RIFABUTIN WORKS!

A multi-center trial conducted by community-based clinical trial programs including CRIA, has shown that the experimental drug Rifabutin can nearly cut in half the rate at which patients develop Mycobacterium avium complex (MAC, also called MAI). The drug's manufacturer, Adria Pharmaceuticals, has submitted an application to the FDA for full marketing approval of the drug.

According to the company, an additional study being conducted simultaneously has also shown that Rifabutin can prevent MAC. The news could benefit many of the approximately 75,000 AIDS patients in the US, most of whom have yet to develop MAC.

Dr. Donald Kotler, a member of the CRIA Board, said, "This study suggests that we have an important new weapon against AIDS-related illness. Adria Pharmaceuticals is to be commended both for their rapid and rigorous testing of Rifabutin, and for their commitment to testing the drug in partnership with the affected communities. I hope that this study will provide a paradigm for future AIDS research."

The study involved 590 patients, who were randomly assigned to take either two 150mg capsules of Rifabutin a day, or a placebo. 14.4% of the 298 patients receiving placebo developed MAC infections in their bloodstream, compared to 8.2% of the 292 patients given Rifabutin. Even among the people who became infected, Rifabutin appeared to significantly delay the development of illness.

The most serious side effects associated with Rifabutin appear to be low white blood-cell counts and elevated liver enzymes, however very few patients in the two studies had to discontinue the drug because of toxicity. Currently the drug is available through a Treatment IND program. Physicians interested in enrolling their patients can contact Adria Laboratories at 1-800-552-7228.

MOTHERS AGAINST AIDS

This Mothers' Day, President Bush and other elected officials will receive greeting cards from more than 100,000 mothers from throughout America, demanding that AIDS be placed at the top of our country's domestic agenda. Mothers' Voices, an AIDS awareness and advocacy campaign, was created by Dory Bless, Phyllis Danilow, Ivy Duneier, David Pearl and Lili S. Rundback to mobilize the hearts and voices of our nation's mothers. Through Mothers' Voices, parents, families and friends of those who are infected and affected, will no longer grieve in private, but can use their energies to effect change in governmental AIDS policy. Seed funding for Mothers' Voices was provided by People Taking Action Against AIDS (PTAAA). To participate, send cards to the President or to your elected representative expressing your support for increased AIDS funding and education.

CRIA Update
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The Community Research Initiative on AIDS
CRIA is an independent, non-profit community-based AIDS research center dedicated to the study of new treatments for HIV-related diseases. CRIA's goal is to rapidly improve the length and quality of life for people with AIDS/HIV through clinical research.

SPRING 1992
WHY PREVENT MAC?

Mycobacterium avium complex (MAC) is a life-threatening bacterial opportunistic infection that is common in people with late-stage AIDS. Two similar types of mycobacteria, Mycobacterium avium and Mycobacterium intracellulare, cause MAC. Due to their similarities, together they are referred to as Mycobacterium avium complex, or MAC. The organisms that cause MAC are similar to those which cause tuberculosis and leprosy. Despite its relation to tuberculosis, MAC is not a communicable infection. The organisms that cause MAC occur naturally in food, water, and soil. As a result, however, avoiding exposure is extremely difficult.

In non-immunocompromised patients, MAC is primarily organ-specific, usually occurring in the lungs and respiratory tract. In AIDS patients, MAC is usually a disseminated infection. It is believed that the MAC bacteria usually enter the body through the respiratory or digestive systems, and spread to organs throughout the body, including the spleen, liver, lymph nodes and bone marrow.

Once the patient is infected, the disease progresses slowly. Long-term MAC infection often results in severe diarrhea, excessive weight loss, anemia and malabsorption of food and nutrients. Left untreated, the disease can be fatal.

Fifteen to 24 percent of people with AIDS will be diagnosed with MAC, however autopsy studies suggest that up to 52% of people with AIDS have evidence of MAC colonization at death. MAC is considered the leading cause of the wasting syndrome suffered by many AIDS patients.

In most cases (76 to 90%), MAC appears late in the course of HIV—well after AIDS has been diagnosed. It generally occurs when the CD4+ cell count drops below 60, and is rare in PWAs with CD4+ cell counts above 100.

Only 24 MAC cases had been reported in medical publications through 1980. By 1982, reports of MAC infection had increased dramatically. As of December 31, 1991, more than 14,400 cases of MAC had been reported to the CDC.

In the early 1980s, MAC was not considered a contributing factor in the deaths of AIDS patients. The majority of PWAs died from complications associated with Pneumocystis carinii pneumonia (PCP) and MAC was rarely discovered unless an autopsy was performed. The development of new therapies used in the treatment of AIDS and its associated opportunistic diseases has more than doubled the life-expectancy of AIDS patients. Opportunistic infections that appear early on in the course of the disease are now being treated successfully. As a result, other opportunistic diseases, such as MAC, are becoming more prominent and more deadly in those patients suffering from AIDS.

"MAC is terrible," said Robert, a person with AIDS in New York City. "I was losing about five pounds a week, and really becoming unable to care for myself."

Although there is currently no standard treatment universally accepted or approved for MAC infection, most physicians agree that two to five drugs must be used in combination to have any possibility of effectiveness. Drugs commonly used to treat MAC include Amikacin, Ciprofloxacin, Clarithromycin, Clofazimine, Cycloserine, Ethambutol, Ethionamide, Rifampin, Sparfloxacin and Streptomycin. Specific combinations and regimens vary from patient to patient and from doctor to doctor. Multi-drug regimens are used because MAC organisms appear to become resistant to therapies in which only a single antibiotic is administered. In addition, MAC organisms are not very susceptible to most of the drugs that are usually effective in fighting other mycobacterial infections.

Because MAC is associated with significant sickness and death, is difficult to treat, and affects a large number of PWAs, a potential prophylactic therapy will provide a useful weapon in AIDS treatment. "If Rifabutin can prevent MAC," said Robert, "it will be very important for PWAs."

PENTOXIFYLLINE STUDY NOW ENROLLING

CRIA is beginning a study of Pentoxifylline (Trental) to treat an AIDS-related immune abnormality that may speed progression of the disease. Early studies suggest that the drug may lower levels of Tumor Necrosis Factor (TNF), a naturally-produced protein that has been associated with HIV reproduction, anemia and wasting. Pentoxifylline has also shown activity against HIV in the test tube. This placebo-controlled study will determine whether or not Pentoxifylline can reduce elevated TNF levels in people with 50-300 T-cells.

VACCINE CONFERENCE: SPECIAL BULLETIN ANNOUNCEMENT

A special edition of the CRIA newsletter will summarize the recent forum on Vaccines & Immunotherapies which CRIA co-sponsored with GMHC. Speakers included scientists from the NIH, Genentech Inc., the Veteran's Administration, Viral Technologies, Inc., and Immuno AG. For more information, contact Spencer Cox at (212) 889-1958.
COMMUNITY RESEARCH INITIATIVE ON AIDS

STUDY UPDATE: Pentoxifylline To Reduce TNF
Pentoxifylline (Trental) is approved by the FDA for treatment of a vascular disorder. Early studies suggest that the drug may lower levels of Tumor Necrosis Factor (TNF), a protein that has been associated with increased HIV reproduction and wasting. TNF levels are often raised in PWAs. Additionally, Pentoxifylline has shown activity against HIV in the test tube. This study will determine whether or not Pentoxifylline can reduce raised TNF levels. The study is now enrolling.

PEOPLE WITH FASHION
The competition got hot on April 10, between nine beautiful Click models, each selling chances to win outfits donated by leading American designers Zang Toi, New Republic, Isabel Toledo, Betsey Johnson, Nicole Miller, Todd Oldham, Randolph Duke, Alpina Bawa and Thea Anema at TILT, a new downtown nightclub. All proceeds were donated to CRIA.

Two weeks earlier, actor Casey Siemaszko, a co-owner of TILT, contributed his birthday checks to CRIA at a private party attended by Stephen Sprouse, Tatum O'Neal, and Jungle Fever star Annabella Sciorra. Siemaszko, a star of TV's Young Rebels, will also appear in the new John Malkovitch film Of Mice and Men.

CAREMARK CARES
Caremark, Inc. has donated more than $100,000 to CRIA for operating expenses and drug research. "Caremark's generous decision to donate to the community will enable CRIA to continue its search for effective AIDS drugs," said Neil Mitzman, President of CRIA's Board. "This company is a model corporate citizen."

FILM BENEFITS CRIA
Five sold-out showings of the film version of David Leavitt's award-winning novel "The Lost Language of Cranes" benefitted the Community Research Initiative on AIDS (CRIA). The film was directed by Nigel Finch, and featured Brian Cox, Eileen Atkins of A Room of One's Own, Angus MacFadyen, thirtysomething's Corey Parker and Rene Auberjonois. CRIA Board member Phyllis Danilow said, "This is a great film – it's intelligent, sensitive and very sexy. I loved it."

Mr. Leavitt welcomed guests to the screening, which was donated to CRIA through the generosity of Nigel Finch and the BBC. Special support was generously provided by Matthew Bank and Homo Xtra.

HAPPY BIRTHDAY!!
The Board and Staff of CRIA would like to wish a very special happy birthday to volunteer par excellence Kiki Mason. Kiki's support has been a vital part of CRIA's ongoing efforts to expand our research programs. We know that Kiki deserves to have all of his birthday wishes come true!

STUDY UPDATE: Dronabinol to Reverse AIDS-related Wasting
People with AIDS often experience dramatic weight loss, associated with HIV infection of cells in the digestive tract, or with opportunistic diseases such as CMV or MAC that may decrease appetite and impair digestion. Dronabinol (Marinol) is a therapy that has been approved by the FDA for treatment of weight loss associated with cancer chemotherapy. CRIA is studying the effect of the drug on AIDS-related appetite loss and wasting. This study is completely enrolled.

STUDY UPDATE: Rifabutin to Prevent MAC
Mycobacterium avium Complex (MAC), a disease caused by parasites similar to those which cause leprosy and tuberculosis, is common in late-stage AIDS, causing spiking fevers and dramatic weight loss. MAC is a significant cause of death in People with AIDS. Rifabutin is now being tested for treatment of MAC, and CRIA is testing the drug for prevention of MAC in people at high risk for the disease. This study has been completed, with positive results (see page 1). Physicians can obtain drug for their patients by contacting Adria Laboratories at 1-800-552-7228.

Volunteers Needed
CRIA depends on the generosity of volunteers to provide essential clerical assistance to CRIA's medical and administrative staff. Volunteers are always needed to answer phones, make copies, assist with mass mailings, and distributing information. People with skills such as accounting or medical library research are often needed to provide assistance on special projects. If you would like to volunteer for CRIA, please contact Gary Bonasorte from 10am to 3pm, Monday through Friday at (212) 889-1958.
We'd like to salute the generous people who have contributed valuable time, energy and resources to CRIA’s fight against AIDS: Thea Anema, the AmFAR Treatment Directory Staff, Matthew Bank, Alpina Bawa, Marc Berkley, Sandra Bernhard, Abe Black & Sons, Marcus Boone, Pitney Bowes, Diane Bressler, Mark Cattano, Peter Cattano, Michelle Ciulla, Shelly Clark, Click Models, Frank Costronovo, Coffee Shop, Joseph D’Aquila, Randolph Duke, Clyde Duneier, Inc, Eldorado Petit, Fat City Cycles, Nigel Finch, John Forde, Michael Goff, Vincent Gagliostro, Gabriel Guimaraes, Doris Hillman, Deborah Holland, Homo Xtra, Betsey Johnson, Dayna Johnston, Kaye/Schorler, Robert Klein, Benjamin Liu, Kiki Mason, Marriott Marquis Hotel, Nicole Miller, Morrison & Foerster, Neil N. Mitzman, New Republic, Nippon Travel, New York Forward Action, Todd Oldham, Opera Manhattan, Out Magazine, Matthew Pantel, Carlos A. Rosas, The Saint At Large, Jeff Sharp, Audree Siden, Robert Shields, Brian Sommers, Marion Tarnofsky, Bill Fitzpatrick Taylor, Brian Taylor, Tilt, Zang Toi, Isabel Toledo, Barbara Tolls, Weisbach and Greenfield, Irv Welzer, John Yunis

Community Research Initiative on AIDS
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CRIA is dependent on private charitable giving and volunteerism to produce results. Your contribution can make a difference.

Yes, I want to help CRIA test promising experimental drugs for AIDS/HIV infection. Enclosed is my contribution of:

☐ $25  ☐ $50  ☐ $100  ☐ $250  ☐ $500  ☐ $1000  ☐ other

☐ Please contact me about volunteering with CRIA.  ☐ Please add my name to your mailing list.

Name

Address

City, State, Zip

In Honor/Memorium of:
Donations to CRIA are tax deductible to the full extent provided by law.