CDC Advisory Committee on Immunization Practices (ACIP) Unanimously Votes to Provisionally Update Recommendations for Hepatitis A Vaccination

Release Date: Thursday, June 27, 2019 7:15 pm EDT

Dateline City: KENILWORTH, N.J.

Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that the U.S. Centers for Disease Control and Prevention’s (CDC’s) Advisory Committee on Immunization Practices (ACIP) voted to update multiple recommendations to protect against hepatitis A, which can be a serious liver disease caused by hepatitis A virus (HAV). ACIP unanimously voted to recommend that all children and adolescents aged 2 through 18 years who have not previously received hepatitis A vaccine be vaccinated routinely at any age (i.e., children and adolescents are recommended for catch-up vaccination). Another vote taken by ACIP unanimously recommended updating the language around the utilization of hepatitis A vaccine in the Vaccines for Children program.

These pediatric updates are in addition to the current CDC recommendation for the routine vaccination of children aged 12-23 months. Details of the ACIP recommendations for hepatitis A will be available from the CDC. The recommendations are under review by the director of the CDC and the Department of Health and Human Services and final recommendations will become official when published in the CDC's *Morbidity and Mortality Weekly Report (MMWR)*.

All inactivated hepatitis A vaccines are indicated for two doses. VAQTA® (Hepatitis A Vaccine, Inactivated) is Merck’s vaccine for the prevention of disease caused by HAV. VAQTA is indicated for the prevention of disease caused by HAV in persons 12 months of age and older. The primary dose should be given at least 2 weeks prior to expected exposure to HAV. VAQTA should not be administered to individuals with a history of immediate and/or severe allergic or hypersensitivity reactions (e.g., anaphylaxis) after a previous dose of any hepatitis A vaccine, or to individuals who have had an anaphylactic reaction to any component of VAQTA, including neomycin. Please read below for Select Safety Information.

“Today’s ACIP vote comes at a time when the United States continues to experience a widespread outbreak of hepatitis A with more than 20,000 cases reported since 2017,” said Richard M. Haupt, MD, MPH, vice president and head of vaccines and infectious diseases, Global Medical Affairs at Merck. “We strongly support ACIP’s votes on hepatitis A vaccination recommendations, including the vote to strengthen the recommendation that children and adolescents aged 2 through 18 years who have not previously received vaccination be routinely vaccinated at any age. We look forward to the CDC’s final, published recommendations.”

About the ACIP

The ACIP develops written recommendations for the routine administration of vaccines to children and adults. The ACIP, which consists of 15 experts in immunization and related fields, provides advice to assist the CDC and the nation in reducing the incidence of diseases that may be prevented with vaccines and to increase the safe usage of vaccines and related biological products. The CDC reviews advice from the ACIP and publishes final recommendations in the *MMWR*. The Affordable Care Act (ACA) requires coverage for all vaccines administered in accordance with final CDC recommendations. This requirement applies to all non-grandfathered commercial plans and Medicaid expansion beneficiaries. Individuals or other healthcare providers should contact their health insurance plan to determine vaccine coverage and reimbursement requirements as well as adoption timeframes.

**Important information about VAQTA in children and adolescents**

**Indication**
VAQTA® (Hepatitis A Vaccine, Inactivated) is indicated for the prevention of disease caused by hepatitis A virus (HAV) in persons 12 months of age and older. The primary dose should be given at least 2 weeks prior to expected exposure to HAV.

**Dosage and Administration**

**Children/Adolescents (12 months through 18 years of age):** The vaccination schedule consists of a primary 0.5-mL dose administered intramuscularly and a 0.5-mL booster dose administered intramuscularly 6 to 18 months later. Booster Immunization Following Another Manufacturer’s Hepatitis A Vaccine: A booster dose of VAQTA may be given at 6 to 12 months following a primary dose of Havrix.[i]

**Adults (19 years of age and older):** The vaccination schedule consists of a primary 1.0-mL dose administered intramuscularly and a 1.0-mL booster dose administered intramuscularly 6 to 18 months later. Booster Immunization Following Another Manufacturer’s Hepatitis A Vaccine: A booster dose of VAQTA may be given at 6 to 12 months following a primary dose of Havrix.[i]

**Select Safety Information**

Do not administer VAQTA (Hepatitis A Vaccine, Inactivated) to individuals with a history of immediate and/or severe allergic or hypersensitivity reactions (e.g., anaphylaxis) after a previous dose of any hepatitis A vaccine, or to individuals who have had an anaphylactic reaction to any component of VAQTA, including neomycin.

The vial stopper and the syringe plunger stopper and tip cap contain dry natural latex rubber that may cause allergic reactions in latex-sensitive individuals.

The most common local adverse reactions and systemic adverse events (≥15%) reported in different clinical trials across different age groups when VAQTA was administered alone or concomitantly were:

- **Children 12 through 23 months of age:** injection-site pain/tenderness (37.0%), injection-site erythema (21.2%), and fever (16.4% when administered alone, and 27.0% when administered concomitantly).
- **Children/Adolescents 2 through 18 years of age:** injection-site pain (18.7%).
- **Adult 19 years of age and older:** injection-site pain, tenderness, or soreness (67.0%), injection site warmth (18.2%), and headache (16.1%).

Safety and effectiveness in infants below 12 months of age have not been established.

Hepatitis A virus has a relatively long incubation period (approximately 20 to 50 days). VAQTA may not prevent hepatitis A infection in individuals who have an unrecognized hepatitis A infection at the time of vaccination.

Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished immune response to VAQTA and may not be protected against HAV infection after vaccination.

Vaccination with VAQTA may not result in a protective response in all susceptible vaccinees.

In clinical trials in children, VAQTA was concomitantly administered with one or more of the following US-licensed vaccines: Measles, Mumps, and Rubella Virus Vaccine, Live; Varicella Vaccine, Live; Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine, Adsorbed; Measles, Mumps, Rubella, and Varicella Vaccine, Live; Pneumococcal 7-valent Conjugate Vaccine; and Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate). Safety and immunogenicity were similar for concomitantly administered vaccines compared to separately administered vaccines.

In adults, VAQTA (Hepatitis A Vaccine, Inactivated) may be administered concomitantly with Immune Globulin, human, using separate sites and syringes.

There are no adequate and well-controlled studies designed to evaluate VAQTA in pregnant women, including those 19 years of age or younger. Available post-approval data do not suggest an increased risk of miscarriage or major birth defects in women who received VAQTA during pregnancy.

It is not known whether VAQTA is excreted in human milk. Data are not available to assess the effects of VAQTA on the breastfed infant or on milk production/excretion. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for VAQTA and any potential adverse effects on the breastfed child from VAQTA or from the underlying maternal condition.

The total duration of the protective effect of VAQTA in healthy vaccinees is unknown at present.

In clinical trials in adults, VAQTA was concomitantly administered with typhoid Vi polysaccharide and yellow fever vaccines. Safety and immunogenicity were similar for concomitantly administered vaccines compared to separately administered vaccines.
About Hepatitis A

Hepatitis A is a serious liver disease. It is caused by the hepatitis A virus (HAV). HAV is spread from person to person through contact with the feces (stool) of people who are infected, which can easily happen if someone does not wash his or her hands properly. You can also get hepatitis A from food, water, or objects contaminated with HAV. Symptoms of hepatitis A can include fever, fatigue, loss of appetite, nausea, vomiting, and/or joint pain; severe stomach pains and diarrhea (mainly in children), or jaundice (yellow skin or eyes, dark urine, clay-colored bowel movements). Symptoms usually appear 2 to 6 weeks after exposure and usually last less than 2 months, although some people can be ill for as long as 6 months.

Children often do not have symptoms, but most adults do. HAV can be spread by people who are asymptomatic. Hepatitis A can cause liver failure and death, although this is rare and occurs more commonly in persons 50 years of age or older and persons with other liver diseases, such as hepatitis B or C. Most people who get hepatitis A recover completely.

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 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 2018 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).

Please see the full Prescribing Information for VAQTA (Hepatitis A Vaccine, Inactivated) at https://www.merck.com/product/usa/pi_circulars/v/vaqta/vaqta_pi.pdf

[i] Havrix is a registered trademark of GlaxoSmithKline.

Media Contacts:
Pamela Eisele
(267) 305-3558
Skip Irvine
(267) 305-0338

Investor Contacts:
Teri Loxam
(908) 740-1986