Transcript Details

This is a transcript of a continuing medical education (CME) activity. Additional media formats for the activity and full activity details (including sponsor and supporter, disclosures, and instructions for claiming credit) are available by visiting:
https://reachmd.com/programs/cme/rsv-vaccination-and-immunoprophylaxis-optimism-for-the-future/15407/

Time needed to complete: 53m

ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

RSV Vaccination and Immunoprophylaxis – Optimism for the Future

Announcer:
Welcome to CME on ReachMD. This episode is part of our MinuteCME curriculum.

Prior to beginning the activity, please be sure to review the faculty and commercial support disclosure statements as well as the learning objectives.

Dr. Simoes:
Hello, my name is Eric Simoes. I'm a Professor of Pediatrics and Epidemiology at the University of Colorado and the Colorado School of Public Health. I'm going to discuss RSV Vaccination and Immunoprophylaxis - Optimism for the Future.

The next generation of RSV prevention is dependent on - happened in 2015 with the description of the prefusion form of the RSV F protein, and this has made dramatic changes to the landscape of RSV prevention. Monoclonal antibodies were developed to different epitopes on the surface of the prefusion form of the RSV F protein. YTE mutations in the Fc domain of immunoglobulin allows the antibodies to last for at least 6 months, thus making it possible to give a single dose of a monoclonal antibody lasting for 6 months for prevention. And mRNA technology allowed the development of mRNA vaccines for COVID, but it was based actually on the prefusion F protein that was described in 2015. The RSV F protein - prefusion protein vaccines rapidly developed for use in older adults based on the mRNA technology and the development of the prefusion F in 2015.

Other RSV vectored vaccines have also been developed for older adults, adenovirus vector and non-replicating vaccina virus as well as nanoparticle technology, all in phase 3 trials currently.

Let's start with RSV monoclonal antibodies, they were developed to different epitopes on the surface of the prefusion F glycoprotein. Nirsevimab is directed to the uppermost part, the site 0. On the RSV F protein, there are variably six or seven sites on the RSV prefusion F and the postfusion F form to which different antibodies are directed. Clesrovimab is directed to site IV/V of the antibody. And a monoclonal antibody now known as RSM01, that was developed by the Gates Foundation for use in low and middle-income countries, is also directed at site 0.

Nirsevimab is the first in class to complete and report phase 2 and 3 trials. It resulted in a 75% reduction in lower respiratory tract infections caused by RSV that were medically attended. And it protected all infants across the RSV season with a single dose. It was safe for all babies, not just the ones at high risk for which palivizumab is currently indicated.

Clesrovimab is now in phase 2 and phase 3 trials, both of which are either completed or close to completion. The data was presented at a meeting in Lisbon a few months ago in February 2023. RSM01 is in phase 1 trials, and no reports are available.

A second strategy for babies is maternal immunization. Based on the development of the prefusion F, maternal immunization has been used as a strategy. The prefusion F has been stabilized as a protein, and it was administered to pregnant mothers. It has been shown to produce good neutralizing antibody responses with 2 transplacental transfer without any safety concerns. It showed efficacy in a phase two trial published in the *New England Journal*. And the phase 3 also shows efficacy presented at the same meeting in Lisbon, with potential protection up to potentially 9 months of age.

The same technology of the prefusion F but now stabilized as an mRNA. Two vaccines have been produced for older adult immunization, and they showed initial promise between 70 and 90% efficacy against severe RSV LRI. In older adults. An mRNA vaccine based on the same structure has also been shown to be at least 80% effective against RSV LRTD in older adults. And an adenovirus vectored vaccine has shown to be effective, not only in the first season, but surprisingly over three seasons in older adults. This data was presented at an earlier meeting last year in Belfast.

The future now of RSV vaccines is really today. Nirsevimab has already been licensed for use in the EMA for the first season, early - or late last year in 2022.

Nirsevimab and an RSV maternal vaccine are being considered for licensure in the U.S. in 2023, and are being discussed at ACIP with potential for recommendations coming as early as later this year. Two prefusion F RSV protein vaccines for older adults are also being considered by the FDA for potential licensure as early as May or June this year, with ACIP recommendations coming imminently thereafter.

The future is very bright, and I'd like to thank everyone for their attention. Thank you.

Announcer:
You have been listening to CME on ReachMD. This activity is jointly provided by Global Learning Collaborative (GLC) and TotalCME, Inc. and is part of our MinuteCME curriculum.

To receive your free CME credit, or to download this activity, go to ReachMD.com/CME. Thank you for listening.