### U.S. Centers for Disease Control and Prevention



## Maternal/Pediatric Respiratory Syncytial Virus (RSV) Work Group

Jefferson Jones MD MPH FAAP
Co-Lead, Maternal/Pediatric RSV Work Group

Presenting on behalf of Helen Chu, MD, MPH Chair, Maternal/Pediatric RSV Work Group

ACIP Meeting

April 16, 2025

# CDC and ACIP recommend all infants should be protected against severe RSV disease with either maternal RSV vaccine or nirsevimab

**Maternal vaccine** 

Abrysvo, Pfizer



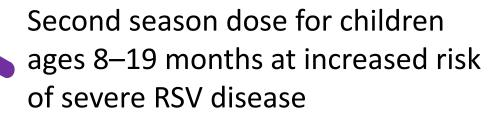
Pregnant women 32 through 36 weeks' gestation

Administer September through January in most of the continental United States†

#### **Nirsevimab**

Beyfortus, Sanofi & AstraZeneca

All infants <8 months\*



Administer October through March in most of the continental United States<sup>†</sup> (as early as possible<sup>¥</sup>)



\**Either* maternal RSV vaccine or nirsevimab is given to protect infants against severe RSV disease – only one is needed in most instances

<sup>†</sup> Timing of administration for RSV immunization may differ in jurisdictions with RSV seasonality that differs from most of the continental United States; ¥ The optimal timing for nirsevimab administration is shortly before the RSV season begins (e.g., October–November), or within a baby's first week of life if born October through March (ideally during the birth hospitalization.)

## Today we will be reviewing data on a second, long-acting monoclonal antibody for protection of infants from severe RSV disease

## Maternal vaccine Abrysvo, Pfizer

Pregnant women 32 through 36 weeks' gestation

Administer
September through
January in most of
the continental
United States†

#### Nirsevimab

Beyfortus, Sanofi & AstraZeneca

All infants <8 months\*

Second season dose for children ages 8–19 months at increased risk of severe RSV disease

Administer October through March in most of the continental United States† (as early as possible<sup>¥</sup>)

### Clesrovimab

Merck

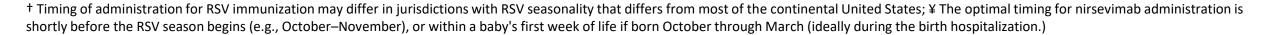
**Currently <u>not</u> FDA approved Target action date: 6/10/25** 



All infants <8 months\*

Administer October through March in most of the continental United States† (as early as possible<sup>¥</sup>)

\**Either* maternal RSV vaccine or an infant antibody is given to protect infants against severe RSV disease – only one is needed in most instances



## Timeline of Maternal/Pediatric RSV work group and ACIP review of clesrovimab

### September 2024

- Maternal/Pediatric RSV work group reviewed and discussed data from Merck on safety and efficacy of clesrovimab

#### October 2024

- ACIP reviewed and discussed data from Merck on safety and efficacy of clesrovimab and work group interpretation of these data

### November 2024 – April 2025

- Maternal/Pediatric RSV work group reviewed and discussed
  - GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) for clesrovimab
  - Evidence to Recommendations Framework for clesrovimab

## Today's agenda: April 16, 2025

- Evidence to Recommendation Framework: Clesrovimab Ms. Danielle Moulia (CDC/NCIRD)
- Clinical Considerations Dr. Jefferson Jones (CDC/NCIRD)

## **Clesrovimab: Looking forward**

- FDA has set a Prescription Drug User Fee Act (PDUFA) date, or target date for regulation action, of June 10, 2025, for clesrovimab.
- June 2025 ACIP meeting
  - Presentation of any updates to the Evidence to Recommendation Framework and Clinical Consideration for clesrovimab
  - Vote on recommendation of clesrovimab (pending FDA regulatory action)

## Work group members (external)

#### **ACIP Members**

Helen Chu (chair)

**Oliver Brooks** 

Denise Jamieson

#### **Liaisons**

James McAuley (IDSA)

Nicole Chaisson (AAFP)

Sean O'Leary (AAP)

Jennifer Schuster (PIDS)

Molly Howell (AIM)

Stacy Buchanan (NAPNAP)

Caitlin Newhouse (CSTE)

#### **Ex Officio Members**

Lucia Lee (FDA-CBER)

Yodit Belew (FDA-CDER)

Prabha Viswanathan (FDA-CDER)

Yugenia Hong-Nguyen (FDA-CDER)

Sonnie Kim (NIH-NIAID)

April Killikelly (Public Health Agency of Canada)

Elissa Abrams (Public Health Agency of Canada)

Jessica Lee (CMS/CMCS)

Terry Dalle-Tezze (HRSA)

Matthew Clark (IHS)

#### **Consultants**

Cody Meissner (Dartmouth Geisel School of Medicine)

Kevin Ault (Western Michigan University)

Pablo Sanchez (Nationwide Children's Hospital)

## Work group members (CDC)

#### CDC

Jefferson Jones (co-lead)

Danielle Moulia (co-lead)

Meredith McMorrow

Mila Prill

**Natalie Thornburg** 

Ismael Ortega-Sanchez

Melissa Coughlin

Jamison Pike

Lauren Roper

Tami Skoff

**Angie Campbell** 

Michael Melgar

**Amadea Britton** 

Amanda Payne

Noelle Molinari

Fiona Havers

Pragna Patel

**Ruth Link-Gelles** 

Monica Godfrey

Heidi Moline

Hannah Rosenblum

Manisha Patel

**Heather Scobie** 

Michele Hlavsa

**Monica Patton** 

Jarrett Gartin

**Dennis Wang** 

**Jordan Singleton** 

Fatimah Dawood

Agustin Lopez

Lakshmi Panagiotakopoulos

Suzanne Heitfeld

Molly Gaines-McCollom

**Amber Rose Kautz** 

Allison Ciesla

**Christine Olson** 

Anne Hause

Andrew Leidner

**David Shav** 

Pedro Moro

Tarayn Fairlie

John Su

Micheal McNeal

Julianne Gee

Naomi Tepper

Ellen Boundy

Alaya Koneru

Melissa Taylor

**Ebony Thomas** 

**CDC ACIP Staff** 

Melinda Wharton

**Stephanie Thomas** 

Jessica MacNeil

## Thank you

For more information, contact CDC 1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U.S. Centers for Disease Control and Prevention.

