DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Use of Macrocyclic Lactones as Inhibitors of Vacuolar-Type ATPases for the Treatment of Cancer

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the invention embodied in: 60/122,953 filed 3/5/99 (Provisional I, DHHS ref. No. E–244–97/2); 60/169,564 filed 12/8/99 (Provisional II, DHHS ref. No. E–244–97/0) and PCT (PCT/US00/05582), filed 3/3/00 and claiming priority to both Provisionals I and II, ''Vacuolar-Type (H^+) ATPase Inhibiting Compounds, Compositions and Uses Thereof;'' and 60/053,784, filed 7/25/97 (DHHS Ref. No. E–244–97/1), converted into PCT/US98/15011 filed 7/23/98, ''Antitumor Macrocyclic Lactones, Compositions and Methods of Use'', to Attenuon, L.L.C., having a place of business in San Diego, CA. The aforementioned patent rights have been assigned to the United States of America.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before May 24, 2002, will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Wendy R. Sanhai, Ph.D., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; e-mail: *sanhaiw@od.nih.gov*; Telephone: (301) 496–7056, ext. 244; Facsimile: (301) 402–0220.

SUPPLEMENTARY INFORMATION: This invention describes a class of macrocyclic lactones (benzolactone enamides) derived from marine sponges, and which inhibit vacuolar-type (H^+) ATPases (V–ATPases). Selective inhibition of V–ATPases may represent an effective means of treating various disease states: Alzheimer's disease, glaucoma and osteoporosis and cancer (via affecting cellular proliferation, angiogenesis, tumor cell invasiveness, metastasis and drug resistance). The compounds have been shown to be active against a specific group of human tumors when tested in the NCI 60-cell line panel. The licensee of these inventions will be required to comport with all applicable federal and country-of-collection policies relating to biodiversity.

The field of use may be limited to the treatment of cancer, angiogenesis-dependent diseases and osteoporosis.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, NIH 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 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response 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: March 14, 2002.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: GPRA Client Outcomes for the Substance Abuse and Mental Health Services Administration (SAMHSA)—(OMB No. 0930–0208, Extension)

The mission of the Substance Abuse and Mental Health Services Administration (SAMHSA) is to improve the effectiveness and efficiency of substance abuse and mental health treatment and prevention services across the United States. All of SAMHSA's activities are designed to ultimately reduce the gap in the availability of substance abuse and mental health services and to improve their effectiveness and efficiency.

Data are collected from all SAMHSA knowledge development and application and targeted capacity expansion grants and contracts where client outcomes are to be assessed at intake and post-treatment. SAMHSA-funded projects are required to submit this data as a contingency for their award. The analysis of the data will also help determine whether the goal of reducing health and social costs of drug use to the public is being achieved.

The primary purpose of the proposed data collection activity is to meet the reporting requirements of the Government Performance and Results Act (GPRA) by allowing SAMHSA to quantify the effects and accomplishments of SAMHSA programs. In addition, the data will be useful in addressing goals and objectives outlined in ONDCP's *Performance Measures of Effectiveness*. Following is the estimated annual response burden for this effort.

Center	Number of clients	Responses/client	Hours/response	Annual burden hours
Center for Substance Abuse Treatment	3,750	3	.70	2,625