LIVE ORAL SHIGELLA DYSENTERIAE VACCINE

Technology Summary

Shigella cause millions of cases of dysentery every year, which result in 700,000 deaths worldwide. *Shigella dysenteriae* serotype 1, one of about forty serotypes of *Shigella*, causes a more severe disease with a much higher mortality rate than other serotypes. There are no licensed vaccines available for protection against *Shigella*. The fact that many isolates exhibit multiple antibiotic resistance complicates the management of dysentery infections.

FDA Researchers developed a *Salmonella* typhi Ty21a construct comprising a *Shigella dysenteriae* O-specific polysaccharide (O-Ps) inserted into the Salmonella typhi Ty21a chromosome, where heterologous *Shigella dysenteriae* serotype 1 O-antigen is stably expressed together with homologous *Salmonella* typhi O-antigen. The constructs elicit immune protection against virulent *Shigella dysenteriae* challenge, as well as *Salmonella* typhi challenge. The construct can be used as a new vaccine candidate, stable for vaccine manufacture, and provides combined protection against enteric fevers due to *Salmonella typhi* and *Salmonella sonnei.*

Potential Commercial Applications

- One component of a multivalent anti-shigellosis vaccine under development
- Shigella vaccines, therapeutics and diagnostics

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

Development Stage: *in vivo*, mouse challenge studies

Inventors: Dennis Kopecko, De Qi Xu

Publications:

"Core-linked LPS expression of Shigella dysenteriae serotype 1 O-antigen in live Salmonella Typhi vaccine vector Ty21a: preclinical evidence of immunogenicity and protection." *Vaccine* 2007 Aug;25(33):6167-75 PMID: 17629369

Intellectual Property:

United States Patent: 8,071,113, issued 12.06.2011
United States Patent: 8,337,831, issued 12.25.2012
United States Patent: 8,790,635, issued 07.29.2014
United States Patent: 8,968,719, issued 03.03.2015
United States Patent: 9,402,889, issued 08.02.2016
European Patents: 1756149, issued 09.04.2013

Product Area: Biologics, Vaccines

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