

# positively POSITIVE →

The official publication from **Body Positive Inc.** A peer support organisation for people living with HIV/AIDS

## New Hope for Aids vaccine



The search for an HIV vaccine has taken a major step forward with the discovery of a potential Achilles heel of the virus that causes Aids.

Two powerful antibodies that attack a vulnerable spot common to many strains of HIV have been identified, improving the prospects for a vaccine against a virus that affects an estimated 33 million people and kills over 2 million each year.

The discovery is important because it highlights a potential way around HIV's defences against the human immune system, which have so far thwarted efforts to make a workable vaccine. The hope is that a vaccine that stimulates the production of these antibodies could remain effective against HIV even as the virus mutates.

Scientists from the International Aids Vaccine Initiative (IAVI) are already examining the antibodies for clues to vaccine design. The new techniques used to discover the antibodies also promise further progress, as they should reveal other weaknesses in HIV that a vaccine might exploit.

"The findings themselves are an exciting advance toward the goal of an effective Aids vaccine because now we've got a new, potentially better target on HIV to focus our efforts for vaccine design," said Wayne Koff, senior vice president of IAVI, which led the

consortium behind the research.

"Having identified this one, we're set up to find more, which should further accelerate global efforts in Aids vaccine development."

Aids vaccine research has foundered to date because HIV mutates more quickly and easily than any other human pathogen yet discovered.

Vaccines work by teaching the immune system to recognise a particular germ and release antibodies to neutralise it, but HIV's shape-shifting nature allows it to evade these defences very rapidly.

The newly discovered antibodies, called PG9 and PG16, are promising because they recognise parts of the virus that do not appear to change on a spike that HIV uses to infect cells. This suggests that they should be capable of attacking the virus in all its forms.

Dennis Burton, Professor of Immunology and Microbial Science at the Scripps Research Institute in La Jolla, California, who led the research team, said: "These new antibodies, which are more potent than other antibodies described to date while maintaining great breadth, attach to a novel, and potentially more accessible site on HIV to facilitate vaccine design.

## K'Road Clinic now offering Full Sexual Health Check



A new service is about to be added to the K'Road Clinic, The clinic operates out of Samoa House which is situated at 283 Karangahape Road in the heart of Auckland's "gay" district. Auckland Hospital moved the Sexual Health clinic to Greenlane Hospital's Out patients clinic a number of years ago making the trip difficult for some to make. A full sexual health screening will be available as well as a specialist service for people living with HIV. The builds on the free rapid HIV testing service made available at the K'Road Clinic now for over a year. Bruce Kilmister from Body Positive says this will be an added service meeting a strong need in our community. **Access to this clinic is by appointment, phone (09)309 3989.**

"So now we may have a better chance of designing a vaccine that will elicit such broadly neutralising antibodies, which we think are key to successful vaccine development."

PG9 and PG16, details of which are published in the journal *Science*, are particularly important because they appear to be effective against a multitude of HIV strains, including those found in Africa where Aids is most prevalent.

While a handful of similar broadly-neutralising antibodies have been identified before, these have all come from HIV patients infected with strains circulating in Europe and America.

The next challenge for the research is to identify substances called immunogens which stimulate the body's immune system to start making the PG9 and PG16 antibodies. Such an immunogen could then be evaluated as a candidate for a vaccine.

The antibodies were discovered in a study of blood samples from more than 1,800 HIV-positive volunteers, from several countries in sub-Saharan Africa as well as the UK, the US, Thailand and Australia. The samples

were then screened for broadly-neutralising antibodies against the virus, which very few patients make themselves.

The antibodies would not have been identified without a new method of hunting for them, developed by a company called Monogram Biosciences. Christos Petropoulos, its chief scientific officer, said: "If you think of it as a fishing expedition, we and the rest of the field were previously using the wrong bait in the search for HIV-specific broadly neutralizing antibodies."

Seth Berkley, president and chief executive of IAVI, said: "The story of the discovery of these two new antibodies demonstrates the challenges of Aids vaccine research but also the power of the collaboration that formed to produce this advance.

"This is what can happen when you have researchers from the global North and South, from academia and industry, from within and outside the HIV field, working together in a framework to speed innovation. By working in this manner, I am confident we will continue to move toward solving the AIDS vaccine challenge, one of the greatest scientific and public health challenges of our time."

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## HIV rises in USA



In the late 1970s and early 1980s, gay and bisexual men – who are sometimes referred to as men who have sex with men (MSM) – were the main risk group affected by AIDS when it first appeared. Today, in Australia, Canada and the United States, these men continue to be the risk group most commonly diagnosed with HIV infection.

In the early years of the AIDS epidemic, gay community groups organized and conducted educational efforts resulting in safer-sex programs. These activities highlighted the danger of the riskiest activity—unprotected anal intercourse. As a result, HIV infection rates slowed in the 1990s, at least among some gay and bisexual men in

the United States and perhaps other high-income countries.

In 1998, researchers in these countries noticed a troubling trend: Rates of syphilis began to increase among gay and bisexual men. Sexually transmitted infections (STIs) such as syphilis can cause sores, lesions and inflammation in the genitals, which can make a person more susceptible to HIV infection.

### Trends

An international research team recently finished its analysis of HIV and syphilis testing data among MSM collected between 1995 and 2005 from the following high-income countries:

- Australia;
- Canada;
- France;
- Germany;
- Netherlands;
- Spain;
- United Kingdom;
- United States.

They found that HIV infection rates decreased by about 5% per year between 1996 and 2000. However, after 2000, infection rates rose by about 3% per year. They also found that, on average, the age at which MSM were diagnosed with HIV infection was increasing, from 34 years in 1996 to 36 years in 2005. These trends held for all countries except Spain, where the data made available for this study was limited.

The study also found that syphilis rates increased sharply after 2000. This disease may have played a role in the subsequent increase in HIV transmission.

### Noteworthy

The increase in HIV infection rates after 2000 does not appear to be linked to increased rates of HIV testing. Moreover, the trends found in this study occurred in several countries on different continents all around the same time. Overall, the research team suggests that HIV infection rates have indeed increased among gay and bisexual men. The psychosocial reasons underpinning this increase in HIV transmission rates is unclear.

### What is to be done?

The findings from the international study suggest that gay and bisexual men continue to be at high risk for HIV infection and syphilis. The research team stated: “New HIV prevention interventions at multiple levels—individual, couple, group, community and structural—should be considered high priorities for prevention scientists and program experts.”

They added that their results “call for urgent attention to further our understanding of the reasons for this resurgence, to develop new HIV prevention interventions for the highest-risk MSM, and to deploy available interventions aggressively in these at-risk populations.”

## Korea: Ban on foreign AIDS patients to be lifted

The plan emerged in the face of protest from foreigners and legal experts against what they call discriminatory measures.

They claim such policies infringe on human rights and have little effect on protecting Koreans from the contagious disease.

Under the immigration law, authorities can ban the entry of foreign nationals who test positive for HIV/AIDS, and then deport them. U.N. Secretary General Ban Ki-moon suggested that Korea abolish the policy.

According to the Korea Centers for Disease Control and Prevention, there are 13 countries that ban the entry of foreign AIDS patients: the United Arab Emirates, Brunei, Egypt, Iraq, Korea, Malaysia, Oman, Singapore, Sudan, Yemen, Tunisia, the Turks and Caicos Islands and Qatar.

“The relevant ministries have yet to reach a conclusion on the issue,” said Park Il-hoon, deputy director of the Ministry for Health, Welfare and Family Affairs.

“However, we will continue to restrict AIDS patients in the entertainment business. Immigration officials will make necessary changes to the regulations.”

Meanwhile, the Korea Immigration Service (KIS) said it has yet to decide whether to revise visa regulations requiring foreigners



applying for certain types of visa to take AIDS tests.

It is mandatory for foreigners seeking E-2 (foreign language instructors), E-6 (entertainers, artists, athletes and models) and E-9 (non-professional employees) to submit HIV-negative confirmation statements.

“There will be no changes for E-6 visa applicants. We do not deal with non-professional workers as the Labor Ministry is responsible for AIDS tests on E-9 visa applicants,” Ahn Kyu-seok, the KIS spokesman told the Korea Times.

“However, if the Constitutional Court rules that making foreign instructors submit documents on HIV tests is unconstitutional, we may have to scrap the requirement,” Ahn added.

A group of human rights lawyers, called “Gong-Gam,” last July filed a petition with the Constitutional Court against visa regulations requiring foreign English teachers to undergo HIV and drug tests.

In February, a foreign teachers group filed complaints with the National Human Rights Commission of Korea, claiming the visa regulations were biased against foreign English teachers.

A court concluded last December that the immigration office should cancel the deportation order against a foreigner who tested positive for HIV, saying it was in the interest of Koreans to detect and treat HIV/AIDS rather than deport the victims.

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## Visiting Australia - read this

New figures to be released today at a major sexual health summit show Australian doctors detected 995 new cases of HIV during 2008.

This was down fractionally from 1,051 diagnoses in 2007, but Associate Professor David Wilson from the University of NSW cautions a change in data collation contributed to the decline.

"This last year is the first year in the last decade that we have not seen an increase ... but some of that might be tied to slight changes in methodology," says Prof Wilson, who is head of the university's Surveillance and Evaluation Program for Public Health.

"I wouldn't read too much into the small dip - the big point is we're still at very high levels.

"Over the last three years, we've had around 1,000 cases and that's much higher than where we were ten years ago."

Australia's annual number of new HIV diagnoses has increased by 38 per cent over the decade, from 718 cases in 1999.

Gay men continue to account for most of the new diagnoses of HIV, with 64 per cent of diagnoses in 2008 occurring among men who have sex with men.

The next largest group (21 per cent) contracted HIV through heterosexual contact, while the remaining cases were linked to injecting drug users or "undetermined".

The latest cases take Australia to a total 28,330 diagnoses of HIV, leading to 10,348 cases of AIDS and 6,765 AIDS-related deaths since records began.

At December 31 last year, there were 17,444 Australians living with HIV, though - in some good news - the number who go on to develop AIDS is in decline.

This figure peaked at about 1000 AIDS cases annually in the early 1990s, but it has since dropped to about 240 people a year since 2001.

"That's fantastic ... and it's entirely due to the uptake of retrovirals (medication)," says Dr Jonathan Anderson, who is president of the Australasian Society for HIV Medicine.

"HIV-positive people have acquired the virus, but they may not have any symptoms, while AIDS is the collection of diseases people get when the body's immune system has been damaged over a number of years by having (undiagnosed and untreated) HIV."

Dr Anderson says despite the plateau in cases, Australia should not be content with

a thousand new HIV diagnoses a year.

Public health officials should lead a renewed effort to tackle the virus, he says, as too many people were still turning up at clinics in well advanced stages of HIV.

"I don't think another scare campaign would work," Dr Anderson says pointing to the infamous Grim Reaper-themed public awareness campaign.

"I think we need to explore more the rate of undiagnosed HIV in our society, it's hard to change behaviour but it's much easier for the health system to test more routinely for this."

The report - HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2009 - is to be officially released at the Australian Sexual Health Conference 2009, which is under way this week in Brisbane.

The report also finds Chlamydia continued its rapid rise in the Australian community,



particularly in those aged 15 to 25.

There were more than 58,400 new diagnoses of the infection - which can lead to infertility - during 2008 and this was up 10 per cent on the year before.

There were 211,700 Australians living with chronic hepatitis C infections in 2008, and while annual rates of new infection have fluctuated there has been a decline over five years.

## HIV-positive - Get the swine flu vaccine

People who are HIV-positive or living with AIDS are being advised to get vaccinated for the H1N1 virus, commonly called the swine flu, later this year when the vaccine becomes available.

Health officials stress there is no evidence to suggest that people living with HIV are any more susceptible to the swine flu than they would be for the seasonal flu.

"They should think of it as the same as the seasonal flu. Whatever their reaction would be for the seasonal flu should be their reaction for H1N1," said Dr. Susan Fernyak, the US health department's director of communicable disease control and prevention. "If they don't care about the seasonal flu, they shouldn't be up in arms about swine flu."

Health officials in the USA have long advised HIV-positive people to get vaccinated for the seasonal flu each year, and that is still the case this year. Each year 6,000 Californians die due to influenza.

"It is still a serious disease in California and people should get immunized for seasonal flu," said Amy Pine, director of the USA health department's communicable disease prevention unit. "Everyone should get [vaccinated], including people with weakened immune systems."

Although people with immunosuppression due to medications or an HIV infection are at a higher risk for contracting the swine flu, they are not considered to be among the groups most at risk, according to health officials in the USA.

Californian health officials have predicted there could be a possible flu pandemic afflicting 25 percent of Californians if its spread is not checked. To date, the virus has claimed 125 lives in California, state Health and Human Services Agency Secretary Kim Belshe told reporters Tuesday, September 1 during a tour of the nine-year-old state Department of Health Services laboratory campus in Richmond, where samples are tested to verify if a person indeed has the swine flu.

Governor Arnold Schwarzenegger joined her on the tour to bring attention to the vaccination efforts.

"We urge everyone to take this very seriously," Schwarzenegger said, citing predictions that the virus could "take thousands and thousands of lives."

At a flu forum San Francisco health officials held for medical providers, school officials, and the media last week, Fernyak said it is unclear if this year's flu season will be the worst ever, but it is likely to be severe since there are two strains of flu circulating, the seasonal flu and the swine flu.

"There is no indication the swine flu will be more severe than what we have seen over the last five months. The virus is quite stable, which is great news," she said. "We hope to see that continue through the northern hemisphere autumn season."

For most people, though, symptoms are mild to moderate. Since April, when San Francisco reported its first case of the swine flu, there has been little evidence

to show that people infected with HIV are more at risk of getting the H1N1 strain, said health officials.

But the news last week that Castro bar owner Doug Murphy had died in Palm Springs within weeks of contracting the swine flu has raised concerns within the city's LGBT community about who is at risk. The official cause of death was cardio pulmonary arrest.

Supervisor Bevan Dufty has been working with staff at Magnet, the gay men's health center in the Castro, to become better informed about flu issues. The center already is offering seasonal flu shots and is looking at the possibility of also administering the H1N1 vaccine.

"The basic message is if you have an individual who is very healthy, robust, doing well on their drug regimen, that person is not a high priority for H1N1 vaccine barring other circumstances," said Dufty, who along with drag persona Donna Sachet will get the seasonal flu vaccine today (Thursday, September 3) at the city's travel and immunization clinic to mark its 10th anniversary.

According to interim guidelines issued by the Centers for Disease Control and Prevention and last updated in June, there is "insufficient data available at this point" to know who has the highest risk for contracting the swine flu, though people who are HIV-infected, particularly those with low CD4-cell counts or AIDS "can experience more severe complications of seasonal influenza and it is possible that HIV-infected adults and adolescents are

also at higher risk for [H1N1] virus infection complications."

Fernyak said that the vast majority of people who have had the H1N1 flu virus have not had severe cases. The CDC estimates that 1 million Americans have already been exposed to the swine flu.

"With most people who get H1N1, it is a very mild disease," she said.

And as reported in the Bay Area Reporter last week, of those who have been hospitalized or died due to swine flu, there is no evidence to suggest they are more likely to be HIV-positive. Fernyak told the paper she would have heard if that were the case.

"We are not seeing people with HIV being harder hit with this disease than other people who don't have HIV," Fernyak said.

Due to state laws restricting how a patient's HIV status can be disclosed, local health officials are not reporting to the state's health department whether those people hospitalized with or who die from the H1N1 virus are also HIV-positive.



## The benefit of starting medication for people living with HIV



The benefit of starting medication has been obvious since medication was available. Not only did it save your life it rebuilt your immune system – unfortunately never back to the same level and strength it was before you became HIV infected. In the following years since antiretroviral medication has been available there has been a debate as to when to start medication. Initially it was suggested to start when your CD4 cell count (a measure of your immune system) was sitting at a count of 200 copies per 100ml of blood. Slowly but surely the trigger level of CD4 cell count has risen to 350 and some even suggest a 500 CD4 cell count. Some suspicious minds claimed this was a plot by the pharmaceutical companies to increase profits but the increasing amount of science indicates starting early has significant benefits.

In a recent study major resistance mutations were seen more frequently among patients who initiated medication at lower CD4 cell counts of 200. Although the numbers of this study were small it adds to other cohort data to suggest that early medication does not appear to increase the risk for resistance to develop. In fact the evidence suggests that patients starting medication with a higher CD4 cell count will be less likely to develop resistance.

## NEW HIV drug to be funded by Pharmac

PHARMAC  
Pharmaceutical Management Agency

The Merck Sharp & Dohme new drug Raltegravir (Trade name Isentress) will be funded by Pharmac, the New Zealand Government's drug funding agency from 1st October 2009. This will make the drug widely available in New Zealand for HIV + people who are experiencing resistance issues with their current medication. Resistance to medication usually is a result of non compliance of prescription dosing or failure to take medication as prescribed. For HIV medication to be effective a compliance regime of 95% is required to avoid resistance building. This strict regime is often difficult for people and missing no more than two doses a month can be hard.

Raltegravir has a good record to date of avoiding resistance developing and is a new class of drugs called Integrase Inhibitors. Body Positive lobbied Merck Sharp and Dohme to make this drug available in New Zealand under the "Early Access Scheme" which allows positive people failing other medication to start this new drug under a compassionate scheme before Pharmac funded the drug. Approximately 60 people are accessing this drug before the Government will fund it from October.

## Drug company fined \$3.4 billion (US\$2.3) for Health Care Fraud

American pharmaceutical giant Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. (hereinafter together "Pfizer") have agreed to pay US\$2.3 billion, the largest health care fraud settlement in the history of the Department of Justice, to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products, the Justice Department announced today.

Pharmacia & Upjohn Company has agreed to plead guilty to a felony violation of the Food, Drug and Cosmetic Act for misbranding Bextra with the intent to defraud or mislead. Bextra is an anti-inflammatory drug that Pfizer pulled from the market in 2005. Under the provisions of the Food,

Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses - i.e., any use not specified in an application and approved by FDA. Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns. The company will pay a criminal fine of \$1.195 billion, the largest criminal fine ever imposed in the United States for any matter. Pharmacia & Upjohn will also forfeit \$105 million, for a total criminal resolution of \$1.3 billion.

In addition, Pfizer has agreed to pay \$1 billion to resolve allegations under the civil False Claims Act that the company

illegally promoted four drugs - Bextra; Geodon, an anti-psychotic drug; Zyvox, an antibiotic; and Lyrica, an anti-epileptic drug - and caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs. The civil settlement also resolves allegations that Pfizer paid kickbacks to health care providers to induce them to prescribe these, as well as other, drugs. The federal share of the civil settlement is \$668,514,830, and the state Medicaid share of the civil settlement is \$331,485,170. This is the largest civil fraud settlement in history against a pharmaceutical company.

As part of the settlement, Pfizer also has

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agreed to enter into an expansive corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services. That agreement provides for procedures and reviews to be put in place to avoid and promptly detect conduct similar to that which gave rise to this matter.

Whistleblower lawsuits filed under the qui tam provisions of the False Claims Act that are pending in the District of Massachusetts, the Eastern District of Pennsylvania and the Eastern District of Kentucky triggered this investigation. As a part of today's resolution, six whistleblowers will receive payments totaling more than \$102 million from the federal share of the civil recovery.

## ★ HIV SERVICES AVAILABLE AT BODY POSITIVE ★

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- Pot-luck Dinner monthly on last Thursday
- Social Get Together monthly on last Saturday
- Annual HIV Treatments Update Seminar
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