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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.

Ketone Bodies to Protect Tissues from Damage by Ionizing Radiation

Description of Technology: The invention relates to methods of using ketogenic compounds to protect against the adverse effects of radiation exposure, including ionizing radiation tissue damage. NIH inventors have discovered that ketone esters can be used to reduce tissue damage if administered before or after exposure to radiation. Specifically, the invention relates to esters and oligomers of (R)-3-hydroxybutyrate that are capable of elevating blood levels of (R)-3-hydroxybutyrate and acetoacetate to sufficient levels to reduce cell death caused by radiation-induced damage of DNA and RNA. The development of effective radioprotectant molecules such as these is of great importance in reducing tissue damage following intentional or accidental radiation exposure. This discovery can also increase the therapeutic efficacy of radiation therapies by protecting non-target tissues from incidental radiation damage.

Potential Commercial Applications:

• Effective therapeutic agent for reducing tissue damage following radiation exposure

• Protects populations subjected to accidental, incidental, or military exposure to radiation

• Protects non-target tissue during radiation therapy

Competitive Advantages:

• Can be administered before or after radiation damage

• Stable at room temperature, allowing easy storage

Development Stage: In vitro data available

Inventor: Richard L. Veech (NIAAA)

Intellectual Property: HHS Reference No. E-258-2012/0 – US Application No. 61/722,630 filed 05 Nov 2012

Licensing Contact: Charlene Sydnor, Ph.D.; 301-435-4689; sydnorc@mail.nih.gov

Collaborative Research Opportunity: The NIAAA is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Ketone Bodies to Protect Tissues from Damage by Ionizing Radiation. For collaboration opportunities, please contact Peter B. Silverman, Ph.D., J.D. at psilverm@mail.nih.gov or 301-402-6966.

mTOR Inhibition for the Prevention of Epithelial Stem Cell Loss and Mucositis

Description of Technology: The integrity of the epidermis and mucosal epithelia is highly dependent on self-renewing stem cells and, therefore, is vulnerable to physical and chemical damage from common cancer treatments, such as radiation or chemotherapy. Consequently, many cancer patients undergoing these treatments develop mucositis, a debilitating condition involving painful and deep mucosal ulcerations. Since current prevention and treatment options for mucositis are limited, providing only minor relief and no protection to stem cells, novel therapies are needed.

The NIH inventors have recently discovered that the mammalian target of rapamycin (mTOR) mediates stem cells exhaustion in the skin and leads to progressive hair loss. More importantly, they have shown that mTOR inhibition reduces oxidative stress in the epithelial stem cells and mTOR inhibitors can be used to increase the re-populative capacity of tissue resident stem cells to maintain tissue homeostasis after

injury or stress. Therefore, this technology could be used to prevent epithelial stem cell loss and provide relief from radiation-induced mucositis. Likewise, it could be used to prevent mucositis and hair loss in patients undergoing chemotherapy and stem cell transplantation. For optimal delivery and effectiveness, rapamycin or other mTOR inhibitor could be administered in the form of a mouthwash or gel product to patients prior to receiving radiation (or other) treatments.

Potential Commercial Applications: Prevention and treatment of epithelial stem cell loss and mucositis.

Competitive Advantages:

• Reduces the oxidative stress in epithelial stem cells and can increase their repopulative capacity.

• Preserves the integrity of the oral mucosa and protects from radiation-induced stem cell loss and mucositis.

Development Stage:

• Pre-clinical

• In vitro data available

• In vivo data available (animal)

Inventors: Silvio Gutkind (NIDCR), Ramiro Iglesias-Bartolome (NIDCR), Vyomesh Patel (NIDCR), Ana Cotrim (NIDCR), Alfredo Molinolo (NIDCR), James Mitchell (NCI)

Publication: Iglesias-Bartolome R, et al. mTOR inhibition prevents epithelial stem cell senescence and protects from radiation-induced mucositis. Cell Stem Cell. 2012 Sep 7;11(3):401-14. [PMID 22958932]

Intellectual Property: HHS Reference No. E-257-2012/0 – U.S. Provisional Application No. 61/696,681 filed 05 Sep 2012

Related Technology: HHS Reference No. E-300-2008 – U.S. Patent Application No. 13/376,984 filed 08 Dec 2011

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

Combination Chemotherapeutics for the Treatment of Chordoma

Description of Technology: Utilizing high-throughput screening methodology, NIH scientists have identified two classes of clinically-available drugs, proteasome inhibitors and topoisomerase inhibitors, that synergize to promote chordoma cell death. Moreover, use of the two-part chemotherapeutic regimen in animal models effectively suppressed the growth of chordoma cells and resulted in significant tumor regression. Currently, no chemotherapeutic agents have been approved for the treatment of chordoma. Using FDA approved drugs in a combination therapeutic regimen will help expedite the availability of a therapeutic for chordoma.

Chordoma is a rare form of bone cancer that arises within the skull, sacrum or bony spine. Surgical resection and radiation therapy are the current standards-of-care; however, post-treatment complications remain significant and neither modality is effective for the control of metastatic tumors.

Potential Commercial Applications:

• Chemotherapeutic regimen for the treatment of inoperable chordomas.

• Therapy for the treatment of recurrent or metastatic chordomas.

• Therapeutic kit combining an FDA-approved proteasome inhibitor with a topoisomerase inhibitor.

Competitive Advantages:

• Therapy utilizes FDA-approved drugs with known pharmacokinetics and safety profiles.

• Reduced drug dosing from combination therapy may result in fewer patient side effects.

• Combination therapy inhibits multiple molecular targets, enhancing disease response.

Development Stage:

• Pre-clinical

• In vitro data available

• In vivo data available (animal)

Inventors: Menghang Xia, Ruili Huang, Christopher P. Austin (all of NCATS)

Intellectual Property: HHS Reference No. E-156-2012/0 – US Application No. 61/692,560 filed 23 Aug 2012

Licensing Contact: Sabarni Chatterjee, Ph.D., MBA; 301-435-5587; chatterjeesa@mail.nih.gov

Collaborative Research Opportunity: The National Center for Advancing Translational Sciences, Division of Pre-Clinical Innovation, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Combination Chemotherapeutics for the Treatment of

Chordoma. For collaboration opportunities, please contact Lili M. Portilla, MPA at lilip@nih.gov.

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Date

Richard U. Rodriguez,
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Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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