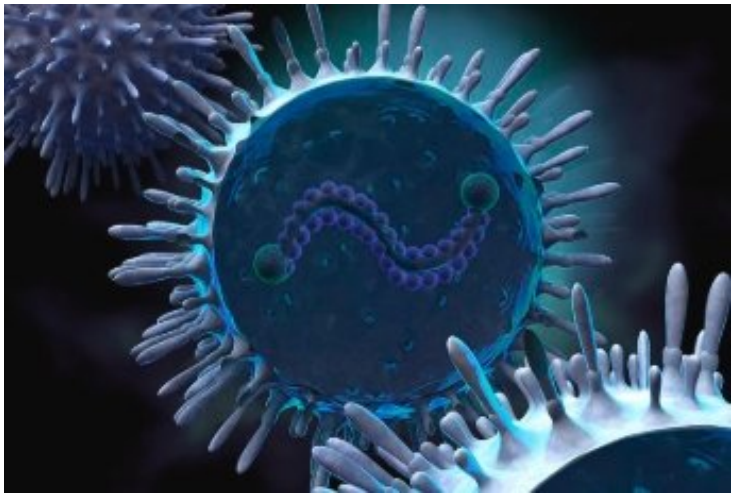
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Korea's SK bioscience in-licenses RSV preventive mAb candidate from Gates Medical Research Institute

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SK to advance novel early-clinical stage RSV preventive monoclonal antibody in-licensed from Gates Medical Research Institute



South Korea-based SK bioscience will advance a novel respiratory syncytial virus (RSV) monoclonal antibody (mAb) for global health under license from the Gates Medical Research Institute (Gates MRI). SK bioscience has entered into a license agreement with Gates MRI, a nonprofit medical research organization, an affiliate of the Gates Foundation, to develop and commercialise a clinical-stage monoclonal antibody candidate prophylactic treatment for the prevention of RSV infection.

The RSV preventive mAb candidate, engineered by Adimab in collaboration with Gates MRI is designed to be administered to newborns and infants born during or entering their first RSV season, with a single dose intended to provide rapid and durable protection through an RSV season. If the mAb candidate is proven safe and effective in clinical trials, this approach could support broader supply and expand access to RSV prevention, enabling more infants to benefit and helping to address current gaps where protection remains limited for a variety of reasons.

In preclinical studies, the antibody (known as RSM01) demonstrated strong inhibition of viral infection and replication in both in vitro and in vivo models, including activity against certain RSV strains reported to show reduced susceptibility to currently available licensed products.

In a Phase 1a first-in-human study conducted in healthy adults in the United States, the candidate was shown to be generally safe and well-tolerated in healthy adults, and the data suggested the potential for sustained protection throughout the RSV season following a single administration. Based on these findings, SK bioscience plans to move swiftly into a Phase 1b clinical trial in infants to accelerate this mAb's development.

Under the license agreement, SK bioscience has secured exclusive worldwide rights to commercialize the candidate mAb if proven safe and effective, including in high-income countries, with non-exclusive supply in India and Gavi-eligible countries. In addition, the agreement includes Global Access commitments by SK bioscience that are aligned with the Gates MRI's

charitable mission to advance equitable access to lifesaving health technologies for populations most in need.

In parallel, the company plans to advance large-scale manufacturing process development to enable affordable supply to low-resource settings, where RSV-associated infant mortality remains high.

RSV is a leading cause of severe lower respiratory tract disease in infants and young children worldwide, with an estimated 100,000 deaths annually among infants under six months of age—a critical window targeted for protection by monoclonal antibodies.