DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of Cancer Therapeutics in Humans

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 PCT Application Serial No. PCT/US07/083027 and foreign equivalents thereof, entitled ''Smoothened Polypeptides and Methods of Use'' [HHS Ref. No. E–014–2007/0]; PCT Application Serial No. PCT/US07/083772 and foreign equivalents thereof, entitled ''Self-Assembling Nanoparticles Composed of Transmembrane Peptides and Their Application for Specific Intra-Tumor Delivery of Anti-Cancer Drugs'' [HHS Ref. No: E–256–2006/0]; and U.S. Patent No. 7,105,488, and foreign equivalents thereof, entitled ''G Protein-Coupled Receptor Antagonists'' [HHS Ref. No: E–290–1997/0] to Calidris Therapeutics which is registered in Japan. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive licensed territory may be worldwide and the field of use may be limited to peptidomimetic drugs for the treatment of cancer as claimed in the Licensed Patent Rights. These cancers may be limited to multiple myeloma, colon, lung, melanoma, liver, breast, prostate, ovarian, pancreatic cancers, ALL, AML, NHL, rhabdomyosarcoma, neuroblastoma, osteosarcoma and medulloblastoma. With respect to the GPCR technology, the exclusive license field of use may be limited to antagonists of the GPCR CXCR4.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before June 30, 2008, 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: Jennifer Wong, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4633; Facsimile: (301) 402–0220; E-mail: *wongje@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The first technology describes inhibitors Smoothened protein (SMO), a receptor involved in the Hedgehog/Patched (HH/PTCH) pathway. HH/PTCH is a common pathway involved in proliferative disorders including cancer and psoriasis.

The technology is directed towards several synthetic peptides (including all-D analogs) corresponding to specific region of the SMO protein. Experiments *in vitro* demonstrate that they potentially suppress the growth of cancer cells and inhibit the expression of the HH/PTCH pathway genes. Due to their high hydrophobic properties, these peptide inhibitors can be easily formulated for specific intratumor delivery or topical creams for skin disorders.

The second technology relates to peptides corresponding to transmembrane domains of a number of integral membrane proteins. These peptides spontaneously self-assemble in aqueous solutions into stable and remarkably uniform nanoparticles. The nanoparticles of the current invention are fully synthetic, and their surfaces can be engineered to provide specific binding to cell surface receptors over-expressed on tumor cells. Thus, they are even more specific for tumor targeting.

Nanoparticles constructed from transmembrane domains of certain receptors and transporters have biological activities of their own and inhibit metastasis or drug resistance thus sensitizing tumors to therapy. Hydrophobic drugs can be easily entrapped inside the nanoparticles, which not only solve the problem of drug insolubility under physiological conditions, but also generate a form of a drug that concentrates in tumors due to enhanced permeability and retention effects.

The third technology relates to GPCRs. GPCRs are a large family of transmembrane receptors involved in the regulation of physiological activities. The inventors have found that if a peptide consisting of one of the GPCR transmembrane regions has a charged amino acid on the extracellular side and if said peptide is brought into contact with a cell with same GPCR, the GPCR function is disrupted. The inventors have developed inhibitory GPCR CXCR4 peptides. CXCR4 plays a significant role in cancer development as it is involved in tumor cell proliferation, migration, and metastasis.

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.

April 21, 2008.

David Sadowski,

Deputy 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: Method To Treat Psoriasis in Humans

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 U.S. Provisional Patent Application No. 60/855,422 and PCT Application Serial No. PCT/US07/083027 and foreign equivalents thereof, entitled ''Smoothened Polypeptides and Methods of Use'' [HHS Ref. No. E–014–2007/0], to Lee's Pharmaceuticals, Ltd., which is located in Hong Kong, China. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive licensed territory may be Asia and the field of use may be limited to the use of Licensee's proprietary delivery formulation for the treatment of