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U.S. FDA Accepts for Priority Review Pfizer's Application for TicoVac™ (Tick-borne Encephalitis Vaccine)

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Tick-borne encephalitis (TBE) is a viral infection, endemic to parts of Europe and Asia

If approved, the vaccine 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) accepted for Priority Review the company's Biologics License Application (BLA) for TicoVac™, its tick-borne encephalitis (TBE) vaccine for active immunization to prevent TBE in individuals 1 year of age and older.[1,2] If approved, TicoVac would be the first vaccine in the U.S. to help protect adults and children who are visiting or living in TBE endemic areas. In line with Priority Review designation, the FDA will target an action within six months of the application submission date,[3] with the anticipated Prescription Drug User Fee Act (PDUFA) action date expected for August 2021.

TBE is a viral infection of the brain and spine,[4] which is transmitted to humans through the bite of an infected tick.[5] To date, ticks infected with the TBE virus have been identified in more than 35 countries across Europe and Asia.[5] The European Centre for Disease Prevention and Control (ECDC) currently recommends TBE vaccination for people who live in or are traveling to these risk areas.[6]

"For many years, our TBE vaccine has helped protect millions of people in Europe from this potentially serious disease. We are proud that today's U.S. FDA Priority Review acceptance acknowledges the potential value that our vaccine candidate can bring," said Nanette Cocero, Ph.D., Global President, Vaccines, Pfizer Inc. "If approved in the U.S., we hope this vaccine will help protect those traveling to or residing temporarily in at-risk locations, potentially including military personnel who are serving overseas."

The BLA is based on results from more than 40 years of experience and evidence outside the U.S.[7] In clinical trials, the safety and immunogenicity of TicoVac was assessed across two age groups (1-15 years of age and 16-65 years of age).[7] In these studies, pooled seropositivity rates were 99-100% in 1-15 year olds and 94-99% in adults >15 years following three doses.[*8,9] Clinical studies demonstrated that TicoVac was well-tolerated with no unexpected adverse events or vaccine-related serious adverse events observed.[8,9] Subsequent real-world studies have shown that the vaccine is 96-99% effective in people who have received at least two doses of the vaccine,[10,11] and two to three doses of the vaccine were shown to be sufficient to provide a long-lasting immune memory.[1,2,12]

About TicoVac™ (TBE vaccine, whole virus inactivated)

Pfizer's TBE vaccine, marketed under the brand names TicoVac and FSME-Immun™ in Europe, is an inactivated whole virus vaccine developed using a master 'seed' virus that is similar to the TBE virus found in

nature.[13] Therefore, 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.[14] The vaccine helps provide protection against all known subtypes of the TBE virus in both children (from one year of age) and adults,[1,2,14] including the European, Siberian and Far Eastern subtypes.[15,16]

More than 40 years of experience with the Pfizer TBE vaccine exist outside the U.S., and more than 160 million doses of the vaccine have been distributed since 1976.[7,17]

About TBE

TBE is a viral infection of the brain and spine,[4] transmitted to humans through the bite of an infected tick,[5] and less frequently by ingestion of unpasteurized milk or milk products from infected animals.[4] It may initially be mistaken for summer flu,[18,19] but can be a serious condition with possible long-term consequences.[4,19] More than 1 in 3 people can have long-term effects that last months or yearsincluding cognitive changes, muscle weakness or permanent paralysis,[4,19] and in rare cases (0.5-2%; up to 20% in Russia), people may die.[20,21] 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.[4,21]

Although TBE is not endemic in the U.S., TBE has been reported in more than 35 countries, ranging from Western Europe to Japan.[5] Currently there is no cure or treatment for TBE, only management of symptoms.[4] The potential vaccine could help protect people from the U.S. who are traveling to or living in endemic regions.

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, 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 Pfizer's tick-borne encephalitis (TBE) vaccine, including and a potential indication 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, 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 Pfizer's TBE vaccine; whether and when the BLA pending in the U.S. may be approved and 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 Pfizer's TBE vaccine 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 Pfizer's TBE vaccine; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities regarding Pfizer's TBE vaccine 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, 2019 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) and enzyme-linked immunosorbent assay (ELISA) responses.

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