

A Phase I, Open-Label, Uncontrolled, Single-Center, Extension Study of the Safety, Tolerability, and Immunogenicity of the Chiron Recombinant Meningococcal B G 287 Vaccine in Healthy Adults who Previously Completed Study MBI001

IRB# 2004-018

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Synopsis:

The pre- and post-vaccination serum samples from this closed vaccine trial are currently being studied in functional opsonophagocytosis and serum bactericidal assays against *Neisseria meningitidis* serogroup B strains. The results from the three vaccine groups that received Outer Membrane Vesicle vaccine (OMV), indicate that in some individuals post-vaccination where no bactericidal killing was demonstrated there is opsonic killing activity against homologous and heterologous NmB strains. There is a significant difference in opsonic activity between the group that received the OMV vaccine alone and OMV combined with GNA2132 antigen against heterologous Nm strain, with an increased number with positive opsonic activity in the latter group ($p < 0.01$ Fisher exact test). Before immunization, 13 to 22 percent of subjects had SBA titers $\geq 1:4$, depending on the strain, but a positive OPA titer ($\geq 1:5$) was present in only 9 percent against one strain. After immunization, the prevalence of SBA and OP increased against all three strains, and up to 75% of SBA-negative subjects had OP titers $\geq 1:5$. These results are currently being written up for publication (Plested et al., in preparation).