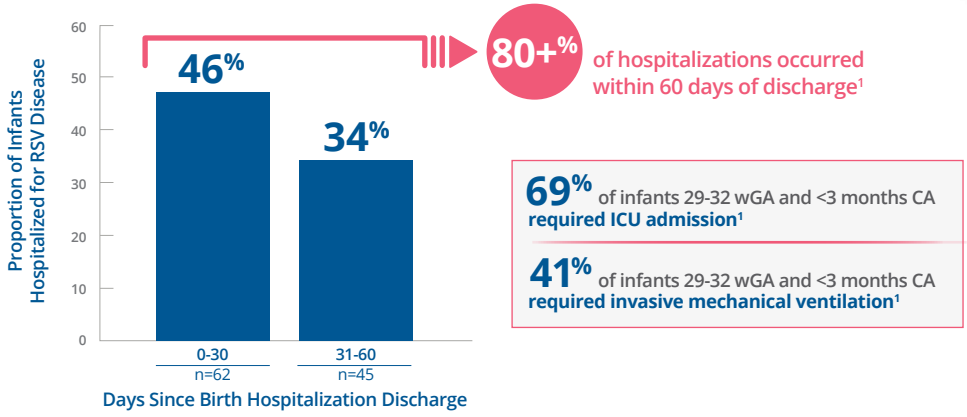
# SYNAGIS in the NICU

## *A Critical Line of Defense Against Severe RSV*

The SENTINEL1 study demonstrated
**Premature infants** hospitalized with RSV **who did not receive SYNAGIS experienced significant morbidity**[1]

In a subgroup analysis of the SENTINEL1 study[1,2*]




**80+%** of hospitalizations occurred within 60 days of discharge[1]

**69%** of infants 29-32 wGA and <3 months CA **required ICU admission**[1]

**41%** of infants 29-32 wGA and <3 months CA **required invasive mechanical ventilation**[1]

**SENTINEL1 STUDY DESIGN:** A multicenter, retrospective and prospective observational study of RSV hospitalizations among US infants born at 29-35 wGA not receiving SYNAGIS in the 2014-2015 and 2015-2016 RSV seasons. Infants born at 29-35 wGA (29 weeks, 0 days through 35 weeks, 6 days) who were hospitalized ≥24 hours for laboratory-confirmed RSV disease (index RSV hospitalization) that was either community acquired or nosocomial RSV disease AND who were <12 months of age at the time of index RSV hospitalization were included in the study. Of the 1,378 eligible preterm infants with community-acquired RSV hospitalization, 481 infants were enrolled for in-depth characterization of their hospitalizations.[1,2]

*Among infants discharged from their birth hospitalization from November 1 through March 31 (n=267). Among infants in the days since birth hospitalization discharge group: 61-90 (n=16), 91-120 (n=6), 121-150 (n=2), and 151-180 (n=1), the proportion of infants hospitalized for RSV disease were 12%, 5%, 2%, and 1%, respectively.[1]

From 2003-2020, the relative risk of RSV hospitalization was significantly higher among **infants <29 wGA** vs term infants in their first year of life[3]

**Commercially insured infants ~3x more likely**

**Medicaid-insured infants more than 3.5x more likely**

## INDICATION

SYNAGIS, 50 mg and 100 mg for injection, is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients:

- with a history of premature birth (≤35 weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season
- with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season
- with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of RSV season

## LIMITATIONS OF USE

The safety and efficacy of SYNAGIS have not been established for treatment of RSV disease.

## CONTRAINDICATIONS

Previous significant hypersensitivity reaction to SYNAGIS.

## IMPORTANT SAFETY INFORMATION

**Hypersensitivity Reactions:** Anaphylaxis and anaphylactic shock (including fatal cases) and other severe acute hypersensitivity reactions have been reported. Permanently discontinue SYNAGIS and administer appropriate medication if such reactions occur.

All imagery is for illustrative purposes only.

CA=chronological age; ICU=intensive care unit; NICU=neonatal intensive care unit; wGA=weeks gestational age.

**Please see additional Important Safety Information on page 2. Click here for full Prescribing Information for SYNAGIS, including Patient Information.**

SYNAGIS®
PALIVIZUMAB

**20+ YEARS OF CLINICAL EXPERIENCE**
**HELPING TO PROTECT HIGH-RISK INFANTS FROM RSV**

*Protection From Severe RSV Starts in the NICU*

# DOSE BEFORE DISCHARGE

*"Hospitalized infants at risk for severe RSV infection should receive prophylaxis 48 to 72 hours before discharge and every 30 days until the end of the season"*[4]

**—The American Academy of Pediatrics**

In premature infants ≤35 wGA initiated on SYNAGIS as outpatients, **average time to receipt of first dose was 35 days post-NICU discharge**[5]

## EFFECTIVE TRANSITION OF CARE IS CRITICAL

***Help ensure eligible high-risk infants receive monthly doses (every 28-30 days) throughout the RSV season***[6]

Patients identified in the NICU may be potential candidates for continued protection in the outpatient setting.

3 steps to complete prior to discharging your high-risk infants from the NICU into the community:

1. Dose before discharge
2. Click here to complete and submit the electronic Transition of Care form through the CoverMyMeds® portal
3. Remind parents/caregivers to ask their baby's pediatrician if their baby should receive SYNAGIS once home

### IMPORTANT SAFETY INFORMATION (continued)

**Coagulation Disorders:** SYNAGIS should be given with caution to children with thrombocytopenia or any coagulation disorder.

**RSV Diagnostic Test Interference:** Palivizumab may interfere with immunological-based RSV diagnostic tests, such as some antigen detection-based assays.

**Serious Adverse Reactions:** The most common serious adverse reactions occurring with SYNAGIS are anaphylaxis and other acute hypersensitivity reactions.

**Most Common Adverse Reactions:** The most common adverse reactions are fever and rash.

**Postmarketing Experience:** Severe thrombocytopenia and injection site reactions have been identified during post approval use of SYNAGIS.

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

**These are not all the possible risks associated with SYNAGIS.**

**Please click here for full Prescribing Information for SYNAGIS, including Patient Information.**

**To report suspected adverse reactions, contact Sobi North America at 1-866-773-5274 or the FDA at 1-800-FDA-1088.**

**References: 1.** Anderson EJ, DeVincenzo JP, Simões EA, et al. SENTINEL1: two-season study of respiratory syncytial virus hospitalizations among U.S. infants born at 29 to 35 weeks' gestational age not receiving immunoprophylaxis. *Am J Perinatol.* 2020;37(4):421-429. **2.** Chatterjee A, Mavunda K, Krilov LR. Current state of respiratory syncytial virus disease and management. *Infect Dis Ther.* 2021;10:S5-S16. **3.** Packnett ER, Winer IH, Larkin H, et al. Trends in outpatient palivizumab use and rates of RSV-related hospitalization in very preterm (born at <29 wGA) infants: 2003-2020. Poster presented at: 38th Annual Advances in Care Conference – Advances in Therapeutics and Technology: Critical Care of Neonates, Children, and Adults; March 30, 2022; Alta, UT. **4.** American Academy of Pediatrics Committee on Infectious Diseases; American Academy of Pediatrics Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics.* 2014;134(2):415-420. **5.** Data on file, Sobi, Inc. **6.** SYNAGIS [package insert]. Waltham, MA: Sobi, Inc.

**Colorado prescribers, please click here for additional information.**

Learn more about us at SOBI.com

sobi rare strength

SYNAGIS® PALIVIZUMAB

20+ YEARS OF CLINICAL EXPERIENCE
HELPING TO PROTECT HIGH-RISK INFANTS FROM RSV