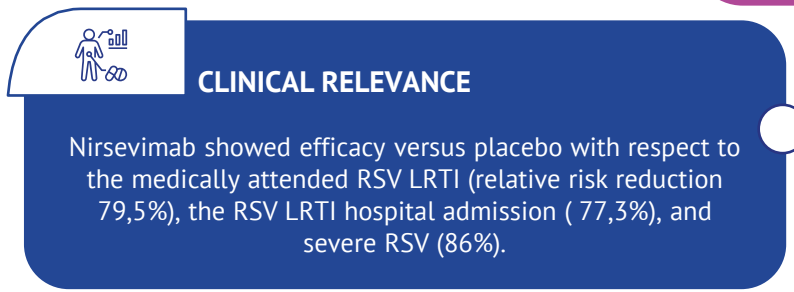
medicines patent pool

WATCHLIST

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

Nirsevimab showed efficacy versus placebo with respect to the medically attended RSV LRTI (relative risk reduction 79,5%), the RSV LRTI hospital admission (77,3%), and severe RSV (86%).

INTELLECTUAL PROPERTY LANDSCAPE

Patents covering nirsevimab have been filed or granted in several LMICs and they are expected to expire between 2028 and 2035. Secondary patents covering a formulation and a treatment regimen with expiry dates in 2038 and 2040 were filed in several LMICs.

SERVICE DELIVERY ENABLERS

Nirsevimab is an injectable monoclonal antibody, administered intramuscularly that requires cold chain storage. As such, supply chain, health facility, and healthcare worker requirements may be minimized through integration of nirsevimab in national neonate immunization packages and corresponding administration at birth, especially as nirsevimab injection is deemed compatible with concomitant newborn vaccine injections.

REGULATORY

Nirsevimab is approved by stringent regulatory authorities. Potential licensees could rely on mechanisms like EU-M4all for quality assurance. Complete biosimilarity exercise with respect to analytical similarity, preclinical and clinical assessment needs to be done. Clinical trial waivers would not be an option.

MANUFACTURING

Complex manufacturing process since product is a monoclonal antibody. Aseptic processing is required. No challenges with respect to excipients. Final pack is PFS, which would be considered as a device. Shelf life is 2 years under refrigeration.

MARKET

Nirsevimab is scarcely available even in private sectors in developed countries and there is no presence in LMICs. Nirsevimab's price is estimated to be high (as all monoclonal antibodies) and there is currently no information on access strategies for LMICS.