WATCHLIST

CLESROVIMAB

RESPIRATORY SYNCYTIAL VIRUS

MSD

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 hospitalization, and between 66,000 to 199,000 fatalities, 99% of which are in low- and middle-income countries (LMICs).

CLINICAL RELEVANCE

Preliminary data shows that a single dose of clesrovimab could provide 74.2% efficacy for the prevention of medically attended lower respiratory tract RSV infection for a duration of 5 months in infants. However, these data are preliminary and more evidence on efficacy is needed.

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 may be filed

SERVICE DELIVERY ENABLERS

Clesrovimab is an injectable monoclonal antibody, likely to be administered intramuscularly and requires cold chain storage. As such, supply chain, health facility, and healthcare worker requirements may be minimised through the integration of clesrovimab in national neonate immunization packages and corresponding administration at birth.

REGULATORY

Clesrovimab is not approved by any stringent regulatory authorities. Potential licensees could rely on mechanisms like EU-M4 all for quality assurance. Complete biosimilarity exercise with respect to analytical similarity, preclinical and clinical assessment likely to be done. Clinical trial waivers likely would not be an option.

MANUFACTURING

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

MARKET

Clesrovimab is not available yet in HIC or LMICs. Clesrovimab's price is estimated to be high (as most of monoclonal antibodies) and there is currently no information on access strategies for LMICS.