DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notification of Charter Renewal: National Preparedness and Response Science Board (Previously Known as the National Biodefense Science Board)

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of the Department of Health and Human Services has renewed the charter of the National Preparedness and Response Science Board (NPRSB), previously known as the National Biodefense Science Board, for an additional two-year period through July 3, 2016.


SUPPLEMENTARY INFORMATION: As stipulated by the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2 Section 9(c), the U.S. Department of Health and Human Services is hereby giving notice of the renewal of the NPRSB charter for an additional two-year period. The Board shall provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary on other matters related to public health emergency preparedness and response.

Dated: June 13, 2014.

Nicole Lurie,
Assistant Secretary for Preparedness and Response.

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BILLING CODE 4150–37–P
pharmacologically active small molecules sensitized cisplatin-resistant non-small cell lung cancer (NSCLC) cells to DNA crosslinking agent(77). Thus, USP1 inhibitors hold promise in combination therapy with the existing anti-cancer drugs to improve the efficacy and lower the toxic effect of the existing drugs.

More recently we have developed small molecules that target the USP1/UAF1 DUB complex(1). These compounds were identified via a high-throughput screen and subjected to medicinal chemistry optimization leading to one of the most potent and selective DUB inhibitors reported to date. Moreover, the inhibitors act synergistically with cisplatin, a DNA damaging anti-cancer drug, to overcome chemoresistance and enhance cytotoxicity. These results suggest the inhibitors may also improve the efficacy and potency of other commonly prescribed chemotherapy agents that are known to induce DNA damage. Furthermore the USP1/UAF1 small molecule inhibitors also hold promise in the single-agent therapy.

Under the CRADA, the chemical series will be further characterized and optimized to address specific aspects of this target product profile. The CRADA scope will also include studies beyond candidate selection including all aspects of preclinical studies such as toxicity studies, xenograft studies and chemistry GMP scale up of selected compounds and manufacture of control leading to a successful investigational new drug (IND) application. Collaborators should have experience in pre-clinical development of small molecules with a focus on cancer and a track record of successful submission of IND applications to the FDA.

The full CRADA proposal should include a capability statement with a detailed description of (1) collaborator’s expertise in the areas of modulation of small molecule physicochemical and pharmacokinetic properties; (2) expertise in formulation of small molecules and ability to manufacture sufficient quantities of chemical compounds according to FDA guidelines and under Good Manufacturing Practice (GMP); (3) expertise on oncology and/or other diseases which may benefit from USP1/UAF1 inhibition; (4) expertise in regulatory affairs, particularly at the IND filing and early clinical trial stages; (5) collaborator’s ability to support, directly or through contract mechanisms, and ability, upon the successful completion of the application phases, to support the ongoing pharmacokinetics and biological studies, long term toxicity studies, process chemistry and other pre-clinical development studies needed to obtain regulatory approval of a given molecule so as to ensure a high probability of eventual successful commercialization; (6) collaborator’s ability to provide adequate funding to support some of the project’s pre-clinical studies.

Publications


Patent Status


PCT Application No. PCT/US2013/073984 is entitled, “Inhibitors of the USP1/UAF1 Deubiquitinase Complexes and Uses Thereof” filed December 26, 2013 Inventors: Thomas Dexheimer (NCATS), Ajit Jadhav (NCATS), Qin Liang (University of Delaware), Diane Luci (NCATS), David Maloney (NCATS), Andrew Rosenthal (NCATS), Anton Simeonov (NCATS), Zhihao Zhuang (University of Delaware) NIH Ref. No.: E–043–2013/0–PCT–02.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, 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. 209 and 37 CFR Part 404 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 CONTACT: 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.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

AMA1–RON2 Complex-Based Vaccine Against Malaria

Description of Technology: This technology relates to a malaria vaccine composed of a protein complex of Apical Membrane Antigen (AMA1) and rhesopy neck protein 2 (RON2) with an adjuvant. AMA1 is a crucial component of the *Plasmodium* invasion machinery and is a leading candidate for antimalarial vaccine development.