The patent rights in these inventions have been assigned to the Government of the United States of America. The prospective patent license will be granted worldwide and in a field of use not broader than radiotherapeutics for somatostatin-receptor expressing neuroendocrine tumors.

The invention pertains to a radiotherapeutic against neuroendocrine tumors that express somatostatin receptor. Radionuclide therapies directed against tumors that express somatostatin receptors (SSTRs) have proven effective for the treatment of advanced, low- to intermediate-grade neuroendocrine tumors. The subject radiotherapeutic covered by the subject patent estate includes a somatostatin (SST) peptide derivative like octreotide (TATE), conjugated to an Evans Blue (EB) analog, and further chelated via DOTA to therapeutic radionuclide $^{177}$Lu, a beta emitter. The EB analog reversibly binds to circulating serum albumin and improves the pharmacokinetics of SST peptide derivatives and reduce peptide-receptor radionuclide therapy toxicity. EB analog conjugated to octreotide (EB-DOTATATE) has been shown by the inventors to provide reversible albumin binding in vivo and extended half-life in circulation. When EB-TATE is slowly released into the tumor microenvironment, tumor uptake and internalization into SSTR positive tumors resulted in delivery of radioactive particles and tumor cell killing. EB-TATE displayed significantly more favorable pharmacokinetics than TATE alone by achieving higher tumor to non-tumor penetration as evidenced by positron emission tomography.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive patent license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the NHLBI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license.

Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 20, 2018.
Michael A. Shmilovich,
Senior Licensing and Patenting Manager,
National Heart, Lung, and Blood Institute,
Office of Technology Transfer and Development.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Molecular Targeting Technologies, Inc. (MTTI); a Delaware corporation, with its principle place of business in West Chester, Pennsylvania, to practice the inventions embodied in the patent application listed in the SUPPLEMENTARY INFORMATION section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development August 27, 2018 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Michael Shmilovich, Esq., Senior Licensing and Patent Manager, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892–2479, phone number 301–435–5019, or shmilovm@mail.nih.gov.

Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

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BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice To Announce Commission of a Surgeon General’s Report on Oral Health

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: On behalf of the United States Department of Health and Human Services, the Office of the Surgeon General, the National Institutes of Health, and the National Institute of Dental and Craniofacial Research, the U.S. Public Health Service’s Oral Health Coordinating Committee announces the commission of a Surgeon General’s Report presenting prominent issues affecting oral health. The report will document progress in oral health in the twenty years since the 2000 Surgeon General’s Report on Oral Health, identify existing knowledge gaps, and articulate a vision for the future.

FOR FURTHER INFORMATION CONTACT:
Bruce A. Dye, DDS, MPH, Dental Epidemiology Officer, Office of Science Policy and Analysis, NIDCR, NIH, 31 Center Drive, Room SB55, Rockville, MD, 20892. Phone: 301–496–7765. Email: bruce.dye@nih.gov.

SUPPLEMENTARY INFORMATION:
Scope of Problem: The charge for the first Surgeon General’s report on oral health in 2000 was to define, describe, and evaluate the interaction between oral health and health and well-being (quality of life), through the lifespan in the context of changes in society. The overarching message from that report clearly communicated that oral health is essential to the general health and well-being of all Americans and can be achieved by all. In the intervening two decades, oral health has improved for many Americans, but not for all. Many Americans are retaining more of their natural teeth, complete tooth loss among older adults is at the lowest level ever measured, and many younger children have less untreated tooth decay. Over the past two decades, we have learned more about how changes across the lifespan can substantially influence oral health and how health promotion activities and interventions targeted for specific life stages can benefit oral health and quality of life. However, many Americans continue to experience unnecessary pain and complications from poor oral health that adversely affect their well-being, adding substantial economic and social costs. Poor oral health also impacts our nation’s ability to recruit young adults for military service and maintain military readiness.

Oral health workforce models and care delivery systems have evolved in the past two decades. There has been a substantial effort to incorporate early detection and preventive oral health measures into primary care settings and the expansion of the State Children’s Health Insurance Program, Medicaid, and other health insurance programs have helped many Americans of all ages. Yet, as there have been some successes in integrating oral health into the broader health care system in the United States, many still view oral health care as a supplemental benefit, and not a priority benefit. This separate view of oral health negatively impacts our nation in a variety of ways, including the increasing use of emergency departments at substantial cost to treat dental pain and related conditions. Finally, the increasing problems of substance misuse and use disorders during the past two decades have impacted oral health at the patient, community, and provider level, which has raised awareness of the need to address dental provider prescribing patterns and pain management practices.

The first Surgeon General’s report on oral health addressed determinants for oral health and disease. Twenty years later, the knowledge gained from science and technology has continued to provide a better understanding of the etiology and natural history of oral and craniofacial diseases and conditions, and we have gained a better understanding of these determinants. This knowledge has led to therapeutic interventions that have improved oral health over the past two decades. Ongoing research is improving our understanding of the biological influences on oral health, the relationship between oral diseases and general health, the role of technology and advanced materials in improving dental care, and the benefits of good oral health to overall well-being and the community. Although we benefit from numerous advances that influence oral health, we still face challenges as we try to reach our goal of oral health for all.

Approach: The scope of the Surgeon General’s Report is intended to be broad and comprehensive, with the goal of mapping the current landscape of the key issues that affect oral health. It will present information from a variety of data sources such as the National Health and Nutrition Examination Survey, Medical Expenditure Panel Survey, Behavioral Risk Factor Surveillance System, and others. These sources highlight changes in oral health over time, providing opportunities to monitor how determinants for health have changed, and the effect of those changes over the past 20 years. The report is intended to: (1) Underscore the critical nature of poor oral health as a public health issue; (2) provide a comprehensive review of the importance of oral health throughout life; (3) describe important contemporary issues affecting oral health and the promise of science to transform the oral health of the nation; (4) outline a vision for future directions; and (5) educate, encourage, and call upon all Americans to take action.

Potential Areas of Focus: Areas of focus in the report may include a description of the epidemiology of diseases and conditions that affect the craniofacial complex; a review of health promotion and disease prevention activities; factors that affect the etiology of poor oral health at the individual and population level; social determinants of health and their influence on oral health disparities; biological factors including the microbiome; social, economic, and health consequences of poor oral health; mental health, substance misuse and addiction impact on the oral health of individuals, providers, and communities; the state of oral health care access and coverage as it relates to prevention and treatment for dental diseases and related conditions; integration of oral health into primary health care settings; organization and financing of the provision of dental care within the health care system; ethical, legal, and policy issues; and the application of scientific research in the field, including methods, challenges, and current and future directions.

Lawrence A. Tabak,
Deputy Director, National Institutes of Health.

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