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Preclinical development of HeV-sG as a vaccine and m102.4 as a post exposure prophylaxis against *Henipavirus* infections

*Henipavirus*es, Nipah virus (NiV) and Hendra virus (HeV) are enveloped negative-sense RNA viruses causing fatal diseases in a variety of animal hosts and in humans. They are listed as category C biothreat agents by the NIH and CDC and overlap select agents by HHS and USDA. There is no approved human vaccine or therapeutic against either virus. NiV morbidity and mortality matches those of Ebola virus with incubation period 1-3 weeks, 40 to 90% mortality in 2-7 weeks, with evidence of human to human transmission. No human to human transmission were recorded with HeV, however, survivors developed relapsed encephalitis up to 2 years after the disease. In collaboration with Chris Broder of USUHS and Tom Geisbert, UTMB, we are developing HeV-sG, the ectodomain of HeV attachment glycoprotein, as a human vaccine and m102.4, an antiviral antibody, for post-exposure prophylaxis. A HeV-sG based vaccine protected cats, ferrets, African green monkeys and horses from lethal challenges with either HeV or NiV. The m102.4 has shown complete post-exposure protection against either HeV or NiV challenge in ferrets and AGMs. Master Cell Banks (MCB) and toxicology lots for each of HeV-sG and m102.4 were prepared. A GLP tox study in rats confirmed that m102.4 is safe for Phase 1 clinical studies. A GLP tox study in rabbits for HeV-sG will be executed in 2015. Animal efficacy studies with m102.4 showed 100% protection of AGMs against NiV and over 75% protection against HeV. Animal efficacy studies for HeV-sG/Alum formulation are ongoing. Preliminary data showed protection of AGMs after 2 doses with 100 ug HeV-sG/Alum.

Biography

Timothy R Fouts is one of the Founders and Principle Scientists at Profectus Biosciences. He directs a team of scientists in the discovery and preclinical development of vaccines, small molecule and antibody based antiviral therapies and microbicides that are within the Profectus research portfolio, in particular HIV and certain biothreat viruses. He has more than 35 scientific publications that have appeared in peer-reviewed journals and book chapters. He has received his PhD in Immunology from the University of Maryland, Baltimore and did a Postdoctoral Fellowship at the Aaron Diamond AIDS Research Center at Rockefeller University in NYC.

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