**Immunogenicity of Bivalent rLP2086 (MenB-FHbp), a Meningococcal Serogroup B Vaccine, in US Adolescents: Results From a Phase 3 Trial**

Timie Vesikari, MD, PhD,† Shelly Senders, MD, Judith Absalon, MD, MPH‡, Joseph J. Eden, MD, PhD, Kathrin U. Jansen, PhD, Johannes Beeslar, MD, Laura Y. Jork, PhD, Thomas R. Jones, PhD, Roger Maansson, MS, Shannon L. Harris, PhD, Robert E. O’Neill, PhD, John Giinis, BS, Annaliesse S. Anderson, PhD, John L. Perez, MD, MA


**ABSTRACT**

Background

Meningococcal serogroup B (MnB) is a leading cause of invasive meningococcal disease (IMD) and is a priority for global vaccination. The MnB disease burden is highest in young adults aged 10–25 years. This global phase 3, randomized, active-controlled, observer-blinded, multicenter study evaluated the immunogenicity of bivalent rLP2086, in which half of subjects were enrolled in the United States, to extend phase 2 data, the basis for accelerated approval in the United States.

**OBJECTIVES**

- To assess the primary immunogenicity endpoints of bivalent rLP2086 in the evaluable US immunogenicity population, subjects who received ≥2 doses of rLP2086.
- To assess inferiority of bivalent rLP2086 against each primary strain; 85.7% achieved a composite response after dose 3. Corresponding response) after dose 3. Lot consistency was assessed with hSBA GMTs for 2 strains, with all GMRs close to 1.

**METHODS**

Study Design

This was a phase 3, randomized, active-controlled, observer-blinded, multicenter study of bivalent rLP2086. The study was powered to assess immunogenicity in US and total populations for MnB strains, with all GMRs close to 1.

**RESULTS**

Subjects

1205 subjects enrolled in the United States were randomized to receive bivalent rLP2086; one subject had a protocol violation. Of the 3596 subjects randomized, 1806 (50.2%) were from the United States. Table 1. Genotypic Characteristics of MnB Test Strains

**CONCLUSIONS**

The 4 primary test strains are representative of diverse MnB phylogenetic subgroups that are a leading cause of IMD in the United States. The 4 primary test strains are representative of diverse MnB phylogenetic subgroups that are a leading cause of IMD in the United States. The 4 primary test strains are representative of diverse MnB phylogenetic subgroups that are a leading cause of IMD in the United States.