Pfizer Reports Top-Line Results Of A Phase 3 Clinical Trial Comparing The Efficacy And Safety Of VFEND® (voriconazole) And ERAXISTM (anidulafungin) Combination Therapy To VFEND Alone In Invasive Aspergillosis

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Detailed Results to be Submitted to Future Scientific Meeting and/or Medical Journal

(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) today reported the top-line results of an international Phase III clinical trial which compared the combination of VFEND® (voriconazole) and ERAXISTM (anidulafungin) to VFEND monotherapy for primary therapy of invasive aspergillosis (IA), a life-threatening invasive fungal infection that can develop as a complication in patients with compromised immune systems. The primary analysis of this double-blinded prospective randomized clinical trial was to compare mortality rates at six weeks after initiation of study treatment in patients with a diagnosis of proven or probable IA.

In the primary analysis, treatment with the combination of VFEND and ERAXIS resulted in a lower all-cause mortality rate at six weeks compared to VFEND alone. However, this difference in mortality did not achieve the pre-specified threshold for statistical superiority. The safety and tolerability of the combination of VFEND and ERAXIS in this study was similar to that of VFEND monotherapy.

Pfizer plans to submit the detailed results of the study to a future scientific meeting and/or a medical journal.

About the Phase 3 Trial

This was a prospective Phase III, double-blind clinical trial conducted in cooperation with the international Mycoses Study Group, a consortium of academic centers with the expressed purpose of investigating the epidemiology, diagnosis and treatment of invasive fungal infections. Patients were randomized at study entry to receive initial treatment with either the combination of VFEND and ERAXIS or VFEND and an inactive placebo. After completing two to four weeks of blinded combination treatment, patients were allowed to continue treatment with VFEND monotherapy. A total of 454 patients from 24 countries were enrolled into the study during the period from July 2008 to February 2011. A diagnosis of proven or probable invasive aspergillosis at study entry was confirmed in 277 patients by an independent blinded Data Review Committee managed by the Mycoses Study Group. The primary objective of the study was to compare all-cause mortality at six weeks from study entry.

About Invasive Aspergillosis

Invasive aspergillosis is the most common mould infection in people with compromised immune systems.i,ii Though considered relatively rare – data suggest that invasive aspergillosis affects about sixteen out of every thousand patients with stem cell transplants each yeariii – its true incidence is probably underestimated due to the low sensitivity of diagnostic tests.ii

Invasive aspergillosis usually manifests as a severe pulmonary infection that is often accompanied by chest pain, fever and coughing or breathlessness.iv The infection may spread throughout the body and can settle in numerous organs, including the brain. If left untreated, invasive aspergillosis can be fatal.v

ABOUT VFEND®

VFEND (voriconazole) IV/Oral is the only broad-spectrum IV/oral triazole antifungal medication specifically indicated for the first-line treatment of both mould and yeast infections. VFEND is indicated for use in the treatment of the following fungal infections:

Invasive aspergillosis; Candidemia in nonneutropenic patients and the following Candida infections: disseminated infections in skin and infections in the abdomen, kidney, bladder wall, and wounds; Esophageal candidiasis; and Serious fungal infections caused by Scedosporium apiospermum and Fusarium spp, including F. solani, in patients intolerant

of, or refractory to, other therapy.vi

ABOUT ERAXISTM

ERAXIS (anidulafungin) for Injection belongs to the echinocandin class of antifungal drugs and is used to treat serious fungal infections caused by Candida, a yeast commonly found on the skin, in the digestive tract, or as a contaminant on medical equipment and devices.

ERAXIS is indicated for the treatment of the following fungal infections caused by Candida:

Candidemia and other forms of Candida infections (intra-abdominal abscess and peritonitis). Esophageal candidiasis (US)

ERAXIS has not been studied in endocarditis, osteomyelitis, or meningitis due to Candida, and has not been studied in sufficient numbers of neutropenic patients with Candida infections to determine efficacy in this group. ERAXIS is not indicated for the treatment of invasive aspergillosis. In some countries, anidulafungin is marketed under the brand name ECALTA.

VFEND IMPORTANT SAFETY INFORMATION

The most frequently reported adverse events (all causalities) in therapeutic trials were visual disturbances, fever, rash, vomiting, nausea, diarrhea, headache, sepsis, peripheral edema, abdominal pain, and respiratory disorder. Treatment-related adverse events that most often led to discontinuation in clinical trials were elevated liver function tests, rash, and visual disturbances. There have been uncommon cases of serious hepatic reactions during treatment with VFEND (clinical hepatitis, cholestasis, and fulminant hepatic failure, including fatalities). Liver function tests should be evaluated at the start of and during the course of therapy. VFEND treatment–related visual disturbances are common. The effect of VFEND on visual function is not known if treatment continues beyond 28 days. There have been postmarketing reports of prolonged visual adverse events, including optic neuritis and papilledema. If treatment continues beyond 28 days, visual function should be monitored.

Patients have rarely developed serious exfoliative cutaneous reactions, such as Stevens-Johnson syndrome, during treatment with VFEND. If a patient develops an exfoliative cutaneous reaction, VFEND should be discontinued. VFEND has been associated with photosensitivity skin reaction. Patients should avoid strong, direct sunlight during VFEND therapy. In patients with photosensitivity skin reactions, melanoma and squamous cell

carcinoma of the skin have been reported during long-term therapy. If a patient develops a skin lesion consistent with squamous cell carcinoma or melanoma, VFEND should be discontinued.

For more information about VFEND, please visit http://www.vfend.com.

ERAXIS Important Safety Information

Abnormalities in liver function tests have been observed with ERAXIS. Clinically significant hepatic abnormalities have occurred in some patients with serious underlying medical conditions who were receiving multiple medications concomitantly with ERAXIS. Isolated cases of significant hepatic dysfunction, hepatitis, or worsening hepatic failure have been reported, but a causal relationship with ERAXIS has not been established. Patients who develop abnormal Liver function tests during ERAXIS therapy should be monitored for evidence of worsening hepatic function and evaluated for risk/benefit of continuing ERAXIS therapy. Possible histamine-mediated symptoms have been reported with ERAXIS, including rash, urticaria, flushing, pruritus, dyspnea, and hypotension. These events are infrequent when the rate of infusion does not exceed 1.1 mg/min.

For more information about ERAXIS, please visit http://www.eraxisrx.com.

Pfizer Inc.: Working together for a healthier world™

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer 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 the world's leading biopharmaceutical company, we also 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, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of September 30, 2011. 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 a product candidate, VFEND and ERAXIS combination therapy, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for such product candidate as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; 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, 2010 and in its reports on Form 10-Q and Form 8-K.

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i Steinbach WJ, Stevens DA, Denning DW, Moss RB. Advances Against Aspergillosis. Clin Infect Dis. 2003; 37 (suppl 3): S155-S156.

ii Denning DW, Ribaud P, Milpied N, et al. Efficacy and Safety of Voriconazole in the Treatment of Acute Invasive Aspergillosis. Clin Infect Dis. 2002; 34: 563-571.

iii Kontoyiannis, D., et al. Prospective Surveillance for Invasive Fungal Infections in Hematopoietic Stem Cell Transplant Recipients, 2001–2006: Overview of the Transplant-Associated Infection Surveillance Network (TRANSNET) Database. Clin Infect Dis. 2010; 50:1091–1100.

iv Centers for Disease Control and Prevention, Division of Foodborne, Bacterial and Mycotic Diseases. Aspergillosis. Available at: http://www.cdc.gov/nczved/divisions/dfbmd/diseases/aspergillosis/. Accessed September 12, 2011.

v Latgé JP. Aspergillus fumigatus and aspergillosis. Clin Microbiol Rev. 1999;12:310-350.

vi VFEND® (voriconazole) Prescribing Information. Pfizer Inc., New York, New York.

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