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Contact: Mitchell Warren, +1-914-661-1536, mitchell@avac.org

New AVAC Report on Pre-Exposure Prophylaxis Calls for Immediate Planning to Anticipate Study Results of Potential New HIV Prevention Option

Now is the time to anticipate and plan for various study outcomes

Mexico City, Mexico, August 3, 2008 – The AIDS Vaccine Advocacy Coalition (AVAC) today released a new report, *Anticipating the Results of PrEP Trials*, calling for increased action from governments, global health institutions, donors, researchers, and advocates to prepare for initial results – expected as early as 2009 – from the first trials of antiretroviral drugs being tested for HIV prevention, known as PrEP or pre-exposure prophylaxis. The report also provides the most up-to-date information about ongoing and planned PrEP research, and lays out an agenda for action on key issues that must be addressed as research on this promising HIV prevention intervention moves forward.

The new report is available online at www.avac.org/prep08.pdf.

PrEP clinical trials are currently planned or underway in countries in Africa, Asia, Latin America and North America. These studies are looking at the safety and efficacy of PrEP, an unproven strategy in which HIV negative people could take an antiretroviral drug (ARV), or combination of ARVs, on a regular basis in the hopes of reducing their risk of acquiring HIV.

The AVAC report was released today at a special session of researchers, advocates and other stakeholders, held at the XVII International Conference on AIDS in Mexico City to discuss the challenges of translating PrEP and other HIV prevention research into effective policy and practice.

“PrEP trials are taking place within a changing landscape of HIV prevention research,” said AVAC Executive Director Mitchell Warren. “Disappointing results have emerged from recent studies of vaccine and microbicide candidates, while male circumcision was found to be partially effective at preventing HIV transmission in some populations and is being rolled out in some African countries.

“Although still unproven human clinical research, PrEP is considered one of the promising clinical interventions against HIV currently in development,” Warren continued. “By mid-2009, more people will be enrolling in PrEP studies than in both HIV vaccine and microbicide efficacy trials combined. Advocates and communities affected by HIV need to understand PrEP and its implications for the AIDS advocacy and global health agendas, and government and private funders committed to global health must step forward now to ensure that PrEP research is fully funded.”

“We cannot wait for the study results to begin to prepare for the optimal use and delivery of PrEP,” said Pedro Goicochea, an investigator of the iPrEx PrEP study currently underway in Peru and Ecuador “Instead, we should look ahead to consider all of the possible outcomes of these trials and make real plans for making PrEP available to those who can benefit from it, as quickly and safely as possible if it is proven effective.”

Anticipating the Results of PrEP Trials provides an up-to-date status report on current PrEP research; addresses concerns about PrEP, including the possibilities of drug resistance, partial efficacy, and the

potential for increased risk behavior and social stigma; looks at the potential impact of PrEP on future HIV prevention research; and considers what questions should we be preparing to ask now based on possible different research outcomes as PrEP studies begin reporting data in the next few years.

“This report provides an important overview of PrEP research and lays out the many difficult issues that are critical for advocates, communities and public health experts to understand as trials continue and report results,” said Warren. “We cannot shy away from discussing issues such as potential drug resistance, the difficulty of adhering to a once-a-day pill regimen for people who are not sick, or the cost of providing PrEP. This report and today’s meeting lay the groundwork for these important discussions.”

AVAC’s report identifies five priority issues that need attention now, including:

1. *Ensure that current clinical trials have the best chance of providing results:* Clinical trials now underway in Thailand, Africa, Latin American and the U.S. could establish the safety and effectiveness of PrEP, but only if these trials produce clear answers. Trial sponsors, regulatory agencies and the global health community must work together to ensure that these studies are supported to produce the data needed to determine next steps on the possible use of PrEP.
2. *Identify and invest in additional research:* A plan for launching additional studies – including studies on the safety and efficacy on intermittent PrEP dosing, bridging studies in additional populations, and safety and efficacy of other candidates – is needed now and will require additional funding.
3. *Plan now for optimal use of PrEP:* A plan of action for using PrEP to maximum public health impact should be developed now. This plan should address the issues set out in a *Lancet* paper of July 2007, which called for assessing appropriate settings and populations for PrEP use, determining what level of efficacy would warrant widespread delivery and determining where targeted vs. more generalized delivery would be more appropriate.
4. *Prepare for global procurement and delivery of PrEP:* Plans for PrEP delivery must include a well-planned and resourced campaign to deliver PrEP, an understanding of which global funders will pay for PrEP, plans for rollout, and guidance and support similar to that implemented for male circumcision.
5. *Provide adequate financing:* Underinvestment in PrEP is hampering progress and must be corrected. Government and private funders committed to global health must step forward now to ensure that PrEP research is fully funded.

AVAC’s *Anticipating and Understanding Results* series provides timely analysis of trials of new HIV prevention options. For other publications in the series, visit www.avac.org.

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About AVAC: Founded in 1995, the AIDS Vaccine Advocacy Coalition (AVAC) is an international non-profit, community- and consumer-based organization that uses public education, policy analysis, advocacy and community mobilization to accelerate the ethical development and global delivery of AIDS vaccines and other HIV prevention options. For more information, visit www.avac.org.