

## TOXIN MEDICAL COUNTERMEASURES - DEVELOPMENT OF NOVEL, BROAD-SPECTRUM COUNTERMEASURES FOR TOXIN EXPOSURE

### Evaluation Of Staphylococcal Enterotoxin B Subunit Vaccine; Assessment Of Vaccine Efficacy And Residual Toxicity

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Staphylococcal enterotoxin B (SEB), classified as a superantigen, cause food poisoning and toxic shock syndrome. Although the toxin poses a high potential risk for being misused as a biological weapon, there is currently no approved vaccine against SEB. It is urgently needed to develop preventive vaccines as effective countermeasure against bioterrorism using SEB. In previous study, we developed novel SEB subunit vaccine candidates which removed toxicity by mutagenesis of critical residues in TCR and MHC II receptor binding sites. Here, SEB vaccine candidate, ABN701, was finally selected and evaluated for vaccine efficacy and residual toxicity. ABN701 elicited specific immune response in mice, and vaccination group survived 100% upon the challenge with SEB. When ABN701 was administered to rabbits, it induced high titers of anti-SEB IgG and their serum showed neutralizing activity in passive protection assay. Also, vaccinated monkeys with ABN701 showed high levels of protective antibody. No emetic response was observed after intravenous challenge of SEB. To confirm residual toxicity of ABN701, house musk shrews were exposed to wtSEB or ABN701. No vomiting response was observed in the ABN701 group injected at five-fold higher doses than wtSEB injected group. Furthermore, when treated to human peripheral blood mononuclear cells (PBMCs), there was minimal change of cytokine levels induced by ABN701 while SEB induced superantigen activity. These results demonstrate that ABN701 is a non-toxic substance and has both efficacy and safety as SEB vaccine. We believe ABN701 will become a promising countermeasure to defend against SEB.