

A Novel Anthrax Vaccine Candidate

Technology Summary

Currently, the only licensed vaccine against anthrax in the United States is AVA BioThrax®. Although efficacious, AVA BioThrax® suffers from several limitations. AVA BioThrax® requires six injectable doses over 18 months to stimulate protective immunity, requires a cold chain for storage, and in many cases has been associated with adverse effects.

FDA inventors developed a vaccine candidate against Anthrax comprising a modified plasmid encoding the *B. anthracis* protective antigen (PA) gene with optimal expression and stability, linked to an inducible promoter for maximal expression in the host, and fused to the secretion signal of the *Escherichia coli* alpha-hemolysin protein (HlyA) on a low-copy-number plasmid. This plasmid was introduced into the licensed typhoid vaccine strain, *Salmonella enterica* serovar Typhi strain Ty21a, and was found to be genetically stable. Immunization of mice with three vaccine doses elicited a strong PA-specific serum immunoglobulin G response with a geometric mean titer of 30,000 (range, 5,800 to 157,000) and lethal-toxin-neutralizing titers greater than 16,000. Vaccinated mice demonstrated 100% protection against a lethal intranasal challenge with aerosolized spores of *B. anthracis* 7702. The ultimate goal is a temperature-stable, safe, oral human vaccine candidate against anthrax infection that can be self-administered in a few doses over a short period of time

Potential Commercial Applications

- Anthrax vaccines, therapeutics and diagnostics.

Competitive Advantages

- Vector is well-characterized.
- Simple manufacturing process.
- Potential low-cost vaccine.
- Oral vaccine - avoids needles and can be administered rapidly during emergencies.
- Temperature-stable manufacturing allows for vaccine distribution without refrigeration.

Development Stage: *in vitro*

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Publications: Kopecko, D.J. et al., Anthrax protective antigen delivered by *Salmonella enterica* serovar Typhi Ty21a protects mice from a lethal anthrax spore challenge. *Infect Immun.* 2009 Apr;77(4):1475-82, PMID: [19179420](#)

Intellectual Property: United States Patent No. [7,758,855](#) issued 2010-07-20, United States Patent No. [8,247,225](#) issued 2012-08-21, United States Patent No. [8,709,813](#) issued 2014-04-29, International patents also issued

Product Area: Vaccine candidate, biodefense, biodefense countermeasure

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