Crucell

Developing Ebola & Marburg vaccines

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To date, numerous attempts to protect against Ebola infection using a variety of strategies have failed. However, in 2003 a National Institutes of Health (NIH) study published in Nature demonstrated that a single dose of a recombinant vaccine provided solid protection against an otherwise deadly infection in animal models. Based on these results, we decided to develop an Ebola vaccine using the same approach. Furthermore, the Ebola virus is on the US government's Category "A" list of bioterror agents. In 2003 the US government announced that, once available, an Ebola vaccine may be stockpiled as part of its preparation for bio-terror attacks under Project Bioshield. The Bioshield Act was enacted in July 2004, with a total appropriation of US$ 5.6 billion across all programs.

Development status

In 2002, we entered into a Collaborative Research and Development Agreement (CRADA) with the VRC of the NIH to develop jointly, test and manufacture an adenovirus-based Ebola vaccine. Under the terms of the agreement, we have an option for exclusive worldwide commercialization rights to the Ebola vaccine resulting from this collaboration. In August 2002, the CRADA was extended to cover vaccines against Marburg and Lassa infections.

In experiments conducted in 2004 by the VRC together with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), our vaccine candidate confirmed single-dose protection of monkeys against Ebola. Our results are distinct from the earlier trials in that our vaccine is based on PER.C6® cells, making it suitable for large-scale manufacturing.

In 2005, we extended the CRADA with the VRC of the NIH to develop and produce vaccines against Ebola, Marburg and Lassa infections. Crucell was also granted an exclusive license to patents owned by the NIH to develop and commercialize vaccines against Ebola. Furthermore, Crucell signed a contract of up to €21.4 million with the NIH to produce Ebola vaccines.

Crucell's Ebola vaccine entered Phase I studies in Q3 2006. For this randomized, double-blind, placebo-controlled study, two groups of 16 healthy volunteers were enrolled and vaccinated. The study showed safety and immunogegicity at the doses evaluated.

Based on these results, a second Phase I study is anticipated. This will use alternative multivalent adenovirus vectors that are able to bypass pre-existing immunity against the more commonly used adenovirus serotype 5 (Ad5).

In October 2008, Crucell announced that it had secured a NIAID/NIH award to advance the development of Ebola and Marburg vaccines, with the ultimate aim of developing a multivalent filovirus vaccine. The award provides funding of up to $30 million, with additional options worth a further $40 million. Under this award, the use of alternative multivalent adenovirus vectors that are able to bypass pre-existing immunity against Ad5 will be evaluated.

For more information please visit our website: www.crucell.com.