Pfizer Receives Refusal To File Letter From U.S. FDA On Tafamidis New Drug Application

Sunday, April 03, 2011 - 09:45pm

Company Remains Committed to Advancing the Tafamidis Program

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that it has received a Refusal to File letter from the United States Food and Drug Administration (FDA) for tafamidis, the company’s novel, oral investigational compound for patients with Transthyretin Familial Amyloid Polyneuropathy (TTR-FAP).

Upon preliminary review, the FDA determined that the application, which was submitted in February 2011, was not sufficiently complete to permit a substantive review. The company believes that the additional information needed to support this filing is available without further clinical studies. Pfizer is currently working closely with the FDA to resubmit the application as quickly as possible. A Refusal to File letter does not provide comment on the acceptability of the clinical data, and no judgment was made on the efficacy or safety of tafamidis as part of the letter.

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 April 4, 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 that involves substantial risks and uncertainties about a product candidate, tafamidis, including its potential benefits and the anticipated resubmission of a new drug application with the FDA including additional information that is available without further clinical studies. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; whether and when the Company will resubmit a new drug application for tafamidis with the FDA, and whether and when the FDA will accept any such resubmission based on additional information that is available without further clinical studies; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for tafamidis 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.

Pfizer Inc.Victoria Davis, 484-865-5194or 347-558-3455Victoria.Davis@pfizer.comorInvestors:Jennifer Davis, 212-733-0717Jennifer.M.Davis@pfizer.com