NEWS RELEASE

Moderna Receives U.S. FDA Approval for RSV Vaccine mRESVIA(R)

5/31/2024

mRESVIA is Moderna's second approved product and the only RSV vaccine available in single-dose pre-filled syringes

CAMBRIDGE, MA / ACCESSWIRE / May 31, 2024 / Moderna, Inc. (NASDAQ:MRNA) today announced that the U.S. Food and Drug Administration (FDA) has approved mRESVIA (mRNA-1345), an mRNA respiratory syncytial virus (RSV) vaccine, to protect adults aged 60 years and older from lower respiratory tract disease caused by RSV infection. The approval was granted under a breakthrough therapy designation and marks the second approved mRNA product from Moderna.

"The FDA approval of our second product, mRESVIA, builds on the strength and versatility of our mRNA platform," said Stéphane Bancel, Chief Executive Officer of Moderna. "mRESVIA protects older adults from the severe outcomes of RSV infection, and it is the only RSV vaccine available in a pre-filled syringe designed to maximize ease of administration, saving vaccinators' time and reducing the risk of administrative errors. This approval is also the first time an mRNA vaccine has been approved for a disease other than COVID-19. With mRESVIA, we continue to deliver for patients by addressing global public health threats related to infectious diseases."

RSV is a highly contagious seasonal respiratory virus and a leading cause of lower respiratory tract infections and pneumonia that causes a particularly large burden of disease in infants and older adults. Each year in the U.S., approximately 60,000-160,000 older adults are hospitalized and 6,000-10,000 die due to RSV infection.[1]

The FDA's approval of mRESVIA is based on positive data from the Phase 3 clinical trial ConquerRSV, a global study

conducted in approximately 37,000 adults ages 60 years or older in 22 countries. The primary analysis with 3.7 months of median follow-up found a vaccine efficacy against RSV lower respiratory tract disease (LRTD) of 83.7% (95.88% CI 66.0%, 92.2%). These results were published in **The New England Journal of Medicine**. A follow-up analysis of the primary endpoint was performed during FDA review, including cases that started before the primary analysis cut-off date but were not confirmed until afterward. The results were consistent with the primary analysis [VE 78.7% (CI 62.9%, 87.8%)] and were included in the U.S. package insert. An additional longer-term analysis showed continued protection against RSV LRTD over 8.6 months median follow-up.

No serious safety concerns were identified in the Phase 3 trial. The most commonly reported solicited adverse reactions were injection site pain, fatigue, headache, myalgia and arthralgia.

Moderna expects to have mRESVIA available for eligible populations in the U.S. by the 2024/2025 respiratory virus season.

Moderna has filed for mRNA-1345 approval with regulators in multiple markets around the world.

About mRESVIA® (RSV Vaccine, mRNA)

mRESVIA®is an RSV vaccine that consists of an mRNA sequence encoding a stabilized prefusion F glycoprotein. The F glycoprotein is expressed on the surface of the virus and is required for infection by helping the virus to enter host cells. The prefusion conformation of the F protein is a significant target of potent neutralizing antibodies and is highly conserved across both RSV-A and RSV-B subtypes. The vaccine uses the same lipid nanoparticles (LNPs) as the Moderna COVID-19 vaccines.

About Moderna

Moderna is a leader in the creation of the field of mRNA medicine. Through the advancement of mRNA technology, Moderna is reimagining how medicines are made and transforming how we treat and prevent disease for everyone. By working at the intersection of science, technology and health for more than a decade, the company has developed medicines at unprecedented speed and efficiency, including one of the earliest and most effective COVID-19 vaccines.

Moderna's mRNA platform has enabled the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases and autoimmune diseases. With a unique culture and a global team driven by the Moderna values and mindsets to responsibly change the future of human health, Moderna strives to deliver the greatest possible impact to people through mRNA medicines. For more information about Moderna, please visit **modernatx.com** and connect with us on X (formerly Twitter), Facebook, Instagram, YouTube and LinkedIn.

INDICATION

mRESVIA (RSV Vaccine, mRNA) is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in adults 60 years of age and older.

IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer mRESVIA to individuals with a history of severe allergic reaction (e.g., anaphylaxis) to any component of mRESVIA.

Warnings and Precautions

Management of Acute Allergic Reactions: Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of mRESVIA.

Syncope: Syncope (fainting) may occur in association with administration of injectable vaccines, including mRESVIA. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence: Immunocompromised individuals, including those receiving immunosuppressive therapy, may have a diminished immune response to mRESVIA.

Adverse Reactions

In a clinical trial, the most commonly reported (≥10%) adverse reactions were injection-site pain (55.9%), fatigue (30.8%), headache (26.7%), myalgia (25.6%), arthralgia (21.7%), axillary (underarm) swelling or tenderness (15.2%) and chills (11.6%).

To report suspected adverse reactions, contact ModernaTX, Inc. at 1-866-663-3762 or VAERS at 1-800-822-7967 or **www.vaers.hhs.gov**.

Please click for mRESVIA Full Prescribing Information.

Moderna Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding: the vaccine efficacy and safety of mRNA-1345; the potential for mRESVIA to reduce disease burden from RSV; Moderna's pending marketing authorization applications for mRNA-1345; and Moderna's expectation to have mRESVIA available for eligible populations in the U.S. by the

2024/2025 respiratory virus season. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include, among others, those risks and uncertainties described under the heading "Risk Factors" in Moderna's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, and in subsequent filings made by Moderna with the U.S. Securities and Exchange Commission, which are available on the SEC's website at **www.sec.gov**. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date of this press release.

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[1] **https://www.cdc.gov/rsv/high-risk/older-adults.html**

SOURCE: Moderna, Inc.