

ORAL SHIGELLOSIS VACCINE

Technology Summary

Bacillary dysentery and enteric fevers continue to be important causes of morbidity in both developed and developing nations. *Shigella* cause greater than one hundred and fifty million cases of dysentery and enteric fever occurs in greater than twenty-seven million people annually. Currently, there is no licensed vaccine to prevent the occurrence of shigellosis. Increasing multiple resistance in *Shigella* commonly thwarts local therapies.

FDA Researchers developed a *Salmonella typhi* Ty21a construct comprising a *Shigella sonnei* O-antigen biosynthetic gene region inserted into the *Salmonella typhi* Ty21a chromosome, where heterologous *Shigella sonnei* form 1 O-antigen is stably expressed together with homologous *Salmonella typhi* O-antigen. The constructs of this invention elicit immune protection against virulent *Shigella sonnei* challenge, as well as *Salmonella Typhi* challenge. Also claimed in this application are methods of recombineering a large antigenic gene region into a bacterial chromosome.

Potential Commercial Applications

- A component of a multivalent oral Shigellosis vaccine candidate

Competitive Advantages

- Oral vaccine - no needles required
- Lower cost of production
- Low cost vaccine
- Temperature-stable manufacturing process - avoids need for refrigeration during vaccine distribution

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Publications:

“Stable expression of *Shigella sonnei* form I O-polysaccharide genes recombineered into the chromosome of live *Salmonella* oral vaccine vector Ty21a” *Int J Med Microbiol.* 2013 Apr;303(3):105-13. PMID: [23474241](https://pubmed.ncbi.nlm.nih.gov/23474241/)

Intellectual Property:

United States Patent: US [9,750,793](#) B2, issued 09.05.2017

China patent application: 201380059559.5, filed 05.14.2015

European patent application: 13836396.5, filed 03.18.2015

Israel patent application: 237339, filed 02.22.2015

Japan patent application: 2015-532125, filed 03.17.2015

Korea patent application: 10-2015-7010066, filed 04.17.2015

Product Area: vaccines, diagnostics, therapeutics

FDA Reference No: E-2012-016

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