

A Study of BLB-201 RSV Vaccine in Infants and Children

NCT05655182

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Blue Lake Biotechnology Inc.
Enrollment	137 participants

Key Eligibility Criteria

Inclusion (14)

- Healthy children at least 18 months but less than 60 months of age whose legally-acceptable representative (LAR) understands and signs the trial informed consent and agrees to vaccine administration following a detailed explanation of the trial.
- Determined by medical history, targeted physical exam, and clinical judgement of the investigator to be in a good state of health. Screening laboratory values slightly outside lab normal ranges may be acceptable if the site investigator determines that they are not clinically significant. Permitted concomitant medications include nutritional supplements, medications for gastroesophageal reflux, eye drops, and topical medications, including topical steroids, topical antibiotics, and topical antifungal agents.
- Sero+ for RSV as defined by serum RSV antibody titer assay
- Participant is expected to be available for the duration of the trial.
- The LAR confirms that the subject has received routine immunizations appropriate for age based on the current Advisory Committee on Immunization Practices (ACIP) Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger.

... and 9 more (see full listing online)

Exclusion (66)

- <8 months of age and >60 months of age at the time of planned vaccine inoculation.
- Born at less than 34 weeks gestation for subjects e 1 year of age at enrollment
- Born at less than 37 weeks gestation, and at the date of inoculation less than 1 year of age.
- Maternal history of a positive HIV test before or during pregnancy.
- Maternal history of illicit drug abuse or alcohol abuse.

... and 61 more (see full listing online)

Locations (11 total)

Paradigm Clinical Research, La Mesa, California, United States
Paradigm Clinical Research - Modesto, Modesto, California, United States
Velocity Clinical Research, Boise, Meridian, Idaho, United States

... and 8 more locations