

Vaccine Protection Against *Shigella sonnei* Disease

Technology Summary

Shigellosis is a global human health problem. Transmission usually occurs by contaminated food and water, or through person-to-person contact. The bacterium is highly infectious by the oral route, and ingestion of as few as 10 organisms can cause an infection in volunteers. An estimated 200 million people worldwide suffer from shigellosis, with more than 650,000 associated deaths annually. The CDC recently estimated the occurrence of over 440,000 annual shigellosis cases in the United States alone, approximately eighty percent (80%) of which are caused by *Shigella sonnei*. *Shigella sonnei* is more active in developed countries. *Shigella* infections are typically treated with a course of antibiotics. However, due to the emergence of multidrug resistant *Shigella* strains, a safe and effective vaccine is highly desirable. No vaccines against *Shigella* infection currently exist. Immunity to *Shigellae* is mediated largely by immune responses directed against the serotype specific O-polysaccharide.

FDA inventors developed compositions and methods for inducing an immunoprotective response against *S. sonnei*. Specifically, an attenuated bacteria capable of expressing an *S. sonnei* antigen comprised of the *S. sonnei* form I O-polysaccharide expressed from the *S. sonnei* rfb/rfc gene cluster is claimed. The inventors have demonstrated the candidate vaccine compositions provide one hundred percent (100%) protection against parenteral challenge with virulent *S. sonnei* in mice.

Potential Commercial Applications

- Shigella/Typhoid vaccine for travelers, military
- Shigella/Typhoid vaccine for developing countries
- Shigella/Typhoid diagnostics

Competitive Advantages

- Low cost of production
- Temperature stable formulation
- Safety/efficacy of Ty21a established in humans

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Publications:

- Kopecko, D et al., Molecular cloning and characterization of genes for *Shigella sonnei* form I O polysaccharide: proposed biosynthetic pathway and stable expression in a live salmonella vaccine vector. *Infect Immun.* 2002 Aug;70(8):4414-23. PMID:[12117952](https://pubmed.ncbi.nlm.nih.gov/12117952/)

Intellectual Property:

United States Patent: US [7,541,043](#) B2 issued 06.02.2009
United States Patent: US [8,071,084](#) B2 issued 06.12.2011
United States Patent: US [8,337,832](#) B2 issued 12.25.2012
United States Patent: US [8,992,943](#) B2 issued 03.31.2015
United States Patent: US [9,333,251](#) B2 issued 05.10.2016

Product Area: Shigella Vaccine, Shigella therapeutic, Shigella diagnostic

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