



Alliance for Microbicide Development Weekly News Digest

October 10, 2003
Volume 4, Number 20

The following items have been excerpted from the sources listed below:

CDC Prevention News Update (<http://www.cdcnpin.org/news/prevnews.htm>)

The Kaiser Daily Health Reports (<http://report.kff.org/>)

Lexis-Nexis (<http://www.nexis.com>)

If you wish to be removed from the Alliance Listserv at any time, please send us an Email to that effect and we will remove you from our list. Comments and questions are welcome; we would also like to hear your thoughts about other microbicide-relevant topics that we might cover.

Areas Covered in this Week's News Digest:

1. Microbicides
2. Relevant Journal Articles
3. HIV/AIDS Vaccines
4. STDs
5. Politics and Policy
6. Behavior
7. Upcoming Conferences and Announcements

1. Microbicides

Microbicides 2004 Abstract Deadline Approaching

The third international conference dedicated to microbicides research, **Microbicides 2004**, will be held from **28 - 31 March 2004 in London**. Microbicides 2004 will provide: updates on recent microbicides R&D; a forum for the discussion of new developments including ethical, clinical, behavioral and methodological issues; and opportunities for knowledge-sharing between microbicide researchers, public-health workers, and advocacy organizations. **The deadline for abstract submission is 31 October 2003**. Please visit www.microbicides2004.org.uk for more information.

Microbicide Discovery and Development:

Developing Partnerships in Pharmaceutical Research: Announcement

"I am a pharmaceutical product development scientist, with prime interest towards the development of Microbicide formulations. For over a decade, I have been involved with development of several preclinical and clinical formulations including Praneem polyherbal preparations, Acidform, and Cellulose sulphate. I am reasonably well trained and experienced in cGMP/GLP issues. In last 5 years, most of my group's efforts were focussed on novel, slow release, bioadhesive vaginal systems such as tablets, films, capsules, and gels/creams, tailored to the required geographical and cultural conditions. These activities have been in close association with leading groups and organizations such as TOPCAD, CONRAD, NIPER, and PATH. The outcome of these efforts is clearly reflected in the patents and publications.

“Recently, I have moved to School of Pharmacy, University of Auckland, New Zealand. I am in the process of establishing microbicide development laboratory and would be happy to help and work with anyone in the field on the following;

1. Physico-chemical characterization of new molecular entities, drug solubility and stability assessment and/or improvement
2. Analytical method development and validation, impurity profiling
3. Development of conventional and novel vaginal/rectal formulations, optimized for bioadhesion, retention, release profiles, and other physico-chemical characteristics, novel excipients and models
4. Registration dossier
5. Formulation for preclinical and clinical studies
6. Training and exchange programs

“The University of Auckland has a very active research environment and supports the contractual and collaborative research, taking due care of the IPR issues.

“For further enquiries, please contact;

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2. Relevant Journal Articles

Title: Novel Human Immunodeficiency Virus (HIV) Inhibitors That Have a Dual Mode of Anti-HIV Action

Authors: Miguel Stevens, Christophe Pannecouque, Erik De Clercq, and Jan Balzarini

Reference: Antimicrobial Agents and Chemotherapy, October 2003, p. 3109-3116, Vol. 47, No. 10

Published Abstract: We have found that novel pyridine oxide derivatives are inhibitors of a wide range of human immunodeficiency virus (HIV) type 1 (HIV-1) and HIV-2 strains in CEM cell cultures. Some of the compounds showed inhibitory activities against recombinant HIV-1 reverse transcriptase (RT), whereas others were totally inactive against this viral protein in vitro. Partial retention of anti-HIV-1 activity against virus strains that contain a variety of mutations characteristic of those for resistance to nonnucleoside RT inhibitors and a lack of inhibitory activity against recombinant HIV-2 RT suggested that these pyridine oxide derivatives possess a mode of antiviral action independent from HIV RT inhibition. Time-of-addition experiments revealed that these pyridine oxide derivatives interact at a postintegration step in the replication cycle of HIV. Furthermore, it was shown that these compounds are active not only in acutely HIV-1-infected cells but also in chronically HIV-infected cells. A dose-dependent inhibition of virus particle release and viral protein expression was observed upon exposure to the pyridine oxide derivatives. Finally, inhibition of HIV-1 long terminal repeat-mediated green fluorescence protein expression in quantitative transactivation bioassays indicated that the additional target of action of the pyridine oxide derivatives may be located at the level of HIV gene expression.

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Title: Novel bis-Tetrahydrofuranylurethane-Containing Nonpeptidic Protease Inhibitor (PI) UIC-94017 (TMC114) with Potent Activity against Multi-PI-Resistant Human Immunodeficiency Virus In Vitro

Authors: Koh Y, Nakata H, Maeda K, Ogata H, Bilcer G, Devasamudram T, Kincaid JF, Boross P, Wang YF, Tie Y, Volarath P, Gaddis L, Harrison RW, Weber IT, Ghosh AK, Mitsuya H.

Reference: Antimicrob Agents Chemother. 2003 Oct;47(10):3123-3129

Published Abstract: We designed, synthesized, and identified UIC-94017 (TMC114), a novel nonpeptidic human immunodeficiency virus type 1 (HIV-1) protease inhibitor (PI) containing a 3(R),3a(S),6a(R)-bis-tetrahydrofuranylurethane (bis-THF) and a sulfonamide isostere which is extremely potent against laboratory HIV-1 strains and primary clinical isolates (50% inhibitory concentration [IC(50)], approximately 0.003 micro M; IC(90), approximately 0.009 micro M) with minimal cytotoxicity (50% cytotoxic concentration for CD4(+) MT-2 cells, 74 micro M). UIC-94017 blocked the infectivity and replication of each of HIV-1(NL4-3) variants exposed to and selected for resistance to saquinavir, indinavir, nelfinavir, or ritonavir at concentrations up to 5 micro M (IC(50)s, 0.003 to 0.029 micro M), although it was less active against HIV-1(NL4-3) variants selected for resistance to amprenavir (IC(50), 0.22 micro M). UIC-94017 was also potent against multi-PI-resistant clinical HIV-1 variants isolated from patients who had no response to existing antiviral regimens after having received a variety of antiviral agents. Structural analyses revealed that the close contact of UIC-94017 with the main chains of the protease active-site amino acids (Asp-29 and Asp-30) is important for its potency and wide spectrum of activity against multi-PI-resistant HIV-1 variants. Considering the favorable pharmacokinetics of UIC-94017 when administered with ritonavir, the present data warrant that UIC-94017 be further developed as a potential therapeutic agent for the treatment of primary and multi-PI-resistant HIV-1 infections.

Correspondence: Department of Chemistry, University of Illinois at Chicago, Chicago, Illinois 60607

3. HIV/AIDS Vaccines

Increasing Number of HIV Vaccines Undergoing Human Clinical Trials

Date: October 6, 2003

Source: Kaiser Daily HIV/AIDS Report

<http://cme.kff.org/Key=511.F1R.H.D.DdGYxp>

An increasing number of HIV vaccines undergoing human clinical trials has led to optimism in the field that progress is being made toward finding an effective HIV/AIDS vaccine, the AP/Las Vegas Sun reports. About 24 potential vaccines are currently being tested on 12,000 volunteers throughout the world, and several more vaccines are scheduled to begin clinical trials soon. The National Institute of Allergy and Infectious Diseases budget for HIV vaccine research has grown from \$182 million in fiscal year 1999 to \$456 million in FY 2004, and on Sept. 29 the agency awarded \$81 million in contracts to four groups working on HIV vaccine development. At least a dozen drug companies are developing vaccines, according to the AP/Sun. "I'm certainly more optimistic than just a couple of years ago," Dr. Robert Gallo, head of the Institute of Human Virology at the University of Maryland, said, adding, "We can see the light at the end of the tunnel." However, NIAID Director Dr. Anthony Fauci said, "I tend to stay away from the word 'optimism.' I see things happening that make me feel better about the process. But I don't want to give an impression that this is a new dawn in America. We still have a long way to go" (Elias, AP/Las Vegas Sun, 10/5).

4. STDs

Bacterial Vaginosis May Heighten the Risk for Acquiring Herpes Simplex Virus-2

Date: October 3, 2003

Source: Women's Health Weekly/ CDC HIV/STD/TB Prevention News Update

A study conducted by T.L. Chernes and colleagues at the University of Pittsburgh, Medical Center, discovered that bacterial vaginosis may heighten the risk of acquiring herpes simplex virus-2. The researchers conducted a longitudinal cohort study of sexually active women ages 18-30 to identify variables associated with HSV-2 infections, following up 670 HSV-2-seronegative women at four-month intervals for one year. They detected acquisition of HSV-2 antibodies in 32 of those women.

"Black race, less than or equal to 12 years of education, having a new sex partner, and bacterial vaginosis (BV) were associated with HSV-2 seroconversion on univariate analysis," the investigators wrote. "Antecedent HSV-1 infection was not protective against HSV-2 acquisition."

After controlling for other risk factors in multivariable models, the scientists found that the diagnosis of BV remained associated with an increased risk of HSV-2 infection. "In this study, the population attributable risk of BV for HSV-2 seroconversion was 21 percent," according to the report.

The authors recommended further research to determine whether screening and treatment of BV could reduce women's susceptibility to HSV-2 infection. The report, "Association Between Acquisition of Herpes Simplex Virus Type 2 in Women and Bacterial Vaginosis," appeared in *Clinical Infectious Diseases* (2003;37(3):319-325).

5. Politics and Policy

NIH Director Zerhouni Discusses 'Roadmap' at Joint Congressional Hearing

Date: October 3, 2003

Source: Kaiser Daily Health Policy Report

<http://cme.kff.org/Key=500.Gwb.G.D.y9nPC>

At a joint hearing of the Senate Health, Education, Labor and Pensions and House Energy and Commerce committees on Thursday, NIH Director Dr. Elias Zerhouni discussed the "NIH Roadmap" plan he announced earlier this week, *CongressDaily* reports (Rovner, *CongressDaily*, 10/2). The \$2 billion plan is intended to foster greater participation by the agency in medical research and more innovative approaches by members of the medical industry to develop new treatments. The roadmap, created in cooperation with more than 300 consultants from the health industry and academic sectors, designates three areas that the NIH would like to develop: new technologies to study molecules' networks in cells, bolstered training and cooperation among research teams in its 27 institutes and centers, and improved processes to study drugs in clinical trials. Zerhouni said the plan, which does not need congressional approval, would be funded by contributions made by separate NIH units from their existing budgets (*Kaiser Daily Health Policy Report*, 10/1). During the hearing, Zerhouni stressed the need to reform the agency's "silo" structure, under which each institute and center receives separate funding, saying that the current structure slows scientific advances. "Often, research done in one institute eventually finds its greatest application in the mission of another," he said. He added that with improved cooperation among the agency's institutes and centers and changes in research protocol, NIH could "more quickly translate discoveries into practice." However, Harold Varmus, a former NIH director who currently heads New York's Memorial-Sloan Kettering Cancer Center, said that more radical reforms should be implemented -- primarily, the fusion of the agency's 27 institutes and centers into five large units and an "NIH Central" that the director would oversee. House Energy and Commerce Committee Chair Billy Tauzin (R-La.) said that Congress, which has doubled NIH funding in the past five years, "may want to consider establishing a system of greater transparency of NIH research activities to guarantee that NIH is held accountable for taxpayer investments." Sen. Edward Kennedy (D-Mass.) questioned the size of the NIH funding allocation Congress has proposed for fiscal year 2002, saying, "Even with the increases provided by the Senate, the number of new (research) grants would actually decrease by 75" (*CongressDaily*, 10/2).

Plans Should Have Congressional Oversight, Editorial Says

Zerhouni's roadmap -- which would restructure clinical research, correct funding imbalances, reward "original thinkers" and "turn the [NIH's] lumbering bureaucracy into a nimble scientific mystery-busting force" -- should receive funding from Congress, but the plan also needs oversight to ensure it is not "overrun by pharmaceutical industry self-interest," a Los Angeles Times editorial states. Some critics say they are concerned that Zerhouni's "vague" promises to remove regulatory roadblocks "could be shorthand for dismantling regulations aimed at insulating government researchers from market and interest group pressures," the editorial says. The editorial surmises that Zerhouni "will almost certainly fall short of his lofty goal," adding that the funding he intends to spend "won't be enough to overturn deep-seated problems," including "imbalances" in funding preventive measures and treatments (*Los Angeles Times*, 10/3).

Senate Confirms Randall Tobias as Head of Global AIDS Initiative

Date: October 6, 2003

Source: Kaiser Daily HIV/AIDS Report

<http://cme.kff.org/Key=511.FIR.C.D.D3V5pK>

The Senate by voice vote on Friday confirmed former Eli Lilly CEO Randall Tobias as the head of the new State Department Office of the Global AIDS Coordinator, the AP/San Francisco Chronicle reports (AP/San Francisco Chronicle, 10/3). Tobias was nominated by President Bush on July 2 to head the new office, which was created under the five-year, \$15 billion global AIDS initiative. As coordinator, Tobias will work under the secretary of state and will be able to distribute funds directly to nongovernmental organizations and transfer funds between government agencies. The position carries the rank of ambassador. The new office will oversee U.S. international assistance in the fight against HIV/AIDS and coordinate activities of the various agencies and departments that will deliver the aid. Some advocates have raised concerns about Tobias' links to the pharmaceutical industry, saying that he could avoid promoting affordable access to antiretroviral drugs to protect the profits of drug makers. However, during his confirmation hearing on Tuesday, Tobias said he will represent the interests of the United States and employ the most cost-effective methods to help people with HIV/AIDS throughout the world. He also said that he supports Bush's plan to direct most of the funding for global AIDS initiative projects through U.S. programs instead of through the Global Fund to Fight AIDS, Tuberculosis and Malaria. In addition, Tobias said that the primary obstacle to implementing an antiretroviral program in sub-Saharan Africa is a lack of infrastructure, not the lack of available drugs or funds (Kaiser Daily HIV/AIDS Report, 10/3).

Reaction

Global Health Council President and CEO Nils Daulaire said Tobias' nomination "marks a critical juncture in the world's effort to address the global AIDS pandemic. Working together with the AIDS community and those committed to improving health around the world, ... Randall Tobias now holds the key role in achieving the monumental task outlined by President Bush in his State of the Union address." He added, "Only together can we develop and implement effective programs to deliver on the president's promise" (GHC release, 10/3). The AIDS Healthcare Foundation lauded Tobias' Senate confirmation but expressed concern that that "with the clearing of this final hurdle the pressure is squarely on the Bush administration to launch its program with no further delay," according to an AHF release. AHF President Michael Weinstein said, "Congress responded with remarkable speed in authorizing President Bush's global AIDS plan, but success will be measured in lives saved by the next State of the Union, and Tobias must ensure that date arrives with not a token but many thousands in treatment to claim credibility for the U.S. effort" (AHF release, 10/3). Mark Isaac, vice president of the Elizabeth Glaser Pediatric AIDS Foundation, said, "We are elated that the Senate acted to put in place an HIV/AIDS Response Coordinator, and we are confident that Mr. Tobias has the skills and commitment to lead the global battle against AIDS" (EGPAF release, 10/3). Isaac added, "The next crucial step is for Mr. Tobias to quickly move the necessary resources into the field to help the millions of children and families suffering from HIV/AIDS" (Groppe, Indianapolis Star, 10/4).

Appointment of John E. Lange as a Deputy Coordinator in the Office of the Global AIDS Coordinator

Date: October 9, 2003

Source: US Department of State

Former U.S. Ambassador to Botswana John E. Lange has been named as a Deputy Coordinator in the new Office of the Global AIDS Coordinator at the Department of State. He will report directly to Ambassador Randall L. Tobias, who was sworn in on October 6, 2003, as the Coordinator of United States Government Activities to Combat HIV/AIDS Globally. Dr. Joseph F. O'Neill also serves as a Deputy Coordinator and as Chief Medical Officer in the office.

The Global AIDS Coordinator oversees all U.S. international HIV/AIDS assistance and coordinates the efforts of the various agencies and departments that deliver it. President George W. Bush announced on January 28, 2003, the historic \$15 billion, five-year plan that is expected to deploy over \$2 billion in the first year and steadily increase expenditures over the next four years. The President's Emergency Plan for

AIDS Relief includes specific goals aimed at preventing seven million new HIV infections, treating two million HIV-infected people and caring for ten million HIV-infected individuals and AIDS orphans. As the United States continues to work to combat HIV/AIDS globally, the plan will focus a significant amount of resources on 14 of the most afflicted countries in Africa and the Caribbean that account for nearly 20 million HIV-infected men, women and children—almost 70 percent of the total in all of Africa and the Caribbean.

Following is Ambassador Lange's biography:

John E. Lange, a career member of the Senior Foreign Service with the rank of Minister-Counselor, has a broad range of experience dealing with HIV/AIDS and other humanitarian and foreign policy issues in Africa, Latin America, and the Caribbean. Lange's Africa experience includes assignments to U.S. Embassies in West Africa (Togo), East Africa (Tanzania), and Southern Africa (Botswana). Lange's most recent assignment was at the Foreign Service Institute, where he was Associate Dean for the State Department's Senior Seminar executive leadership program. From 1999-2002, he served as U.S. Ambassador to Botswana and as Special Representative of the Secretary of State to the Southern African Development Community. Secretary of State Colin Powell lauded his leadership in bringing together seven U.S. Government agencies, the Government of Botswana, the media and international and local partners to create new avenues of cooperation on HIV/AIDS, and the Department of State recommended that all U.S. Embassies consider developing interagency AIDS programs based on the Gaborone model of "The Partnership." Lange served as Deputy Chief of Mission at the U.S. Embassy in Dar es Salaam from 1997 to 1999 and headed the Embassy as Charge d' Affaires from January to September 1998. He received the Distinguished Honor Award of the Department of State for "skilled leadership" and "extraordinary courage" in the aftermath of the devastating terrorist bombing of the Embassy on August 7, 1998. While at the U.S. Mission to the United Nations in Geneva, Lange managed U.S. Government assistance to international organizations for African and Caribbean refugee and humanitarian crises. He also worked in the Africa Bureau and the Western Hemisphere Affairs Bureau of the State Department as well as in the American Embassies in Mexico City and Paris. He is a "distinguished graduate" of the National War College and a graduate cum laude of the University of Wisconsin Law School. He speaks French and Spanish.

Vatican Tells People Worldwide That Condoms Do Not Prevent HIV Infection, Despite Scientific Consensus That They Do

Date: October 9, 2003

Source: Kaiser Daily HIV/AIDS Report

<http://cme.kff.org/Key=563.F0y.D.D.HpWh0d>

Members of the Roman Catholic clergy are telling people worldwide that condoms are permeable enough to allow HIV to pass through, despite scientific consensus that condoms are effective in preventing HIV transmission, London's Guardian reports (Bradshaw, Guardian, 10/9). The Vatican, which is opposed to contraception, has consistently refused to encourage the use of condoms to prevent HIV transmission and instead advocates behavior change to prevent the virus. However, the church is now telling people that condoms do not work, according to a BBC1 Panorama program, titled "Sex and the Holy City," which is scheduled to air on Sunday. Cardinal Alfonso Lopez Trujillo, president of the Vatican's Pontifical Council for the Family, says on the program, "The AIDS virus is roughly 450 times smaller than the spermatozoon. The spermatozoon can easily pass through the 'net' that is formed by the condom. These margins of uncertainty ... should represent an obligation on the part of the health ministries and all these campaigns to act in the same way as they do with regard to cigarettes, which they state to be a danger." However, a World Health Organization spokesperson said that "consistent and correct" condom usage can reduce the risk of HIV infection by 90%, adding that the Catholic Church's "incorrect statements about condoms and HIV are dangerous when we are facing a global pandemic which has already killed more than 20 million people and currently affects around 42 million" (BBC News, 10/9). The program includes a Catholic nun who advises her HIV-positive choir director not to use condoms with his wife because "the virus can pass through." The program also found Catholics making similar claims about condom permeability, including that condoms can spread HIV, in Asian and Latin American countries (Guardian, 10/9).

6. Behavior

'Urgent' Attention to World's Youth Needed to Curb Poverty, AIDS: UN

Date: October 8, 2003

Source: Agence France Presse/ CDC HIV/STD/TB Prevention News Update

If countries want to break the cycle of AIDS and poverty, then meeting the needs of the world's 1.2 billion adolescents, especially in terms of sex education, will be an "urgent priority," said a UN Population Fund report released today.

"Nearly half of all people are under the age of 25. About 20 percent are adolescents between the ages of 10 and 19," said the document, "State of World Population 2003." Nine out of 10 of these 10- to 19-year-olds live in developing countries, where sex education on how to prevent early pregnancies and deadly diseases such as AIDS is often insufficient, and social pressures perpetuate inequality.

"An estimated 238 million youth - almost one in four - face the constraints of extreme poverty," the authors wrote. Nearly as many live on the streets, and more than 13 million children under age 15 have become AIDS orphans. Additionally, "a youth is infected with HIV every 14 seconds, and youth (increasingly women) account for nearly half of the new cases of HIV infection worldwide."

The report said the central AIDS prevention message should be "ABC - Abstain from sexual activity, Be faithful to one partner, and use Condoms correctly and consistently." Breaking the cycle of infection and poverty will "require more investments in adolescent reproductive health needs and education, and in a supportive policy environment," UNPF urged. Failure to act would result in premature deaths, higher STD rates, unwanted pregnancies, slower economic growth, civil unrest and gender disparities.

Preventing HIV infections among youths would boost development and agricultural output, with a consequent economic benefit of \$34,600 per person. In seven Caribbean countries, an effort to educate adolescents about early pregnancy would save about \$235 a year each time it helped an adolescent avoid pregnancy.

Meeting the challenge will require more than the \$18.5 billion estimated during a 1994 International Conference on Population and Development, at which richer countries pledged to pay one-third of the costs of population- and sex-related health services in developing nations.

7. Upcoming Conferences and Announcements

Upcoming Conferences:

The **15th International AIDS Conference will be held from July 11-16, 2004 in Bangkok, Thailand.**

The meeting will be hosted by the International AIDS Society in collaboration with the Thai Ministry of Health and UNAIDS. The **deadline for abstract submission is January 14, 2004.** Please go to

<http://www.ias.se/aids2004/> for more information.

Announcements:

Improving Enrollment of Women and Minorities in HIV/AIDS Clinical Trials

Read Enrolling Women and Minorities into HIV/AIDS Clinical Trials:

http://gal.org/ct/wpzFzT61id1n/Grants_guide

The National Institute of Allergy and Infectious Diseases (NIAID)

(http://gal.org/ct/sdzFzT61id1i/NIAID_NIH/) seeks applications proposing innovative and practical approaches to accessing, enrolling and retaining women and racial/ethnic minorities in HIV/AIDS research trials in the United States.

Barriers to participation in clinical trials at the community and individual levels include:

* Inaccessibility of the research site due to distance, lack of transportation and inconvenient clinic hours;

- * Competing family responsibilities and language issues;
- * Inability of research site to coordinate other health care needs, such as dental, eye and psychiatric care and case management;
- * Fear and distrust of health care, research or governmental involvement; and
- * Lack of incentives for participation, both on the part of the researcher and the individual.

Research institutions and community organizations, such as faith- and community-based organizations; health care agencies; universities; federal and state governmental entities; and North American Indian tribal governments, are welcome to apply. NIAID is particularly interested in applications submitted by research institutions and community organizations that have entered a cooperative agreement.

To apply, candidates must complete Department of Health and Human Services (DHHS), Public Health Service (PHS) application kit 398, which is available online (http://ga1.org/ct/wdzFzT61id1y/PHS_398_Application_PDF_-_Online).

Please note: Each application must include a Dun and Bradstreet (DUNS) number. For more information about the system and/or to obtain a DUNS number, click here: http://ga1.org/ct/s1zFzT61id18/DUNS_Number/.

Application deadlines vary depending upon the amount of funding requested; visit: http://ga1.org/ct/w7zFzT61id1h/Grant_Submission_Schedule for a detailed listing and explanation of all application deadlines, or refer to application kit (http://ga1.org/ct/wdzFzT61id1y/PHS_398_Application_PDF_-_Online).

For further assistance with the application process, please e-mail: GrantsInfo@nih.gov or call (301) 435-0714. Financial and/or grant management matters should be referred to:

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