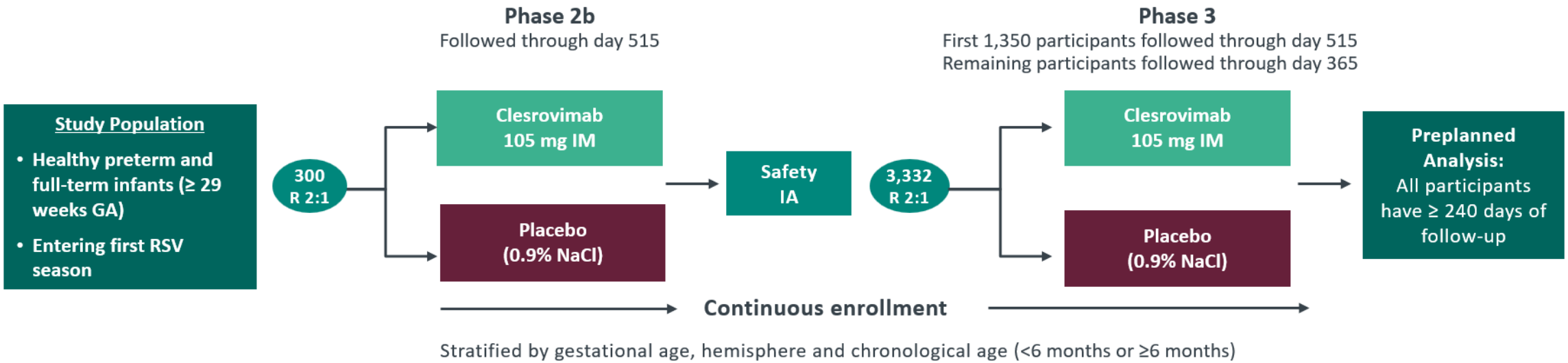
PN004 CLEVER Study Design

Randomized, Double-blind, Placebo-controlled, Pivotal Phase 2b/3 Trial



Primary Objectives:

- Safety and tolerability of clesrovimab compared to placebo
- Efficacy of clesrovimab against RSV-associated MALRI requiring ≥ 1 indicators of LRI or severity days 1-150 *[hypothesis tested]*

Secondary Objectives:

- Efficacy of clesrovimab against RSV-associated hospitalization, days 1-150 *[hypothesis tested]*
- Efficacy of clesrovimab against RSV-associated MALRI requiring ≥ 1 indicators of LRI or severity days 1-180

ClinicalTrials.gov identifier: NCT04767373. IA=interim analysis. GA=gestational age. MALRI= medically attended lower respiratory tract infection. LRI= lower respiratory tract infection IM=intramuscular injection. LB=lower bound

Zar HJ, Simoes EAF, Madhi SA et al. A Phase 2b/3 Study to Evaluate the Efficacy and Safety of an Investigational Respiratory Syncytial Virus (RSV) Antibody, Clesrovimab, in Healthy Preterm and Full-Term Infants. Oral Presentation. *Infectious Diseases Society of America (IDSA)* 2024