applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: 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.

Matrix Metalloproteinase-9 Blade-1 Region Peptides: Use as Cell Migration Modulators

Description of Technology: Matrix metalloproteinase-9 (MMP–9) is an enzyme integrally involved in many normal physiological processes that require degradation and remodeling of the extracellular matrix, such as cell migration and invasion, wound repair, bone remodeling, angiogenesis, and embryonic growth. MMP–9 is shown to be involved in the progression of several diseases including many cancers, cardiovascular diseases, CNS diseases, respiratory diseases, and arthritis. In cancer, MMP–9 is thought to promote growth, migration, and spread of cancer cells by catalyzing the degradation of extracellular matrix proteins, releasing bound growth factors, and allowing cancer cells to escape from the primary tumor.

NIH *Inventors* have discovered that specific polypeptides corresponding to Blade-1 region of MMP–9 hemopexin domain can stimulate migration of cells, specifically the migration of cells expressing β1 integrin. The present technology can be used to develop novel therapeutic candidates for the prevention and treatment of human disease conditions mediated by MMP–9 promoted cell migration, e.g., cancer, inflammation, fibrotic diseases, cardiovascular diseases, CNS diseases, respiratory diseases, angiogenesis and arthritis.

Applications: Development of therapeutics for treating or preventing human diseases (cancer) using MMP–9 Blade-1 domain polypeptides or peptide analogs.

Development Status: Early-stage.

Inventors: SK Akiyama *et al.* (NIEHS)

Patent Status: U.S. Provisional Application No. 61/360,328 filed 30 Jun 2010 (HHS Reference No. E–146–2010/0–US–01)

Licensing Status: Available for licensing.

Licensing Contact: Suryanarayana Vepa, PhD, J.D.; 301–435–5020; *vepas@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute of Environmental Health Sciences, Laboratory of Molecular Carcinogenesis, Cell Adhesion Group, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Elizabeth M. Denholm, PhD at 919–541–0981 or *denholme@mail.nih.gov* for more information.

Melanocyte Pigmentation or Proliferation With Neuregulin: Compositions and Methods to Treat Skin Disorders, Including Skin Cancer

Description of Invention: Human skin pigmentation is regulated by complex and intricate interactions among melanocytes and keratinocytes in the epidermis and fibroblasts in the dermis. A number of factors secreted from keratinocytes and/or from fibroblasts have been shown to be involved in regulating skin pigmentation after UV exposure. NIH investigators have previously demonstrated that the less pigmented and thicker skin on the palms and soles is regulated by underlying fibroblasts in those areas, specifically via a secreted factor (DKK1) that modulates Wnt signaling. Now, using microarray analysis to compare gene expression patterns in 15 different primary dermal fibroblast populations derived from the dorsal trunk skin of three different skin phototypes (I, III and VI), these investigators have identified a number of genes that differ dramatically in expression. One among them, neuregulin 1 (NRG–1), secreted by fibroblasts derived from dark skin, effectively increases the pigmentation of melanocytes in tissue culture and in an artificial skin model and regulates their growth, suggesting it is one of the major factors determining human skin color. NRG-l was observed to be highly expressed by fibroblasts derived from darker skin. NIH investigators believe that NRG–1 increases the proliferation of human melanocytes via the phosphorylation of Akt. These results suggest a potential role for NRG–1 in regulating constitutive human skin color and perhaps its dysfunction in pigmentary skin diseases. Based on these observations, NIH investigators are currently developing compositions and methods of modulating pigmentation and proliferation of a melanocyte to prevent or treat skin disorders, including skin cancer.

Applications:

- Therapeutics for skin disorders.
- Therapeutics for skin cancer.

Development Status: Early stage and studies on reconstructed skin model and in melanocytes.

Inventors: Vincent J. Hearing and Wonseon Choi (NCI)

Related Publications:

1. Choi W, Wolber R, Gerwat W, Mann T, Hearing VJ. Characterization of the influence of fibroblasts on melanocyte function and pigmentation. In: Proc. XXth Intl. Pigment Cell Conf., edited by K. Jimbow, Bologna, Italy: Medimond, 2008, p. 79–82.

2. Choi W, Wolber R, Gerwat W, Mann T, Batzer J, Smuda C, Liu H, Kolbe L, Hearing VJ. A novel fibroblast-derived melanogenic paracrine factor neuregulin-1 (NRG–1) that modulates the constitutive color and melanocyte function in human skin. J. Cell Sci. in press, 2010.

Patent Status: U.S. Provisional Application No. 61/357,846 filed 23 Jun 2010 (HHS Reference No. E–100–2010/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Suryanarayana Vepa, PhD, J.D.; 301–435–5020; *vepas@mail.nih.gov*.

Collaborative Research Opportunity: The Center for Cancer Research, Laboratory of Cell Biology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of NRG–1 (or modifiers of its function) to regulate skin pigmentation. Please contact John Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: August 17, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–20862 Filed 8–20–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) New Jersey District Office, in cosponsorship with the Society of Clinical Research Associates (SoCRA) is announcing a public workshop. The public workshop on FDA's clinical trial requirements is designed to aid the clinical research professional's understanding of the mission, responsibilities, and authority of FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRBs). Individual FDA representatives will discuss the informed consent process and informed consent documents; regulations relating to drugs, devices, and biologics; as well as inspections of clinical investigators, IRBs, and research sponsors.

Date and Time: The public workshop will be held on November 4 and 5, 2010, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Hyatt Regency Jersey City, Two Exchange Pl., Jersey City, NJ 07302, 1–800–233–1234. (The hotel is connected to the PATH Train to New York City). Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of $169 plus applicable taxes (available until October 20, 2010, or until the SoCRA room block is filled).

Contact: Joan Lytle, Food and Drug Administration, 120 North Central Dr., North Brunswick, NJ 08902, 732–940–8946 ext. 33, FAX: 732–940–8936, or Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., suite 109, Chalfont, PA 18914, 800–762–7292, FAX: 215–822–8633, email: *SoCRAmail@aol.com*, Web site: *http://www.SoCRA.org*.

Registration: The registration fee covers the cost of actual expenses, including refreshments, lunch, materials, and speaker expenses. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order or receipt of registration. Those accepted into the workshop will receive confirmation. The cost of registration is as follows: SoCRA member ($575.00), SoCRA nonmember (includes membership) ($650.00), FDA/Federal Government member ($450.00), FDA/Federal Government nonmember ($525.00).

If you need special accommodations due to a disability, please contact SoCRA (see *Contact*) at least 10 days in advance.

Extended periods of question and answer and discussion have been included in the program schedule. This program offers 13.3 hours of continuing medical education (CME) and continuing nursing education (CNE) credit. *CME for Physicians*: SoCRA is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. *CNE for Nurses*: SoCRA is an approved provider of continuing nursing education by the Pennsylvania State Nurses Association (PSNA), an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation (ANCC). ANCC/PSNA Provider Reference Number: 205–3–A–09.

Registration instructions: To register, please submit a registration form with your name, affiliation, mailing address, phone, fax number, and email, along with a check or money order payable to "SoCRA". Mail to: SoCRA (see *Contact* for address). To register via the Internet, go to *http://www.socra.org/html/FDA_Conference.htm*. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the workshop, contact SoCRA (see *Contacts*).

SUPPLEMENTARY INFORMATION: The public conference helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, IRB inspections, electronic record requirements, and investigator initiated research. Topics for discussion include the following: (1) What FDA expects in a pharmaceutical clinical trial; (2) adverse event reporting—science, regulation, error, and safety; (3) Part 11 Compliance—Electronic signatures; (4) informed consent regulations; (5) IRB regulations and FDA inspections; (6) keeping informed and working together; (7) FDA conduct of clinical investigator inspections; (8) meetings with FDA: why, when, and how; (9) investigator initiated research; (10) medical device aspects of clinical research; (11) working with FDA's Center for Biologics Evaluation and Research; (12) the inspection is over—what happens next? Possible FDA compliance actions.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The public workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The public workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) as outreach activities by Government agencies to small businesses.

Dated: August 17, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–20834 Filed 8–20–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Quality and Compliance in Merging and Emerging Cultures; Public Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public conference entitled "The New Paradigm: Quality and Compliance in Merging and Emerging Cultures." The conference, cosponsored with the Parenteral Drug Association (PDA), will focus on challenges facing the medical products industry in navigating regulatory compliance, achieving worldwide quality improvement, and enhancing quality system controls in an environment of merging and emerging cultures.

Date and Time: The public conference will be held on Monday, September 13, 2010, from 7 a.m. to 6 p.m.; Tuesday, September 14, 2010, from 7:30 a.m. to 6:30 p.m.; and Wednesday, September 15, 2010, from 7:30 a.m. to 12:15 p.m.

Location: The public conference will be held at the Renaissance Hotel, 999 9th St., NW., Washington, DC 20001, 202–898–9000, FAX: 202–289–0947.

Contact: Wanda Neal, Parenteral Drug Association, PDA Global Headquarters, Bethesda Towers, 4350 East-West Hwy., suite 200, Bethesda, MD 20814, 301–656–5900, FAX: 301–986–1093, email: *info@pda.org*.

Accommodations: Attendees are responsible for their own