VARIVAX, Merck’s Varicella (Chickenpox) Vaccine, Awarded WHO Pre-Qualification Status

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KENILWORTH, N.J., Feb. 9, 2018 – VARIVAX® (varicella virus vaccine live), the live attenuated varicella-zoster (VZV) vaccine from Merck & Co., Inc (known as MSD outside the U.S. and Canada) that helps prevent varicella (chickenpox) in individuals 12 months of age and older, has been awarded pre-qualification status by the World Health Organization (WHO). WHO pre-qualification allows for expanded access to VARIVAX and provides a greater opportunity to help protect more people from varicella.

VARIVAX, which has been part of the Pan American Health Organization (PAHO) vaccine portfolio for several years and is used in many national vaccination programs, is the first varicella vaccine to receive WHO prequalification. Because VARIVAX has been pre-qualified by the WHO, the vaccine is now eligible for procurement by the United Nations Children’s Fund (UNICEF) and other United Nations agencies, for use in their national vaccination programs.

In the United States, VARIVAX is indicated for active immunization for the prevention of varicella in individuals 12 months of age or older and is administered via a subcutaneous injection. Do not administer VARIVAX to individuals with: a history of severe allergic reaction to any component of the vaccine (including neomycin and gelatin) or to a previous dose of varicella vaccine; immunosuppressed or immunodeficient individuals, including those with a history of primary or acquired immunodeficiency states, leukemia, lymphoma, or other malignant neoplasms affecting the bone marrow or lymphatic system, AIDS, or receiving immunosuppressive therapy; any febrile illness or active infection, untreated tuberculosis; or those who are pregnant.

“Chickenpox is a highly infectious disease that affects millions of people every year worldwide, and is deemed a public health burden. While most healthy children will recover, some may suffer from serious complications such as skin and soft tissue infections, pneumonia, or encephalitis, which can be fatal,” says Ruxandra Draghia-Akli, vice president, Public Health and Scientific Affairs, Merck. “We are committed to supporting global efforts to increase vaccine access to people around the world. The WHO pre-qualification for VARIVAX is a significant step toward increasing availability and potentially reducing global burden of varicella disease.”

The WHO pre-qualification aims to ensure that vaccines meet the WHO’s standards of quality, safety and efficacy, which in conjunction with other criteria, is used by the UN and other agencies to make purchasing decisions.

Varicella occurs worldwide and in the absence of a vaccination program, affects nearly every person by mid-adulthood. In 1998, the WHO recommended that childhood varicella vaccination be included in national immunization programs in countries where the disease is considered to be an important public health and socioeconomic matter. In 2015, varicella vaccine was added to the WHO list of essential medicines.

**Additional Important Information about VARIVAX® (varicella virus vaccine live)**

Evaluate individuals for immune competence prior to administration of VARIVAX if there is a family history of immunodeficiency. Vaccine recipients should avoid contact with high-risk individuals susceptible to varicella due to possible risk of transmission. Defer vaccination for at least 5 months following blood or plasma transfusions or administration of immune globulins. Avoid use of salicylates for 6 weeks following administration of VARIVAX to children and adolescents.

Frequently reported (>10%) adverse reactions in children ages 1 to 12 years who were monitored for 42 days include: fever ≥102.0°F (38.9°C) oral: 14.7%; injection-site complaints: 19.3%. Frequently reported (>10%) adverse reactions in adolescents and adults ages 13 years and older monitored for up to 42 days include: fever ≥100.0°F (37.8°C) oral: 10.2%; injection-site complaints: 24.4%. Other reported adverse reactions in all age groups include: varicella-like rash (injection site) and varicella-like rash (generalized).

In a clinical trial involving children who received 2 doses of VARIVAX 3 months apart, the incidence of injection-site clinical complaints (primarily erythema and swelling) 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%).

There are insufficient data to assess the rate of protection of VARIVAX® (varicella virus vaccine live) against the serious complications of chickenpox in adults (eg, encephalitis, hepatitis, pneumonia), and during pregnancy (congenital varicella
syndrome).

The duration of protection from varicella infection after vaccination with VARIVAX is unknown.

Vaccination with VARIVAX may not result in protection of all healthy, susceptible children, adolescents, and adults.

A boost in antibody levels has been observed in vaccinees following exposure to wildtype varicella, which could account for the apparent long-term persistence of antibody levels in these studies.

Due to the concern for transmission of vaccine virus, vaccine recipients should attempt to avoid, whenever possible, close association with susceptible high-risk individuals for up to 6 weeks following vaccination.

VARIVAX is contraindicated for use in pregnant women because the vaccine contains live, attenuated varicella virus, and it is known that wild-type varicella virus, if acquired during pregnancy, can cause congenital varicella.

It is not known whether varicella vaccine virus is excreted in human milk.

**Dosage and administration**

Each dose of VARIVAX is approximately 0.5 mL after reconstitution and is administered subcutaneously.

- Children (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.

**About VARIVAX**

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

In clinical trials, the efficacy of VARIVAX has been evaluated in more than 17,000 children, adolescents, and adults. The most common side effects were fever, injection site reactions, and varicella-like rash. VARIVAX® (varicella virus vaccine live), has been available for more than 20 years in the United States and is available in 53 countries.

**About Varicella (Chickenpox)**

Globally, an estimated 140 million cases of chickenpox occur each year, of which 4.2 million suffer from severe complications. Varicella is an infectious disease caused by the highly contagious varicella-zoster virus (VZV) and can affect people of all ages. It usually occurs in childhood and is characterized by a generalized pruritic vesicular rash and fever. Symptoms that develop prior to the onset of rash include malaise, pruritus, anorexia, and listlessness.

Skin manifestations in varying stages of evolution consist of maculopapules, vesicles, and scabs.

Adults may have more severe disease and have a higher incidence of complications. Potentially severe complications of chickenpox can occur, including bacterial skin infections, pneumonia, and encephalitis.

**About Merck**

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit [www.merck.com](http://www.merck.com) and connect with us on Twitter, Facebook, Instagram, YouTube and LinkedIn.

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

This news release of Merck & Co., Inc., Kenilworth, 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. 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 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 2016 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

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