# United States Senate

WASHINGTON, DC 20510

November 17, 2023

Mr. Brian R. Foard
U.S. Country Lead, Sanofi US
Sanofi Building D, 55 Corporate Drive
Bridgewater, NJ 08807

Dr. Ruud Dobber, Ph.D.
Executive Vice President and President,
BioPharmaceuticals Business Unit,
AstraZeneca
1800 Concord Pike
Wilmington, DE 19850

Dear Mr. Foard and Dr. Dobber:

We write to urge your companies, who manufacture nirsevimab, to do everything in your power to make this lifesaving monoclonal antibody as easily and readily accessible as possible for American families to protect the Nation's youngest infants from severe disease resulting from respiratory syncytial virus (RSV) infection. As our Nation braces for the 2023-2024 RSV season, we are concerned that health care providers and families are having difficulty accessing this new immunization product that can be used to prevent severe RSV infections in infants.

According to the Centers for Disease Control and Prevention (CDC), RSV is a very contagious virus that can lead to serious respiratory illness for infants. Two out of three infants are infected with RSV during their first year of life, and almost all children are infected by their second birthday. In the United States, RSV is the leading cause of hospitalization in infants under 12 months, averaging 16 times higher than the annual rate for influenza.

In July 2023, the Food and Drug Administration (FDA) approved nirsevimab for neonates and infants younger than eight months of age born during or entering their first RSV season, as well as in children 8 to 19 months of age who remain vulnerable to severe RSV disease through their second RSV season. Subsequently, the CDC Advisory Committee on Immunization Practices (ACIP) voted unanimously to recommend the use of nirsevimab in this population and for its inclusion in the Vaccines for Children (VFC) program, which is a Federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay.

Tragically, just as nirsevimab was beginning to be ordered and administered through the commercial marketplace and the VFC program, it was discovered that there was a severe supply shortage and the VFC program instituted a temporary pause on ordering. Soon after, it was announced that the manufacturer was no longer taking orders for the 100mg doses for infants who weigh more than 5kg and could only fulfill orders that had already been placed. The VFC program subsequently reopened orders for nirsevimab but had to do so with an allocation system to ensure an equitable distribution between state VFC programs.

In addition, the CDC has issued a Health Alert Network (HAN) Health Advisory to provide options for clinicians to protect infants from RSV in the context of a limited supply of

nirsevimab. Through the HAN, the CDC suggests prioritizing available 100mg doses for infants at the highest risk for severe RSV disease: young infants (age <6 months) and infants with underlying conditions that place them at highest risk for severe RSV disease. In addition, CDC further recommends that providers suspend using nirsevimab in palivizumab-eligible children aged 8–19 months for the 2023–2024 RSV season; these children should continue to receive palivizumab per American Academy of Pediatrics (AAP) recommendations. However, nirsevimab should continue to be offered to American Indian and Alaska Native children aged 8–19 months who are not palivizumab-eligible.

This supply shortage is impacting large hospitals and small health clinics alike, which highlights a concern for equitable care and access. It leaves parents searching for this immunization and desperate for an option to reduce risk of illness and save children's lives. We must prioritize safeguarding our most vulnerable neonates, infants and children as we begin RSV season.

We recognize the first season of implementation carries complexity and challenges, from forecasting demand months in advance, to efficient supply chains and distribution, as well as public awareness and education. However, inadequate supply, along with onerous out-of-pocket costs for providers, has caused the rollout of nirsevimab to be more chaotic than anticipated. To better understand how we can urgently address this issue, we respectfully request that Sanofi and AztraZeneca brief us on the current situation with regards to nirsevimab supply, including providing answers to the following questions:

1. On what date did Sanofi and AstraZeneca become aware internally of this shortage in North America?
2. On what date did Sanofi and AstraZeneca provide voluntary notice to FDA on this shortage?
3. What are the barriers to scaling up nirsevimab production and distribution to meet demand in the United States?
4. Given that we know last RSV season was so severe, we were surprised to hear about the disparity between the estimated and actual demand for nirsevimab this year. What factors led to the significant underestimation of demand for the product and what actions will you take to adjust these estimates going forward?
5. What mitigating factors have you put in place to address the demand today?
6. How are you communicating with providers and healthcare systems regarding supply and mitigating strategies?
7. How are you prioritizing where and who receives the current supply? How are you ensuring distribution and access that prioritizes typically underserved communities?
8. Can you assure us that the 50mg doses will remain available during the 23-24 RSV season?
9. Why has Sanofi chosen to charge the same amount of $495 for both the 50 mg and 100 mg 5-pack of one dose syringes?

Given the urgent public health need to proactively encourage RSV immunization ahead of the fall and winter RSV season, we request that Sanofi and AstraZenca provide a response to this letter by November 30, 2023, and we thank each company in advance for taking swift action to ensure that every eligible child can be protected from this potentially deadly virus.

Sincerely,

Tammy Duckworth
United States Senator

Kirsten Gillibrand
United States Senator

Ron Wyden
United States Senator

Edward J. Markey
United States Senator

Richard Blumenthal
United States Senator

Jon Ossoff
United States Senator

Elizabeth Warren
United States Senator