

## **An Investigational Study of a Meningococcal Vaccine Administered Concomitantly with Routine Vaccines**

### **The Disease**

- The majority of bacterial meningitis has been caused by *Haemophilus influenzae* type B (H. flu type B), *Streptococcus pneumoniae* (pneumococcus), and *Neisseria meningitidis* (meningococcus).
- The sequelae of meningitis can be very severe. Many people are left with neurological impairments such as deafness, mental retardation and behavioral problems.
- Vaccines against H.flu type B (Hib) and Pneumococcus (Prevnar) have significantly reduced the incidences of these types of meningitis, but *Neisseria* is still prevalent.
- *Neisseria* - The serogroups B, C, and Y cause 90% of the disease, with type B is the most common during non-epidemics and last year caused half the cases of meningococcal disease in the US (CDC). The other two serogroups (A and W-135) comprising the remaining 10%.
- Meningococcal meningitis has a case fatality rate of 5-10%, and meningococcal septicemia fatality rate can be as high as 20 to 40%

### **The Current licensed meningococcal vaccines (Menactra and Menomune)**

- The current vaccines are made of serogroups A, C, Y, and W135.
- Menactra and Menomune are licensed for children age 2 and older.
- There is no current vaccine against meningococcal meningitis in children under 2 years old.

### **The Investigational Vaccine - Meningococcal ACWY vaccine (MenACWY)**

- The study vaccine is made to potentially protect against serogroups A, C, W and Y.
- More than 15,000 patients have received the final formulation of this vaccine in clinical trials
- It has been found to be immunogenic in all age groups from infants to adults.
- The vaccine has been shown in clinical trials to be generally well-tolerated with a reaction profile similar to other meningococcal vaccines.
- Persistence of bactericidal antibodies has been demonstrated against all 4 serogroups both in infants prior to the 12 month booster and in adolescents 1 year after vaccination.

### **The Research Study (Safety and Immunogenicity)**

The purpose of this research study is to see if the vaccine is tolerated and if it works when given together with routine infant vaccines

- Infants have a 50 percent chance of being in either group (1:1)
  - o Group 1 - injection of MenACWY plus concomitant routine vaccinations at 2, 4, 6, and 12 months of age (4 total doses of MenACWY)
  - o Group 2 - only routine vaccination through the time of the blood draw at 13 month visit, with one dose of MenACWY given at 18 months of age.
  - o 3 extra blood draws (We normally do a blood draw at 12 months of age)
  - o 6 to 7 visits over 18 months

### **Inclusion Criteria**

- Healthy 2 month-old infants (aged 55 - 89 days).
- Babies must have been born after a full-term pregnancy with an estimated gestational age > 37 weeks and a birth weight > 2.5 kg.

### **Exclusion Criteria (Some, but not all inclusive)**

- Prior vaccination with vaccines against meningococcus, diphtheria, tetanus, pertussis, polio (IPV or OPV), *H. influenzae* type b (Hib) or pneumococcus.
- Subjects who have a previous confirmed or suspected disease caused by *N. meningitidis*, *C. diphtheriae*, *C. tetani*, poliovirus, Hepatitis B, Hib, pneumococcus or *B. pertussis*.
- Fever (temperature > 38.0°C [100.4°F]) within the previous 3 days.
- Severe acute or chronic infection within the previous 7 days

### **Compensation**

Participants will be compensated for time and travel.

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Version 18Feb2010