

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Department of Health and Human Services.

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.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by contacting the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892-2479; telephone: 301-402-5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

Long Acting Therapeutic Conjugates With Evans Blue

This invention is a platform technology that pertains to the advantages of conjugating therapeutics to Evans Blue thus providing long lasting pharmacokinetic profiles by complexing with albumin. Notably, albumin bound therapeutic- or prodrug-Evans Blue conjugates provide a complex with a total molecular size above 60 kDa thus eliminating the risk for renal clearance. Interestingly, since albumin also crosses the blood-brain barrier and since all circulating Evans Blue is bound to albumin, Evans Blue bound therapeutics or prodrugs can also cross the blood-brain barrier. By way for example but not limitation, Evans Blue can be conjugated to insulin, GLP-1, exendin-4, exendin (9-39), octreotide, bombesin, RGD peptide (arginylglycylaspartic acid), vascular endothelial growth factor (VEGF), interferon (IFN), tumor necrosis factor (TNF), asparaginase, or adenosine deaminase, exenatide, dipeptidyl peptidase-4 inhibitors, neuropilin, epidermal growth factor, islet neogenesis associated protein, alpha-1 antitrypsin, anti-inflammatory agents, glulisine, glucagons, local cytokines, modulators of cytokines, anti-apoptotic

molecules, aptamers, asparaginase, adenosine deaminase, interferon α 2a, interferon α 2b, granulocyte colony stimulating factor, growth hormone receptor antagonists, doxorubicin, paclitaxel, gemcitabine, camptothecin, and temozolomide. Evans Blue conjugates according to this invention can additionally include radionuclides like ^{18}F , ^{76}Br , ^{124}I , ^{125}I , or ^{131}I , or $^{117\text{m}}\text{Sn}$ for tracking or use in diagnostics.

Potential Commercial Applications:

- Diabetes therapeutics
- Cancer therapeutics
- CNS therapeutics
- Pharmacokinetic/distribution studies

Competitive Advantages:

- long pharmacokinetic profile
- no renal clearance of circulating drug

Development Stage:

- Early stage
- Inventors:* Xiaoyuan Chen, Lixin Lang, Gang NIU (all of NIBIB).

Intellectual Property: HHS Reference No. E-143-2015/0; U.S. Provisional Patent Application 62/182,694 filed June 22, 2015; International Patent Application PCT/US2016/38475 filed June 21, 2016.

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

Dated: June 23, 2016.

Michael Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2016-15442 Filed 6-29-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Data and Information on Technologies Used for Identifying Potential Developmental Toxicants

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests available data and information on approaches and/or technologies currently used for identifying potential developmental toxicants. Submitted information will be used to assess the state of the science and determine technical needs for non-animal test methods used to evaluate the potential of chemicals to induce adverse effects in offspring.

DATES: *Receipt of information:* Deadline is August 15, 2016.

ADDRESSES: Data and information should be submitted electronically to niceatm@niehs.nih.gov.

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, NICEATM; email: warren.casey@nih.gov; telephone: (919) 316-4729.

SUPPLEMENTARY INFORMATION:

Background: NICEATM, which fosters the evaluation and promotion of alternative test methods for regulatory use, is supporting efforts to develop, validate, and implement alternative approaches for identifying potential developmental toxicants. The goal of these alternative approaches is to replace, reduce, or refine the use of animals in testing. Testing a chemical's potential to cause developmental toxicity is required by multiple regulatory agencies and may require the use of large numbers of animals.

Request for Information: NICEATM requests available data and information on approaches and/or technologies currently used to identify potential developmental toxicants. Respondents should provide information on any activities relevant to the development or validation of alternatives to *in vivo* developmental toxicity test methods currently required by regulatory agencies, including data from non-animal chemical tests for developmental hazard potential. NICEATM also requests any available data resulting from *in vivo* developmental studies, ethical human or animal studies, or accidental human exposures, using the same chemicals.

Respondents to this request for information should include their name, affiliation (if applicable), mailing address, telephone, email, and sponsoring organization (if any) with their communications. The deadline for receipt of the requested information is August 15, 2016. Responses to this notice will be posted at: <http://ntp.niehs.nih.gov/go/dev-nonanimal>. Persons submitting responses will be identified on the Web page by name and affiliation or sponsoring organization, if applicable.

Responses to this request are voluntary. No proprietary, classified, confidential, or sensitive information should be included in responses. This request for information is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.