

# RSV ANTIBODY!

THE WHAT, WHY, HOW, WHEN  
OF NIRSEVIMAB

While waiting to start, feel free to  
mingle in the chat and meet other  
families with babies of similar ages!



# RSV IMPACT

- RSV is the most common cause of hospitalization in U.S. infants
- Highest hospitalization rates in first months of life
- Risk declines by month with increasing age in infancy and early childhood
- Prematurity and other chronic diseases increase risk of RSV-associated hospitalization, but most hospitalizations (72%) are in healthy, term infants



# ENTER: NIRSEVIMAB

- Nirsevimab directly neutralizes RSV and blocks cell-to-cell fusion, with similar neutralization potency for RSV subtypes A and B!
- Takes about 6 days (on average) to reach peak levels in circulation
- Half life of 71 days
- Should provide protective effect for at least 5 months.
- Nirsevimab did not inhibit a natural immune response to RSV exposure



# ACTIVE VS PASSIVE

- Nirsevimab is a passive immunization
- Passive immunity is when a person receives antibodies from an external source
  - Transplacental or breastmilk
  - Direct administration of antibodies, such as IVIG or monoclonal antibodies like nirsevimab
- Active immunity results from infection or vaccination, which triggers an immune response. This is long-lasting because the immune system builds up a library of 'memories' and can generate antibodies quickly when encountering the disease in the future.
- Passive immunity wanes as the antibodies break down. Because the immune system didn't make these antibodies, it does not have a memory of how to make them in the future.



# EFFICACY

- In the combined pre-licensing studies:
  - Medically attended RSV lower respiratory tract infection  
79.0% (95% CI: 68.5%–86.1%)
  - RSV lower respiratory tract infection with hospitalization  
80.6% (95% CI: 62.3%–90.1%)
  - RSV lower respiratory tract infection with ICU admission  
90.0% (95% CI: 16.4%–98.8%)
- Phase 3b trial:
  - RSV hospitalization: 83% (95% CI 68%–92%)
  - Severe disease (SaO<sub>2</sub> <90% and oxygen given) : 76% (95% CI 33%–93%)
  - All-cause hospitalization with LRTI during RSV season: 58% (95% CI 40%–71%)



# SAFETY

- Most commonly reported adverse reactions were injection site reactions (0.3%) and rash (0.9%)
- No serious adverse effects attributable to nirsevimab



# DOSING UNDER 8 MO

Babies under 5 kg

Babies 5 kg or more



**5 KG IS ROUGHLY 11 POUNDS**



# CHILDREN AGED 8–19 MO

Children aged 8–19 months recommended to receive nirsevimab when entering their second RSV season because of increased risk of severe disease:

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season
- Children with severe immunocompromise
- Children with cystic fibrosis who are weight-for-length <10<sup>th</sup> percentile or have manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable)
- American Indian and Alaska Native children

**200 mg:**



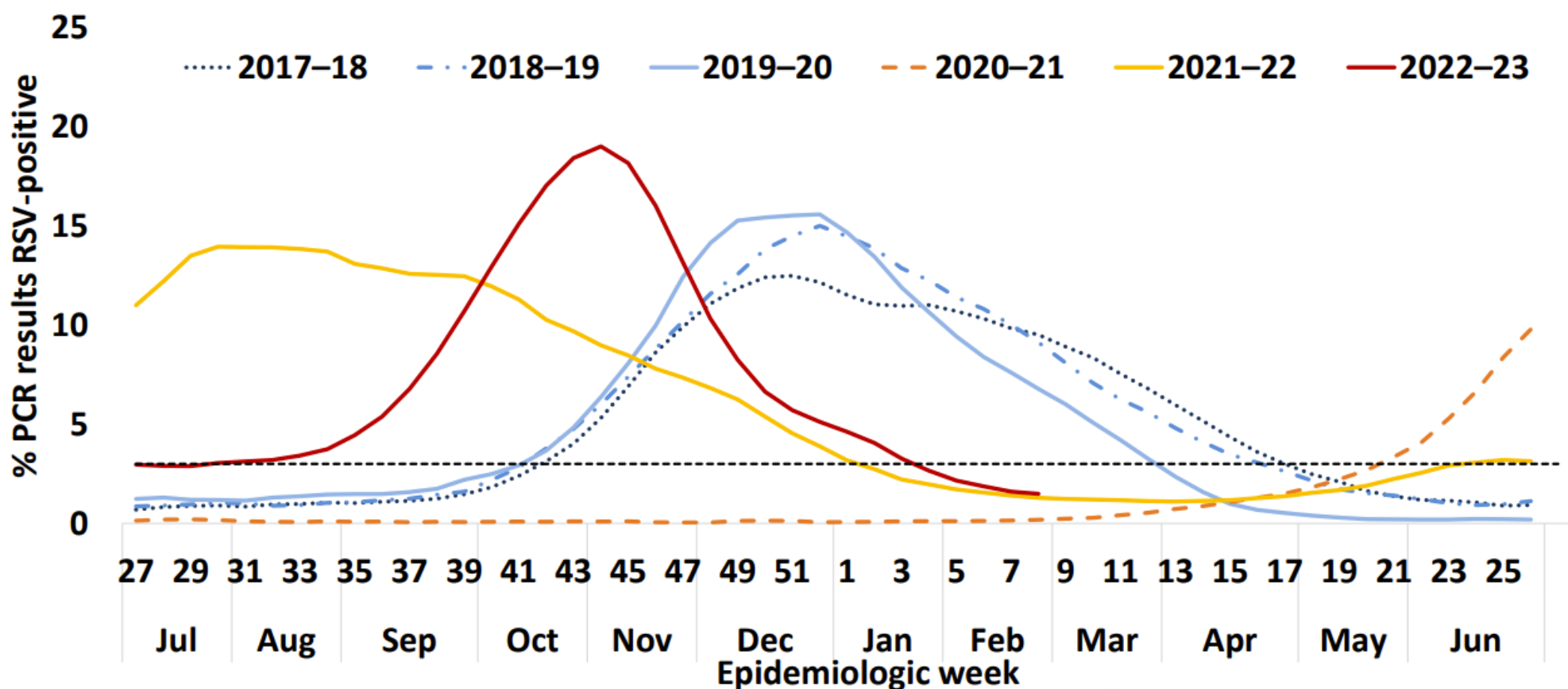


# WHEN?

- In the first week of life for infants born shortly before and during the season
- Shortly before the start of the RSV season for infants aged < 8 months
- Shortly before the start of the RSV season for children aged 8–19 months who are at increased risk of severe RSV disease
- Based on pre-pandemic patterns, this means nirsevimab could be administered in most of the continental United States from October through the end of March
- Because timing of the onset, peak, and decline of RSV activity may vary, providers can adjust administration schedules based on local epidemiology



# Changes in seasonality of RSV transmission following SARS-CoV2 introduction— NREVSS<sup>1</sup>, 2017–2023



Abbreviation: PCR = polymerase chain reaction; RSV = respiratory syncytial virus.

\* 3-week centered moving averages of percentage of RSV-positive PCR results nationwide. The black dotted line represents the threshold for a seasonal epidemic (3% RSV-positive laboratory PCR results).

1. <https://www.cdc.gov/mmwr/volumes/72/wr/mm7214a1.htm>



# COADMINISTRATION

- Can be given at the same visit as routine childhood vaccines
- In clinical trials, when nirsevimab was given concomitantly with routine childhood vaccines, the safety and reactogenicity profile of the coadministered regimen was similar to the childhood vaccines given alone
- When coadministered, nirsevimab is not expected to interfere with the immune response to vaccines



# LOGISTICS

## **Intergalactic patients:**

Your baby can receive the antibody at their regular visit, or

Text to arrange an earlier time to come in

## **Community members:**

Text us at 206-203-2509 to ask about current availability, and please include your baby's date of birth and weight so we know which product they'll need



INTERGALACTIC LOGISTICS