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TAG
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tagline

NEWS ON THE FIGHT FOR BETTER TREATMENT, A VACCINE, AND A CURE FOR AIDS

Reinvigorating the Search for a Cure

BY RICHARD JEFFREYS

In Vienna, Austria, on July 16 and 17, 2010, immediately prior to the XVIII International AIDS Conference, the International AIDS Society (IAS) held a workshop titled "Towards a Cure: HIV Reservoirs and Strategies to Control Them." Cosponsors included the French National Agency for Research on AIDS and Viral Hepatitis, the German Bundesministerium für Wissenschaft und Forschung, the U.S. National Institutes of Health, Sidaction, and Treatment Action Group (TAG). Chaired by IAS president elect and Nobel laureate Françoise Barré-Sinoussi, the workshop was a high-profile illustration of the reinvigoration of the research effort toward curing HIV infection.

Over the two days, attendees—including basic and clinical researchers, policy makers, community advocates, and journalists—heard presentations covering a range of relevant topics including viral sanctuary sites and cellular reservoirs, mechanisms of HIV latency, novel therapeutic approaches, and drug development issues. There is a fairly broad consensus among scientists that antiretroviral therapy (ART) is capable of completely suppressing HIV replication in most individuals; as mentioned by both Steve Deeks and Frank Maldarelli at the workshop, the evidence supporting this conclusion includes the lack of HIV evolution in people on long-term suppressive ART; the homogenous nature of the very low levels of virus that are detectable despite ART (suggesting this virus emerges from cells that were infected prior to ART initiation as opposed to reflecting ongoing replication); and the absence of a reduction in residual viral load levels in most studies that have attempted to "intensify" ART by adding additional drugs.

There is, however, some evidence that HIV replication may occur and contribute to viral persistence. At the workshop Joe Wong presented data suggestive of low-level replication in the terminal ileum of the gut, and Una O'Doherty debuted results indicating that the virus replicates sporadically in some individuals. O'Doherty's results were obtained with a new assay that measures the amount of HIV DNA integrated into cellular DNA compared to the amount of unintegrated HIV DNA; an "excess" of the latter is suggestive of active replication.

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Microbicide Field Wrestles with the Implications of Success

BY RICHARD JEFFREYS AND SCOTT MORGAN

In July of this year, the stubborn persistence and commitment of microbicide researchers, advocates, and trial participants was finally rewarded with positive results from a South African trial of the gel form of the antretroviral drug tenofovir (trade name Viread). The CAPRISA 004 study, led by the wife-and-husband investigator team of Quarraisha and Salim Abdool Karim, was relatively small (a total of 889 participants were included in the final analysis) but showed a statistically significant 39% reduction in risk of HIV infection. Unexpectedly, the microbicide also reduced the risk of acquiring herpes simplex virus type 2 (HSV-2) by 51%. Preliminary findings from studies looking at tenofovir levels in vaginal tissues (conducted by pharmacologist Angela Kashuba) are consistent with the efficacy

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Researchers presented a variety of potential therapeutic approaches. Sandrina Da Fonseca showed that a cellular marker named PD-1 is preferentially expressed on memory CD4 T cells harboring HIV, and inhibiting PD-1 may awaken the silent viral genomes in these cells. PD-1 inhibitors are currently in human trials for the treatment of cancer, and Da Fonseca suggested they deserve evaluation as a potential reservoir-depleting strategy in HIV. Much discussion centered around drugs called HDAC inhibitors, which have been shown to activate latent HIV in vitro. Daria Hazuda from Merck described a study in monkeys in which an HDAC inhibitor and another drug called a protein kinase C activator were added to ART; the approach reduced virus levels in tissues but did not prevent a rebound in viral replication when ART was interrupted. The researcher David Margolis is currently planning a human trial of an HDAC inhibitor named SAHA.

Brigitte Autran outlined the design of two trials (named Eramune 01 and 02) that will evaluate the effect of adding immune-based therapies to ART. Eramune 01 will explore ART intensification plus modulation of the immune system with IL-7, a cytokine that may be able to deplete latent HIV from memory CD4 T cells. Eramune 02 involves the addition of a therapeutic vaccine to intensified ART, with the goal of bolstering the ability of the immune system to specifically recognize and eliminate HIV-infected cells. Details of both trials are available in the clinical trials database at http://www.clinicaltrials.gov.

At the close of the workshop, Françoise Barré-Sinoussi stressed that IAS is committed to making cure-related research an ongoing priority. Full presentations and rapporteur summaries of each session are available on the IAS website at http://www.iasociety.org/Default.aspx?pageId=349. A meeting report will be published in the Journal of the International AIDS Society before the end of 2010.

In addition to the IAS workshop, a number of other recent developments have helped push the search for a cure back to the top of the research agenda:

- The non-profit organization amfAR has instituted a targeted program supporting collaborative cure-related research, named the amfAR Research Consortium for HIV Eradication (ARCHE). Rowena Johnston from amfAR provides the background to this program in an open-access article published in the journal *AIDS Research and Human Retroviruses* at http://www.liebertonline.com/doi/full/10.1089/aid.2010.0087.

- The NIH has issued a request for funding applications for a "collaboratory" project to accelerate and streamline cure research: http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-10-009.html. The idea derives from an opinion piece published by Doug Richman and colleagues in the journal *Science*. The project has been named in honor of one of the authors of the opinion piece, the AIDS activist and founder of Project Inform, Martin Delaney, who died last year.

- In the July 9, 2010, issue of *Science*, an article reviewing issues that need to be addressed in cure research was published by Didier Trono, Carine Van Lint, Christine Rouzioux, Eric Verdin, Françoise Barré-Sinoussi, Tae-Wook Chun, and Nicolas Chomont: http://www.sciencemag.org/cgi/content/short/329/5988/174.

- Ahead of the 2010 International AIDS Conference, a community-based organization called the AIDS Policy Project issued a report on cure research calling for more funding and summarizing current approaches; the report is available online at http://www.aidspolicyproject.org.

- TAG held a workshop in November 2008 along with amfAR and Project Inform at which many of the issues leading to this year's progress were discussed: http://www.treatmentactiongroup.org/publication.aspx?id=2738. Plans are being developed for another such workshop focusing on clinical and regulatory issues related to studies of potential HIV curative approaches to take place early next year.

Writing Toward a Cure

The growing interest in cure-related research has spurred a slew of informative articles in the community, medical and popular press.

Positively Aware, September/October 2010

Includes an interview with researcher Sharon Lewin by Jeff Berry, articles by Bob Huff and Enid Vasquez, and a column by Matt Sharp.
http://positivelyaware.com/2010/10_05/index.shtml

POZ Magazine, October/November 2010

Feature article "From Mice Into Men" by Regan Hofmann with Tim Horn and an interview with Anthony Fauci, MD, director of the National Institute of Allergy and Infectious Diseases.
http://www.poz.com/archive/2010_Oct_2536.shtml

Topics in HIV Medicine, August/September 2010

Open access article: "What Do We Need to Do to Cure HIV Infection?" by Robert F. Siliciano, MD, PhD
http://www.iasusa.org/pub/topics/2010/issue3/104.pdf

Los Angeles Times, August 21, 2010

"HIV-Resistant Cells Work in Mice. Can They Help Humans?" by Rachel Bernstein
http://www.latimes.com/news/science/la-sci-hiv-therapy-20100822,0,2873266.story

Nature, July 15, 2010

Open access article: "The Outlook for a Cure" by Virginia Hughes
http://www.nature.com/nature/journal/v466/n7304_supp/full/nature09240.html

Access to Hepatitis C Treatment: A Global Movement Gains Momentum

BY TRACY SWAN

Being a person living with HIV/AIDS, hepatitis C, and an injection drug user, I look at my body. People want to treat my virus—my immune system—people want to treat my chest—my TB—but no one wants to treat my liver, so we have to find someone who wants to treat our livers. WHO calls this a viral time bomb. No one is acting on this time bomb. It is going to explode. Donors are waiting, the governments are waiting, are they waiting for us to die?

—Loon Gangte, President, Delhi Network of Positive People

AIDS activists have set precedent for demanding—and securing—access to lifesaving antiretroviral therapy (ART) for millions of people around the world. Many people think of hepatitis C virus (HCV) as a common, potentially deadly coinfection of HIV, but hepatitis C itself is a global health threat. Like HIV, HCV is highly prevalent among current and former injection drug users. The mode of transmission is often used as a reason to withhold treatment, which is a violation of human rights and a disastrous public health strategy.

For several years, a few activists have been pushing for global access to treatment for HCV. Although HCV treatment remains unaffordable, momentum for global access to such treatment is building. In June 2010, activists from Southeast Asia met to share their resources, goals, and progress, and develop advocacy strategies. In July 2010, the XVIII International AIDS Conference included its first session on access to HCV treatment, with speakers from Brazil, India, and Ukraine, and Treatment Action Group's Tracy Swan, who outlined the global HCV epidemic, barriers to treatment access, and ideas to surmount them. The session can be accessed online, at http://pag.aids2010.org/session.aspx?s=687#3.

Hepatitis C: Global Overview

The World Health Organization (WHO) estimates that 130 million people have HCV. At least 20% of them—or 34 million people—will develop cirrhosis, putting them at risk for liver cancer and liver failure. Each year, more than 350,000 people die from these hepatitis C complications.

HCV can be treated—and sometimes cured—with six to twelve months of pegylated interferon and ribavirin. Some people are fortunate enough to live in countries where treatment is provided, but many have no access unless they can pay for it themselves. According to *Viral Hepatitis: Global Policy*, a recent publication from the World Hepatitis Alliance, (available online at http://www.worldhepatitisalliance.org/Libraries/Campaign_Materials/Viral_Hepatitis_Global_Policy.sflb.ashx) more than 40% of people with HCV are living in countries that do not fund treatment.

Most people who have HCV cannot do anything about it, because treatment is too expensive. In Eastern Europe, where the annual per capita income is $7,382, a year of treatment costs $26,000. In Thailand, annual per capita income is less than $4,000, yet a year of HCV treatment costs $18,000. This does not include diagnostics, monitoring, other lab work, and administrative costs, which bring the total to $33,000.

About Interferon and Ribavirin

Neither interferon alfa or ribavirin was originally discovered or developed as a treatment for hepatitis C. Interferons are proteins that the human body makes in response to viral and bacterial infections (among other things). There are different types of interferon. The standard of care for HCV is a man-made version of interferon alfa that has been pegylated (meaning that a molecule is attached to keep it active in the body for a longer period of time, which makes it more convenient and more effective than nonpegylated interferon). Interferon alfa has been used to treat certain types of leukemia, melanoma, Kaposi's sarcoma, hepatitis B, and genital warts.

Ribavirin, an antiviral, is used in combination with pegylated interferon; although it lowers replase rates and boosts response rates to HCV treatment, it is not an effective treatment for hepatitis C when used alone. Ribavirin has also been used to treat influenza, rabies, and other viruses.

Generic Pegylated Interferon

Before 2000 in the global South, HIV treatment was $1200 per person, per year. But it can come down to as low as $60 to $80. . . . AIDS history tells us that only when generic ARVs come on board does the price drop. We have to move down this price [for pegylated interferon] . . . and we can do it."

—Loon Gangte, President, Delhi Network of Positive People

Patent Issues

Although branded and generic formulations of ribavirin are available, only two companies, Merck (formerly Schering-Plough) and

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Genentech (formerly Roche) produce pegylated interferon; this market exclusivity keeps prices high. In the United States and Western Europe, Merck's Peg-Intron is patented until 2016 and Genentech's Pegasys is patented until 2017. According to Sean Flynn, associate director of the Program on Information Justice and Intellectual Property at Washington College of Law, neither interferon itself or the pegylation process is patentable when used alone.

Patents can be challenged. Governments can provide access to unaffordable drugs by issuing a compulsory license. This is a mechanism allowing countries to manufacture drugs for serious illnesses, as long as they are intended for local markets or exported to low-income countries that would otherwise lack access.

Regulatory Issues

Patent protection is not the only barrier; there are regulatory and scientific issues to consider. Interferons are biologics (substances made through a biological rather than a chemical process). Both branded and generic biologic products (called biosimilars, biogenerics, or follow-on biologics) have a different regulatory pathway than drugs made through a chemical process.

Generic drugs do not need to undergo formal safety and efficacy studies; they must only demonstrate therapeutic equivalence (meaning that they contain active substances identical to those of the branded drug) and bioequivelence (meaning that absorption, distribution, metabolization, and elimination of a generic is within a similar range to that of the branded drug).

Although generic biologics do not have to go through an entire development program, they do have to demonstrate similarity in quality and in both nonclinical and clinical parameters. This means that they must be studied thoroughly in people to see if they work as well as the branded product.

Development of generic interferon is further hampered by the lack of harmonized regulatory standards, although the European Medicines Agency (EMA) and the WHO have already issued guidance. In 2006, the EMA released its *Guideline on Similar Biologic Medicinal Products*, and six products have already been approved through this pathway (available at http://www.bio.org/healthcare/followonbkg/GuidelineonSimilarBiologicalProductsContainingBiotechderivedproteinsQualityIssues.pdf). In October of 2009, the WHO released its *Guidelines on Evaluation of Similar Biotherapeutic Products* (available at: http://www.who.int/biologicals/areas/biological_therapeutics/biotherapeutics_for_web_22april2010.pdf). The U.S. Food and Drug Administration (FDA) is expected to release its guidance for development of biosimilars at the end of 2010. The Agency will be holding a two-day public hearing on November 2nd and November 3rd to seek input to inform the upcoming guidance.

Manufacturing Issues

Good manufacturing practices and adequate regulatory oversight are critical for generic biologics. Proteins such as interferon are complicated, and their structure may vary from batch to batch. Impurities from the manufacturing process—or in the product itself—can trigger immunogenicity, an immune response that may have an impact on safety and efficacy. Immunogenicity can cause acute or delayed hypersensitivity reactions or injection-site reactions, and it may reduce treatment efficacy.

Despite these obstacles, production of generic pegylated interferon may be underway, although it is difficult to find information about its development and regulatory status. Companies in Pakistan and Egypt are said to be producing generic pegylated interferon, and the Brazilian government is discussing production of generic pegylated interferon with partners in Cuba.

Solutions

Broadening global access to HCV treatment will require the involvement of governments, the pharmaceutical industry, regulatory agencies, and civil society.

- Governments must allocate adequate funding for HCV surveillance, education, prevention, care, and treatment programs. Hepatitis C treatment should be considered essential.

- Governments should consider several strategies to lower the price of pegylated interferon, such as issuing compulsory licenses, supporting patent challenges, and negotiating better prices for HCV diagnostics and treatment. Ministries of health must be encouraged to create or adapt HCV treatment guidelines and to launch educational initiatives to increase the pool of qualified clinicians.

- Pharmaceutical companies can facilitate access to HCV treatment by cutting the cost of pegylated interferon in low- and middle-income countries, registering their HCV drugs in every country, and producing less costly biosimilar products.

- In turn, regulatory agencies should harmonize requirements for development of biosimliar products so that manufacturers have a clear pathway to approval and to ensure adequate oversight of product development.

- Members of civil society must mobilize to raise HCV awareness, and demand access to prevention tools, diagnostics, and HCV care and treatment, keeping pressure on their governments and on pharmaceutical companies. Strategies that have worked with HIV, such as using the legal system to gain treatment access by challenging patents and blocking their expansion, can also be used to expand HCV treatment access.

- HCV education, diagnostics, care, and treatment can be integrated into HIV programs when feasible and relevant to do so. For example, the Global Fund to Fight AIDS, Tuberculosis and Malaria has funded HCV treatment programs in Georgia, Ukraine, and Kyrgyzstan for 1,000 people. Donors need to become aware of the extent and severity of the global hepatitis C epidemic, and members of civil society must make sure that HCV is included in—and kept on—their agendas.

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results; there were statistically significant associations between higher drug levels and protection from both HIV and HSV-2. When these results were announced at the International AIDS Conference in Vienna, the presenters received a standing ovation.

Since the conference presentations, a number of organizations have issued detailed descriptions of the findings and analyses of their implications, with AVAC's "Understanding the Results of CAPRISA 004" being the most comprehensive.

CAPRISA 004 Resources

AVAC, "Understanding the Results of CAPRISA 004" http://www.avac.org/ht/d/sp/a/GetDocumentAction/i/29403

CAPRISA—Centre for the AIDS Programme of Research in South Africa http://www.caprisa.org

Sean R. Hosein, Canadian AIDS Treatment Information Exchange, "PrEP—Hope and Excitement Greet First Successful Microbicide" http://bit.ly/bjtpCs

Global Campaign for Microbicides: CAPRISA 004 Telebriefing and Satellite Meeting Webcast: http://www.global-campaign.org/CAPRISA004.htm

Simon Collins, HIV i-Base, "Results from the Caprisa 004 Tenofovir Microbicide Trial" http://i-base.info/htb/13821

Quarraisha Abdool Karim, Salim S. Abdool Karim, et al., "Effectiveness and Safety of Tenofovir Gel, an Antiretroviral Microbicide, for the Prevention of HIV Infection in Women" http://www.sciencemag.org/cgi/content/full/329/5996/1168

Charting the Route from Here

There is now an urgent need to confirm and extend the findings from CAPRISA 004 in larger trials, involving different populations and dosing strategies. There are currently four follow-on trials to CAPRISA 004 in various stages of design, protocol review, and funding:

- MDP 302 is a confirmatory study to be led by the MRC Microbicides Development Programme that will take place across sub-Saharan Africa. This trial will differ from CAPRISA 004: the dosing regimen will be one of single use before sexual intercourse. The trial is estimated to cost US$40 million and there is approximately $7 million from the UK government believed to be allocated for this trial. It is possible that the funding gap will be reduced after a full spending review by the new UK government in late October or early November 2010. Nonetheless, there will be a considerable shortfall that will need to be addressed before the trial can move forward.

- FACTS001 is another confirmatory trial in South Africa, which is in a draft protocol stage. In addition to a study arm to confirm efficacy of tenofovir-based gel as prevention for HIV, another arm will study the effects on HSV-2 prevention. A subgroup will undergo an intensive safety study in 16- and 17-year-old girls. The South African Ministry of Health and its Ministry of Science and Technology, as well as assistance from USAID, will fund the trial. CONRAD is providing tenofovir gel for the study. While the draft budget has not yet been finalized and is likely to change in the review process, if all donors make good on provisional commitments, funding is likely to come up short by roughly $3–$5 million.

- CAPRISA 008 will study the effectiveness of using family planning clinics as a method for distributing tenofovir gel in communities where the trial took place. The control arm will use the same protocol as CAPRISA 004 and provide tenofovir gel to participants who did not seroconvert during the trial; the intervention arm will use trained nurses to provide counseling and gel distribution in family planning clinics. The study is designed to help determine effective ways of implementing programs to distribute the microbicide once licensure is secured.
- CAPRISA 009 will follow all trial participants who became HIV infected during CAPRISA 004 and will test the effectiveness of tenofovir- and non-tenofovir-based first-line treatment for HIV. The study will monitor the evolution of the disease to see if there are differences among women who took part in the trial and to ensure that these volunteers receive appropriate care and treatment. This data will contribute to design of future trials and to the safe and proper use of microbicides if licensure becomes a reality. It's important to note that all women who became HIV-positive during CAPRISA 004 will receive care and treatment for HIV whether or not they participate in CAPRISA 009. The two additional CAPRISA studies will cost, collectively, an estimated $19 million in total over three years. CAPRISA 008 is in draft protocol and is provisionally funded by the South African Government and USAID. CAPRISA 009 is very early in development, but is estimated at $4.5 million for three years.

In addition to these protocols, another ongoing trial being conducted by the Microbicide Trials Network, named VOICE or MTN-003, is comparing oral daily dosing of tenofovir or Truvada to daily application of the tenofovir gel; at the last update in July, close to 1,000 women out of a planned total of 4,200 had been enrolled.

Tradeoffs in a Complex Path to Licensure

Tenofovir gel is the first microbicide that has possibly demonstrated sufficient efficacy to bend the calculus of the epidemic. One of the principal investigators, Salim Abdool Karim, estimates there is potential to prevent 1.3 million new HIV infections and 800,000 deaths over a 20-year period in the country of South Africa alone. Yet the global economic environment has donors and foundations struggling to commit modest sums, in relative terms, to fund multiple trials. A presentation on September 27, 2010 in Atlanta by UNAIDS estimated a $42 million shortfall to fund these trials.[1] Yet consider that over the past five years, more than $1 billion has

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Deadly Economics Threaten Progress to Global Health Goals

BY COCO JERVIS AND SUE PEREZ

Over the last few years, G8 and other national leaders have lamented that health care systems in poor countries are inadequate to keep pregnant women, mothers, babies, and children healthy and that universal access to HIV/AIDS prevention, treatment, and care services cannot be attained. Yet, at the same time they continue to make promises that they fail to fully fund. Despite public statements by world leaders that they remain committed to the United Nations' Millennium Development Goals (MDGs), they fail time and time again to put the necessary financial resources on the table to realize them.

At the recent MDG Summit held in New York, September 20–22, global health leaders gathered to take stock of progress. With five years left to the target date of 2015, the three goals related to health—MDG 4, to reduce child mortality; MDG 5, to improve maternal health; MDG 6, to combat HIV/AIDS, malaria, and other diseases—remain seriously off track in a number of developing countries. Addressing summit participants, President Barack Obama called on donor nations, "let's honor our respective commitments. Let's resolve to put an end to hollow promises that are not kept." But we have yet to see the president's rhetoric match the U.S. share of what is needed.

Some progress has been made over the last decade, but the United States lacks a clear, consistent strategy for realizing the MDGs. Just this September, the U.S. government released *Celebrate, Innovate & Sustain Toward 2015 and Beyond: The United States' Strategy for Meeting the Millennium Development Goals*. The document broadly describes the U.S. government's approach to the MDGs but disappoints by filling up pages with vague statements about what will, should, and must be done to achieve them—while leaving out any substantive details.

The global economic crisis and its aftermath have made advocacy to regain the global political will, drive, and ambition to realize the MDGs much more difficult. G8 country governments are slashing overall development aid—aid to civil society organizations and contributions to important global health funders. Advocacy has been chilled by threats of austerity, and as a result advocates are fighting much harder for smaller increases in funding. With elections coming up in November and a possible takeover of the U.S. Congress by Republicans, we could soon be fighting just to maintain the status quo and to avoid deep cuts in global health and HIV/AIDS funding. This leaves the question of how flatlined and reduced spending in the short term will affect progress toward the fight against HIV/AIDS in the long term.

The Global Fund to Fight AIDS, Tuberculosis and Malaria, a vital source of health financing for affected countries, needs G8 countries to pony up $20 billion over the next three years if it is to continue helping countries to move closer to reaching MDG targets. Currently, there are over ten million people living with HIV who need life saving ARVs but do not have access; 7,400 more people become infected every day. Treatment as prevention, along with exciting development of new microbicides, may bend the cost and epidemiological curve in the very near future. With the upcoming donor pledging meeting for the Global Fund to take place in early October in New York, activists are staging actions, protests, and letter-writing campaigns, calling for bold pledges to reach the $20 billion mark in hopes that their demands will result in serious cash.

Please show your support by signing the Global Day of Health Action petition to G8 leaders calling for them to commit $20 billion over the next three years to support the Global Fund and to fulfill promises of universal access to essential HIV medicines. You can sign on at http://arasa.info/index.php?option=com_petitions&view=petition&id=75&Itemid=102.

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been spent on microbicide research and, in 2009 alone, $868 million of the $1.65 billion invested in HIV prevention research and development was spent on vaccine research.

In a global economic environment that is straining public-funder purses and influencing the politics of funding, how can more than one trial be justified? The results of CAPRISA 004 must be replicated for licensure, hopefully with higher levels of efficacy while still maintaining safety. Were only one confirmatory study to take place and *not* show efficacy with statistical significance, then the conundrum would be: of the two studies,which was flawed? This would compel another study, which would run out to at least 2017. Thus, to provide sufficient data by 2013 to unequivocally prove efficacy, a minimum of two confirmatory trials is required.

There is currently no certainty on which trials will go forward and which might end up on the scrap heap due to lack of funding. It seems likely that the trials with the smallest funding gap—FACTS 001 and CAPRISA 008—will have the best opportunity to proceed. Stakeholders will soon be meeting with the U.S. Food and Drug Administration in order to discuss requirements for licensure, and this should help in the prioritization process.

The CAPRISA 004 results are an exhilarating breakthrough in biomedical prevention, a field that has been littered with disappointments over the years. Activists and researchers must capitalize on this breakthrough to secure small sums of money, relatively speaking, for the necessary confirmatory research. Cast under the shadow of the cost of lifelong treatment for women at the current level of HIV incidence, the funding requirements continue to diminish in relative terms. Most important, moving these confirmatory trials forward quickly has the potential to save millions of lives if the results support licensure.

1. Hankins, K., "Why an AIDS Vaccine," Presentation by UNAIDS for journalist training seminar in HIV vaccine research, National Press Foundation and Global HIV Vaccine Enterprise, Atlanta, September 27, 2010.

National Institutes of Health Donates Protease Inhibitor Patent to UNITAID Medicines Patent Pool

Innovative approach to intellectual property has the potential to reduce HIV treatment costs by up to $6.3 billion over the next five years.

BY MARK HARRINGTON

On September 30, 2010 the U.S. National Institutes of Health (NIH) became the first research funder to license intellectual property rights to the Medicines Patent Pool essential to manufacturing anti-HIV protease inhibitors. The patent pool is an innovative initiative that—by pooling patents from diverse inventors—will allow the manufacture of low-cost, high-quality generic medications for people with HIV and other life-threatening diseases in low- and middle-income countries.

By becoming the first research funder to license medical patents to the Medicines Patent Pool, the NIH has taken a historic step toward facilitating equitable global access to medical innovations created with taxpayer funds to fight such diseases of global concern as HIV, tuberculosis, and malaria.

The NIH donated a use patent covering the HIV protease inhibitor darunavir (Prezista), which is marketed by Johnson & Johnson/Tibotec.

The Medicines Patent Pool is seeking voluntary licenses from the patent holders who market additional anti-HIV drugs, including lopinavir and ritonavir from Abbott; nevirapine from Boehringer-Ingelheim; atazanavir from Bristol-Myers Squibb; tenofovir and FTC from Gilead; efavirenz and raltegravir from Merck; etravirine and darunavir from Tibotec; and 3TC, abacavir, fosamprenavir, and maraviroc from GSK's joint venture with Pfizer, ViiV.

For the past decade, activists, scientists, and political leaders have worked together to bring down the costs of anti-HIV drugs by over 99%, allowing more than 5.2 million people around the world to be able to receive lifesaving HIV therapy. The current global economic recession and the associated threats of widespread scale-back of country and donor support for health programs in low- and middle income countries makes it imperative that further innovations are pursued to reduce the costs of treatment. The UNITAID-sponsored Medicines Patent Pool is one such mechanism which can help to ensure HIV medicines become more widely available at lower cost without compromising quality. The Patent Pool works by pooling intellectual property (patents) from diverse patent holders including government agencies such as NIH and private pharmaceutical and biotechnology companies.

The patent pool is an initiative of UNITAID, the global funding mechanism established by a group of countries that agreed to levy a small transaction tax on air travel to provide support for expensive second-line HIV and tuberculosis drugs, and for pediatric formulations. The pool, by reducing the costs of HIV treatments and making it easier to manufacture high-quality generic medications, will help to reduce the yawning funding gap for global HIV treatment. UNAIDS has estimated that US$ 28 billion to US$ 50 billion would be needed globally every year from 2010 to 2015 in order to progressively reach universal access targets for HIV/AIDS by 2015.[1] Though 5.2 million people with HIV are receiving HIV treatment around the world, 10 million more need treatment and are not receiving it. According to UNAIDS, the funding gap will rise to $20 billion per year by 2015.

The patent pool by itself cannot fill the treatment funding gap. However, it can drive continuous reductions in HIV drug combination costs by diversifying manufacturers; expanding the generic market; facilitating improved formulations such as pediatric dosing regimens and fixed-dose combinations to improve treatment adherence; reducing transaction costs; and increasing legal and market certainty to allow generic companies to plan for the long term and invest in high-quality, lower-cost HIV treatments.

UNITAID estimates that the patent pool has the potential to reduce HIV drug costs by between $52 million and $1.3 billion per year or a savings of $260 million to $6.3 billion over a five-year period.

TAG urges BI, BMS, Gilead, Merck, Tibotec, and ViiV to provide licenses for their anti-HIV medications to the Patent Pool in order to broaden access to lifesaving treatments around the world. TAG also recommends that the patent pool be broadened to include expensive second-line tuberculosis drugs and pediatric formulations.

1. WHO, UNAIDS, UNICEF. Towards universal access: scaling up priority HIV/AIDS interventions in the health sector: progress report 2009. Geneva: WHO; 2009.

AIDS Drug Assistance Program in Crisis

Over 3,500 people with HIV are on waiting lists for lifesaving antiretroviral drugs. Many more lack access because of other funding cuts and program restrictions. Congress and President Barack Obama must act now to make sure all persons with HIV have the treatment and care they need until health care reform begins in 2014.

Your voice is needed. Please join Save America's ADAPs and be part of a national grassroots movement to demand full access to HIV medication for all who need it. You will learn all the tools needed to communicate with your elected officials before and after the November elections about the ADAP crisis.

To join, send an email to mfriedman@projectinform.org with "ADAP" in the subject field. Include your name, city, and state in the body of the email. You can also join on Facebook by typing "Save America's ADAPs" in the search field.

TAG NEW WAYS TO CONTRIBUTE

Supporting TAG is a wise investment in AIDS treatment advocacy. With a small but well-organized and highly respected staff of professionals, every donation to TAG brings us one step closer toward better treatments, a vaccine, and a cure for AIDS. There are several ways you can support TAG today!

Make a tax deductible gift now by credit card using our secure website (www.treatmentactiongroup.org) or by calling Joe McConnell at 212.253.7922 to request a donation envelope.

Celebrate!
Expand your support for TAG by asking your friends and family to make a donation in your honor to celebrate your birthday, anniversary, or the holidays. An acknowledgment will be sent to donors, and you will be informed of gifts made in your honor. Please call Joe McConnell at 212.253.7922 to request that materials be sent to friends and family.

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