News Release

FOR IMMEDIATE RELEASE

U.S. FDA Approves Intramuscular Administration for Merck's MMRV Family of Vaccines: M-M-R®II (Measles, Mumps, and Rubella Virus Vaccine Live), VARIVAX® (Varicella Virus Vaccine Live), and ProQuad® (Measles, Mumps, Rubella and Varicella Virus Vaccine Live)

With this additional route of administration, the MMRV Family now joins other routinely recommended vaccines that can be administered intramuscularly

RAHWAY, N.J., March 6, 2023 – Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced today that the U.S. Food and Drug Administration (FDA) has approved the addition of the intramuscular (IM) route of administration to the United States Product Insert (USPI) for Merck's MMRV family of vaccines: M-M-R®II, VARIVAX®, and ProQuad®.

While these vaccines have a long history in the U.S., until now they have only been administered via subcutaneous (SC) injection.

"Building on our history of innovation in the world of vaccines, we're proud to introduce another method of administration for M-M-R®II, VARIVAX®, and ProQuad® vaccines, which have been important in the fight against measles, mumps, rubella, and varicella in the U.S.," said Dr. Eliav Barr, senior vice president, head of global clinical development and chief medical officer, Merck Research Laboratories.

With these approvals, healthcare professionals now have the option to choose to administer all routinely recommended injectable pediatric vaccinations included in the CDC immunization schedule, via the same IM route. In the U.S., the only measles, mumps, rubella, and varicella vaccines that can be administered IM are M-M-R®II, VARIVAX®, and ProQuad®. Additionally, the MMRV family of vaccines has already been licensed for IM administration in the European Union.

"As a pediatrician who routinely vaccinates children, I am excited to now have the option to administer these vaccines intramuscularly," said Dr. Todd Wolynn, co-founding pediatrician of Kids Plus Pediatrics. "This approval provides our practice with an additional route of administration."

About the MMRV Family of Vaccines

ProQuad® is a vaccine indicated for active immunization for the prevention of measles, mumps, rubella, and varicella in children 12 months through 12 years of age. It was approved

by the FDA in 2005. VARIVAX® is a vaccine indicated for active immunization for the prevention of varicella in individuals 12 months of age or older. It received FDA approval in 1995 and remains the only varicella vaccine available for use in the U.S. M-M-R®II is indicated for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age or older and received FDA approval in 1978.

Indications and Usage

ProQuad is a vaccine indicated for active immunization for the prevention of measles, mumps, rubella, and varicella in children 12 months through 12 years of age.

VARIVAX is a vaccine indicated for active immunization for the prevention of varicella in individuals 12 months of age or older.

M-M-R®II is indicated for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age or older.

Selected Safety Information

Hypersensitivity: ProQuad, M-M-R®II, and **VARIVAX** are contraindicated in patients with a history of anaphylactic reaction or hypersensitivity to any component of the vaccine (including gelatin or neomycin) or to a prior dose of measles, mumps, rubella, or varicella-containing vaccine. Use caution when administering **ProQuad** and **M-M-R®II** to individuals with anaphylaxis or immediate hypersensitivity to eggs.

ProQuad, M-M-R®II, and **VARIVAX** are contraindicated in certain individuals, including those with: immunodeficiency or who are immunosuppressed; an active febrile illness; untreated tuberculosis.

Pregnancy: ProQuad, M-M-R®II, and **VARIVAX** are contraindicated for use in pregnant women. Do not administer **ProQuad** or **VARIVAX** to individuals who are planning to become pregnant in the next 3 months. Do not administer **M-M-R®II** to individuals who are planning to become pregnant in the next month.

Febrile Seizures: Administration of **ProQuad** (dose 1) to children 12 to 23 months old who have not been previously vaccinated against measles, mumps, rubella, or varicella, nor had a history of the wild-type infections, is associated with higher rates of fever and febrile seizures at 5 to 12 days after vaccination when compared to children vaccinated with a first dose of both **M-M-R®II** and **VARIVAX** administered concomitantly.

Febrile Seizures: Use caution when administering **ProQuad** and **M-M-R®II** to individuals with a history of febrile seizures.

Family History of Immunodeficiency: Vaccination with **ProQuad, M-M-R®II,** and **VARIVAX** should be deferred in individuals with a family history of congenital or hereditary immunodeficiency until the individual's immune status has been evaluated and the individual has been found to be immunocompetent.

Thrombocytopenia: Transient thrombocytopenia has been reported within 4-6 weeks following vaccination with measles, mumps, and rubella vaccine. Carefully evaluate the potential risk and benefit of vaccination in children with thrombocytopenia or in those who experienced

thrombocytopenia after vaccination with a previous dose of a measles, mumps, and rubella-containing vaccine.

Varicella Transmission and Precautions: Advise vaccinees administered **ProQuad** or **VARIVAX** to avoid:close contact with high-risk individuals susceptible to varicella for up to 6 weeks following vaccination since transmission of varicella vaccine virus to susceptible contacts has been reported. Varicella vaccine virus transmission may occur between vaccine recipients and contacts susceptible to varicella including healthy individuals.

Immune Globulins and Transfusions: Immune Globulins and other blood products should not be given concomitantly with **ProQuad, M-M-R®II,** or **VARIVAX**.

Use of Salicylates: Avoid use of salicylates in children and adolescents administered **ProQuad** or **VARIVAX** for 6 weeks following vaccination due to the association of Reye Syndrome with salicylate therapy and wild-type varicella infection.

Adverse Events: The following adverse events have been reported for both subcutaneous and intramuscular injections of **ProQuad, M-M-R®II,** and **VARIVAX**: fever, injection-site reactions (pain/tenderness/soreness, erythema, and swelling); and rash on the body or at the injection site. Additionally, irritability has been reported for the subcutaneous injections of **ProQuad, M-M-R®II,** and **VARIVAX.**

ProQuad Systemic Vaccine-Related Adverse Events: Systemic vaccine-related adverse events that were reported at a significantly greater rate in recipients of subcutaneous **ProQuad** than in recipients of the component vaccines administered concomitantly were fever and measles-like rash.

VARIVAX Dose-related Adverse Events: In a clinical trial involving children who received 2 doses of **VARIVAX** 3 months apart, the incidence of injection-site clinical complaints observed in the first 4 days following vaccination was slightly higher post-dose 2 (overall incidence 25.4%) than post-dose 1 (overall incidence 21.7%), whereas the incidence of systemic clinical complaints in the 42-day follow-up period was lower post-dose 2 (66.3%) than post-dose 1 (85.8%).

Concomitant Vaccines With ProQuad: ProQuad may be administered concomitantly with diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed (DTaP), *Haemophilus influenzae* type b conjugate (meningococcal protein conjugate) and hepatitis B (recombinant) vaccine. It may also be administered concomitantly with pneumococcal 7-valent conjugate vaccine and/or hepatitis A vaccine (inactivated) at separate injection sites.

Concomitant Vaccines With VARIVAX: **VARIVAX** can be administered with other live viral vaccines. If not given concurrently, at least 1 month should elapse between a dose of a live attenuated measles virus-containing vaccine and a dose of **VARIVAX**. In children, at least 3 months should elapse between administration of 2 doses of a live attenuated varicella virus-containing vaccine.

Tuberculin Testing: If a tuberculin test is to be done with **M-M-R®II** and **ProQuad,** it should be administered either any time before, simultaneously with, or at least 4 to 6 weeks after vaccination. With **VARIVAX,** tuberculin testing may be performed before the vaccine is administered or at least 4 weeks following vaccination.

Additional M-M-R®II Precautions: Additional adverse reactions, which have been reported without regard to causality, include febrile convulsions, arthritis, thrombocytopenia, anaphylaxis, anaphylactoid reactions, arthritis, encephalitis and encephalopathy in their diverse clinical presentations.

Additional VARIVAX Precautions: It is not known if varicella vaccine virus is excreted in human milk. A boost in antibody levels has been observed in vaccinees following exposure to wild-type varicella, which could account for the apparent long-term persistence of antibody levels in studies. The duration of protection from varicella infection after vaccination is unknown.

ProQuad/VARIVAX and Herpes Zoster: The long-term effect of VARIVAX on the incidence of herpes zoster, particularly in those vaccinees exposed to wild-type varicella, is unknown at present.

Efficacy: Vaccination with **ProQuad, VARIVAX,** or **M-M-R®II** may not result in protection in 100% of vaccinees.

Dosage and Administration

ProQuad:

Each dose of **ProQuad** is approximately 0.5 mL and is administered intramuscularly or subcutaneously.

At least 1 month should elapse between a dose of a measles-containing vaccine such as **M-M-R®II** and a dose of **ProQuad**. At least 3 months should elapse between a dose of varicella-containing vaccine and **ProQuad**.

VARIVAX:

Each dose is approximately 0.5 mL and is administered intramuscularly or subcutaneously.

The first dose is administered at 12 to 15 months of age.
The second dose is administered at 4 to 6 years of age.
There should be a minimum interval of 3 months between doses.
12 months to 12 years of age: If a second dose is administered, there should be a minimum interval of 3 months between doses.
Adolescents (≥13 years of age) and Adults: 2 doses, to be administered with a minimum interval of 4 weeks between doses.

M-M-R®II:

The dose for any age is approximately 0.5 mL administered intramuscularly or subcutaneously.

The recommended age for primary vaccination is 12 to 15 months and the second dose should be given at 4 to 6 years of age.

Before administrating VARIVAX® (Varicella Virus Vaccine Live), M-M-R®II (Measles, Mumps, and Rubella Virus Vaccine Live), or ProQuad® (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), please read the Prescribing Information. The Patient Information also is available for VARIVAX, M-M-R®II, and ProQuad.

About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-

intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit www.merck.com and connect with us on Twitter, Facebook, Instagram, YouTube and LinkedIn.

Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of the global outbreak of novel coronavirus disease (COVID-19); the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's Annual Report on Form 10-K for the year ended December 31, 2021 and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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Please see Prescribing Information for M-M-R®II at http://www.merck.com/product/usa/pi_circulars/m/mmr_ii/mmr_ii_pi.pdf and Patient Information for M-M-R® II at http://www.merck.com/product/usa/pi_circulars/m/mmr_ii/mmr_ii_ppi.pdf.

Please see Prescribing Information for VARIVAX® at http://www.merck.com/product/usa/pi_circulars/v/varivax/varivax_pi.pdf and Patient Information for VARIVAX® at http://www.merck.com/product/usa/pi_circulars/v/varivax/varivax_ppi.pdf.

Please see Prescribing Information for ProQuad® at http://www.merck.com/product/usa/pi_circulars/p/proquad/proquad_pi_4171.pdf and Patient Information for ProQuad® at https://www.merck.com/product/usa/pi_circulars/p/proquad/proquad_ppi.pdf.

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