FOR FURTHER INFORMATION CONTACT:
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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Agents for Treatment.” This draft guidance addresses nonclinical development, early phases of clinical development, phase 3 protocol designs, and endpoints for the treatment of CHC, including in patients who are treatment naïve or experienced, patients without cirrhosis, patients with compensated and decompensated cirrhosis, and patients co-infected with HCV and HIV. Important issues addressed in this guidance include: Drug development methods to reduce the emergence of drug resistance, types of trial designs to assess optimal dose and treatment duration, combination therapy with multiple investigational drugs, recommendations on development of drugs to meet unmet medical needs, and use of treatment INDs or other smaller scale, smaller safety protocols to provide early access of multiple DAAAs for patients at risk of imminent progression of liver disease.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on developing DAAAs for treatment of CHC virus infection. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0001, the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0014, and the collections of information in 21 CFR part 316 have been approved under OMB control number 0910–0031, and the collections of information in 21 CFR parts 312 and 314 have been approved under OMB control number 0910–0032. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 and have been approved.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: September 8, 2010.

Leslie Kux, Acting Assistant Commissioner for Policy.
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.

ADDRESSES: 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.

Licensing Contact: John D. Hewes, PhD at 301–435–5560; mccuepat@mail.nih.gov.

Available for licensing.

Licensing Status: Available for licensing.


Licensing Contact: Patrick P. McCue, PhD; 301–435–5560; mccuepat@mail.nih.gov.

Fenoterol and Fenoterol Analogues for Treatment of Glioma, Glioblastoma, and Astrocytoma

Description of Invention: To date there is no effective treatment for the brain tumors or brain cancers identified as gliomas, glioblastomas, or astrocytomas.

This technology relates to the discovery that fenoterol and related analogues block astrocytoma and glioblastoma cell division at low doses. In a xenograft model utilizing the 1321N1 astrocytoma tumor implanted in the flank of SKID mice, the (R,R)-4-methoxyfenoterol analogue significantly decreased tumor growth relative to a control group receiving vehicle and studies utilizing [3H]-(R,R)-4-methoxyfenoterol have shown that the compound readily passes the blood–brain barrier. The anti-tumor effect is associated with the ability of fenoterol and related analogues to induce production of cyclic adenosine monophosphate (cAMP), which is normally decreased in glioblastomas and astrocytomas. Induced cAMP production inhibits brain tumor growth in vivo. Fenoterol and related analogues are beta-2 adrenergic receptor (β2 AR) agonists and the anti-tumor effect is associated with the expression of this receptor. Since there is a heterogeneous expression of β2 AR in human brain tumors, patients who will respond to fenoterol therapy can be predetermined leading to individualized treatment. In addition to use in the initial treatment of brain tumors, the systemic and CNS bioavailability of the drug after oral