

- * 4. Proposed labeling for oxycodone HCl IR capsules, PMRS, NDA 209155 (Dec. 2017).
- * 5. Complete Response letter, NDA 209155 (November 16, 2017).
- * 6. "Filing Communication Responses," PMRS, NDA 209155.
- * 7. "Request for Priority Review Designation," PMRS, NDA 209155.
- * 8. "Memorandum of Meeting Minutes" for Type B, Pre-NDA, July 11, 2016 teleconference (August, 8, 2016).
- * 9. "NDA 209155 CMC Information Request 5-25-17," PMRS, NDA 209155.
- * 10. Centers for Disease Control, "Integrated Prevention Services for HIV Infection, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis for Persons Who Use Drugs Illicitly: Summary Guidance From the CDC and the U.S. Department of Health and Human Services," *Morbidity and Mortality Weekly Report*, vol. 61, pp. 1-40, 2012.
- * 11. National Institute on Drug Abuse, "What is heroin and how is it used?," available at <https://www.drugabuse.gov/publications/research-reports/heroin/what-heroin> (accessed June 13, 2018).
- * 12. FDA News Release, "FDA requests removal of Opana ER for risks related to abuse" (June 8, 2017), available at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.
13. Hunt, R. et al., "A Mechanistic Investigation of Thrombotic Microangiopathy Associated with IV Abuse of Opana ER," *Blood*, Feb. 16, 2017.
- * 14. FDA Guidance for Industry "Abuse-Deterrent Opioids—Evaluation and Labeling," available at <https://www.fda.gov/downloads/Drugs/Guidances/UCM334743.pdf>.

Dated: October 25, 2018.

Denise Hinton,
Chief Scientist.

[FR Doc. 2018-23710 Filed 10-29-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Council on Nurse Education and Practice

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Advisory Council on Nurse Education and Practice (NACNEP or the Council) has scheduled a public meeting. Information about NACNEP and the agenda for this meeting can be found on the NACNEP website at <https://www.hrsa.gov/>

advisory-committees/nursing/index.html.

DATES: November 19, 2018, 8:30 a.m.–4:15 p.m. ET.

ADDRESSES: This meeting will be held by teleconference and webinar. The conference call-in number is 1-888-455-0640; passcode: HRSA COUNCIL. The webinar link is <https://hrsa.connectsolutions.com/nacnep/>.

FOR FURTHER INFORMATION CONTACT: Tracy L. Gray, MBA, MS, RN, Division of Nursing and Public Health, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, 11N112, Rockville, Maryland 20857; 301-443-3346; or DScott1@hrsa.gov.

SUPPLEMENTARY INFORMATION: NACNEP provides advice and recommendations to the Secretary of Health and Human Services (Secretary) and the U.S. Congress on policy matters arising in the administration of Title VIII of the Public Health Service (PHS) Act, as amended, including the range of issues relating to nurse supply, education, and practice improvements. NACNEP provides an annual report to the Secretary and Congress describing the activities of NACNEP, including findings and recommendations made by NACNEP concerning the activities under this title.

During the November 19, 2018, meeting, NACNEP will continue discussing areas where nursing can take the lead in the transition of the health care system to value-based care through improvements to nurse education and practice, to advance the development of its 15th Report. In addition, the members will discuss strategic priorities and future directions for the Council and discuss possible topics for its 16th Report. Agenda items are subject to change as priorities dictate. Refer to the NACNEP website for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written statements to NACNEP should be sent to Ms. Tracy L. Gray, Designated Federal Official, using the contact information above at least 3 business days prior to the meeting.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018-23685 Filed 10-29-18; 8:45 am]

BILLING CODE 4165-15-P

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 invention listed below is jointly owned by an agency of the U.S. Government with Pontificia Universidad Catolica de Chile and is available for licensing 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 application listed below may be obtained by communicating with Ami Gadhia, JD, LL.M., CLP, Technology Transfer and Patenting Specialist, National Center for Advancing Translational Sciences, NIH, 9800 Medical Center Drive, Rockville, MD 20850, Phone: 301-217-6098, or email ami.gadhia@nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.
c-Abl Tyrosine Kinase Inhibitory Compounds and Methods of Manufacture and Use

Description of Technology

The invention includes compounds that inhibit c-Abl tyrosine kinase, and methods of making them which include administering (i) a therapeutically effective amount of the compound or a stereoisomer, tautomer, pharmaceutically acceptable salt, solvate, or prodrug thereof; or (ii) a therapeutically effective amount of the pharmaceutical compositions to a patient with the disease which involves c-Abl tyrosine kinase, including the overexpression of it. In some embodiments, the compound inhibits c-Abl tyrosine kinase by binding to an allosteric site of the c-Abl tyrosine kinase. In some embodiments, the compound binds to a myristate pocket of the c-Abl tyrosine kinase.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further

development and evaluation under a research collaboration.

Potential Commercial Applications

- Novel therapeutics for neurodegenerative diseases AND other indications which involve c-Abl kinase (e.g., lysosomal storage disorders, cancers, etc.).

Competitive Advantages

- Novel compounds that have a commercial advantage over those currently known because they are able to selectively bind to c-Abl at an allosteric site, can cross the blood-brain barrier, and show robust efficacy in several neurodegenerative models. All of this allows them to potentially treat neurodegenerative diseases, cancer etc.

Development Stage

- Pre-Clinical (in vivo validation).

Inventors

- Juan Marugan, Marc Ferrer, Noel Southall, Andres Dulcey, Xin Hu, Christopher Dextras, Daniel Talley, Alejandra Alvarez, Silvana Zanlungo.

Intellectual Property: 1. C-ABL TYROSINE KINASE INHIBITORY COMPOUND EMBODIMENTS AND METHODS OF MAKING AND USING THE SAME" U.S. Provisional Patent Application NO. 62/641,126 filed on March 9, 2018 (HHS Ref. No. E-252-2017).

Licensing Contact: Ami Gadhia, JD, LL.M., CLP, 301-217-6098; ami.gadhia@nih.gov.

Dated: September 25, 2018.

Lillianne M. Portilla Weingarten,

Technology Development Coordinator, National Center for Advancing Translational Sciences.

[FR Doc. 2018-23616 Filed 10-29-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial

property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; NICHD K99 Teleconference Review.

Date: November 29, 2018.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20894 (Telephone Conference Call).

Contact Person: Helen Huang, Scientific Review Branch (SRB), DER, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, DHHS, 6710B Rockledge Drive, Rm. 2125B, Bethesda, MD 20817, 301-435-8380, helen.huang@nih.gov.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Pediatric Critical Care and Trauma Scientist Development Program (K12) Teleconference Review.

Date: December 3, 2018.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Helen Huang, Scientific Review Branch (SRB), DER, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, DHHS, 6710B Rockledge Drive, Rm. 2125B, Bethesda, MD 20817, 301-435-8380, helen.huang@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: October 24, 2018.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-23615 Filed 10-29-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Second Stage Review.

Date: November 19, 2018.

Time: 8:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892.

Contact Person: Kimberly Firth, Ph.D., National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301-402-7702, firthkm@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: October 24, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-23614 Filed 10-29-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; Ancillary Studies Application Review.

Date: November 2, 2018.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.