

## **An Investigational Pneumococcal Vaccine Compared to Prevnar in Toddlers**

### **The Disease**

- *Streptococcus pneumoniae* (Pneumococcus) is a leading cause of meningitis, pneumonia, and bacterial blood infection, which are the most common manifestations of invasive pneumococcal disease (IPD) in infants and young children throughout the world.
- Pneumococcus also causes less invasive disease, such as ear and sinus infections
- The consequences of bacterial meningitis can be very severe. Many people are left with neurological impairments such as deafness, mental retardation and behavioral problems.
- Pneumococcus has been linked to over one million deaths per year worldwide in children less than 5 years old
- Current pneumococcal vaccine (Prevnar™) has been highly immunogenic and effective against ear infections and invasive disease.
- The current vaccine contains 7 types (serotypes) of *Streptococcus pneumoniae*. Offers protection against 40-90% of IPD cases depending on the geographic region.
- Serotype 19A has become the predominant serotype causing IPD in children in the United States (and is not included in the current 7-type Prevnar vaccine). It is increasingly found to be resistant to first and second-line antibiotics causing many cases of multi-drug resistant ear infections requiring tubes. 19A has been reported globally in countries where Prevnar is and is not routinely used.
- There is a 23-valent polysaccharide vaccine used in adults but it is not effective in infants.

### **The Investigational Vaccine -15-valent pneumococcal conjugate vaccine**

- Contains 15 serotypes of *Streptococcus pneumoniae*, the 7 types in Prevnar + 8 additional types (including serotype 19A)
- The development of the investigational vaccine is designed to address the medical and public health need based on the limited serotype coverage, and limited availability of Prevnar in selected regions, as well as the increase of replacement disease caused by non-Prevnar serotypes.
- Based on the surveillance data from the CDC, this investigational vaccine had the potential to cover up to 71% of the pneumococcal diseases that occurred in the United States in 2004 in the presence of universal recommendations for infant immunization with Prevnar.
- This is the first time that the study vaccine has been used in people. Therefore, side effects are not known. Possible risks may include injection site reactions such as redness, soreness/tenderness and swelling. Other risks may include fever, diarrhea, fussiness or sleepiness, an allergic reaction and a rash. Also, those children who receive the study vaccine will not receive an approved and recommended vaccination. Please talk to your doctor about the full range of risks and benefits of your child participating in this study.

### **The Study**

- The Primary objective is to provide information on whether this investigational vaccine is tolerated and if it works as compared to Prevnar in toddlers aged 12-15 months, who have completed a 3-dose infant series of Prevnar according to the current national vaccination schedule. Immunogenicity (if it works) will be assessed as a secondary objective

- One dose of study vaccine will be administered to healthy toddlers 12-15 months of age.
- 2 visits over 1 month: one injection, 2 blood draws
  - Subjects will be randomized to one of three vaccines (1:1:1):
    - Adjuvanted study vaccine
    - non-adjuvanted study vaccine
    - Prevnar (control)

All subjects must have previously completed the full 3-dose infant series of Prevnar prior to study participation. In addition, subjects are allowed to receive concomitant administration of routine pediatric vaccines regularly administered at 12-15 months of age according to the current national vaccination schedule.

**Inclusion Criteria \***

- Healthy toddlers, 12-15 months of age who have previously completed a documented full 3 dose infant series of Prevnar at 2, 4, and 6 months of age.
- Afebrile, with a rectal temperature  $<38.1^{\circ}\text{C}$  ( $<100.5^{\circ}\text{F}$ ) or axillary temperature  $<37.8^{\circ}\text{C}$  ( $<100.0^{\circ}\text{F}$ ) on day of vaccination.

**Exclusion Criteria \***

- Have received less than the full 3-dose infant series of Prevnar or 3rd dose less than 2 months before study vaccine.
- Subject has received other licensed non-live vaccines administered within the 14 days before receipt of study vaccine. Influenza virus vaccine given according to recommended guidelines within 7 days of receiving study vaccine.
- A recent ( $<72$  hours) febrile illness (rectal temperature  $\geq 38.1^{\circ}\text{C}$  [ $\geq 100.5^{\circ}\text{F}$ ]) occurring within 48 hours before receipt of study vaccine.

\* For more details about these and other inclusion & exclusion criteria, please discuss with the clinical research staff.

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