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

Inventors: Madushini Dharmasena, Dennis Kopecko

Publications:

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

Licensing Contact:
Ken Millburne, J.D.
FDA Technology Transfer Program
Email: FDAInventionlicensing@fda.hhs.gov
Phone: 240-402-4315