Pfizer Logo

Independent Data Monitoring Committee Recommends Discontinuation of the Phase 2b STRIVE Clinical Trial of Staphylococcus aureus Vaccine Following Planned Interim Analysis

Thursday, December 20, 2018 - 11:30am

NEW YORK--(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) announced today that the Phase 2b trial STRIVE (*STaphylococcus aureus* SuRgical Inpatient Vaccine Efficacy) evaluating the company's investigational *Staphylococcus aureus* (*S. aureus*) multi-antigen vaccine (PF-06290510) is being discontinued due to futility. This decision is based on a recommendation from an independent Data Monitoring Committee (DMC), composed of external experts, after conducting a pre-planned interim analysis.

The DMC concluded from these data that the study reached futility, meaning that there is low statistical probability for the study to meet the pre-defined primary efficacy objective in adults undergoing elective spinal fusion surgery after completing a planned Phase 3 expansion of the study.

A safety review by the DMC indicated that the investigational vaccine has been safe and well tolerated. STRIVE trial participants who are enrolled in the study will complete the study's follow-up evaluations.

Pfizer is evaluating next steps for the potential development of a *S. aureus* vaccine.

About Pfizer Inc.: Working together for a healthier world®

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. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. 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 150 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.

PFIZER DISCLOSURE NOTICE: *The information contained in this release is as of December 20, 2018. 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 discontinuation of the Phase 2b trial STRIVE (STaphylococcus aureus SuRgical Inpatient Vaccine Efficacy) evaluating the company's investigational Staphylococcus aureus *(*S. aureus*) multi-antigen vaccine candidate, PF-06290510, 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 study commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing clinical data; continuing evaluation of the estimated costs and benefits associated with the PF-06290510 program or discontinuation of the STRIVE study; further analysis of data from the STRIVE trial as well as other trials of PF-06290510; potential impact of unanticipated costs, expenses, and liabilities; and risks and uncertainties generally characterizing developing new biopharmaceutical products, including those described under the heading "Risk Factors" in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which may be found at www.sec.gov and www.pfizer.com.*

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, 2017 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: Jessica Smith O: 212-733-6213 E: Jessica.M.Smith@pfizer.com Investor Relations: Ryan Crowe O: 212-733-8160 E: Ryan.Crowe@pfizer.com