plasmid, RFP-I-SceI-GR, is a chimera between the ISceI endonuclease and the ligand binding domain of the glucocorticoid receptor (GR) in frame with red fluorescent protein (RFP). This GR chimera will translocate from the cytoplasm to the nucleus upon addition of triamcinolone acetonide, leading to rapid induction of a double-stranded break between the lac and tet arrays.

Applications:

• Tool for drug studies relating to DNA stability and repair.

• Tool to probe the role of nuclear and DNA binding proteins in stability and repair.

Inventors: Thomas A. Misteli and Evi Soutoglou (NCI).

Related Publication: E Soutoglou, JF Dorn, K Sengupta, M Jasin, A Nussenzweig, T Ried, G Danuser, T Misteli. Positional stability of single double-strand breaks in mammalian cells. Nat Cell Biol. 2007 Jun;9(6):675–682.

Patent Status: HHS Reference No. E–264–2009/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: This technology is available as a research tool under a Biological Materials License.

Licensing Contact: Steve Standley, PhD; 301–435–4074; *sstand@od.nih.gov.*

Mouse Embryonic Stem Cell-Based Functional Assay To Evaluate Mutations in BRCA2

Description of Technology: Mutations in breast cancer susceptibility genes BRCA1 and BRCA2 have up to an 80 percent life time risk in developing breast cancer. There are no ''mutation hot spots'' and to date, more than 1,500 different mutations have been identified in BRCA2. The absence of tumor cell lines expressing various mutant BRCA2 alleles has hindered evaluations to determine the functional differences between different mutations.

A simple, versatile and reliable mouse embryonic stem cell and bacterial artificial chromosome based assay to generate cell lines expressing mutant human BRCA2 has been developed and it has been used to classify 17 sequence variants. Available for licensing are wild-type and eleven mutant BRCA2 cell lines developed from this assay that have either truncations or point mutations. These cell lines may be used to evaluate the effect of DNA damaging agents, genotoxins and chemotherapeutic efficacy.

Applications:

• Research tool to generate and study BRCA2 mutations.

• Method to screen for chemotherapeutics.

• Method to evaluate DNA damaging agents.

Advantages: Ready to use portfolio of BRCA2 mutant cell lines to study BRCA2 mutant functional analysis.

Market: An estimated 194,280 new cases of breast cancer will be diagnosed and may cause 40,610 deaths in the U.S. in 2009.

Inventors: Shyam K. Sharan and Sergey Kuznetsov (NCI).

Publication: SG Kuznetsov et al. Mouse embryonic stem cell-based functional assay to evaluate mutations in BRCA2. Nat Med. 2008 Aug;14(8):875–881.

Patent Status: HHS Reference No. E–261–2007/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov.*

Collaborative Research Opportunity: The Mouse Cancer Genetics Program, Center for Cancer Research, National Cancer Institute, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize mouse embryonic stem cell lines suitable for functional analysis of BRCA2 variants. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Establishment of Two Cell Lines That Stably Express Luciferase for In Vivo Tracking

Description of Technology: Available for licensing are two renal carcinoma cell lines, 786-O(luc) and 786-O/VHL/(luc) which both stably express luciferase. 786-O(luc) lacks von Hippel-Landau (VHL) protein expression and it has constitutively high expression of hypoxia-inducible transcription factor-2alpha (HIF-2alpha). The second stably expresses VHL, a tumor suppressor, and has minimal HIF-2alpha expression. These cell lines can be tracked in vivo and can be used to study VHL-dependent and HIF-2alpha dependent events such as tumorigenesis. VHL mutations lead to the clinical manifestations of von Hippel-Lindau disease, a rare autosomal dominant syndrome characterized by abnormal growth of blood vessels in multiple organs, including the brain and kidneys.

Applications: Model to study VHL pathology.

Advantages: Cell lines that stably express luciferase for in vivo tracking.

Benefits: Easy, ready to use positive and negative VHL and HIF-2alpha cells that stably express luciferase for in vivo tests.

Market:

• Incidence of VHL syndrome is 1 in 38,951.

• HCC is the third leading cause of cancer death worldwide.

• HCC is the fifth most common cancer in the world.

• Post-operative five-year survival rate of HCC patients is 30–40 percent.

Inventors: Leonard M. Neckers and W. Marston Linehan (NCI).

Patent Status: HHS Reference No. E–005–2007/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Urologic Oncology Branch, is seeking statements of capability or interest from parties interested in collaborative research to develop further uses for these two cell lines that stably express luciferase for in vivo tracking. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: September 17, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–22974 Filed 9–22–09; 8:45 am]

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.

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.

Osmogels: A New Method for Stabilizing Weak Molecular Complex Interactions

Description of Invention: This invention describes a new method for stabilizing molecular complexes in polyacrylamide gels for analysis by the electrophoretic mobility shift assay. By adding specific osmolytes directly to the gel, investigators have found that weakly interacting molecular complexes can be sufficiently stabilized to allow quantitative analysis of the binding. Experiments with nonspecific labile complexes of two restriction endonucleases, EcoRI and BamHI, show that one of these added solutes is particularly effective at inhibiting complex dissociation, does not interfere with normal gel polymerization, and does not significantly slow normal gel migration. The results also demonstrate that sharp bands can be obtained for non-specific complexes of both enzymes on gels prepared with this solute while only smeared and distorted bands are observed on regular gels prepared without the solute. This method can be used for protein-protein, DNA-protein, and RNA-protein complexes, and can also be extended to include other techniques for separating complexes from free components using gel chromatography and capillary electrophoresis.

The potential market for gels that allow researchers to detect and quantify weak molecular complex interactions is significant; ranging from molecular biologists searching for novel regulatory DNA-binding proteins and convenient ways to detect protein-protein, or protein-DNA/RNA complexes to crystallographers needing reliable techniques to search for optimal conditions of complex formation. This technology has the potential to significantly impact biomedical research and development across many fields.

Application: Detection of weak molecular complex interactions for research and commercial use.

Development Status: Late stage.

Inventors: Nina Y. Sidorova and Donald C. Rau (NICHD).

Publications:

1. NY Sidorova, S Muradymov, DC Rau. Trapping DNA-protein binding reactions with neutral osmolytes for the analysis by gel mobility shift and self-cleavage assays. Nucleic Acids Res. 2005 Sep 9;33(16):5145–5155.

2. NY Sidorova and DC Rau. Differences between EcoRI nonspecific and ''star'' sequence complexes revealed by osmotic stress. Biophys J. 2004 Oct;87(4):2564–2576.

Patent Status: U.S. Patent Application No. 12/485,481 filed 16 Jun 2009 (HHS Reference No. E–214–2009/0–US–01); No foreign patent rights available.

Licensing Status: Available for licensing.

Licensing Contact: Jeffrey A. James, Ph.D.; 301–435–5474; *jeffreyja@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute of Child Health and Human Development, Program in Physical Biology, Laboratory of Physical and Structural Biology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize osmogels for analysis of weak complexes by the electrophoretic mobility shift assay with potential extension of the technique to other separation methods. Please contact Joseph Conrad III, Ph.D. at 301–435–3107 or *jmconrad@mail.nih.gov* for more information.

RNA Nanoparticles and Methods of Use

Description of Invention: The invention hereby offered for licensing is in the field of nanoparticles and their usefulness in a variety of medical applications. More specifically the invention describes the design and synthesis of various RNA nanoparticles. These polyvalent nanoparticles comprise RNA motifs as building blocks that give the particles their unique characteristics. Moreover, the motifs can be pre-defined and chosen to give the particles desired characteristics (e.g. size and shape) tailored for a variety of applications. The polyvalent particles can utilize multiple unique positions to carry functional groups for cell recognition (e.g. cancer cells), therapy and detection. For therapeutic or detection applications the particles typically encompass at least two functional groups, a therapeutic or imaging agent and a targeting agent that will direct the particles to the targeted tissue.

RNA nanoparticles have the potential to serve as excellent drug or imaging delivery systems due to their designability and versatility. Furthermore, the RNA nanoparticles of the invention are also capable of self-assembly and potentially form nanotubes of various shapes which offer potentially broad uses in medical implants, gene therapy, nanocircuits, scaffolds and medical testing.

Applications: The technology can be primarily used for therapeutic and diagnostic applications.

Advantages: RNA nanoparticles potentially offer advantages compared to other conventional nanoparticles:

- They are compatible with biological systems and thus may be readily used for in vivo applications such as therapeutic and diagnostic.
- They are small and have a potential to move efficiently through biological barriers to a target tissue.
- They have multiple binding sites and thus can readily be conjugated with several functional groups (e.g. therapeutic molecule and targeting molecule).
- They are versatile and can be designed in different shapes and sizes for different applications.

Development Status: Early stage.

Market:

- According to U.S. National Science Foundation estimates, by 2015 the annual global market for nano-related goods and services will top $1 trillion, thus making it one of the fastest-growing industries in history. Assuming that these figures prove to be accurate, nanotechnology will emerge as a larger economic force than the combined telecommunications and information technology industries at the beginning of the technology boom of the late 1990s.
- The interest in nanoparticles as carriers of biological materials for medical applications has been growing exponentially in recent years and the commercial potential in the medical field is vast.
- According to market research reports the global medical market for nanotechnology applications is expected to increase from about $1.7 billion in 2007 to an estimated $3.8 billion by 2013, a compound annual growth rate (CAGR) of 14.9%.
- Nanoparticles have the largest share of the market, worth $1.6 billion in 2007. This segment is expected to be worth $3.4 billion in 2013, a CAGR of 13.4%.
- Other nanostructured materials represent the second largest segment, generating $36.5 million in 2007 and an $304.7 million in 2013, for a CAGR of 46.5%.
- Some therapeutics and imaging medical products based on nanoparticles have recently received FDA approval and are ready for commercialization. For example, the Rexin G, a targeted Delivery System (TRS) for treatment of solid tumors is already used commercially in the

Philippine and is currently being commercialized in the US by Epeius Biotechnologies.

Inventor: Bruce A. Shapiro (NCI).

Publications:

1. E Bindewald, C Grunewald, B Boyle, M O'Connor, BA Shapiro. Computational strategies for the automated design of RNA nanoscale structures from building blocks using NanoTiler. J Mol Graph Model. 2008 Oct;27(3):299–308.

2. B Shapiro, E Bindewald, W Kasprzak, Y Yingling. (E Gazit, F Nussinov, eds.) Protocols for the In silico Design of RNA Nanostructures. In: Nanostructure Design Methods and Protocols. Totowa, NJ: Humana Press; 2008. p. 93–115.

3. HM Martinez, JV Maizel Jr, BA Shapiro. RNA2D3D: a program for generating, viewing, and comparing 3-dimensional models of RNA. J Biomol Struct Dyn. 2008 Jun;25(6):669–683.

4. I Severcan, C Geary, L Jaeger, E Bindewald, W Kasprzak, B Shapiro. (G Alterovitz, M Ramoni, R Benson, eds.) Computational and Experimental RNA Nanoparticle Design. In: Automation in Genomics and Proteomics: An Engineering Case-Based Approach. Hoboken: Wiley Publishing; 2009.

5. E Bindewald, R Hayes, YG Yingling, W Kasprzak, BA Shapiro. RNAJunction: a database of RNA junctions and kissing loops for three-dimensional structural analysis and nanodesign. Nucleic Acids Res. 2008 Jan;36:D392–397.

6. YG Yingling and BA Shapiro. Computational design of an RNA hexagonal nanoring and an RNA nanotube. Nano Lett. 2007 Aug;7(8):2328–2334.

7. BA Shapiro and YG Yingling. PCT Application No. PCT/US2007/13027 filed 31 May 2007, which published as WO 2008/039254 on 03 Apr 2008, and U.S. Patent Application No. 12/227,955 filed 02 Dec 2008; both entitled ''RNA Hexagonal Ring and RNA Nanotube.''

Patent Status: U.S. Provisional Application No. 61,187,495 filed 16 Jun 2009 (HHS Reference No. E–059–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contacts: Uri Reichman, Ph.D., MBA; 301–435–4616; UR7a@nih.gov; John Stansberry, Ph.D.; 301–435–5236; js852e@nih.gov

Collaborative Research Opportunity: The National Cancer Institute's Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize RNA nanostructures. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Bactericidal Peptides From Avian Leukocyte Ribonuclease A–2

Description of Invention: These bactericidal polypeptides offer a novel alternative to conventional antibiotics that are used to treat and prevent bacterial infections. As infection-causing bacteria continue to develop antibiotic resistance to first line antibiotics there will always be a need for new antibiotic alternatives. Additionally, a greater understanding of the specific cytoxic activity of RNase A ribonucleases, their functional domains, and their roles in promoting anti-pathogen host defense may provide insight into new therapeutic agents.

This invention includes a novel RNase A ribonuclease from chicken leukocytes and polypeptides that have bactericidal activities against both gram positive and gram negative bacteria, including such pathogens as *Escherichia coli, Salmonella spp.,* and *Staphylococcus.*

Applications:

- Polypeptides exhibiting bactericidal, bacteriostatic, and ribonuclease activity.
- Pharmaceutical compositions comprising the bactericidal polypeptides.
- Methods for treating bacterial infections.

Development Status: Early stage.

Market: With the increase in antibiotic and antibacterial drug resistance, the market for alternatives is growing.

Inventors: Helene F. Rosenberg et al. (NIAID).

Related Publication: T Nitto, KD Dyer, M Czapiga, HF Rosenberg. Evolution and function of leukocyte RNase A ribonucleases of the avian species, *Gallus gallus.* J Biol Chem. 2006 Sep 1;281(35):25622–25634.

Patent Status: U.S. Patent Application No. 12/438,700 filed 24 Feb 2009, claiming priority to 24 Aug 2006 (HHS Reference No. E–281–2006/0–US–03)

Licensing Status: Available for licensing.

Licensing Contact: RC Tang JD LLM; 301–435–5031; tangrc@mail.nih.gov.

Collaborative Research Opportunity: The NIAID Laboratory of Allergic Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact William Ronnenberg, NIAID Office of Technology Development, at 301–451–3522 or *wronnenberg@niaid.nih.gov* for more information.

Dated: September 17, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–22975 Filed 9–22–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0440]

Availability of Grant Funds for the Support of Cooperative Agreement Award to Georgetown University Entitled: Genome Wide Methylation Arrays for Detecting Markers of Increased Susceptibility to Mammary Cancer Caused by In-Utero Exposures to Endocrine Disruptors (U01)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM), and Office of New Animal Drugs (ONADE) is announcing the availability of grant funds for the support of a sole source, cooperative agreement award to Georgetown University, Lombardi Cancer Research Center and Department of Oncology entitled: ''Genome Wide Methylation Arrays for Detection Markers of Increased Susceptibility to Mammary Cancer Caused by In-Utero Exposures to Endocrine Disruptors (U01).'' The main purpose of this study is to help gain an understanding of the extent to which exposures to endocrine disruptors early in life increase later susceptibility to developing breast cancer by inducing heritable epigenetic changes in transcription factors, which are linked to increased breast cancer risk. The study is subject to the requirements of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331, *et seq.*) regulations issued under it and applicable Department of Health and Human Services statutes and regulations.

DATES: Important dates are as follows:

1. The application due date is 30 days from the publication in the **Federal Register**.

2. The anticipated start date is September 2009.

FOR FURTHER INFORMATION CONTACT:

Peer Review/Administrative Contact: Michelle Fuller, Center for