# Drug Name

**ABRYSVO®**

**Category: Best New Biotechnology Agent/Best Pharmaceutical Product**

**Drug or device name:** **ABRYSVO®**

**Compound name:** Respiratory Syncytial Virus Bivalent Stabilized Prefusion F Subunit Vaccine (RSVpreF)

**Trade name:** **ABRYSVO®**

**Date of approval:** Older Adult, May 2023 / Maternal, August 2023 / Adults 18-59 years of age at increased risk for LRTD, October 2024 (in the U.S.)

**Indication:**

ABRYSVO**®** is a vaccine indicated for:

* Active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age.
* Active immunization for the prevention of LRTD caused by RSV in individuals 60 years of age and older.
* Active immunization for the prevention of LRTD caused by RSV in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.

**Therapeutic areas (100 words):**

**Originality:** *Why your research endeavors represent a novel approach or solution in healthcare, showcasing creativity and ingenuity.*

## Background information and need for drug (500 words):

ABRYSVO ® (Respiratory Syncytial Virus Vaccine) offers the broadest RSV vaccine indication for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 60 years of age and older, as well as individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV. Additionally, it remains the only RSV immunization approved for pregnant individuals to protect infants from birth up to 6 months of age.

***RSV disease in young infants***

Globally, in children <5 years of age, there are an estimated 33 million episodes of RSV associated acute lower respiratory infections annually, resulting in an estimated 3.6 million hospitalizations and an estimated 26,300 in-hospital deaths.[[1]](#endnote-2) A recent global metanalysis attempted to quantify additional RSV deaths occurring outside the hospital setting, resulting in an estimated 101,400 total RSV attributable deaths among children <5 each year.1,[[2]](#endnote-3) Globally, 39% of all RSV-associated hospitalizations among children <5 years occur in the first 6 months of life, with 60% of those RSV-associated hospitalizations among infants 0-3 months old.[[3]](#endnote-4) Among infants <6 months of age, RSV is associated with 1.4 million hospital admissions, and 13,000 in-hospital deaths globally each year.[[4]](#endnote-5) Overall, among infants <6 months of age, RSV-attributable deaths in both the hospital and the community are estimated to be 45,700. More than 97% of RSV-attributable deaths occur in low- and middle-income countries.1

Several studies have demonstrated links between RSV lower respiratory tract illness (LRTI) (especially if the illness required hospitalization) and subsequent or recurrent non-RSV LRTI in the first two years of life.[[5]](#endnote-6),[[6]](#endnote-7) Increased risk of bacterial pneumonia (including pneumococcal pneumonia) and acute otitis media have also been documented.[[7]](#endnote-8),[[8]](#endnote-9),[[9]](#endnote-10),[[10]](#endnote-11),[[11]](#endnote-12),[[12]](#endnote-13) There is also evidence of a possible association between severe RSV disease in infancy and subsequent wheezing and asthma in later childhood.10,[[13]](#endnote-14),[[14]](#endnote-15) RSV LRTI in early life increases the risk of asthma not only within the first decade of life but also possibly into adolescence and adulthood.[[15]](#endnote-16),[[16]](#endnote-17)

***Unmet Medical Need in Infants***

Prior to ABRYSVO**®**, there was no approved vaccine to help prevent RSV disease in infants. Treatment of RSV disease consists primarily of supportive care (e.g., nutrition/hydration for infants who cannot maintain hydration, and supplemental oxygen).[[17]](#endnote-18),[[18]](#endnote-19) The benefit of antiviral therapy (e.g., ribavirin) for RSV is unclear, and therefore, rarely used to treat RSV, except in the context of severe immunosuppression, because of inconvenient administration, questionable benefit in immunocompetent patients, teratogenicity concerns based on nonhuman animal data, and high cost.29,[[19]](#endnote-20),[[20]](#endnote-21),[[21]](#endnote-22) Paracetamol and OTC cold medications may be used to relieve milder symptoms.[[22]](#endnote-23)

Humanized monoclonal antibodies against the RSV F glycoprotein have demonstrated clinical efficacy. Products such as Palivizumab, Nirsevimab, and Clesrovimab have been approved by the U.S. FDA as immunoprophylaxis or passive immunization in various groups of infants and young children.[[23]](#endnote-24),[[24]](#endnote-25)[[25]](#endnote-26)

***RSV disease in older adults***

RSV disease burden reported in 2015 demonstrated there were approximately 1.5 million episodes of acute respiratory illness-RSV (ARI-RSV) in older adults (≥65 years of age) in industrialized countries, with approximately 15% of those being admitted to hospitals.[[26]](#endnote-27)

In the US, RSV is responsible for approximately 177,000 hospitalizations and 14,000 deaths annually in adults 65 years of age and older.[[27]](#endnote-28) RSV disease incidence rates in this population are approximately half those of influenza, with variation year to year.23 However, the burden of adult RSV disease could be underestimated since testing for RSV is less common in older adults than in children. RSV disease in adults is also difficult to diagnose based on clinical signs and symptoms alone, and, before the recent broader use of more sensitive detection methods, laboratory confirmation of RSV in adults was challenging because of low levels of virus shedding.[[28]](#endnote-29)

Adults 60 years of age and older are at increased risk of RSV infection, which can trigger exacerbations of underlying comorbid conditions, such as COPD and CHF.24 RSV infection has been associated with up to 22% of acute COPD exacerbations in prospective cohort studies and 11% of wintertime hospitalizations for COPD exacerbations.24 In industrialized countries, case fatality rate of RSV-ARI was 11.7% for adults with comorbidity, while it was 1.6% for the same general population.[[29]](#endnote-30),[[30]](#endnote-31),[[31]](#endnote-32),[[32]](#endnote-33) This indicates that adults with comorbidities have a higher risk of experiencing ARI-RSV and a poorer outcome.25,26,27,28

***Unmet Medical Need in Older Adults***

Prior to ABRYSVO**®**, there was no approved vaccine to help prevent RSV disease in older adults.[[33]](#endnote-34) Treatment of RSV disease consisted primarily of supportive care (eg, fluids, supplemental oxygen, or mechanical ventilation).38 Paracetamol and OTC cold medications may be used to relieve milder symptoms.34 Comprehensive hygiene measures are helpful and cost-effective in limiting the spread of RSV, and should always be advocated as a prophylactic measure, however, they are not sufficiently efficacious to prevent the disease burden.

***RSV disease in adults***

A recent systematic literature review and meta-analysis found that while annual rates of RSV-associated visits increase with age, the magnitude of this age-related‑ increase in incidence is less pronounced for ED and outpatient visits than for hospitalizations.[14](#_ENREF_14). For example, while the reported hospitalization incidence was 15 times higher among adults over 65 years old than those 18 through 49 years old (281.6 versus 18.8 per 100,000), the increase in outpatient visits was only 1.6-fold (2278.2 versus 1401.3 per 100,000). RSV-related medically attended illness remains frequent overall in adults 18 through 49 years of age and those 50 through 64 years of age. Absolute numbers of ED and outpatient events are higher among those <65 years than those >65 years of age due to the greater size of the <65 year old population. For instance, nearly 2 million RSV-related outpatient visits and over 277,000 ED visits occurred in those 18 through 49 years of age each year, which is larger than the 1.4 million outpatient visits and nearly 80,000 ED visits that occurred among those older than 65 years.

Similar trends are seen in Europe, where GP visit incidence rates in the UK were more similar among adult age groups compared to hospitalizations and deaths, which increase sharply among those at least 65 years of age.[18](#_ENREF_18) In absolute numbers, more GP visits for RSV disease occurred among persons under age 65 years than those 65 years and older (313,003 versus 174,244, respectively).

While there is a risk of medically attended RSV illness across the entire population under the age of 60 years, similar to older adults, severe disease risk increases substantially among those with comorbidities and other risk factors.[14](#_ENREF_14),[19](#_ENREF_19) Of note, the elevated incidence for hospitalization among younger adults with RSV risk factors can be comparable to or higher than incidence among older adults without risk factors.[19](#_ENREF_19) For example, in one recent study, the annual incidences among persons age 20 through 39 years and 40 through 59 years of age with CHF were, respectively, 237 and 403 per 100,000 compared to 167 per 100,000 among all persons 65 years and older.[14](#_ENREF_14),[19](#_ENREF_19)

Severe RSV disease can lead to death, and the risk of death following hospitalizations is similar for those over and under the age of 65 years. A recent global meta-analysis among high-income countries found RSV-related hospitalization case fatality rates were 5.7% (range: 4.7-7.0) among those 18 through 64 years of age, versus 6.1% (range: 3.3-11.0) among those at least 65 years of age.[21](#_ENREF_21)

***Unmet Medical Need in Adults***

US adults under the age of 65 years have a substantial annual burden of medically attended RSV disease: over 3 million outpatient visits, approximately 350,000 ED visits, and nearly 60,000 hospitalizations. A large burden is seen globally as well with 537,000 RSV-related hospitalizations estimated to occur in high-income countries annually among persons under 65 years of age.[21](#_ENREF_21) Natural infection with RSV does not lead to long-term immunity, and recurrent infections occur in both children and adults.[25](#_ENREF_25)

Prior to ABRYSVO**®**, there was no approved vaccine to help prevent RSV disease in adults 18 to 59 years of age.[[34]](#endnote-35) As mentioned above, treatment of RSV disease consisted primarily of supportive care, due to a lack of available treatment options. The combination of substantial burden, short-lived natural immunity, and lack of available treatment options supported the need for a safe and effective vaccine for adults 18 years of age and older.

***Conclusions on Unmet Medical Needs***

Historically, RSV has primarily been considered a pediatric pathogen, but during the past 30 years it has been increasingly recognized as an important cause of respiratory disease among older adults. Before the approval of ABRYSVO**®, n**o vaccine to help protect against RSV disease in any population had been authorized.[[35]](#endnote-36) Also, there is no currently approved antiviral therapy for RSV, and the only available treatment options include symptomatic treatment and supportive care.38 While authorized for preventative use in children <2 years of age, limitations of palivizumab use include its high cost and requirement for multiple monthly injections, making it impractical for broad use in infants, or use outside of high resource settings.35,[[36]](#endnote-37),[[37]](#endnote-38) Similarly, although the CDC recommended Nirsevimab in August 2023 to protect infants aged <8 months against RSV-associated lower respiratory tract infection in their first RSV season, cost and the logistics of administration may restrict its use to high-income countries.[[38]](#endnote-39)

### ****DEVELOPMENT & CLINICAL OR PRECLINICAL EVIDENCES (500 words) -**** *History of the discovery and development of the product*

ABRYSVO**® is a bivalent RSV stabilized prefusion F subunit vaccine (**RSVpreF)**.The prefusion F protein is a key antigen target for RSV vaccines, as it plays a critical role in viral fusion and entry into host cells.** The journey to the RSVpreF vaccine began with the breakthrough determination of the crystal structure of prefusion RSV F in complex with an antibody fragment that prevented rearrangement from the prefusion to the postfusion conformation. This enabled a National Institutes of Health laboratory to engineer an incompletely stabilized RSV prefusion F antigen, termed DS-Cav1. This construct elicited approximately 10-fold higher neutralizing antibody titers than postfusion F in laboratory animals.[[39]](#endnote-40),[[40]](#endnote-41),[[41]](#endnote-42) After discovery of the prefusion F crystal structure, Pfizer engineered prefusion RSV F constructs sufficiently stabilized to be practical vaccine antigens. The constructs are RSV F ectodomains “locked” in the prefusion conformation by C-terminal T4 fibritin foldon trimerization domains and internal stabilizing mutations. A stabilized prefusion F subunit construct, designated 847, on which the antigens in RSVpreF are based, elicits >50-fold higher neutralizing titers than a postfusion F antigen in nonhuman primates (rhesus macaques).

The pivotal MATISSE (MATernal Immunization Study for Safety and Efficacy) Phase 3 trial evaluated ABRYSVO® in a maternal immunization setting. The randomized, double-blinded, placebo-controlled study assessed the efficacy, safety, and immunogenicity of ABRYSVO® against medically attended LRTD (MA-LRTD) and severe MA-LRTD in infants born to healthy women vaccinated during pregnancy. The study enrolled approximately 7,400 pregnant individuals, randomized in a 1:1 ratio to receive a single dose of either ABRYSVO® or placebo during the late second to third trimester of their pregnancy. One of the key findings was the significant reduction in severe MA-LRTD due to RSV in infants up to 180 days post-birth.[[42]](#endnote-43) This result underscored the potential of maternal vaccination as a strategy to help protect young infants from RSV. No significant safety concerns were identified during the trial.46

The RENOIR (RSV vaccine Efficacy study iN Older adults Immunized against RSV disease) Phase 3 trial focused on the active immunization of older adults. The randomized, double-blind, placebo-controlled study was designed to evaluate the efficacy, immunogenicity, and safety of a single dose of ABRYSVO**®** in adults 60 years of age and older. The trial enrolled approximately 37,000 participants, randomized to receive 120mg ABRYSVO**®** or placebo in a 1:1 ratio. ABRYSVO**®** showed strong efficacy in preventing RSV-associated LRTD with three or more symptoms, maintaining this efficacy across two seasons.[[43]](#endnote-44) The vaccine's efficacy was consistent for both RSV A and RSV B subgroups, with high efficacy rates for LRTD with three or more symptoms. It also shows sustained efficacy against less severe LRTD, defined by two or more symptoms, across both seasons. There was no significant safety concerns identified in this study.47

MATISSE and RENOIR, along with the extensive preclinical and early-phase clinical trials, are significant in the development of ABRYSVO**®.** Despite challenges posed by the COVID-19 pandemic, which impacted RSV transmission patterns and seasonality, both trials yielded compelling evidence supporting the vaccine's efficacy and safety profile. The results from these trials were instrumental in the regulatory approval process and recommendations for the use of ABRYSVO**®**, for maternal immunization to prevent RSV disease in young infants nd active immunization of adults 60 years and older to prevent RSV disease. ABRYSVO**® is approved for its maternal and adult indications in several countries including the United States, the European Union, the United Kingdom, Canada, Japan, Argentina, and Brazil. Further, in March 2025, the WHO prequalified** ABRYSVO**® as the first maternal RSV vaccine to protect infants at birth through 6 months of age.**

**Innovations (500 words) –** *Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition*

***RSVpreF Vaccine***

The licensing of a vaccine against RSV that utilizes structure-guided vaccine antigen design marks a huge accomplishment in the field of vaccinology, capping over 60 years of scientific struggle, perseverance, and innovation. Since RSV was identified in 1956, efforts to develop a vaccine faced numerous setbacks, including the infamous 1966 trial where a formalin-inactivated RSV vaccine not only failed to protect but also exacerbated the disease in some children.[[44]](#endnote-45) The breakthrough came with the advent of structural biology techniques, which allowed scientists to understand the precise configuration of the RSV F protein in its prefusion state. The trimeric RSV F surface glycoprotein is the primary target of neutralizing antibodies and is the basis for the engineered antigens in ABRYSVO**®**. During RSV entry into cells, F rearranges from a prefusion to a postfusion conformation. As it rearranges, F fuses the viral and host cell membranes. Structural data show that the postfusion F conformation targeted by many prior failed vaccine approaches is very different from the predominant prefusion conformation that is present on virions. The structural difference between conformations results in antigenic differences. In contrast to postfusion F, prefusion F is in a metastable conformation that needs to be stabilized to be useful as an improved vaccine antigen.43,44 Based on this new understanding, Pfizer developed 2 structurally engineered, stabilized prefusion F vaccine antigens, 1 for each RSV subgroup (RSV A and RSV B). This innovative antigen design enhances the vaccine’s ability to induce robust and durable immune responses, thereby providing superior protection against RSV infection compared to previous vaccine candidates. This milestone not only highlights the triumph over decades of challenges but also heralds a new era in vaccine development, where structure-based design can significantly accelerate the delivery of effective vaccines for other elusive pathogens.

***Active Immunization of Adults 60 Years of Age and Older to Prevent RSV Disease***

**Clinical trial data shows that** ABRYSVO**® provides robust protection against RSV for adults 60 years of age and older, reducing the risk of RSV-associated LRTD and severe complications. Following vaccination,** ABRYSVO**® offers protection for at least two years, a substantial duration that enhances its practicality and appeal for older adults who may face challenges with more frequent vaccination schedules.**[[45]](#endnote-46) **This prolonged immunity is particularly important for the elderly who are more susceptible to severe RSV outcomes, including hospitalization and death. By ensuring sustained defence against RSV,** ABRYSVO**® has the potential to, not only improve individual health outcomes, but also to help alleviate the broader public health burden associated with RSV in this age group.**

***Maternal Immunization to Prevent RSV Disease in Young Infants***

Maternal immunization to help protect infants is anticipated to overcome the barriers to direct infant immunization. One barrier is the very early peak of RSV disease, occurring approximately 1 to 2 months after birth, which affords little time for a neonatal vaccine to elicit a protective immune response.[[46]](#endnote-47) Other barriers include the immaturity of the neonatal immune system and potential suppression of active RSV antibody responses by maternal antibodies.[[47]](#endnote-48) Perhaps the greatest barrier to direct infant immunization is the history of vaccine-mediated RSV disease enhancement following immunization of RSV-naive infants with a formalin-inactivated RSV vaccine.[[48]](#endnote-49)

The goal of maternal immunization is to boost preexisting RSV-neutralizing antibody titers in the mother. Maternal antibodies are transferred transplacentally to the fetus and thus protect babies for the first months of life, when they are most vulnerable to severe RSV disease. Maternal immunization with ABRYSVO® is designed to help protect infants through their first 6 months of life when the risk of RSV hospitalization is highest (50% and 75% of hospitalizations during the first year of life occur in the first 3 months and 6 months of life, respectively).8 Importantly, this approach can confer protection that is present at birth, without the logistical challenges that might be involved with direct infant immunization or prophylactic monoclonal antibody administration, such as adding an additional product into a complex infant immunization schedule and ensuring vaccine administration prior to any opportunities for RSV exposure, the latter of which could require an additional and potentially unanticipated well-child visit if RSV seasonality remains difficult to predict. Maternal immunization has the potential to circumvent the issue of suboptimal immune responses to active immunization in very early infancy that can necessitate administering multiple vaccine doses over several months, leaving the infant unprotected or suboptimally protected in the meantime. It also induces a polyclonal antibody response and therefore has a low likelihood of applying selective pressure against circulating viruses.

**Summary**

Maternal immunization with ABRYSVO**® is crucial as it provides a means to help protect young infants, who are at the highest risk of severe RSV-related illness. By vaccinating pregnant individuals, maternal antibodies specific to RSV are potentially transferred across the placenta to the developing fetus, conferring passive immunity during the first months of life when infants are most vulnerable. This approach offers a vital strategy for helping to prevent RSV infections and its associated complications in newborns.**

Furthermore, ABRYSVO**® can offer a promising solution for active** immunization in adults, who are also at heightened risk of severe RSV disease. With advancing age, individuals may experience waning immunity to RSV, making them more susceptible to severe respiratory infections. By vaccinating adults, ABRYSVO**® aims to bolster their immune responses against RSV, reducing the likelihood of severe illness and hospitalization.**

ABRYSVO® represents a landmark achievement in vaccinology and global health. Prior to ABRYSVO**®, d**espite several decades of development efforts, no RSV vaccine has been licensed, highlighting the critical need for an effective solution. The vaccine, leveraging the RSVpreF antigen, offers a novel approach to inducing protective immunity against RSV through maternal and active immunization, addressing a longstanding gap in preventive measures for vulnerable populations.

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