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AstraZeneca announces CDSCO approval of preventive therapy for Respiratory Syncytial Virus

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RSV is the second most common cause of death in children under 1 year of age

AstraZeneca Pharma India has announced the marketing approval from Central Drugs Standard Control Organisation (CDSCO) to import and market ‘Palivizumab’ injection 100 mg/ml (r-DNA origin) (50mg/0.5mL & 100 mg/mL presentations in single-dose vials administered through intramuscular route) in India.

Respiratory Syncytial Virus (RSV) in children is a ‘major’ public health challenge faced across the globe today and is the second most common cause of death in children under 1 year of age (second only to malaria). WHO estimates that RSV accounts for >60% of acute respiratory infections in children and >80% in infants <1 year old. The disease is responsible for nearly 50% of pneumonia cases and up to 90% of bronchiolitis cases among infants. In India, RSV is the most common cause of hospitalisation in children <1 years old.

This innovative therapy is indicated for prevention of serious lower respiratory tract disease requiring hospitalisation caused by RSV in children at high risk for RSV disease.

Dr Sanjeev Panchal, Country President and Managing Director, AstraZeneca India, said: “Currently, there is neither a vaccine nor a targeted treatment for RSV in India. *Palivizumab* however, is the only preventive therapy now approved in India that can help."