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Development of a therapeutic vaccine to prevent cytomegalovirus infection in transplant recipients

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ASP0113 is a DNA vaccine designed to prevent cytomegalovirus (CMV) infection in both hematopoietic and solid organ transplant recipients at risk for CMV disease. The vaccine consists of two plasmids which encode the tegument protein pp65 and the surface protein gB of CMV. pp65 induces cell-mediated responses and gB induces humoral responses in persons infected with CMV. A Phase 1, dose-ranging trial evaluated safety and immunogenicity of the vaccine in CMV-seronegative and CMV-seropositive healthy volunteers. No significant safety events occurred and a cultured ELISPOT assay detected T cell responses in 56-62.5 % of seronegative subjects. A Phase 2 exploratory, double-blind, placebo-controlled trial evaluated the efficacy, immunogenicity, and safety of the vaccine in cytomegalovirus-seropositive hematopoietic cell recipients. 108 transplant recipients received the vaccine. The efficacy population comprises 74 subjects: 34 in the placebo arm and 40 in the ASP0113 treatment arm. The safety population comprises the 108 subjects treated. 19 (48%) of the ASP0113 recipients received cytomegalovirus-specific CMV anti-viral therapy compared with 21 (62%) of placebo recipients (p=0.145). 13(33%) of the ASP0113 recipients reached > 500 copies/mL of CMV by central assay compared with 21 (62%) of placebo recipients (p=0.008). In addition, there was a reduction in the number of CMV infection episodes (p=0.017) and the time to initial viremia (p=0.003). One subject discontinued the vaccine after a hypersensitivity reaction but responded well to conservative medical therapy. Based on these positive findings, further evaluation of the efficacy and safety of the vaccine is planned.

Biography

Michele Gerber , MD, MPH is a Medical Director at Astellas Pharma. She graduated from the University of Michigan Medical School in 1986 and the University of Michigan School of Public Health in 2005. She is a board -certified rheumatologist with experience in vaccine development in academia and the pharmaceutical industry. She is currently working on the development of a therapeutic DNA vaccine for the prevention of cytomegalovirus viremia and/or disease in patients with impaired cell-mediated immunity due to transplantation.

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