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U.S. FDA Approves TICOVAC™, Pfizer's Tick-Borne Encephalitis (TBE) Vaccine

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TICOVAC™ may help reduce the risk of TBE for people traveling to endemic areas, potentially including military personnel serving in these locations

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) today announced that the U.S. Food and Drug Administration (FDA) has approved TICOVAC™ (tick-borne encephalitis (TBE) vaccine) 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 TBE virus when visiting or living in TBE endemic areas. Following today's FDA approval, the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) is expected to discuss recommendations on the safe and appropriate use of TICOVAC™.

"We are proud to deliver the first vaccine to help protect people in the U.S. against TBE, if they are traveling to any risk areas," said Nanette Cocero, Ph.D., Global President, Vaccines, Pfizer. "This vaccine has helped to protect millions of people in TBE endemic regions since its first approval outside the U.S. 45 years ago. This authorization helps to ensure that people from the U.S. are also able to receive this vaccination if needed, reflecting our commitment to provide health for all."

TBE is a viral infection of the brain and spine,[2] which can be transmitted to humans through the bite of an infected tick.[3] Although TBE is not endemic in the U.S., to date, it has been identified in more than 35 countries across Europe and Asia.[3] The European Centre for Disease Prevention and Control (ECDC) currently recommends TBE vaccination for people who live in or are traveling to risk areas.[4]

More than 45 years of experience with the Pfizer TBE vaccine exist outside the U.S., and more than 170 million doses of the vaccine have been distributed since 1976.[5,6]

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., is developed using a master 'seed' virus that is similar to the TBE virus found in nature.[7] It is able to induce neutralizing antibodies against the natural TBE virus, as the sequence and structure of the virus subtype match those found in nature.[8]

In clinical trials, the safety and immunogenicity of TICOVAC™ were assessed across two age groups (1-15 years of age and >16 years of age).[6] In these studies, seropositivity rates were 99.5% in 1-15 year olds and 98.7-100% in adults >15 years following three doses.*[6,9,10] Clinical studies demonstrated that TICOVAC™ was generally well-tolerated with no unexpected adverse events or vaccine-related serious adverse events observed.[11,12] The most common adverse reactions across both age groups were local tenderness, headache, local pain, fever, restlessness, fatigue, and muscle pain.[11,12] Real-world studies from Austria have shown that the vaccine

is 96-98.7% effective in people who have received at least three doses of the vaccine.[13,14]

About TBE
TBE is a viral infection of the brain and spine,[2] transmitted to humans through the bite of an infected tick,[3] and less frequently by ingestion of unpasteurized milk or milk products from infected animals.[4] It may initially be mistaken for summer flu,[15,16] but can be a serious condition with possible long-term consequences.[2,16] 1 in 3 people can have long-term effects that last months or yearsincluding cognitive changes, muscle weakness or permanent paralysis,[2,16] and in rare cases (0.5-2%; up to 20% in Russia), people may die.[17,18] TBE can affect people of all ages who come into contact with ticks whenever they do outdoor activities in countries where ticks infected with TBE are prevalent.[2,18]

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
- Some individuals with altered immunocompetence may have reduced immune responses to TICOVAC
- TICOVAC contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). No cases of transmission of viral diseases, CJD or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products
- Vaccination with TICOVAC may not protect all vaccine recipients against tick-borne encephalitis
- 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 August 13, 2021. 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 an approval in the U.S. for active immunization to prevent TBE in individuals 1 year of age and older 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; 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 .

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

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