent No. 0754192, issued on January 29, 2003, entitled "Fusion Proteins Comprising Circularly Permuted Ligands" [E-047-1994/0-IT-06]; Luxembourg Patent No. 0754192, issued on January 29, 2003, entitled "Fusion Proteins Comprising Circularly Permuted Ligands" [E-047-1994/0-LU-07]; Netherlands Patent No. 0754192, issued on January 29, 2003, entitled "Fusion Proteins Comprising Circularly Permuted Ligands" [E-047-1994/0-NL-09]; German Patent No. 0754192, issued on January 29, 2003, entitled "Fusion Proteins Comprising

Circularly Permuted Ligands" [E-047-1994/0-DE-10]; Austria Patent No. 0754192, issued on January 29, 2003, entitled "Fusion Proteins Comprising Circularly Permuted Ligands" [E-047-1994/0-AT-11]; Australia Patent No. 694211, issued on November 5, 1998, entitled "Fusion Proteins Comprising Circularly Permuted Ligands" [E-047-1994/0-AU-12]; Belgium Patent No. 0754192, issued on January 29, 2003, entitled "Fusion Proteins Comprising Circularly Permuted Ligands" [E-047-1994/0-BE-13]; Canada Patent No. 2187283, filed on April 6, 1995, entitled "Fusion Proteins Comprising Circularly Permuted Ligands" [E-047-1994/0-CA-14]; European Patent No. 0754192, issued on January 29, 2003, entitled "Fusion Proteins Comprising Circularly Permuted Ligands" [E-047-1994/0-EP-15]; France Patent No. 0754192, issued on January 29, 2003, entitled "Fusion Proteins Comprising Circularly Permuted Ligands" [E-047-1994/0-FR-16]; Ireland Patent No. 0754192, issued on January 29, 2003, entitled "Fusion Proteins Comprising Circularly Permuted Ligands" [E-047-1994/0-IE-17]; Liechtenstein Patent No. 0754192, issued on January 29, 2003, entitled "Fusion Proteins Comprising Circularly Permuted Ligands" [E-047-1994/0-LI-18]; and U.S. Patent No. 6,011,002, issued on January 4, 2000, entitled "Circularly Permuted Ligands And Circularly Permuted Chimeric Molecules" [E-047-1994/1-US-01] to Protoc Therapeutics, Inc., which has offices in Vancouver, British Columbia, Canada. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the use of Interleukin-4/cytotoxin fusion proteins for the treatment of cancer.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before February 28, 2006 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Jesse S. Kindra, J.D., M.S., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5559; Facsimile: (301) 402-0220; E-mail: kindraj@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The technology relates to circularly permuted ligands having the ability to

change the conformation of certain proteins so that they can be more effectively used as therapeutics. Specifically, growth factors such as IL-4 can be used in fusion proteins to target cell surface receptors. Accordingly, these growth factors can be used, when linked with cytotoxic moieties (i.e., Pseudomonas Exotoxin), to target and then kill desired cells. These circularly permuted molecules are advantageous over prior molecules in that they allow greater binding specificity of an immunotoxin to the targeted cell. This change in conformation is a result of the production of new carboxyl and amino termini. The new termini are located away from the active binding site and hence cause less steric hindrance between the active site and the fused protein. Hence, the targeting moiety is closer to its native conformation. Without such a conformational change, binding specificity for the immunotoxin is greatly reduced. Therefore, these circularly permuted molecules allow for greater binding specificity without retarding the cytotoxicity of the toxin to which they are bound.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: December 14, 2005.

Steven M. Ferguson,

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

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