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HIV, AN EPIDEMIC…

– Definition and Statistics

- Acquired Immunodeficiency Syndrome (AIDS) is an infectious disease caused by a retrovirus, the Human Immunodeficiency Virus (HIV). The disease is characterized by a progressive decline of the functioning of the immune system.
- Although antiviral therapy has had a great impact on managing the disease, the global HIV/AIDS epidemic continues in the absence of an effective vaccine
  - 40 million people are living with HIV/AIDS
  - 3 million deaths are attributed to AIDS
- There are 2 main subfamilies of HIV: HIV-1 and HIV-2. HIV-1 is found globally while HIV-2 is found predominantly in Africa.

– Background on ALVAC™-HIV vaccine

- In 1995, sanofi pasteur focused efforts in its ALVAC-vectored candidate, based on ALVAC's demonstrated utility as a veterinary vaccine, its safety and immunogenicity profile in humans and its efficacy in non-human primate retrovirus challenge studies.
- A canarypox-based vectored vaccine--a large virus (250 x 350 nm) with a linear DNA genome, completely sequenced (326,700 bp)--was isolated from a pox lesion from an infected canary at Rentschler Bakterologishes Institute, Germany - 200 serial passages in CEFs attenuated strain and commercialized as a live-attenuated vaccine for canaries (KANAPOX) by Merial
- The vaccine hypothesis under investigation called for a candidate capable of inducing both humoral and cellular responses to HIV. Founded on this hypothesis, sanofi pasteur focused on developing a "prime-boost" schedule based on the dual ability of pox viruses to induce cellular responses and prime for antibody responses that could be boosted with recombinant envelope proteins, thus providing the best platform to achieve a broad constellation of immunological responses against HIV.
- To that end, prime-boost B-and E-clade program were started in the United States and Thailand, respectively, and culminated in a large field efficacy trail in Thailand, called RV-144.

– Background on the RV-144 Trial

- The Thai Phase III trial is the largest HIV vaccine trial ever conducted, and tested a "prime-boost" vaccine strategy comprised of two investigational vaccines.
- The study, which began in 2003, was an international collaborative effort that involved more than 16,000 Thai volunteers and hundreds of scientists and clinicians from Thailand, Europe and the United States.
- The Thai Phase III HIV Vaccine Trial has contributed essential knowledge about HIV vaccines and represents an important scientific milestone for global HIV/AIDS research.
- The collaborators also gained great insights into how to build the infrastructure necessary to conduct such a major clinical study and how to effectively engage the community.
- This trial was a tremendous operational achievement, involving more than 16,000 volunteers, with nearly 300,000 patient visits and 700,000 processed samples.
- The trial's success is a testament to the international collaboration involving many partners from the Thai and U.S. governments, private companies, non-profit organizations, and more than 16,000 volunteers.
- Thai Phase III Trial collaborators are already working with international scientific experts to expedite the design and implementation of appropriate future studies so the benefits of this research will be available as quickly as possible.

– The Trial Collaborators

- The HIV vaccine trial was executed by the Thai Ministry of Public Health and included a team of leading Thai and U.S. researchers.
- The official sponsor of this trial was the U.S. Army Surgeon General via the U.S. Army Medical Materiel Development Activity.
- The U.S. Government, specifically the Division of AIDS, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) and the U.S. Army Medical Research and Materiel Command, Department of Defense funded this clinical trial.
- The Thai Ministry of Public Health and Sanofi Pasteur, as well as each of the collaborators, provided extensive in-kind support.
- ALVAC™HIV, the prime vaccine, is manufactured by Sanofi Pasteur.
- AIDSVAX® B/E, the booster vaccine used in the trial, was developed by VaxGen.[1]

[1]VaxGen underwent a corporate restructuring since the start of the trial, resulting in the closure of most operations and divestiture of intellectual property holdings. In March 2008, VaxGen formalized an agreement with Global Solutions for Infectious Diseases (GSID), a not-for-profit organization. Through this agreement, GSID has been granted rights to the intellectual property associated with the AIDSVAX B/E vaccine candidate and and has assumed responsibility for the continued development and, if necessary, manufacturing of this product.


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