Pfizer Logo

CDC Advisory Committee on Immunization Practices Votes to Recommend TicoVac™, Pfizer's Tick-Borne Encephalitis (TBE) Vaccine, For Those at Risk of Virus Exposure

Wednesday, February 23, 2022 - 03:45pm

NEW YORK, NY, February 23, 2022 – Pfizer Inc. (NYSE:PFE) today announced that the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted to recommend Pfizer's TicoVac™ (tick-borne encephalitis (TBE) vaccine) for active immunization to prevent TBE in individuals 1 year of age and older, in the following U.S. populations:

For persons who travel or move to TBE endemic areas:

- TBE vaccine is recommended for persons who are moving or traveling to a TBE-endemic area and will have extensive exposure to ticks based on their planned outdoor activities and itinerary.
- *Additionally*, TBE vaccine may be considered for persons traveling or moving to a TBE-endemic area who might engage in outdoor activities in areas ticks are likely to be found. The decision to vaccinate should be based on an assessment of their planned activities and itinerary, risk factors for a poorer medical outcome, and personal perception and tolerance of risk.

For laboratory workers: TBE vaccination is recommended for those with a potential exposure to the TBE virus (TBEV).

"Today's ACIP recommendation is an important update that offers clear guidance to healthcare providers regarding when a TBE vaccine should be recommended to prevent infection," said Nanette Cocero, Ph.D., Global President, Vaccines, Pfizer. "We are seeing that travel is opening back up. Those traveling to risk areas in Europe or Asia, whether for leisure or work, including military personnel, or those at risk of exposure to the TBE virus through laboratory work, are now able to have conversations with their healthcare providers about whether vaccination is the right option for them."

The ACIP recommendation will be forwarded to the director of the CDC and the U.S. Department of Health and Human Services for review and approval. Once approved, the recommendations will be published in the Morbidity and Mortality Weekly Report (MMWR). The published recommendation will be accompanied by additional information around preventive measures to avoid tick bites.

On August 13, 2021, the U.S. Food and Drug Administration (FDA) approved TicoVac™ for active immunization to prevent TBE in individuals 1 year of age and older.[1] TicoVac™ is the only FDA-approved vaccine to help protect U.S. adults and children against the TBEV when traveling or moving to TBE endemic

areas. More than 45 years of experience with the Pfizer TBE vaccine exists outside the U.S., and more than 170 million doses of the vaccine have been distributed since 1976.[2-4]

About TicoVac™ (Tick-borne encephalitis vaccine)
Pfizer's TBE vaccine, marketed under the brand names FSME-Immun® and TicoVac™ in Europe and TicoVac™ in the U.S., induces protective antibodies against the three most prevalent subtypes of the TBEV circulating globally.[5]

In clinical trials, the safety and immunogenicity of TicoVac™ were assessed across two age groups (1-15 years and 16 years and above).[1] In these studies, seropositivity rates were 99.5% in 1-15 year olds and 98.7-100% in individuals 16 years and above following three doses.*[6,7] TicoVac™ has an acceptable safety and tolerability profile for both children and adults. Clinical studies demonstrated that the most common adverse reactions across both age groups were local tenderness, headache, local pain, fever, restlessness, fatigue, and muscle pain.[8,9] Real-world studies from Austria have demonstrated 96-99% effectiveness in people who have received at least three doses of the vaccine.[10,11]

About TBE
TBE is a rare but serious viral infection of the brain and spine,[12] transmitted to humans through the bite of an infected tick,[13,14] and less frequently by ingestion of unpasteurized milk or milk products from infected animals.[15] There is currently no cure or specific treatment for TBE, but management of symptoms is possible.[12] It may initially be mistaken for summer flu,[16,17] but can be a serious condition with possible long-term consequences.[12,17] 1 in 3 people can have long-term effects that last months or years, including cognitive changes, muscle weakness or permanent paralysis,[12,15] and in rare cases (0.5-2%; up to 20% in Russia), people may die.[18,19] TBE can affect people of all ages who come into contact with TBEV infected ticks whenever they do outdoor activities in countries where ticks infected with the TBEV are prevalent.[14,19]

U.S. Important Safety Information for TicoVac™

- TicoVac™ should not be given to anyone with a severe allergic reaction (e.g. anaphylaxis) to any component of TicoVac™.
- Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of TicoVac™.
- TicoVac™ may not protect all individuals.
- Some individuals with altered immunocompetence may have a reduced response to TicoVac™.
- TicoVac™ contains albumin, a derivative of human blood, and based on effective donor screening and product manufacturing processes carries an extremely remote and theoretical risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD).
- In clinical studies, the most common adverse reactions in subjects 1 through 15 years of age who received TicoVac™ were local tenderness (18.1%), local pain (11.2%), headache (11.1%), fever (9.6%), and restlessness (9.1%).
- In clinical studies, the most common adverse reactions in subjects 16 through 65 years of age who received TicoVac™ were local tenderness (29.9%), local pain (13.2%), fatigue (6.6%), headache (6.3%), and muscle pain (5.1%).
- Safety and effectiveness have not been established in pregnant women.

Please see full prescribing information for TicoVac™ here.

About Pfizer: Breakthroughs That Change Patients' Lives
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and

manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: *The information contained in this release is as of February 23, 2022. Pfizer assumes no obligation to update forward?looking statements contained in this release as the result of new information or future events or developments.*

This release contains forward?looking information about TicoVac™ (tick-borne encephalitis (TBE) vaccine), including the CDC ACIP recommendation for use in the U.S. for active immunization to prevent TBE in individuals 1 year of age and older in certain populations and its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of TicoVac™ and uncertainties regarding the commercial impact of ACIP's recommendation; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any biologics license applications may be filed in any other jurisdictions for TicoVac™; whether and when any such other applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether TicoVac™ will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of TicoVac™; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities regarding TicoVac™ and uncertainties regarding the commercial impact of any such recommendations; the impact of COVID-19 on our business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

Media Contact:

Steve Danehy
+1 (212) 733-1538
Steve.Danehy@pfizer.com

# # # # #

References

1. TicoVac™ Prescribing Information, U.S. Food and Drug Administration http://labeling.pfizer.com/ShowLabeling.aspx?id=15600 Accessed February 2022
2. Pfizer. Data on file. 2021 FSME-IMMUN® doses.
3. Barrett PN. Tick-borne encephalitis virus vaccines, p 773–88. In: Plotkin SA, Orenstein WA, PA O, (ed). Vaccines. Sixth edition. Elsevier Saunders; 2013, Philadelphia, PA.
4. Pfizer. Data on file. 2017 FSME-IMMUN® doses/TicoVac® markets.
5. Orlinger K, et al. A tick-borne encephalitis virus vaccine based on the European prototype strain induces broadly reactive cross-neutralizing antibodies in humans. J. Infect. Dis. 2011;203:1556.
6. Löw-Baselli A, et al. Safety and immunogenicity of the modified adult tick-borne encephalitis vaccine FSME-IMMUN: results of two large phase 3 clinical studies. Vaccine. 2006; 24:5256-63.
7. Löw-Baselli A, et al. Immunogenicity and safety of FSME-IMMUN 0.5 ml using a rapid immunization schedule. IJMM. 2006;296:213?4.
8. Ehrlich HJ, et al. Randomized, phase II dose-finding studies of a modified tick-borne encephalitis vaccine: evaluation of safety and immunogenicity. Vaccine. 2003 Dec 12;22(2):217-23.
9. Pöllabauer EM, et al. Clinical evaluation to determine the appropriate paediatric formulation of a tick-borne encephalitis vaccine. Vaccine. 2010 Jun 23;28(29):4558-65.
10. Heinz FX, et al. Field effectiveness of vaccination against tick-borne encephalitis. Vaccine. 2007;25(43):7559-67.
11. Heinz FX, et al. Vaccination and tick-borne encephalitis, central Europe. Emerg Infect Dis. 2013;19(1):69-76.
12. Lindquist L, et al. Tick-borne encephalitis. *The Lancet*. 2008;371:1861–1871.
13. Dobler G, Erber W, Bröker M, Schmitt HJ, eds. The TBE Book. 4th ed. Singapore: Global Health Press; 2021. Available at https://tbenews.com/tbe/. Accessed February 2022
14. European Centre for Disease Prevention and Control. Key messages about tick-borne encephalitis and tick-borne diseases. Available from: https://www.ecdc.europa.eu/en/tick-borne-encephalitis/facts/key-messages. Accessed: February 2022.
15. Bogovic P, et al. Tick-borne encephalitis: A review of epidemiology, clinical characteristics, and management. World J Clin Cases. 2015;3(5):430-41
16. Travel Health Pro. NaTHNaC – Tick-borne encephalitis. Available from: https://travelhealthpro.org.uk/disease/173/tick-borne-encephalitis. Accessed: February 2022
17. Kaiser R. Tick-borne encephalitis. Infect Dis Clin North Am. 2008;22(3):561-75.
18. Santos, R & Monteiro, S. Epidemiology, control, and prevention of emerging zoonotic viruses. in Viruses in Food and Water: Risks, Surveillance and Control 442–457. Elsevier Ltd. (2013). doi:10.1533/9780857098870.4.442.
19. ECDC. Factsheet about tick-borne encephalitis (TBE). Available from: https://www.ecdc.europa.eu/en/tick-borne-encephalitis/facts/factsheet. Accessed: February 2022

* Seropositivity measured by neutralizing antibody titers (NT) responses.