IAS 2011
17-20 JULY ROME, ITALY

OFFICIAL PRESS RELEASE – DAY 4

EMBARGOED UNTIL 16.30 (CET), WEDNESDAY JULY 20

Late Breaker extracts - newsmakers

First global study of real-world circumcision rollout conducted over three-year period in South Africa amongst 110,000 adults shows a marked reduction (>60%) of HIV acquisition among circumcised adult men .

Elvitegravir once-daily is non inferior to raltegravir twice-daily in treatment experienced patients

iPrEx study: new, long-term data from the first large-scale clinical trial to demonstrate the efficacy of oral pre-exposure prophylaxis shows the durability of PrEP for HIV prevention

Wednesday, 20 July, 2011 (Rome, Italy) -- Researchers presenting late breaking research on the final day of the 6th IAS Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2011) have today focussed on new studies in the field of circumcision, pre-exposure prophylaxis (PrEP) and antiretroviral treatment. The IAS 2011 conference has been attended by over 5000 researchers, clinicians and community leaders since Sunday in Rome.

- ***The roll-out of male circumcision in the South African township of Orange Farm (ANRS 12126) is curbing the spread of HIV*** *(16.30-17.30, SR2)*

B. Auvert[1], D. Taljaard[2], D. Rech[2], P. Lissouba[3], B. Singh[4], D. Shabangu[2], C. Nhlapo[5], J. Otchere-Darko[2],T. Mashigo[2], G. Phatedi[2], R. Taljaard[2], M. Tsepe[2], M. Chakela[2], A. Mkhwanazi[2], P. Ntshangase[2], S. Billy[5],D. Lewis[4]

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Three years after the start of the male circumcision roll-out (ANRS 12126) in the South African township of Orange Farm (110 000 adults), a reduction in HIV prevalence and incidence among men has been observed. These findings demonstrate for the first time that male circumcision roll-out is effective at community level in curbing the spread of HIV. This research is coordinated by Inserm U1018/UVSQ and conducted by Progressus (South Africa), the National Institute of Communicable diseases of the NHLS (South Africa) and is financed by the French National Agency for Research on AIDS and Viral Hepatitis ANRS.

"The real-world effect of the roll-out of medical male circumcision (MMC) on the HIV epidemic has been until today, unknown," said Professor Bertran Auvert, Professor of Public Health at the University of Versailles and principal investigator of the study.

“This study demonstrates that adult male circumcision works to reduce the spread of HIV in an African community highly affected by the epidemic. Reducing the number of new infections with adult male circumcision will save lives and reduce the need for antiretroviral therapy. This study shows also that the roll out of adult safe male circumcision should become a top health priority in Southern and Eastern Africa and that a strong political commitment is needed now,” concluded Auvert.

- ***Completed observation of the randomized placebo-controlled phase of iPrEx: daily oral FTC/TDF pre-exposure HIV prophylaxis among men and trans women who have sex with men*** *(16.30-17.30, SR2)*

R. Grant[1,2], V. McMahan[1], A. Liu[3], J. Guanira[4], M. Casapia[5], J. Lama[4], T. Fernandez[6], V. Veloso[7], S. Buchbinder[3], S. Chariyalertsak[8], M. Schechter[9], L.-G. Bekker[10], K. Mayer[11], E. Kallas[12], P. Anderson[13], K.R. Amico[14], D. Glidden[2], for the iPrEx Study Team

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New research will be presented from investigators of the iPrEx study, the first large-scale clinical trial to demonstrate the efficacy of oral pre-exposure prophylaxis (PrEP) as HIV prevention. Data presented here demonstrate that the HIV prevention impact of PrEP was durable throughout the iPrEx study and across participant subgroups, with no evidence of HIV drug resistance among individuals infected with HIV after starting PrEP and a very low rate of side effects.

"PrEP is an important HIV prevention tool with the potential to prevent significant numbers of new HIV infections," said iPrEx Protocol Chair Robert Grant, investigator at the Gladstone Institute of Virology and Immunology in San Francisco and Associate Professor of Medicine at the University of California.

"These data confirm that PrEP is safe and effective in MSM, one of the populations most affected by HIV worldwide. A four-continent open-label extension of the iPrEx study is underway. Global and national public health experts and advocates should work expeditiously to determine how to best make this lifesaving HIV prevention tool available for MSM, who bear the brunt of the epidemic in many parts of the world, “concluded Grant

- ***Results of the Gilead 145 trial: Elvitegravir once-daily is non inferior to raltegravir twice-daily in treatment experienced patients: 48 week results from a phase 3 multicenter, randomized, double blind study*** *(16.30-17.30, SR1)*

J.-M. Molina[1], A. LaMarca[2], J. Andrade Villanueva[3], B. Clotet[4], N. Clumeck[5], Y.-P. Liu[6], L. Zhong[6], A. Cheng[6], J. Szwarcberg[6], S.L. Chuck[6], for the Study 145 Group

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This is the first head to head comparison of elvitegravir an investigational once-daily HIV integrase inhibitor to raltegravir, the only approved integrase inhibitor today.

In this international phase III study involving 234 sites in United States, Europe, Canada, Mexico, Australia and Puerto Rico, 702 HIV-infected patients failing their current antiretroviral regimen with drug-resistant viruses, were randomized to receive in a double-blind fashion either once-daily elvitegravir or twice daily raltegravir in combination with a boosted protease inhibitor and a third agent. The primary efficacy endpoint at week 48 demonstrated similar efficacy of the two regimens with a virologic response rate (plasma HIV viral load below 50 copies/ml) of 59 and 58% in the elvitegravir and raltegravir arms, respectively using an intent to treat analysis, with a treatment difference of 1.1% (95% CI : -6.2;8.2).

The safety of the two regimens was also similar with only 2-3% of patients in both arms discontinuing treatment because of adverse events. Finally, the emergence of integrase resistance among patients with virologic failure was only 27% and 21% in the elvitegravir and raltegravir arms, respectively.

Overall, these results demonstrate the efficacy and safety of elvitegravir in combination with a ritonavir-boosted protease inhibitor for treatment-experienced patients, and position elvitegravir as an alternative once-daily integrase inhibitor.

“For many people, HIV treatment might just have got simpler," said Jean-Michel Molina, the study’s principal investigator and Head of the Department of Infectious Diseases at the Hopital Saint Louis in Paris. “This study is good news for people living with HIV - pending FDA approval they will now have available a new antiretroviral drug that only needs to be taken once a day which in itself will also promote better adherence,” concluded Molina.

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Online Coverage of IAS 2011 at www.ias2011.org

The online Programme-at-a-Glance, available through the website, includes links to abstracts, as well as session slides with audio and speeches (all abstract findings are embargoed until date and time of delivery at the conference). Additional online programming is provided by IAS 2011’s two official online partners: Clinical Care Options and NAM. Reporters and others can also follow key developments on the IAS 2011 blog at http://blog.ias2011.org or on Twitter at www.twitter.com/ias2011.

About the IAS 2011 Organizers

IAS: The International AIDS Society (IAS) is the world's leading independent association of HIV professionals, with over 16,000 members from more than 196 countries working at all levels of the global response to AIDS. Our members include researchers from all disciplines, clinicians, public health and community practitioners on the frontlines of the epidemic, as well as policy and programme planners. The IAS is the custodian of the biennial International AIDS Conference and lead organizer of the IAS Conference on HIV Pathogenesis, Treatment and Prevention, which will be held in Rome, Italy in July 2011.

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ISS: The Instituto Superiore di Sanità (ISS) is the leading technical and scientific body of the Italian National Health Service. Its activities include research, clinical trials, and control and training in public health. It also serves as a major national clearing-house for technical and scientific information on public health issues. Among other things, the Institute conducts scientific research in a wide variety of fields, from cutting-edge molecular and genetic research, to population-based studies of risk factors for disease and disability, to Global Health research.

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