

A Phase 2b Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of MEDI8897, a Monoclonal Antibody With an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Preterm Infants

Inclusion Criteria

Subjects must meet all of the following criteria:

1. Healthy infants born between 29 weeks 0 days and 34 weeks 6 days GA
2. Infants who are entering their first full RSV season at the time of screening
3. Subject is available to complete the follow-up period, which will be 1 year after receipt of the dose of study drug

Exclusion Criteria

Any of the following would exclude the subject from participation in the study:

1. Meets AAP or other local criteria to receive commercial palivizumab
2. Any fever ($\geq 100.4^{\circ}\text{F}$ [$\geq 38.0^{\circ}\text{C}$], regardless of route) or lower respiratory illness within 7 days prior to randomization
3. Acute illness (defined as the presence of moderate or severe signs and symptoms) at the time of randomization
4. Active RSV infection (a child with signs/symptoms of respiratory infection must have negative RSV testing) or known prior history of RSV infection
5. Any drug therapy (chronic or other) within 7 days prior to randomization or expected receipt during the study with the exception of: 1) multivitamins and iron; 2) infrequent use of over the counter medications for the systemic treatment of common childhood symptoms (eg, pain relievers, decongestants or cough suppressants) that may be permitted according to the judgment of the investigator
6. Any current or expected receipt of immunosuppressive agents
7. History of receipt of blood transfusion or immunoglobulin products
8. Receipt of any investigational drug
9. Known renal impairment
10. Known hepatic dysfunction including known or suspected active or chronic hepatitis infection
11. History of CLD/bronchopulmonary dysplasia
12. Clinically significant congenital anomaly of the respiratory tract
13. Chronic seizure or evolving or unstable neurologic disorder
14. Congenital heart disease, except for children with uncomplicated CHD (eg, patent ductus arteriosus, small septal defect)
15. Prior history of a suspected or actual acute life-threatening event
16. Known immunodeficiency, including human immunodeficiency virus (HIV)
17. Mother with HIV infection (unless the child has been proven to be not infected)
18. Any known allergy, including to immunoglobulin products, or history of allergic reaction
19. Receipt of palivizumab or other RSV monoclonal antibody or any RSV vaccine, including maternal RSV vaccination
20. Receipt of any monoclonal or polyclonal antibody (for example, Hepatitis B immune globulin, and intravenous immunoglobulin)