

CANADIAN TREATMENT ACTION COUNCIL

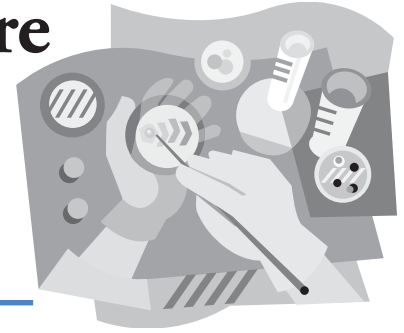


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Accessing the future of HIV therapies:

ENTRY AND ATTACHMENT INHIBITORS



by Enrico Mandarino

DESPITE THE MANY ADVANCES in antiretroviral therapy, researchers are always looking for new agents to treat HIV infection. Drug resistance, compliance, toxicity, and uncertainty about long-term outcomes are challenges facing people living with HIV/AIDS who are on treatment. Accessing new treatments is often a problem for people living with HIV/AIDS, as new drugs are held up in inefficient drug review processes and/or provincial formularies exclude or remove drugs because of high drug prices.

One area of therapy development that piqued my interest at the 11th Conference on Retroviruses and Opportunistic Infections was the promising data presented on a new class of anti-HIV drugs called entry and attachment inhibitors. These drugs block HIV from entering CD4 immune cells.

HIV enters CD4 cells in three steps: attachment, co-receptor binding, and fusion. HIV uses its gp120 molecule to attach to the CD4 receptor and then binds to another co-receptor such as CCR5 or CXCR4 in order to get into the CD4 cell. CCR5 and CXCR4 are chemokine receptors on the surface of the CD4 cells and are known to play a critical role in virus infection and transmission.

Entry inhibitors are designed to bind to the CD4 surface receptors, blocking HIV from attaching and fusing into the cell. Unlike existing HIV drugs that work inside the CD4 cells and target viral enzymes involved in the replication of the virus, entry inhibitors work by blocking HIV before it enters the CD4 cells and begins its replication process.

The receptor blocking agents closest to entering larger

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Accessing the future of HIV therapies

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clinical studies are TNX-355, which targets the CD4 receptors, and GW 873140 and SCH-D, which target the CCR5 receptors. These agents all have favourable safety and efficacy data.

Researchers are concerned that over time, the use of CCR5 receptor (R5 viruses) blocking agents will cause the emergence of more lethal viruses that use the CXCR4 receptor (X4 viruses) to get into the CD4 cell, hence the need for novel blocking agents.

Data providing proof-of-concept for a novel experimental oral attachment inhibitor, a potential new class of antiretrovirals, was also unveiled at the conference. BMS-488043 is a small molecule that binds to the HIV viral envelope protein gp120, preventing it from attaching to the CD4 receptor,

thereby stopping infection of the CD4 cells.

With investigations underway on a variety of new drug approaches that prevent HIV from attaching itself and fusing into CD4 cells, optimism is growing that new, effective, non-toxic drugs will change the way HIV is treated. It is essential that development of new drug approaches continues and that these drugs are priced fairly and made available to people living with HIV/AIDS in a timely manner. CTAC will continue to monitor new drug developments and their pricing and approval in Canada. ■

Adapted from an article originally printed in Living + magazine, Issue 30, May/June 2004, a publication of the BC Persons With AIDS Society, www.bcpwa.org

Hepatitis C Treatment *Now!*

By Paula Braitstein

AS PEOPLE LIVING WITH HIV/AIDS are living longer with their HIV disease, other problems are emerging, including side effects of antiretroviral drugs, and co-infections. Co-infection with viral hepatitis B or C is a big problem among HIV+ people because of shared routes of transmission. In fact, approximately 30% of all HIV+ people are co-infected with

hepatitis C, and pretty much every individual who acquired HIV through injection drugs and most individuals who were infected via the blood supply are also infected with hepatitis C. It's estimated that about 1% of the entire population of Canada has hepatitis C – about 250,000-300,000 people. So hepatitis C is a big problem.

Unfortunately, so is accessing treatment for hepatitis C in most places in Canada.

Hepatitis C treatment is not easy to take – the combination of pegylated interferon and ribavirin has major toxicities that make people feel like they have a bad case of the flu for the entire treatment period, their saliva glands often dry up resulting in a painful mouth and loss of taste, and perhaps worst of all is the depression and suicidal tendencies that are



biological reactions to the drugs. The good news, though, is that hepatitis C treatment can and does clear the virus in a lot of people, resulting essentially in a cure, and the treatment is not life long – both major differences compared to HIV care. The bad news for HIV+ people is that the current treatment for hepatitis C doesn't work as well

for them as it does in HIV- people: overall, about 40% of HIV+ people will have a sustained virologic response, compared to 55% of HIV-. Hepatitis C genotype also is very important in terms of probability of treatment success, and in HIV- people with genotypes 2/3, 80% can expect to clear the virus, while in HIV+ people with genotypes 2/3, only about 60% will clear. In genotype 1, which is the predominant hepatitis C genotype in North America including among people living with HIV/AIDS, about 45% of HIV- people will clear the virus; whereas less than 30% of HIV co-infected people with hepatitis C genotype 1 can expect to clear.

Most provinces in Canada have pretty big restrictions on who can access hepatitis C treatment, and for how long.

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Hepatitis C Treatment *Now!*

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In general, people with genotypes 2/3 automatically get a maximum of 24 weeks of treatment once they qualify. People with genotypes 1/4 can get a maximum of 48 weeks of treatment, but virtually everywhere they are required to demonstrate a 2 log reduction in their hepatitis C RNA (viral load) by week 12. If they don't fit that Holy Grail, off of treatment they come. This has particular significance for HIV+ people: there is a growing body of evidence to suggest that the dynamics of viral clearance after treatment initiation in people who also have HIV are slower, and while they can achieve a 2 log reduction, it might take a bit longer than 12 weeks.

In many provinces, elevated liver function tests (ALT's mostly) are required on at least two separate occasions within a six month period. The fact that about 25% of people with cirrhosis of the liver will have normal ALT's and the fact that ALT's are a notoriously bad predictor of histologic liver disease appear to be irrelevant to the bureaucrats making these decisions.

In Ontario, for those people with genotype 1, it seems you must have moderate fibrosis (scarring of the liver) that is biopsy proven. It's too bad for folks in Ontario that hepatitis C treatment is known to work best if you don't yet have any fibrosis.

And British Columbia gets the prize for the most stupid criteria of all: that you have to be treatment naïve. Never mind that people were forced into taking Rebetron because BC Pharmacare took so long to even cover pegylated interferon/ribavirin on a special authority basis; never mind that Rebetron and Pegatron cost exactly the same; and never mind that people who relapsed on previous treatment have at least a 35% chance of success, or that even people who didn't respond at all to interferon monotherapy have 35% chance of success. If you had the bad judgement to actually try to treat your hepatitis C before, you will pay for it now.

And then there's the issue of the Holy Grail, and what does it really mean anyway? People don't die of a detectable hepatitis C viral load, they die of end stage liver disease,

including fibrosis and cirrhosis. The bottom line question is, will treatment stabilize or improve liver histology (i.e. scarring of the liver), and increasingly it appears that it does even in the absence of a complete virologic response. The big HALT-C trial which is looking at maintenance treatment will be years yet before providing answers. Hopefully most people who have hepatitis C will be around to benefit from the results. HIV co-infected people, however, since their hepatitis C disease will progress 2-3 times more rapidly, have less time to wait.

It seems like governments' *modus operandi* is something along the lines of 'Just say No'. What we really should be talking about is 'Getting to Yes'. So in addition to all the issues mentioned above, we should also be talking about – and health care policy-makers should be moving on – how to improve the access to and efficacy of the treatments. This means

providing treatments for managing side effects, including growth factors like erythropoietin, and anti-depressants. It involves regular psychiatric monitoring, organizing support groups, and instituting clinics that address HIV infection, hepatitis C infection, and all other health issues in a holistic and multidisciplinary way. I wonder how many people are going to die because they don't have access to any of this? Or because they don't 'fit the criteria'? ■

Many thanks to Ken Thomson, Michelle Marchione, Ken Monteith, Patrick Hooley, and Richard Neron for their valuable contributions to this article.

It's estimated that approximately **1%** of the entire population of Canada has hepatitis C – about **250,000-300,000** people.

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Check out the internet pharmacies update on page 8



Complications and illnesses in HIV-positive people: Update from the Conference on Retroviruses and Opportunistic Infections (CROI)

by Louise Binder

THE COMPLICATIONS related to highly active antiretroviral therapy (HAART) medications have, for some time, been the subject of considerable advocacy work by CTAC. CTAC representatives have been among the groups that encouraged industry to undergo studies to understand the mechanisms causing lipodystrophy and lipoatrophy. CTAC has also urged studies of potential solutions for this problem.

Diabetes

With the advent of HAART, HIV-positive people are increasingly developing glucose (sugar) abnormalities. Two large-scale studies (one among men and one among women) presented at CROI analyzed the risk of pre-diabetes (hyperglycemia, or abnormally high sugar in the blood), diabetes, and their relationship to antiretroviral drugs.

HIV-positive men on HAART were nearly twice as likely to have pre-diabetes and three times more likely to have diabetes than HIV-negative men. HIV-positive women on HAART were twice as likely to have diabetes than HIV-negative women. A HAART regimen containing the non-nucleoside reverse transcriptase inhibitor efavirenz was associated with a higher risk of pre-diabetes. One factor that increases the risk is whether people's CD4 count had ever dropped below 100.

To help regulate blood sugar, avoid these drugs if possible, watch your diet, and exercise. The nutritional supplement chromium picolinate may also help.

Hypertension, lipids, and cardiovascular disease

A large-scale study found that HAART did not create a greater risk of hypertension (elevated blood pressure) after accounting for traditional risk factors, including being male, older, and overweight. However, one large women's cohort suggests that while just being HIV-positive isn't associated with an increased risk, the risk of hypertension does increase with HAART use by about 20%. Other factors associated with hypertension among these women were being older, African American,

poorly educated, overweight, and a smoker.

Lipids (fats in the blood including LDL [bad cholesterol] and triglycerides) are generally associated with risk for heart disease. HAART drugs, especially protease inhibitors (PI), are associated with increased LDL cholesterol and triglyceride levels.

Lipid irregularities are often associated with body fat redistribution, or lipodystrophy. Fat accumulates around the waist and at the back of the neck and disappears from the legs, arms, and face (also called lipoatrophy). In addition to potentially increasing cardiovascular disease risk, this condition can be painful and stigmatizing. PIs and nucleoside analog classes of HAART drugs are associated with lipodystrophy.

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Promising drugs and some disappointments

New strategies to deal with the problem were presented at CROI. One approach is to regulate lipids with medication. Rosiglitazone is a drug taken by diabetics to promote subcutaneous fat and improve vascular function. Unfortunately, in a study of HIV-positive participants, it did not improve lipoatrophy after 48 weeks.

A report on a polylactic acid called New-Fill also dimmed hopes for a treatment for facial wasting. Facial injections of New-Fill did not generally reverse the condition enough to improve quality of life.

CTAC has recently begun following the results of studies of cosmetic interventions for facial wasting, including New-Fill. Although overall trial results have not been encouraging,

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Complications and illnesses in HIV-positive people

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anecdotally a number of HIV+ people who have used New-Fill have reported satisfaction with the results. Thus, CTAC is beginning discussions with physicians and community members who are working to make the drug available in Canada.

Studies presented at CROI supported the strategy of switching people from HAART drugs that are strongly associated with lipid abnormalities. One study compared the nucleosides stavudine (d4T), didanosine (ddI), and indinavir versus the non-nucleoside nevirapine versus the nucleoside lamivudine (3TC). While there were no differences in lipid profiles between the groups, HDL (good) cholesterol increased in the nevirapine group. People treated with indinavir had more visceral fat and all those on stavudine and didanosine lost fat.

Another study switched people on a suppressive PI-based regimen to the nucleoside abacavir or nevirapine or another non-nucleoside, efavirenz. The non-nucleosides performed about the same, with no change in total cholesterol, though HDL rose and LDL dropped. Switching to abacavir resulted in a decrease of both total and LDL cholesterol. Unfortunately, switching off the PI did not impact body shape changes, regardless of which drug was substituted.

Another potential switch is to the new once-daily PI, atazanavir. In treatment-naïve people, it has had little impact on lipids at 48 weeks compared to either efavirenz or lopinavir/ritonavir, both of which raised lipids considerably. In one study it reduced the lipid increases related to the PI drug nelfinavir, although not back to pre-drug levels. In treatment-experienced people, atazanavir boosted with 100mg of ritonavir compared favourably to lopinavir /ritonavir. Time will tell whether these results can be sustained.

CTAC has watched the development of atazanavir with interest, given its once-daily dosing and its apparent different and better lipid profile compared to other drugs in its class. CTAC monitored its progress through Health Canada's drug review process and was pleased to see that it received priority review for review for sale in Canada. CTAC has also been monitoring its progress through the Common Drug Review

process (CDR) which was recently set up in some provinces (Quebec opted out) to create a more efficient, effective and consistent pharmacoeconomic review and recommendation to provinces for reimbursement. CTAC strongly disagreed with CDR's position not to give this drug priority review.

Representatives of CTAC and the Toronto Primary Care Physician's Group met with CDR to voice our concerns, only to be told that there are other PIs so this one is not a priority. We pointed out that the once-daily dosing and favourable lipid profile was potentially much better for some patients and would save the drug budgets money in lipid-lowering agents, which fell on deaf ears. The CDR announced its decision to approve Atazanavir in May. CTAC will be watching to see what participating provinces do with the decision. Ultimately, we want to see how good the CDR decisions are or whether CDR is just adding time to an already slow drug reimbursement process.

Tenofovir is the next drug in the CDR process and we will also be watching it, alerting you of our findings as well as advocating for the best treatment access decision for people living with HIV/AIDS.

To make your voice heard directly at the CDR, contact CTAC at ctac@ctac.ca or (416) 410-6538 for the CDR coordinates, sample letters and any other help you may require to do so.

Adapted from an article originally printed in Living + magazine, Issue 30, May/June 2004. A publication of the BC Persons With AIDS Society, www.bcpwa.org

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CTAC's Annual General Meeting 2004

CTAC's Annual General Meeting (AGM) will be held in Toronto, Ontario **November 7th-8th**. All Members are entitled to participate in the AGM. Full members will receive information packages in July.

For more information, please visit

www.ctac.ca

No Pain, All Gain

By Enrico Mandarino

Adapted from an article originally published on gayguidetoronto.com, March, 2004

OVER THE PAST YEAR, CTAC has been a leader in addressing barriers to accessing medicinal marijuana for Canadians living with HIV/AIDS. CTAC has also been monitoring developments in the scientific community about the benefits of medicinal marijuana.

There has been a lack of clinical trials to provide scientific proof of the benefits of marijuana. The Canadian government and the Canadian Medical Association (CMA) cite lack of clinical research in their reasons for not accepting marijuana as a treatment. However, anecdotal information about the health benefits of marijuana has been known for thousands of years, and at this year's 11th Conference on Retroviruses and Opportunistic Infections in San Francisco, results from an open-label pilot study suggested that smoking marijuana relieves pain associated with HIV neuropathy.

Dr. Cheryl Jay of the University of California noted how preclinical models indicate that cannabis compounds are beneficial in neuropathic pain management and that marijuana does not have untoward interactions with antiretrovirals. Dr. Jay reported on a nine-day inpatient study comprised of 16 HIV infected patients at an average age of 43 and with an average of 6 years of neuropathy. Patients were given marijuana with 3.5% THC (the active ingredient in marijuana) three times daily. In most clinical pain studies, a 30% reduction in pain is considered clinically meaningful; this was the aim for this study. Average pain scores dropped from 47 at the start of the study to 20 at the end of the seven-day period. Marijuana smoking caused a drop in pain score to 20/100 with 10 of 16 of the patients experiencing at least 30% reduction in average daily pain.

On February 18th, 2004, I attended a multi-stakeholder consultation in Ottawa regarding the proposed changes to the Medical Marijuana Access Regulations (MMAR). In attendance were governmental representatives, doctors,



...anecdotal information about the health benefits of marijuana has been known for thousands of years...

pharmacists, police, researchers, the CMA, patient groups and individuals who have been granted an exemption under the current regulations to use medicinal marijuana. Significant changes to the MMAR Phase 2, which will hopefully improve access, include:

- reclassification of symptoms on the application which will only require the endorsement of a general practitioner;
- revised patient and medical practitioner statement placing more responsibility for decision making on the patient;
- doctors will no longer have to "recommend" marijuana;
- simplification of the renewal process;
- automatic disclosure to police of possession of medicinal marijuana license upon signing the application.

A full listing of the proposed changes will be published in *Canada Gazette Part 1* for public comment. Health Canada hopes to have the regulatory amendments in force by late 2004.

The feeling at the end of the consultation was that Health Canada is trying to make this program work for the benefit of the patient. When, out of curiosity, colleagues at my table asked to see my own exemptee authorization cards, it was noticed that I had an expired authorization. The Ottawa staff sergeant and Manager of the Office of Cannabis responded immediately to ensure that I had sufficient documentation to fly home with legal possession of my own medicinal marijuana. ■

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WOMEN'S ISSUES: UPDATE**More research needed on women and HIV treatment**

WOMEN REPRESENT AN INCREASING PROPORTION of new HIV infections and worldwide the incidence of HIV has now met gender parity. In Canada, an increasing proportion of new cases are being diagnosed in women, which has increased from 12% between 1985-97 to 25% in 2001. 45% of AIDS cases in women occur in those between the ages of 15 and 29. Despite these numbers, little is known of the optimal antiretroviral (ARV) therapy and doses of agents to be used in women. In general, compared to men, women have smaller body size, higher body fat content and hormonal influences (natural and medication induced) which could potentially influence antiretroviral pharmacokinetics and ultimately efficacy and/or toxicity. Early in HIV disease, the viral load in women is typically 0.5 log (2.5 x) lower than in men. However, this difference decreases as disease progresses. The reason for this difference is not entirely clear. Expert panels have not recommended changing therapy guidelines based on these differences.

None of the controlled clinical trials of antiretroviral therapy is large enough to analyze by gender, and in general women are under-represented (10-20%). Therefore, data on the appropriate use of ARV therapy comes largely from sub-analysis of the larger studies or from cohort studies which have a number of important confounders making their interpretation difficult.

The data available would suggest that ARV efficacy, as measured by viral load, CD4 count and clinical outcomes, is similar between the genders. In both genders the incidence of opportunistic infections and death rates has declined dramatically since the widespread use of highly active antiretroviral therapy (HAART). However, the toxicity profiles and frequency of adverse events may differ. Cutaneous rash and hypersensitivity (allergic reactions), liver test abnormalities, inflammation of the pancreas and lactic acidosis may be increased, whereas blood fat abnormalities and diarrhea may be lower. The fat redistribution changes of lipodystrophy may also vary by gender.



by Sharon Walmsley

Some studies have shown that women are more likely to discontinue ARV therapy than men because of toxicity. This could eventually impact on efficacy and drug resistance.

The most significant impact of ARV therapy in this gender has been on decreasing rates of maternal to child transmission. Therefore, when women of child-bearing potential are contemplating ARV therapy, it is important that the safety of the agents, should pregnancy occur, be considered. If the woman is on oral contraceptive therapy, potential drug interactions with the ARV agents has to be considered and barrier methods combined.

A woman with HIV infection often has other life factors that may impact upon her ability to have maximal benefit from ARV therapy. This could include, but it is not limited to, injection drug use, hepatitis C, poverty, lack of adequate food and housing, the need to care for an infected partner or child, depression, isolation and guilt. It is important that these other factors be addressed in the context of her complete management. ■

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Sharon Walmsley is the Assistant Director of the Immunodeficiency Clinic at the Toronto Hospital and an Associate Professor of Medicine at the University of Toronto. Her article entitled "Antiretroviral Treatment Responses and Considerations of Therapy in Nonpregnant Women," a report from the Conference on Retroviruses and Opportunistic Infections, was recently published on Medscape.com at the following address: www.medscape.com/viewarticle/470973 (Note: you must be registered with Medscape.com to read this article).

Cross-border internet pharmacies: Update

By Tony Di Pede



THE SALE OF CANADIAN DRUGS via cross-border internet pharmacies is leading to drug shortages in Canada. CTAC has been monitoring this issue closely and is advocating for a halt on cross-border internet pharmacies.

CTAC has facilitated the creation of a coalition of Canadian disability groups that are concerned about the impact of these pharmacies. The coalition met in Washington D.C. in April to adopt a consensus statement (available at www.ctac.ca) and to present its concerns to a committee chaired by the U.S. Surgeon General at the National Institutes for Health. In its presentation, CTAC explained how cross-border internet pharmacies are creating drug shortages in Canada, and that importation of Canadian drugs by Americans is not a sustainable solution to high drug prices in the U.S. Because Canada's population is small compared to the U.S., its supply of prescription drugs is proportionately smaller than that of the U.S. To illustrate, if every drug in Canada were shipped to the U.S. it would only be equal to a 23 day supply for Americans.

CTAC has also been educating federal and provincial ministers and politicians about the risks these pharmacies pose for Canadians. As a result, the Hon. Don Boudria, Liberal MP and member of the House of Commons Standing Committee on Health, tabled a motion in the House of Commons calling on the government to ban internet pharmacies. We hope that Prime Minister Martin was listening. ■

For more information on the detrimental impacts of cross-border internet pharmacies, see "Internet Pharmacies: True Canadian crisis or scapegoat for the U.S.?" CTAC newsletter, March 2004 at www.ctac.ca/english/pdf/newsletter_0304.pdf

Increased CSHA funding at last

THE FEDERAL GOVERNMENT ANNOUNCED on May 15th an increase in funding for the Canadian Strategy on HIV/AIDS (CSHA) over the next five years of twice the present annual amount of \$42.2 million. \$5 million will be targeted to community-based organizations in this fiscal year. The CSHA will receive \$8 million each year for the next three years, and \$ 13.2 million in 2008. As of yet, no amount has been earmarked for any specific strategic area.

We are very gratified that the government has finally recognized what all of the HIV/AIDS stakeholders have known, and have been telling the government for some time. We particularly thank the Hon. Carolyn Bennett, Minister of State (Public Health), who sat on the Standing Committee on Health that recently recommended \$100 million for HIV annually. We are also grateful to the Hon. Anne McLellan, Minister of Public Safety and Deputy Prime Minister, who, in her previous portfolio as Minister of Health, publicly supported significantly increased CSHA funding. The present Minister of Health, the Hon. Pierre Pettigrew also agreed. Last but not least, the Prime Minister, the Honourable Paul Martin, also made public statements of encouragement last year.

Unfortunately, by spreading the funding out over five years the government did not go as far as is needed or far as its own Standing Committee recommended.

Minister Bennett has left the door open for further discussions about accelerating the timing of this funding. CTAC looks forward to this opportunity with great anticipation. ■

PROVINCIAL UPDATES

QUEBEC

by Line Carreau, Quebec Representative
and Ken Monteith, COCQ-Sida Representative

COCQ-Sida met with Philippe Couillard, Minister of Health and Social Services of Québec, to discuss a number of issues, including access to therapeutic drug monitoring (TDM). This test allows the measurement of medication levels in the blood of people living with HIV/AIDS. Mr. Couillard promised to follow up on this issue in order to speed access to TDM.

The Treatment Committee is concerned about the cancellation of the February 2004 publication of the provincial formulary and the possible cancellation of the scheduled June edition. The June publication is expected to include the new medications Tenofovir and Atazanavir and its cancellation might delay access to these important drugs. The Committee has asked CPAVIH, COCQ-Sida and its member organizations to pressure

the Minister of Health and Social Services to return to the former practice of publishing quarterly updates to the formulary. It is notable that, despite the cancellation of the February update, Enfuvirtide (T-20, Fuzeon) was added as a médicament d'exception outside the usual publication process.

The Lipo-Action Committee continues to collect affidavits from people suffering from lipodystrophy with the goal of demanding coverage for surgical procedures to address lipoaccumulation.

The journal Information sur les Traitements de l'Immunodéficience du Québec (ITI) continues to inform people living with HIV/AIDS about treatments and their rights. The next issue, planned for June 2004, will address such topics as osteoporosis, access to new medications, D4T and pregnancy, getting the most from your doctor's appointment, HIV/HCV co-infection and a survey on lipodystrophy. ■

Living in Quebec and want to become a member of CTAC? Visit www.ctac.ca/english/membership.html or call (416) 410-6538.

XV International Conference in Bangkok, Thailand – July 11-16



As the first International Conference to be held in Asia, it is the hope of the conference organizers that this conference will lead to a better understanding of AIDS in that region, which is home to more than one-third of the world's population and

sadly more than one-fourth of the world's new HIV infections.

CTAC will be presenting 8 posters at the conference. For a complete version of the abstracts, please visit the CTAC website at www.ctac.ca.

- **Affecting public policy through community advocacy to improve access to medications in Canada**
E. Mandarino, L. Binder, S. Margolese, R. Rosenes, T. Di Pede
- **Community action leads to policy change on vaccines for HIV positive children in Ontario, Canada**
L. Binder, E. Mandarino, S. Margolese, R. Rosenes
- **Improving access to HIV resistance testing in Canada through community action**
R. Rosenes, E. Mandarino, L. Binder
- **Removing access barriers to medicinal marijuana policies through community action in Canada**
E. Mandarino, S. Margolese, P. Lundrigan, C. Checkland, L. Belle Isle
- **Medicinal Marijuana – what a trip! The Canadian experience**
E. Mandarino, S. Margolese, P. Lundrigan, C. Checkland, L. Belle Isle
- **So you want to have a baby? Questions and answers about HIV and pregnancy**
S. Margolese
- **HIV testing and pregnancy. Protecting access to informed consent through community action in Canada**
S. Margolese
- **Building the foundations for an effective, consumer centered, Post Approval Surveillance System (PASS) for medicines approved for sale in Canada**
L. Binder, P. Lundrigan

Clinical Trials: Update



by *Jim Boothroyd,*
Communications Manager
at the Canadian HIV Trials Network

Therapeutic vaccine trial begins enrollment

The first participants are being enrolled in a Canadian clinical trial of a therapeutic HIV vaccine that aims to reduce dependence on toxic antiretroviral (ARV) drug combinations.

The 12-month, Phase I and II study "Vaccination before treatment interruption" (CTN 173) will enroll 60 patients at Ottawa Hospital, Centre hospitalier de l'Université de Montréal and McGill University Health Centre.

The purpose is to determine if vaccination before structured treatment interruption (STI) is associated with an improvement in immune function, resulting in a delayed and reduced rebound in the amount of virus in the blood. Volunteers must be on at least three ARV drugs, including a protease inhibitor and have had an undetectable viral load for at least two years.

Participants will be randomly assigned to one of three arms of the study. Those in the first arm will receive Remune and ALVAC. Those in the second will receive Remune placebo and ALVAC. Those in the third will receive matching placebos.

Remune is made from whole HIV particles, stripped of the envelope layer and sterilized. It is used to mimic an infection to boost the immune system. ALVAC is a preparation of a modified recombinant canarypox virus, used to transport HIV-1 gene products into the body to stimulate protective immunity.

Participants in all arms will interrupt their ARV therapy at week 24. Viral load and CD4 counts will be monitored frequently before and after the STI.

The study is led by Dr. Jonathan Angel of the University of Ottawa and the Canadian Network for Vaccines and Immunotherapeutics (CANVAC).

Call Sophie Geeraerts at the Canadian HIV Trials Network (1-800-661-4664) and www.hivnet.ubc.ca/ctn.html for details. ■

CALENDAR OF EVENTS SUMMER and FALL 2004

● **July 11th-16th**

XV International AIDS Conference
Bangkok, Thailand
Contact: www.ias2004.org

● **July 18th-23rd**

12th International Congress of Immunology & 4th Annual Conference of the Federation of Clinical Immunological Societies
Montreal, Quebec
Contact: 613-993-7271 or immuno2004@nrc-cnrc.gc.ca

● **August 30th-September 1st**

AIDS Vaccine 2004 Conference
Lausanne, Switzerland
Contact: +41 61 686 77 11 or aids2004@akm.ch

● **September 10th-12th**

Canadian HIV/AIDS Legal Network AGM and Skills Building
Montreal, Quebec
Contact: 514-397-6828 or info@aidslaw.ca

● **September 26th**

Walk for Life
Montreal, Quebec
Contact: 416-270-4900 or farha@farha.qc.ca

● **October 2nd-3rd**

Coalition des organismes communautaires québécois de lutte contre le sida (COCQ-Sida) Annual General Meeting
Montreal, Quebec
Contact: 415-270-4900 or info@cocqsida.com

● **October 27th-30th**

Canadian Aboriginal AIDS Network Annual General Meeting
Halifax, Nova Scotia (location may change)
Contact: 1-888-285-2226 or info@caan.ca

● **November 7th-8th**

Canadian Treatment Action Council AGM and Skills Building
Toronto, Ontario
Contact: 416-410-6538 or www.ctac.ca
Join CTAC for a day of skills building in Toronto! All are welcome to attend. Please see www.ctac.ca for details and to register for the day.

CHAIR'S REPORT

SUMMER 2004

by Louise Binder



AN ACTIVIST FRIEND RECENTLY ASKED

me if I thought our work makes a difference. I answered without hesitation that it absolutely does. Then, a bit surprised at my own unequivocal response, I began to contemplate the reasons I believe this to be true. Is it just the spring flowers? The hope that new life brings? No, it is based on some tangible changes that I have seen lately.

One involves Health Canada's Health Products and Food Directorate, whose mandate includes the review of new drugs for sale in Canada. CTAC has, for many years, led the way in advocating for more efficient review processes and for a meaningful consultative and advisory role for informed consumers. It appeared that this request would never be heard. Yet, within the last year there have been broad consultations with consumers about the structure of the Directorate and the potential processes for consumer involvement. Consumers have been invited to the previously closed meetings of the Advisory Committee on Management for the Directorate and coming up will be Multistakeholder consultations on the Directorate's plans for the future.

On the pharmaceutical industry front, CTAC has been in ongoing, sometimes quite difficult, negotiations with Gilead Sciences regarding its nucleotide drug, Tenofovir. First, the company refused to launch in Canada until it was granted

approval of its proposed price by Canada's Patented Medicines Prices Review Board. Finally, it has agreed to launch without waiting for this review. It also threatened to cut off supply of the drug to people on its Expanded Access Program 90 days after the drug launched, whether or not provinces had agreed to reimburse it. After meeting in February with a CTAC representative and the Co-Chair of the Toronto Primary Care Physicians Group, it reversed its position and agreed to supply the drug until it is covered by provincial formularies. The company has applied to Common Drug Review (CDR) for a recommendation to the provinces to list it for reimbursement and, hopefully, this will not take too long.

These are only two issues that CTAC has been working on, among many others yet to be resolved. Drug review times are often too slow at the federal and provincial levels. CDR is not working in the way it was intended. Cross-border internet pharmacies are creating drug shortages and may ultimately destroy our drug price regulation system. Canada still lacks an active, consumer-centred Post-Approval Surveillance System. The federal government has just set up the Public Health Agency under which AIDS funding will be housed and little is known about how it will function. Yet, I do not find myself in despair nor do I see my fellow CTAC colleagues as such. Rather we celebrate our successes large and small. We also recognize that part of making a difference is being vigilant; being at decision-making tables to influence decisions and keeping the community informed of the access issues that all of us face. Maybe my sense of optimism is spring flowers, but if so, I sure hope it lasts. ■



Interim National Women's Representative

WE WISH TO THANK Shari Margolese for her dedication to the role of CTAC National Women's Representative.

Shari was CTAC's first National Women's Representative and has done a tremendous job at building relationships with other organizations who are working on issues specific to

women living with HIV, as well as bringing women's issues to the forefront at CTAC. Shari has left CTAC, and we wish her well and look forward to working with her in the future.

CTAC is now in the process of selecting an interim National Women's Representative. Check the next issue for an update. ■

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CTAC POSITION PAPERS

Papers

• 2001 - "Improving our Health: The Need to Enhance the Post-Approval Surveillance System for HIV/AIDS Drugs in Canada", author: David Garmaise.

• 2001 - "Making Treatments Accessible: A Policy Paper on Determining Appropriate Pricing for Brand-name Pharmaceutical Treatments for HIV/AIDS in Canada", author: Glen Brown.

• 2000 - "Position Paper on Direct To Consumer Advertising (DTCA) of Prescription Medications", author: Phillip Lundrigan.

• 1999 - "Timeliness and Transparency: Assessing the Review Process for HIV Drugs", author: David Garmaise.

Permission is given to reproduce all or any part of the papers provided appropriate accreditation is given. Papers are available free of charge electronically at www.ctac.ca/english/position_papers.html or on hard copy from the CTAC office (see contact information below).

MEMBERSHIP

Membership applications are available by contacting the CTAC office or by visiting the CTAC web site at www.ctac.ca/english/membership.html.

Full Membership

- Person living with HIV/AIDS
- Group, organization and/or project with a substantive HIV/AIDS mandate

Associate Membership

- Any individual
- Group, organization and/or project whose substantive mandate coincides with the objectives of the Corporation

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Organizational Mandate

The mandate of the Canadian Treatment Action Council (CTAC) is to work with the public and private sectors to:

1. **Support access to therapies and treatments** for people living with HIV/AIDS by informing research and public policy, and by promoting public awareness
2. **Provide mentoring and skills building** in these areas to people living with HIV/AIDS
3. **Encourage and facilitate the exchange** of related information to stakeholders

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