[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, HHS

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.

FOR FURTHER INFORMATION: 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.

Enhanced Nanoparticle Cell-Entry for Cancer Therapy

Description of Technology: Nanoparticles are being used as a method of drug delivery for the treatment of several diseases, cancer in particular. While the use and versatility of these particles have increased over the years, the speed with which these particles can enter the cells and deliver the drugs remains challenging.

This technology describes a method of modifying nanoparticles to markedly enhance their entry into cancer cells and their delivery of therapeutic drugs. The nanoparticles use a multi-shell calcium phosphate nanocore designed with target-specific siRNA and an endocytosis-enhancing agent. The inventors have shown that the intravenous systemic administration of the enhanced nanoparticles noticeably increases nanoparticle cell-entry along with concomitant delivery of siRNA to cancer cells in vivo. They further demonstrate that the composite calcium phosphate nanoparticle delivery of anti-cancer therapy can preferentially target in vivo tumors and cause tumor growth arrest. Consequently, these modified nanoparticles can exert a greater effect on cancer cells.

Potential Commercial Applications:

• Nanoparticle delivery of therapeutic treatments to cancers cells.

• Nanoparticle delivery of imaging agents for the identification and monitoring of tumor cells.

Competitive Advantages:

• Preferentially taken up by cancer cells and not normal cells

• Faster uptake into cells than other nanoparticles

• Tissue and/or cell specific

• Can be customized for targeted therapy

• Extremely versatile – can transport a variety of therapeutic agents and the constructs can incorporate siRNA, chemotherapy agents, targeted drugs, pro-drugs, tracers, and radioactive molecules.

Development Stage:

• In vitro data available

• In vivo data available (animal)

Inventors: King F. Kwong and Lisa A. Tobin (NCI)

Intellectual Property: HHS Reference No. E-164-2012/0 ─ U.S. Patent Application No. 61/648,735 filed 18 May 2012

Licensing Contact: Whitney Hastings; 301-451-7337; hastingw@mail.nih.gov

Collaborative Research Opportunity: The Kwong Laboratory, Surgery Branch, NCI, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize nanoparticles in anti-cancer therapy. For collaboration opportunities, please contact King F. Kwong, M.D. at kwongk2@mail.nih.gov.

Therapy for Cancer and Other Diseases Associated with Angiogenesis Driven by Vascular Endothelial Growth Factor-A

Description of Technology: Vascular Endothelial Growth Factor-A (VEGF-A) is an angiogenic agent that drives blood vessel formation in solid tumors and other diseases, such as macular degeneration and diabetic retinopathy. Several therapies that target the ability of VEGF to stimulate angiogenesis have been approved. These therapies

regulate VEGF-A activity by binding VEGF-A, thereby blocking VEGF-A from binding to its receptor on target cells. This technology utilizes a different approach to regulating VEGF-A activity by providing a VEGF-A protein antagonist that is produced by engineering native VEGF-A protein. The engineered VEGF-A protein disrupts heparan sulfate proteoglycan binding to the VEGF-A/VEGF receptor complex, an activity that is essential for the angiogenic properties of native VEGF-A. The antagonist has a binding affinity for both FLT-1 (VEGFR-1) and KDR/FLK-1 (VEGFR-2) that is equivalent to that of native VEGF-A and specifically antagonizes all VEGF-A-stimulated signaling events.

Potential Commercial Applications: Therapy for solid tumors or other diseases associated with angiogenic activity modulated by Vascular Endothelial Growth Factor-A expression.

Competitive Advantages:

• Specificity/Selectivity

• Cost-effectiveness in production

Development Stage:

• Early-stage

• In vitro data available

• In vivo data available (animal)

Inventors: Donald P. Bottaro and Fabiola Cecchi (NCI)

Intellectual Property: HHS Reference No. E-230-2011/0 ─ U.S. Patent Application No. 61/639,230 filed 27 Apr 2012

Licensing Contact: Susan S. Rucker, CLP; 301-435-4478; ruckersu@mail.nih.gov

Collaborative Research Opportunity: The National Cancer Institute's Urologic Oncology Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize antagonists to VEGF-A and hepatocyte growth factor (HGF) that block signal transduction and associated cellular responses by competitive displacement of native growth factors and concomitant disruption of heparan sulfate proteoglycan binding to the growth factor-receptor complex. For collaboration opportunities, please contact John Hewes, Ph.D. at hewesj@mail.nih.gov.

Methods for Identifying and Isolating Pancreatic Precursor Cells

Description of Technology: Diabetes results when beta cell performance is compromised through loss of cells or reduced cell function. Anti-diabetic drugs that stimulate insulin production, such as sulfonylureas and meglitinides, have limited efficacy when beta cell responsiveness is deficient. There exists a critical need for methods to increase beta cell responsiveness by enhancing cell function or by increasing beta cell numbers.

Notch has been shown to play an important role in pancreas development and diabetes and NIA investigators discovered that pancreatic precursor cells can be identified and isolated using Notch and its ligands. This technology describes methods for identifying pancreatic precursor cells using a Notch ligand, as well as methods for

isolating pancreatic precursor cells from a pancreatic cell sample, such as pancreatic islet cells or pancreatic extra-islet cells from a diabetic patient.

Potential Commercial Applications:

• Isolation and expansion of pancreatic progenitor cells for diabetes therapy

• Development of a diagnostic test to monitor beta cell function

Competitive Advantages:

• New diagnostic strategies for diabetes

• Potential use in regenerative medicine (pancreatic precursor cells recently have been shown to have the potential to develop into other cell types)

Development Stage:

• Early-stage

• In vitro data available

Inventors: Josephine M. Egan and Maire Doyle (NIA)

Publication: Kim W, et al. Notch signaling in pancreatic endocrine cell and diabetes. Biochem Biophys Res Commun. 2010 Feb 12;392(3):247-51. [PMID 20035712]

Intellectual Property: HHS Reference No. E-262-2003/0 ─

• U.S. Provisional Application No. 60/590,281 filed 22 Jul 2004

• PCT Application No. PCT/US2005/026207 filed 22 Jul 2005, which published as WO 2006/023209 on 02 Mar 2006

• U.S. Patent No. 7,888,116 issued 15 Feb 2012

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