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Promising Results of Novel Combination Vaccine
Preclinical Study Provides Strong Rationale for HIV Vaccine Clinical Trials

Leiden, Netherlands, 5 January 2012—Results from a recent study present new insights into the immune responses underlying protection against HIV infection and provide a path forward for HIV vaccine development. Published in this week’s online version of the journal *Nature*, the study shows that novel vaccine combinations can provide partial protection against infection by Simian Immunodeficiency Virus (SIV), a virus similar to HIV, in rhesus monkeys. In addition, the study showed in the animals that became infected, the optimal vaccine combinations also substantially reduced the amount of virus in the blood. The study was a collaboration between Crucell Holland B.V., the Beth Israel Deaconess Medical Center and Ragon Institute of MGH, MIT and Harvard, and the U.S. Military HIV Research Program at the Walter Reed Army Institute of Research.

Preclinical studies of HIV-1 vaccine candidates have typically shown post-infection virologic control, but protection against becoming infected has previously only been reported using less rigorous viral challenges. This proof-of-concept study, which tested MVA, Ad26, and Ad35 vector-based vaccines, is the first to show partial vaccine protection in the stringent animal model involving heterologous, neutralization-resistant SIVmac251 viral challenges in rhesus monkeys. The new Ad26/MVA and Ad35/Ad26 vector-based vaccine regimens resulted in more than 80% reduction in the per-exposure probability of acquisition of infection against repetitive challenges of SIV.

“This study allowed us to evaluate the protective efficacy of several prime-boost vaccine combinations, and these data will help guide the advancement of the most promising candidates into clinical trials,” said Jaap Goudsmit, M.D., Ph.D., Chief Scientific Officer, Crucell Holland B.V.

Further analysis also provided insights into the immune responses that may correlate with protection, called “immune correlates.” The results show that antibodies to Env (the envelope protein that makes up the outer coat of the virus) correlated with preventing infection, whereas both T cell and antibody responses correlated with control of post-infection viral replication. These distinct correlates likely reflect fundamentally different mechanisms needed to block establishment of infection compared with controlling viral replication after infection. Goudsmit also noted that “we have clearly shown that including Env in the vaccine is beneficial.”

These new preclinical findings provide support for advancing the Ad26/MVA prime-boost vaccine candidate into clinical development.

The research was supported by the National Institute of Allergy and Infectious Diseases (NIAID); the Ragon Institute of MGH, MIT, and Harvard; and MHRP.

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