The inventors have discovered that Zinc finger protein 36 like type-2 (ZFP36L2) plays an essential role in hematopoiesis, possibly by affecting the stability of mRNAs involved in this process. ZFP36L2 is a member of the tristetraprolin (TTP) family, which are mRNA-binding proteins involved in mRNA processing and degradation. The invention discloses methods of detecting abnormal hematopoiesis by detecting abnormal ZFP36L2 expression or a mutation in the ZFP36L2 gene, and methods of controlling abnormal hematopoiesis by modulating levels of ZFP36L2 protein.

Applications:

• Diagnostic test to detect abnormal hematopoiesis.

• Therapy for abnormal hematopoiesis.

Development Status: Discovery stage.

Market:

• Over 3.5 million people in the United States suffer from anemia, according to NHLBI, and more than half of all chemotherapy treatment for cancer results in anemia.

• The American Cancer Society estimates that approximately 4300 cases of chronic myelogenous leukemia are diagnosed in the United States every year.

Inventors: Perry J. Blackshear and Deborah J. Stumpo (NIEHS).

Related Publication: DJ Stumpo, HE Broxmeyer, T Ward, S Cooper, G Hangoc, YJ Chung, WC Shelley, EK Richfield, MK Ray, MC Yoder, PD Aplan, PJ Blackshear. Targeted disruption of Zfp36l2, encoding a CCCH tandem zinc finger RNA-binding protein, results in defective hematopoiesis. Blood 2009 Sep 17;114(12):2401–2410.

Patent Status: PCT Application Serial No. PCT/US08/68900 filed on 01 Jul 2008 (HHS Reference No. E–255–2007/0–PCT–02).

Licensing Status: Available for licensing.

Licensing Contact: Tara Kirby, Ph.D.; 301–435–4426; *tarak@mail.nih.gov.*

Collaborative Research Opportunity: The NIEHS Laboratory of Signal Transduction, Polypeptide Hormone Action 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, Ph.D., Director, Office of Technology Transfer, NIEHS, at *denholme@niehs.nih.gov* for more information.

Susceptibility-Matched Multiwell Plates for High-Throughput Screening by Magnetic Resonance Imaging and Nuclear Magnetic Resonance Spectroscopy

Description of Technology: Available for licensing and commercial development is a patent estate that covers multi-well assay plates for high-throughput screening by magnetic resonance imaging (MRI) and nuclear magnetic resonance (NMR) spectroscopy. Multi-well plates are used in a wide variety of high-throughput measurements in clinical chemistry and immunology, as well as in drug discovery and other research applications. Magnetic resonance imaging (MRI) of multi-well plates offers the possibility of performing new kinds of high-throughput assays, including the detection of magnetic nanoparticles attached to or within cells. Moreover, MRI-guided localized nuclear magnetic resonance (NMR) spectroscopy could be used to perform detailed chemical analysis of complex mixtures of metabolites not possible by any other common analytical technique. Best of all, conventional MRI techniques exist which would permit all samples in one or more multi-well plate(s) to be analyzed simultaneously. Unfortunately, conventional multi-well plates typically give poor performance for MRI-based assays since they provide inadequate matching of magnetic susceptibility between the plate, the sample and their surroundings. This results in distortion of the magnetic field within the scanner and thus reduces the sensitivity for detecting magnetic particles and the resolution of NMR spectra.

This invention relates to a new multi-well plate design incorporating one-piece polyetherimide plastic construction for improved magnetic susceptibility matching for aqueous samples. This design can easily be extended to non-aqueous samples by the selection of an appropriate, commercially available plastic resin or resin blend. Further enhancement in susceptibility matching can be accomplished by combining the new plate design with plugs for each well constructed from the same plastic as the plate. These plugs would allow the entire thickness of each sample to be scanned in chemical analyses, improving signal-to-noise ratio and sensitivity. These plugs can optionally be integrated into a single ''cap mat'' so that the entire assembly can be filled and manipulated by standard robotic laboratory equipment already in wide use in the pharmaceutical industry. Alternatively, spherical wells, accessed by narrow fill holes, may be molded into a solid plate, eliminating the need for individual plugs to seal each well. The new multi-well plate/plug design reduces magnetic field distortions and should dramatically improve spectral resolution and sensitivity for NMR and MRI-based high-throughput screening.

Applications:

• NMR Spectroscopy,

• MRI Imaging of magnetic nanoparticles,

• Clinical Chemistry,

• Immunology,

• Drug Discovery,

• Combinatorial Chemistry, and

• Quality Control in the pharmaceutical, chemical and agricultural industries.

Advantages:

• Increased signal-to-noise ratio and sensitivity relative to conventional multi- well plates

• Portability

• Compatible with existing high-throughput robots.

Development Status: Used actively in inventor's lab.

Inventor: Kenneth W Fishbein (NIA).

Patent Status: U.S. Patent Application No. 12/083,501 filed 30 Dec 2008 (HHS Reference No. E–243–2005/0–US–03).

Licensing Status: Available for licensing.

Licensing Contact: Michael Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute on Aging, Magnetic Resonance Imaging & Spectroscopy Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Nicole Darack, Ph.D. at 301–435–3101 or *darackn@mail.nih.gov* for more information.

Dated: October 5, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–24871 Filed 10–15–09; 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.

Engineered Biological Pacemakers

Description of Invention: A common symptom of many heart diseases is an abnormal heart rhythm or arrhythmia. While effectively improving the lives of many patients, implantable pacemakers have significant limitations such as limited power sources, risk of infections, potential for interference from other devices, and absence of autonomic rate modulation.

The technology consists of biological pacemakers engineered to generate normal heart rhythm. The biological pacemakers include cardiac cells or cardiac-like cells derived from embryonic stem cells or mesenchymal stem cells. The biological pacemakers naturally integrate into the heart. Their generation of rhythmic electric impulses involves coupling factors, such as cAMP-dependent PKA and Ca^{2+}-dependent CaMK II, which are regulatory proteins capable of modulating/enhancing interactions (*i.e.* coupling) of the sarcoplasmic reticulum-based, intracellular Ca^{2+} clock and the surface membrane voltage clock, thereby converting irregularly or rarely spontaneously active cells into pacemakers generating rhythmic excitations.

Applications: This technology can be utilized in heart disease characterized by arrhythmia or situations requiring an implantable cardiac pacemaker.

Advantages: In contrast to current implantable cardiac pacemaker technology, this technology is not externally powered, has a lower risk of infection, has decreased potential for interference from other devices, and has full autonomic rate modulation.

Development Status: Early stage.

Inventors: Victor A. Maltsev *et al.* (NIA).

Publications:

1. VA Maltsev and EG Lakatta. Synergism of coupled subsarcolemmal Ca^{2+} clocks and sarcolemmal voltage clocks confers robust and flexible pacemaker function in a novel pacemaker cell model. Am J Physiol Heart Circ Physiol. 2009 Mar;296(3):H594–H615.
2. VA Maltsev and EG Lakatta. Dynamic interactions of an intracellular Ca^{2+} clock and membrane ion channel clock underlie robust initiation and regulation of cardiac pacemaker function. Cardiovasc Res. 2008 Jan 15;77(2):274–284.

Patent Status: U.S. Provisional Application No. 61/180,491 filed 22 May 2009 (HHS Reference No. E–134–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Fatima Sayyid, M.H.P.M.; 301–435–4521; *sayyidf@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute on Aging, Cellular Biophysics Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Vio Conley at 301–496–0477 or *conleyv@mail.nih.gov* for more information.

Sensitizing Cancer Cells to DNA Targeted Therapies

Description of Invention: Chk2 is a protein kinase activated in response to DNA double strand breaks. In normal tissues, Chk2 phosphorylates and thereby activates substrates that induce programmed cell death, or apoptosis, via interactions with p53, E2F1, PML proteins. In cancer tissues, where apoptosis is suppressed, Chk2 phosphorylates and inactivates cell cycle checkpoints (via interactions with Cdc25, phosphatases and Brca1 proteins), which allows cancer cells to repair and tolerate DNA damage. Hence, Chk2 inhibitors would be expected to protect normal tissues by reducing apoptosis, and to sensitize cancer cells to DNA-targeted agents.

Applications:

- Combination with DNA targeted chemotherapeutic agents for the treatment of cancers.
- Single agents therapy for cancers with endogenously activated (''addicted to'') Chk2.
- Antiviral agent against hepatitis, herpes viruses and retroviral infections (HIV).

Advantages: Selective enhancement of the antiproliferative and proapoptotic activities of DNA targeted chemotherapeutic agents in tumors with inactivated p53, while protection of normal tissues by blocking p53-mediated apoptosis (''side effects'') induced by the DNA targeted agents.

Development Status: Optimization of chemical structure for improving drug delivery and pharmacokinetics.

Inventors: Yves G Pommier *et al.* (NCI).

Related Publications:

1. AG Jobson, JH Cardellina 2nd, D Scudiero, S Kondapaka, H Zhang, H Kim, R Shoemaker, Y Pommier. Identification of a Bis-guanylhydrazone [4,4'-Diacetyldiphenylurea-bis(guanylhydrazone); NSC 109555] as a Novel Chemotype for Inhibition of Chk2 Kinase. Mol Pharmacol. 2007 Oct;72(4):876–884.
2. AG Jobson, GT Lountos, PL Lorenzi, J Llamas, J Connelly, D Cerna, JE Tropea, A Onda, G Zoppoli, S Kondapaka, G Zhang, NJ Caplen, JH Cardellina, SS Yoo, A Monks, C Self, DS Waugh, RH Shoemaker, Y Pommier. Cellular inhibition of Chk2 kinase and potentiation of camptothecins and radiation by the novel Chk2 inhibitor PV1019. J Pharmacol Exp Ther. 2009 Sep 9; In press (Epub ahead of print).
3. GT Lountos, JE Tropea, D Zhang, AG Jobson, Y Pommier, RH Shoemaker, DS Waugh. Crystal structure of checkpoint kinase 2 in complex with NSC 109555, a potent and selective inhibitor. Protein Sci. 2009 Jan;18(1):92–100.

Patent Status: U.S. Patent Application No. 11/989,737 filed 29 Jan 2008 (HHS Reference No. E–211–2005/0–US–06); Related international patent application filings.

Licensing Status: Available for licensing.

Licensing Contact: Betty B. Tong, Ph.D.; 301–594–6565; *tongb@mail.nih.gov*.

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

Dated: October 5, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–24869 Filed 10–15–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0328]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Wound Dressing With Poly (Diallyl Dimethyl Ammonium Chloride) Additive; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Wound Dressing With Poly (Diallyl Dimethyl Ammonium Chloride) (pDADMAC) Additive.'' This guidance document describes a means by which wound dressing with Poly (diallyl dimethyl ammonium chloride) (pDADMAC) additive may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify wound dressing with pDADMAC additive into class II (special controls). This guidance document is being immediately implemented as the special control for wound dressing with pDADMAC additive, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on the guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Class II Special Controls Guidance Document: Wound Dressing With Poly (Diallyl Dimethyl Ammonium Chloride) (pDADMAC) Additive'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8502. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sam Arepalli, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3612, Silver Spring, MD 20993, 301–796–6434.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for wound dressing with pDADMAC additive. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Thus, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (§ 10.115). The guidance represents the agency's current thinking on wound dressings with pDADMAC additive. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Class II Special Controls Guidance Document: Wound Dressing With Poly (Diallyl Dimethyl Ammonium Chloride) (pDADMAC) Additive,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1684 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available at *http://www.regulations.gov*.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR