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VACCINE FOR PREVENTION OF SEPSIS AND BROAD PROTECTION AGAINST GRAM-NEGATIVE BACTERIAL INFECTIONS

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Description
Clinical-stage vaccine candidate for prevention of gram-negative bacterial infections in humans & animals

Field
Vaccines

Technology Status
Available for licensing & sponsored research

Patent Status
US CIP Patent 9,616,116, issued 2017

UMB Docket#
AC-2006-005

References

Vaccine. 2015 Nov 27;33(48):6719-26. *Results of Phase 1 trial with/without CpG adjuvant*.
DOI: 10.1016/j.vaccine.2015.10.072

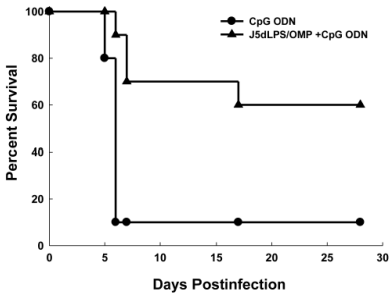
Innate Immun. 2008 Oct;14(5):269-78. *Vaccine protects against pneumonia*.
DOI: 10.1177/1753425908095959

Vaccine. 2014 Oct 21;32(46):6107-14. *Immunization of cows*.
DOI: 10.1016/j.vaccine.2014.08.083

Overview
The "J5dLPS/OMP" vaccine, created by academic and federal research collaborators led by Prof. Alan Cross, is a clinical-stage vaccine for the prevention of sepsis and protection against infection with a wide variety of Gram-negative bacteria. The vaccine comprises detoxified core lipopolysaccharide from Escherichia coli J5 complexed with group B meningococcal outer membrane protein ("J5dLPS/OMP"). Phase 1 clinical trials showed the vaccine to be safe, well tolerated, and immunogenic. This vaccine shows great promise as both a prophylactic and therapeutic approach for control of many types of lethal infections by Gram-negative bacteria.

Market & Applications
Sepsis is the leading cause of death in US hospitals (270,000 deaths/yr) and the most costly (> $24B/yr)

- J5dLPS/OMP vaccine provides broad protection against gram-negative bacterial infections (e.g., *Klebsiella, Pseudomonas, Burkholderia, Francisella, Yersinia, Enterobacter, E.coli, Serratia, Actinobacter, Salmonella, Shigella*)
- Vaccine may prevent lethal complications from burn injuries, graft-versus-host disease, etc., and protect against biological warfare agents
- Antibodies raised from vaccine may be used to treat infections and in rapid response to biological warfare
- J5dLPS/OMP vaccine may be used to protect individuals who work in high-risk professions (e.g., military, police, and firefighters)
- Vaccine also demonstrates potential for veterinary applications



Vaccine Survival 60% (compared to 10% for controls) when mice were immunized i.n. with J5dLPS/OMP vaccine + CpG adjuvant & then challenged i.t. with lethal dose *F. tularensis* LVS.

Stage of Development
Two Phase 1 clinical trials, with & without CpG adjuvant, have validated the J5dLPS/OMP vaccine as safe, well tolerated, and immunogenic (*Vaccine* 2003 & 2015). The vaccine was effective in the neutropenic rat model of sepsis (eliciting a >200-fold increase in anti–J5 LPS antibody, and improving survival in immunized versus control animals: 61% versus 0% in Pseudomonas- and ceftazdime-treated rats; *J. Inf. Disease* 2001). Challenge studies in animal models demonstrated protection against lethal doses of *F. tularensis* (*Vaccine* 2010) and against lethal gram-negative bacillary pneumonia (*Innate Immunity* 2008). And, when cattle were immunized with the J5dLPS/OMP vaccine, high titers of serum anti-endotoxin antibodies were elicited, and were passed to the cow's colostrum (*Vaccine* 2014).

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