



CLINICAL RELEVANCE

Clesrovimab, an investigational monoclonal antibody (mAb), which demonstrated in phase III trials significant efficacy in preventing RSV-associated infections when administered as a single dose to infants of all weights. It showed a 60.4% reduction in RSV-associated medically attended lower respiratory infections, 84.2% reduction in RSV-associated hospitalisations, and a 90.9% reduction in RSV-associated lower respiratory tract infection (LRTI) hospitalisations compared to placebo. Clesrovimab was found to be safe and well-tolerated. The WHO Strategic Advisory Group of Experts on Immunization (SAGE) has recommended RSV preventive mAbs for young infants but has not yet included clesrovimab. Its efficacy and safety, similar to those of nirsevimab, might support an upcoming positive evaluation.

DISEASE BURDEN

Respiratory Syncytial Virus (RSV) is a leading cause of respiratory disease globally. RSV has been estimated to cause 34 million acute lower respiratory tract infections (LRTI) in young children annually, with over 3 million severe cases requiring hospitalisation, and between 66.000 to 199.000 fatalities, 99% of which in LMICs.

NDE

INTELLECTUAL PROPERTY LANDSCAPE

Patents covering clesrovimab have been filed or granted in more than fifty LMICs and they are expected to expire in 2036. Secondary patents covering a formulation expected to expire 2039 were filed in few LMICs. Other secondary patents may be filed.



SERVICE DELIVERY ENABLERS

Clesrovimab is an injectable monoclonal antibody, administered intramuscularly that requires cold chain storage. Supply chain, health facility, and healthcare worker requirements may be minimised through integration in national neonate immunisation packages and corresponding administration at birth, especially as clesrovimab injection should be deemed compatible with concomitant newborn vaccine injections.

CLESROVIMAB



MSD

REGULATORY

Clesrovimab is not approved by any stringent regulatory authorities. Complete biosimilarity exercise with respect to analytical similarity, preclinical and clinical assessment likely to be done. Clinical trial waivers would likely not be an option.



MANUFACTURING

Complex manufacturing process since product is a monoclonal antibody. The product is still in development and technical details are likely product specific.

MARKET

Clesrovimab is not yet approved. Clesrovimab's price is estimated to be high (as nost of monoclonal antibodies) and there is currently no information on access strategies for LMICS, but MSD committed to a global access plan.